ACADEMY OF MEDICAL ROYAL COLLEGES \_\_\_\_\_

## Safe Sedation Practice for Healthcare Procedures

Standards and Guidance

October 2013

#### Academy of Medical Royal Colleges

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### **Executive Summary**

Sedation is ubiquitous in clinical practice. Avoidable morbidity and mortality continue to happen despite multiple sets of recommendations and much research.

In 2001 the Academy of Medical Royal Colleges published guidance.<sup>1</sup> Since then, sedation and clinical procedures have evolved whilst the population of patients for sedation has aged and become frailer with more co-morbidities. Individual specialties have developed guidance on sedation and there has been some improvement in training and practice.

Research and audit have identified continued avoidable morbidity and mortality from sedation. The single most common recurring theme is the lack of formal training for the appropriate administration of sedative drugs and prompt recognition and treatment of sedation-related complications. This must be addressed. It is only through the insistence on formal accredited competency-based training for all healthcare workers using such techniques, that we can improve the safety of sedation practice.

This report defines Fundamental Standards and Development Standards in safe sedation practice and recommends competency-based formal training for all healthcare professionals involved in sedation. It is the recommendation of this document that:

- Safety will be optimised only if practitioners use defined methods of sedation for which they have received formal training. Irrespective of educational background, the competencies required for safe sedation and, crucially, rescue from sedationrelated adverse events, must be the same. There must be one standard for all, but the educational requirements and pathways to attain a common standard will vary for different disciplines. It is the responsibility of all disciplines using sedation techniques to ensure that their trainees receive accredited training in the use of these techniques, to a clearly defined national standard.
- Royal Colleges and associated organisations should define safe sedation techniques (including the human and equipment resources required) for each specialty. Addressing the training needs requires that the necessary competencies for the safe and appropriate administration of sedation and prompt recognition and treatment of sedation-related complications, be defined and specified within approved postgraduate training curricula. Trainees who will be expected to use conscious sedation techniques within their sphere of practice on obtaining their

Certificate of Completion of Training (CCT), must demonstrate acquisition of the necessary competencies at Annual Review of Competency Progression (ARCP), or through an equivalent process.

- Those continuing to be actively involved in administering sedation must be able to demonstrate continued competency through maintenance of an appropriate level of experience, and ongoing participation in relevant life-long learning/CPD programmes, now necessary for revalidation.
- There should be audit of the process and outcome of procedures performed under sedation, particularly the incidence of major complications (e.g. cardiopulmonary arrest, unexpected admission to intensive care and delayed hospital discharge).
- To ensure appropriate governance of sedation within an institution a Sedation Committee should be established to lead and support implementation of these recommendations at hospital level. This committee should include representatives from key clinical teams using procedural sedation and there should be a nominated lead clinician for sedation. In larger institutions, the Sedation Committee should include an anaesthetist.
- To achieve a safe and effective sedation service 'on the ground' across clinical specialties, the concept of a Sedation Team has been developed. The proposed Sedation Team would have both a practical and an educational role, working across an institution to support multidisciplinary staff with both continuing education and 'hands-on' clinical expertise. The Sedation Team would have a role analogous to a pain team, with the aim of improving clinical standards, clinical effectiveness and the quality of patient care in procedural sedation.
- Those responsible for commissioning healthcare in the primary and private sectors should ensure that similar processes are in place to ensure a safe standard of sedation practice.

### Working Party Members

The membership of the core group comprised of:

Professor Robert Sneyd	Chairman, Royal College of Anaesthetists
Professor Jonathan Benger	College of Emergency Medicine
Dr Mike Blayney	Royal College of Anaesthetists
Dr Stephen Furniss	Heart Rhythm UK
Dr Christopher Holden	Society for the Advancement of Anaesthesia in Dentistry
Professor Richard Ibbetson	Royal College of Surgeons of Edinburgh
Dr Gavin Lloyd	College of Emergency Medicine
Dr Alistair McNair	British Society of Gastroenterology
Dr Neil Morton	Association of Paediatric Anaesthetists
Dr Ian Parkinson	Lancaster Patient Safety Research Unit
Dr Anna-Maria Rollin	Royal College of Anaesthetists
Professor Andrew Smith	Lancaster Patient Safety Research Unit
Dr Simon Utting	British Dental Association
Mr David Weatherill	Lay Representative, Royal College of Anaesthetists
Miss Hollie Brennan	Secretary

The following organisations were invited to comment on the guideline throughout the drafting process:

- Association of Dental Anaesthetists British Ophthalmic Anaesthesia Society **British Pain Society British Thoracic Society College of Paramedics Dental Sedation Teachers Group** Faculty of Dental Surgery, RCS(Eng) Faculty of General Dental Practice, RCS(Eng) Faculty of Intensive Care Medicine Faculty of Pre-Hospital Care Intensive Care Society National Confidential Enguiry into Patient Outcomes and Death National Institute of Health and Clinical Excellence
- Resuscitation Council (UK) Royal College of General Practitioners Royal College of Nursing Royal College of Obstetricians and Gynaecologists Royal Society of Medicine – Section of Anaesthesia Scottish Dental Clinical Effectiveness Programme Royal College of Midwives Royal College of Radiologists Royal College of Paediatric and Child Health Royal College of Physcians

### Introduction

By relieving anxiety, reducing pain and providing amnesia, sedation techniques have the potential to render uncomfortable diagnostic and therapeutic procedures more acceptable for patients. However, it must be accepted that these techniques also have the potential to cause life-threatening complications.

Despite a number of authoritative publications describing the principles of safe sedation practice, problems continue to occur and relate principally to a failure to ensure adequate standards of training and practice.

This document makes recommendations to support formal competency-based training for healthcare professionals wishing to use conscious sedation techniques for diagnostic and therapeutic procedures.

This document supercedes the previous Academy publication, Implementing and ensuring safe sedation practice for healthcare procedures in adults.<sup>1</sup>

This report should be regarded as a baseline for all forms of sedation in all areas of practice, including the sedation of children. The Francis Report<sup>2</sup> defines an integrated hierarchy of standards. Fundamental Standards need to be applied by all those who work and serve in the healthcare system. No provider should provide any service that does not comply with these Fundamental Standards, in relation to which there should be zero tolerance of breaches.

This document sets Fundamental Standards in sedation practice. Francis also defines Enhanced Quality and Developmental Standards. This document identifies some practices as Developmental Standards which set longer term goals for providers to improve effectiveness.

Individual specialist groups may usefully specify additional standards for specific areas of practice, however these standards should always be additive to and never subtract from the Fundamental Standards set out here.

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### Background to Implementing and Ensuring Safe Sedation Practice for Healthcare Procedures in Adults 2001<sup>1</sup>

Past publications have demonstrated a worrying incidence of sedation-related adverse events, principally in relation to gastrointestinal endoscopic practice.<sup>3-4</sup> Having undertaken a prospective audit of upper gastrointestinal endoscopy in two regions of England, Quine et al demonstrated a 30-day morbidity and mortality of 1:200 and 1:2000, respectively,<sup>4</sup> arguably one third of the deaths being attributable to inappropriate use of sedation. Cardiopulmonary problems were most prevalent, particularly in the elderly, frail patient. Areas of concern included:

- inadequate pre-sedation assessment
- inadequate monitoring of patients undergoing sedation
- excessive doses in the elderly/frail patient
- failure to titrate drugs to effect
- lack of appreciation of the risks implicit in the use of drug combinations, e.g. synergism
- association of the use of flumazenil, a benzodiazepine antagonist, with the use of excessive doses of benzodiazepine and the lack of, or poor, recovery facilities
- minimal training of those administering sedation and the lack of supervision of inexperienced trainees

Although the above summary of problems relates to GI sedation, similar considerations apply to other areas of sedation practice.

Responding to these concerns in 2001 the Academy of Medical Royal Colleges published Implementing and ensuring safe sedation practice for healthcare procedures in adults<sup>1</sup>, making the key point that safety will be optimised only if practitioners use defined methods of sedation for which they have received formal training. The working party recommended a number of new measures to improve standards of practice and patient safety, and these are listed below:

Royal Colleges, in association with the relevant sub-specialty organisations, should develop guidelines on sedation methods appropriate to clinical practice in their sphere of influence.

- 2 Royal Colleges and their Faculties should incorporate the necessary instruction and assessment into training and revalidation programmes of those specialties that use sedation techniques.
- 3 The clinical governance framework should deliver safe sedation practice at hospital level by enabling a patient-centred culture in which:
  - a multidisciplinary team training ensures that all staff understand their roles
  - **b** those who actually administer sedative drugs are aware of the possible adverse consequences and are able to deal with these; and
  - c audit of adverse incidents, complications (particularly severe ones such as [cardiovascular or respiratory complications requiring] admission to intensive care) and adherence to agreed national and local protocols promote continuous quality improvement.
- 4 NHS Trusts should apply to sedation techniques the standard of the Clinical Negligence Scheme which requires that all medical and dental staff in training be, on appointment, competent in the technical skills and specified tasks expected of them.
- 5 Each hospital should nominate two consultants, one an anaesthetist and the other a user of sedation, to collaborate in the local implementation of guidelines and the provision of a specialist service for patients with particular problems.
- 6 Those responsible for commissioning and providing healthcare in the primary and private sectors should ensure that similar processes are in place to ensure a high standard of sedation practice.

### What has changed in the last 12 years?

In response, the Dental Profession, British Society of Gastroenterology (BSG) and the Royal College of Radiologists published appropriate guidance aimed at improving standards of training and practice.<sup>5-7</sup> However, concerns over safety remain and further recommendations have been made to promote safe practice.

In 2004 the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) published *Scoping our Practice*.<sup>8</sup> This inquiry reviewed 30-day mortality over a 12-month period associated with gastrointestinal endoscopy. Seventy-nine percent of those patients who died (1,818) had received some form of sedation.

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Sedation was considered inappropriate in 14% of cases, excessive doses of sedative drugs and the use of drug combinations, particularly in the elderly, being identified as issues. Reversal of sedation was used in 14% of cases, almost universally, to counteract unanticipated central nervous system depression (i.e. an overdose). The reason so many needed reversal of sedation appeared to be due to poor recognition by the endoscopists of how sensitive those with co-morbidity can be to the effects of sedatives and giving patients a 'standard' dose of sedation, most commonly IV midazolam 5mg, which was clearly too much for many. Inadequate pre-assessment was also highlighted as a problem.

Shortfalls in training were identified, only 47% of those endoscopists having admitted to having attended 'courses' on safe sedation. NCEPOD commented that it is '*ultimately the responsibility of the person providing sedation to ensure that they have training in sedation and know the risks and how to respond to them'*. NCEPOD recommended that all those responsible for administration of sedation should have received formal training and assessment.<sup>8</sup>

In dentistry the General Dental Council continues to require registrants wishing to use sedation to receive appropriate supervised theoretical, practical and clinical training.<sup>5,9</sup>

In 2008 the National Patient Safety Agency (NPSA) published a Rapid Response Report entitled Reducing the risk of overdose with midazolam injection in adults,<sup>10</sup> stating that some adult patients are being overdosed with midazolam injection when used for conscious sedation.

Concerns included:

- That the dose often exceeded that required.
- That the sedative drug is often not titrated to the patient's individual needs.
- Failure to take into account any concurrent medication, e.g. opioids.
- Failure to acknowledge that many patients fall into 'high risk' categories, for example, the frail and the elderly.
- The frequent reliance on flumazenil for reversal of sedation in patients who have been over-sedated.
- The availability of high strength midazolam presentations resulting in overdose.

Recommended actions were:

- The use of low strength midazolam (1mg/ml in 2ml or 5ml ampoules).
- Review of therapeutic protocols to ensure that guidance on use of midazolam is clear and that the risks, particularly for the elderly or frail, are fully assessed.
- Ensuring that all healthcare practitioners participating in sedation techniques have the necessary knowledge, skills and competences required.
- Ensuring that stocks of flumazenil are available where midazolam is used and that the use of flumazenil is regularly audited as a marker of excessive dosing of midazolam.
- Ensuring that sedation is covered by organisational policy and that overall responsibility is assigned to a senior clinician which, in most cases, will be an anaesthetist.

2010 saw the publication of cross-specialty sedation guidance from NICE in relation to children and young people.<sup>11</sup> In addition the Royal College of Surgeons of England, the College of Emergency Medicine, Department of Health, specialist societies and independent expert groups have developed guidance documents.<sup>12–15</sup>

It is encouraging that, following the publication of a number of guidelines making recommendations for improved standards of training and practice, progress, in some fields at least, has been made. A national audit of colonoscopy practice undertaken in 2011 has demonstrated significant improvements in sedation practice within the field of endoscopy. The audit captured data on more than 20,000 colonoscopies over a two-week period with 94% data capture. Around 90% were performed under conscious sedation and benzodiazepine and opiate doses were low. Only 0.1% required reversal agents compared to 14% in the 2004 NCEPOD audit. There was only one death, unrelated to the procedure.<sup>16</sup>

Nevertheless, there remain concerns about the safety of sedation provision. Recently the Department of Health identified overdose of midazolam during conscious sedation as one of the Top Ten 'Never Events' for 2012/2013.<sup>17</sup>

The principal recurring theme is the lack of formal training for the appropriate administration of sedative drugs and prompt recognition and treatment of sedationrelated complications. This must be addressed. It is only through insistence on accredited competency-based training for all healthcare workers using such techniques that we can improve the safety of sedation practice. Through adequate formal training and subsequent supervised experience, the competencies required for safe sedation practice can, and must, be acquired by healthcare professional groups, including doctors, dentists and nurses, wishing to use sedation. This document aims to identify the core practical components of good sedation practice and the competencies required for safe administration of sedative drugs.

### Definitions – what is sedation?

Sedation is a drug-induced depression of consciousness, a continuum culminating in general anaesthesia.

The American Society of Anesthesiologists (ASA) defines three levels of sedation<sup>18</sup> (Table 1).

**Minimal sedation** is a drug-induced state during which the patient responds normally to verbal commands. Cognitive function and physical co-ordination may be impaired, but airway reflexes, and ventilatory and cardiovascular functions are unaffected.

**Moderate sedation** describes a state where a purposeful response to verbal commands either alone (~ conscious sedation), or accompanied by light tactile stimulation, is maintained.

In the United Kingdom **Conscious sedation** is defined as, 'a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used should carry a margin of safety wide enough to render loss of consciousness unlikely'.<sup>1,19</sup> The endpoint is clearly defined and wide margins of safety stipulated. The airway is normally unaffected and spontaneous ventilation adequate.

**Deep sedation** describes a state where the patient cannot easily be aroused but responds purposefully to repeated or painful stimulation. It may be accompanied by clinically significant ventilatory depression. The patient may require assistance maintaining a patent airway, and positive pressure ventilation.

Table 1 Continuum of depth of sedation: definition of general anaesthesia and levels of
sedation/analgesia (ASA October 2009)18

	Minimal Sedation/ Anxiolysis	Moderate Sedation/ Analgesia ('Conscious Sedation')	Deep Sedation/ Analgesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response following repeated or painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained
Escalation of required competencies			

\* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response. Excerpted from Continuum of Depth of Sedation. Definition of General Anesthesia and Levels of Sedation/ Analgesia of the American Society of Anesthesiology. From the ASA, 520N, Northwest Highway, Park Ridge, Illinois, 60068-2573, USA.

In summary, passing along the sedation continuum from minimal through moderate to deep sedation, and ultimately to general anaesthesia, increasing depression of physiological systems is seen. The likelihood of adverse events increases, which if not managed promptly, and effectively, may progress to poor outcomes. Increasing depth of sedation is, therefore, accompanied by an escalation in the level of competency required to ensure safe sedation practice, as emphasised by the ASA position statement shown below:<sup>18</sup>

'Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ('Conscious Sedation') should be able to rescue patients who enter a state of Deep Sedation/Analgesia, whilst those administering Deep Sedation/Analgesia should be able to rescue patients. Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation.'

If verbal responsiveness is lost the patient requires a level of care identical to that needed for general anaesthesia.  $^{\scriptscriptstyle 1}$ 

# Practical components of good sedation practice

The underlying premise is that safety will be optimised only if practitioners use defined methods of sedation for which they have received formal training.

### The target state

Conscious sedation, achieved through careful titration of drug to effect, is considered a safe target state because ventilation is normally adequate and cardiovascular function maintained. However, if verbal responsiveness is lost and the patient becomes deeply sedated, airway interventions may be required and ventilation may be inadequate. Consequently deep sedation is considered to require the same level of care as for general anaesthesia.<sup>1</sup>

Unless otherwise stated, this document aims to give guidance for the safe use of conscious sedation techniques by healthcare professionals to facilitate diagnostic and therapeutic healthcare procedures.

### Pre-assessment

Inadequate pre-assessment is a recurring factor in sedation-related adverse events and poor outcomes, for all specialties.

Sedation is often administered to sick and/or elderly patients who may have significant co-morbidity.<sup>20-21</sup> Even in younger patients, the presence of heart disease, cerebrovascular disease, lung disease, liver failure, anaemia, shock and morbid obesity may indicate dangerous risk factors.<sup>6</sup> Hence the importance of pre-operative assessment and preparation of patients, focusing on medical, social and psychological assessment and evaluation of risk, taking into consideration the limitations of the setting, cannot be overestimated.<sup>8,22-24</sup>

Pre-assessment should, wherever possible, include consultation of previous records.

An important consideration in providing all forms of sedation including conscious/ moderate sedation is the ability to rescue a patient who becomes inadvertently over-sedated and, where necessary, maintain an airway and establish satisfactory ventilation and oxygenation. Sedating practitioners should always ask themselves beforehand 'Will I be able to ventilate this patient, if necessary?'

### Information and consent

Valid consent is an essential preliminary to sedation. Department of Health guidance is available.<sup>25</sup>

Information should be provided at an appropriate time (not at the last moment) when there is a chance to have a discussion and for the patient to be able to ask questions, understand the choices and risks before making a decision to sedate. Risks and benefits must be clearly explained and proper distinction should be made between average risk and personalised risk. Alternatives to sedation (typically general anaesthesia or local anaesthesia with behavioural techniques) should be clearly explained. Psychological preparation of patients, especially children and their carers is an important part of preparation for sedation.

Certain patient groups will require additional bespoke information for example children, pregnant and lactating women.

### Fasting

Pre-operative fasting for sedation is controversial and considered unnecessary by some authorities within dentistry and emergency medicine for conscious sedation.<sup>5,24</sup> Airway reflexes are assumed to be maintained during moderate and minimal sedation, and lost during general anaesthesia. It is not clear where the point of loss of reflexes lies, or if such a point exists. The argument is that using minimal and moderate sedation, airway reflexes are maintained but this does not consider the potential for inadvertent over-sedation and the loss of protective airway reflexes.<sup>26</sup> In the United Kingdom the loss of verbal communication/deep sedation is deemed to require the same level of care as general anaesthesia,<sup>1</sup> and many practitioners therefore follow accepted fasting guidance.<sup>27–28</sup>

Guidance from NICE on sedation of children<sup>11</sup> recommends fasting before sedation unless the sedation is limited to:

- minimal sedation
- sedation with nitrous oxide (in oxygen)
- moderate sedation during which the child or young person will maintain verbal contact with the healthcare professional

For elective procedures using any sedation other than the above (and specifically for deep sedation and moderate sedation during which the child or young person might not maintain verbal contact with the healthcare professional) the 2-4-6 fasting rule applies (that is, two hours for clear fluids, four hours for breast milk and six hours for solids).

For an emergency procedure in a child or young person who has not fasted, the decision to proceed with sedation should be based on the urgency of the procedure and the target depth of sedation.

Careful consideration on a case-by-case basis of the patient's presenting condition, co-morbidities, the nature of the procedure and the limitations of the environment, is important to evaluate the risks of aspiration.

Clinicians who choose to sedate patients without fasting should be prepared to justify this choice.

## Patient management and choice of technique for conscious sedation

In selecting a suitable technique it should be remembered that the principal aims of conscious sedation are to:

- provide sedation and relieve anxiety
- maintain consciousness and patient cooperation
- maintain control of physiological parameters

Drugs do not negate the need for good communication skills and a sympathetic manner. A clear explanation at every stage is essential to reassure the patient, particularly when sudden movements may compromise the procedure.

No one sedation technique is suitable for all patients or procedures. Adopting the principle of minimum intervention, the simplest and safest effective technique, based on patient assessment and clinical need, should be used.

Sedative drugs are usually administered via oral, intravenous or inhalational routes. Using the intravenous and inhalational routes, the drugs used can, and must, be titrated to effect (see below). The use of oral sedation may have a limited role. However, titration to effect with oral dosing is not possible and bioavailability is variable, resulting in an unpredictable response.

The specific technique used should be defined by a relevant specialty organisation.

### Titration to effect

When administering intravenous conscious sedation, the initial drug dose should be determined by careful pre-assessment of the patient and any relevant history, and this dose must have taken full effect before any additional dose is given. The use of fixed doses or boluses is unacceptable. Subsequent doses, if necessary, should be carefully titrated to achieve the desired effect. Safe sedation demands knowledge of each drug's time of onset, peak effect and duration of action. In principle, titrating a drug/ drugs to optimal effect is critical to safely achieving a recognised sedation endpoint, thereby avoiding inadvertent over-sedation or general anaesthesia.

Under-sedation is as unwarranted as over-sedation. Where effective sedation cannot be achieved, despite reasonable doses of hypnotic, consideration should be given to either abandoning the procedure or progression to general anaesthesia, if the appropriate staff and other resources are available.

When the intravenous route is used, secure venous access should be maintained throughout the procedure and into the recovery period, and specific antagonist drugs (i.e. naloxone and flumazenil) must be to hand.

Careful consideration of the demands of the procedure being undertaken, particularly whether it is painful or not, is critical to success.

- **For non-painful procedures** sedation alone is sufficient.
- Painful procedures require, in addition, the administration of a specific analgesic agent. It is important to recognise that many sedative and anxiolytic drugs, e.g. benzodiazepines, possess no analgesic properties and hence their attempted use to control pain may result in significant overdose. For localised procedures, e.g. dental or minor procedures, effective local anaesthetic techniques must be used, once adequate sedation is achieved. For other procedures such as colonoscopy, systemic analgesia in the form of an opioid may be required. Hence, combinations of drugs, e.g. sedatives and opioids, may be needed. This combination of drugs could have a synergistic effect, and increase the depth of sedation.

### Multiple drugs and anaesthetic drugs/infusions

As a general rule single drugs are easier to titrate to effect and safer than concurrent administration of two or more drugs. Drugs in combination typically produce synergistic effects, have differing times to onset and peak effect and hence may be unpredictable or difficult to titrate to effect. Safety margins may be narrowed, increasing the likelihood of overdose, loss of consciousness, respiratory depression and the need for airway interventions. Where a combination of a benzodiazepine and an opioid are administered, the opioid should be given first and the benzodiazepine only given once the peak effect of the opioid is observed. Benzodiazepines may be up to eight times more potent following prior administration of an opioid and so must be titrated with care.<sup>29</sup>

Multiple drug/anaesthetic drug techniques should only be considered where there is a clear clinical justification, having excluded simpler techniques. Irrespective of the setting, where multiple drug/anaesthetic drug techniques are used, the sedation team should have immediate access to the same range of skills and facilities as would be found in an acute NHS Trust, for the prompt recognition and immediate management of adverse events.

Anaesthetic drugs, e.g. propofol, possess a narrow therapeutic index and reduced margins of safety, increasing the likelihood of adverse events.

In the USA and several European Union (EU) countries, the use of propofol by non-anaesthetists is described in the literature, although this practice still remains controversial. European guidelines on the Non-Anaesthetist Administration of Propofol (NAAP) for endoscopy were published in December 2010.<sup>30</sup> They stipulated stringent regulations and demonstration of clearly defined competencies. A formal mentored training programme and achieving an appropriate qualification in the practice was strongly advised and self-training discouraged. Nevertheless, these guidelines have been rejected by many EU national societies of anaesthesia who remain clear that only anaesthetists should administer propofol.<sup>31</sup> Several randomised controlled trials have supported the use of propofol by non-anaesthetists in cardiological and gastroenterology practice. In the UK at present there is no provision for nationally recognised formal training programmes or qualification in NAAP.<sup>32</sup>

However, for some procedures, e.g. endoscopic retrograde cholangiopancreatography (ERCP) and other complex, more prolonged procedures, conscious sedation may be inadequate, and deeper levels of sedation or even general anaesthesia may be required to facilitate technical success and ensure patient comfort.<sup>32</sup>

At this time the administration and monitoring of propofol sedation for such potentially complex endoscopic procedures should be the responsibility of a dedicated and appropriately trained anaesthetist.<sup>32</sup>

**Deep sedation** may be accompanied by clinically significant ventilatory depression and airway interventions may be required to maintain airway patency, and positive pressure ventilation to correct hypoventilation or apnoea. Individuals administering deep sedation must be able to rescue patients who become inadvertently over sedated or enter a state of general anaesthesia. Hence the administration and monitoring of deep sedation for those procedures requiring it should be the responsibility of a dedicated sedation-trained anaesthetist, or alternatively an appropriately trained healthcare professional possessing equivalent competencies, i.e. those required for the safe administration of deep sedation and the prompt recognition and rescue management of potential complications, including general anaesthesia. Such an individual must be proficient in airway management and life support.

### Use of antagonist drugs

The benzodiazepine and opioid antagonists, flumazenil and naloxone, **are usually reserved for emergency use**.

The routine use of flumazenil for reversal of sedation with benzodiazepines is not without potential side effects.<sup>10</sup> Incident data suggests that flumazenil is frequently used to treat inadvertent benzodiazepine overdose and, on occasion, no account is taken for the shorter half-life of flumazenil, compared to midazolam, leading to residual re-sedation.<sup>10</sup> Recommendations have been made that the use of flumazenil should be regularly audited as a marker of excessive dosage of midazolam.<sup>10,16</sup>

# Extremes of age – the very young, the elderly and frail, or at-risk patient

Young children are more sensitive to sedative and opioid drugs than adolescent and adult patients, and possess physiological and anatomical considerations that demand supplementary knowledge and skills. Specific training relevant to children is required. NICE guidance exists for practitioners intending to administer sedation to children and young people.<sup>11</sup>

Elderly patients are more sensitive to many drugs than younger patients. It is well established that the doses of midazolam and opioid they require is usually half or less than those required for younger patients. Subsequent incremental doses should also be reduced. It is important therefore to reduce the dose sufficiently in the elderly, frail or at-risk patients.<sup>20–21</sup>

# Monitoring and the use of supplementary oxygen

Clinical and instrumental monitoring to a degree relevant to the patient's medical status and the sedation method, must be used.<sup>1</sup> Regular communication with the patient, in addition to putting them at ease, allows monitoring of the level of sedation. Existing guidance for patients undergoing anaesthesia identifies the need for pulse oximetry, ECG and automated non-invasive blood pressure monitoring.<sup>33</sup> If verbal communication is lost the patient requires the same level of care as for general anaesthesia.<sup>1</sup> Where conscious sedation is used and continuous verbal contact with the patient maintained, ECG monitoring is not essential.

Respiratory depression may accompany the use of intravenous sedatives and opioid analgesic drugs. Oxygen, via nasal cannulae, should usually be administered from the commencement of sedation, through to readiness for discharge from recovery, particularly for patients with relevant medical conditions, where multiple drug techniques or anaesthetic drugs are used, or deeper levels of sedation administered. Whilst administration of oxygen prevents hypoxia it may mask hypoventilation. Currently, oxygen administration is not administered in fit patients undergoing brief, simple procedures and its use in this group should be considered a Developmental Standard.

The Association of Anaesthetists of Great Britain and Ireland recommend that continuous waveform capnography should be used to monitor adequacy of ventilation for all patients undergoing moderate or deep sedation, and should be available wherever any patients undergoing moderate or deep sedation are recovered<sup>34</sup> and additionally where:

- ventilation cannot be directly observed, e.g. MRI/CT
- multiple drugs/anaesthetic drug techniques are used, and
- pre-assessment highlights increased clinical risk.

Use of capnography was supported in the NAP4 project report 'Complications of airway management in the United Kingdom'; this included not only anaesthesia but also intensive care and the emergency department.<sup>35</sup>

Where not already in use, as a fundamental standard, capnography for patients receiving sedation should be considered a Developmental Standard.

Monitoring should be continued into the recovery period.

Checklists are recommended by the World Health Organization to avoid errors in the surgical process.<sup>36</sup> Useful checklists also support procedures for emergencies including anaphylaxis.<sup>37</sup>

The use of checklists may contribute to Safe Sedation practice, particularly the prompt recognition and management of adverse events. The use of checklists for patients receiving sedation should be considered a Developmental Standard.

### The team and the role of the operatorsedationist

The term 'operator-sedationist' defines an individual who both administers sedation and performs the required procedure. However, it may not be possible for an individual administering the sedation and performing the procedure to be fully cognisant of the patient's condition during sedation. It is essential, therefore, that if this model of care is to be used that an appropriately trained second individual, other than the person performing the procedure, monitors the patient's status.

Current guidance for performing gastroenterological procedures under conscious sedation states that where the gastroenterologist works as an operator-sedationist, a minimum of two endoscopy assistants, of whom at least one is a qualified nurse, be present at endoscopy.<sup>6</sup> One assistant is dedicated solely to patient care, having a key role in monitoring the patient's safety, comfort and well-being and in communicating significant changes to the endoscopist. All endoscopy assistants must be capable of helping the endoscopist in the case of emergencies such as cardiac or respiratory arrest, and adequate training and periodic retraining is required. However, it is deemed acceptable in some specialties, e.g. dentistry, that, where conscious sedation is the target state, a second individual already responsible for monitoring the patient may assist the operator-sedationist with interruptible ancillary tasks of short duration, no third person being required.<sup>5,12</sup>

## Factors supporting the case for dedicated sedationists

- The demands of increasingly complex sedation techniques including multiple drug techniques and anaesthetic drug infusions. Techniques that may demonstrate:
  - synergistic effects (where drug combinations are used)
  - wide inter-individual variation in response, and hence dose regimens
  - unpredictability, where multiple drugs are titrated to effect
  - a narrow therapeutic index and hence an increased potential for over-sedation and adverse events
- More prolonged and more complex procedures are being undertaken under sedation, for example in gastroenterology and radiology, where deeper levels of sedation are required to ensure patient comfort and likelihood of technical success.<sup>32</sup>
- The need to care for an increasing number of elderly, frail patients with multiple co-morbidities.
- The devolution of healthcare to what constitute remote environments.
- Current training deficiencies and needs that must be addressed.

Taking these factors into account, for all but brief and simple procedures, undertaken on fit patients, serious consideration must be given to the use of a trained dedicated sedationist, whose sole responsibility is to administer sedation, monitor the patient and address any sedation-related issues. If a dedicated sedationist is not used, the operator-sedationist must be prepared to justify the decision.

If the operator-sedationist model is to be pursued then the presence of a third trained person is required for all but the simplest procedures, performed on fit (ASA 1 or 2) patients, thus ensuring that one appropriately trained assistant can give the patient their undivided attention to monitor their comfort, level of sedation and physiological parameters.

### Discharge

Patients should be formally assessed for suitability for discharge from the clinical area where sedation has taken place. Discharge criteria are as follows:<sup>15</sup>

- The patient has returned to their baseline level of consciousness.
- Vital signs are within normal limits for that patient.
- Respiratory status is not compromised.
- Pain and discomfort have been addressed.
- If there is a requirement to discharge the patient prior to meeting these criteria they should be transferred to an appropriate clinical environment with continuation of peri-procedure monitoring standards.
- Patients meeting discharge criteria following sedation who go on to be discharged home should be discharged into the care of a suitable third party.
- Verbal and written instructions should be given.

### Record keeping

Patient evaluation, consent, data from monitoring during and after sedation and readiness for discharge should be documented.

### Audit and quality assurance

#### Sedation within an institution: clinical incident reporting and auditable standards.

As part of a robust risk management strategy, all NHS institutions should now have computerised incident reporting systems and all clinical incidents where sedation is a factor should be reported. Midazolam over-sedation is defined as a 'never event' by the Department of Health<sup>17</sup> and reporting of these incidents to the National Reporting and Learning System and to the body commissioning this care is mandatory. Failure to monitor oxygen saturation during sedation is also a 'never event' and should be reported in this way.

Clinical incidents that should be reported and investigated locally, within an institution, include: use of flumazenil to reverse sedation, as a surrogate marker of midazolam oversedation; use of naloxone to reverse sedation where opiates have been administered; sustained drop in oxygen saturation <90%; unplanned instrumentation of the airway or intervention of an anaesthetist or other airway expert; unplanned admission to hospital following a procedure under sedation.

Each clinical team using sedation within an institution should audit the number of cases performed by each sedation practitioner and the rate of complications of this sedation, including the incidents referred to above.

Auditable outcomes include:

- number of procedures performed by each operator
- unplanned admissions and operations within eight days of procedure
- 30-day mortality
- use of flumazenil
- use of naloxone
- need for ventilation
- sustained drop in O₂ saturation <90%

## Sedation within an institution: the Sedation Committee

To ensure appropriate governance of sedation within an institution a Sedation Committee should be established to lead and support implementation of these recommendations at hospital level. This committee should include representatives from key clinical teams using procedural sedation and there should be a nominated lead clinician for sedation. In larger institutions, the Sedation Committee should include an anaesthetist.

Suggested duties of the Sedation Committee include development and review of local guidelines; review of pharmacovigilance of sedative drugs, including midazolam and flumazenil storage and use; review of reported clinical incidents where sedation is a factor; annual audit of numbers of sedation cases and the incidence of complications within the institution; overview of staff training and continuing personal development in sedation practice.

To achieve a safe and effective sedation service 'on the ground' across clinical specialties, the concept of a Sedation Team has been developed. The proposed Sedation Team would have both a practical and an educational role, working across an institution to support multidisciplinary staff with both continuing education and 'hands-on' clinical expertise. The Sedation Team would have a role analogous to a pain team, with the aim of improving clinical standards, clinical effectiveness and the quality of patient care in procedural sedation.

### Educational and training standards

## Safety will be optimised only if practitioners use defined methods of sedation for which they have received formal training.

Irrespective of educational background, the competencies required for safe sedation and, crucially, rescue from sedation-related adverse events, must be the same. There must be one standard for all, but the educational requirements and pathways to attain a common standard will vary for different disciplines.

Successive publications have highlighted a lack of formal training as contributing to sedation-related adverse events.<sup>1,4,6,8,10</sup> Safe Sedation Practice 2001 called on Royal Colleges and their Faculties to incorporate the necessary instruction and assessment into the training and revalidation programmes of those specialties that use sedation techniques. Lack of formal training remains an important issue.

It is the responsibility of all disciplines using sedation techniques to ensure that their trainees receive accredited training in the use of these techniques, to a clearly defined national standard.

Addressing the training needs requires that the necessary competencies for the safe and appropriate administration of sedation and prompt recognition and treatment of sedation-related complications, be defined and specified within approved postgraduate training curricula. Trainees who will be expected to use conscious sedation techniques within their sphere of practice on obtaining their Certificate of Completion of Training (CCT), must demonstrate acquisition of the necessary competencies at Annual Review of Competency Progression (ARCP), or through an equivalent process. Those continuing to be actively involved in administering sedation must be able to demonstrate continued competency through maintenance of an appropriate level of experience, and ongoing participation in relevant life-long learning/CPD programmes, now necessary for revalidation.

A summary denoting the team, skills, monitoring, environment and facilities relevant to the sedation continuum considered by this group has been included (see Table 2 opposite).

In addition, the necessary competencies have been defined within an exemplar core curriculum (see Appendix 1). This exemplar curriculum is based upon competencybased sedation training specified within the basic and intermediate sections of the CCT in Anaesthetics Training Curriculum, published by the Royal College of Anaesthetists.<sup>38–39</sup> Sedation training may be achieved using alternate competencybased syllabus structures that reflect the Fundamental Standards described in this report.

	Minimal Sedation/ Anxiolysis	Moderate Sedation/Analgesia ('Conscious Sedation')	Deep Sedation/ Analgesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response following repeated or painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained

Table 2Continuum of depth of sedation. A summary of the team, skills, monitoring,environment and facilities

N.B. Increasing depth of sedation is accompanied by increasing depression of physiological systems (CNS, RS, CVS). Sedation is a continuum and it is not always possible to predict how an individual patient will respond. Practitioners administering sedation, and those tasked with monitoring, must be trained to promptly recognise and manage patients whose level of sedation becomes deeper than intended and experience respiratory depression, loss of airway and inadequate ventilation

The team	<ul> <li>Operator- sedationist</li> <li>Appropriate second person</li> </ul>	<ul> <li>Brief, simple procedures – a second individual may suffice to monitor the patient and assist the operator-sedationist with interruptible ancillary tasks of short duration<sup>5,12§</sup></li> </ul>	<ul> <li>Operator</li> <li>Dedicated sedation- trained anaesthetist or alternatively an</li> </ul>
		<ul> <li>For all but brief and simple procedures a three person model is advocated:</li> <li>Operator-sedationist</li> <li>Trained assistant to monitor patient</li> <li>Assistant to procedure</li> </ul>	appropriately trained healthcare professional <sup>ss</sup> Trained assistant
		<ul> <li>For complex or prolonged procedures or where patient frailty and significant co- morbidities exist, a dedicated sedationist is required</li> </ul>	

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	Minimal Sedation/ Anxiolysis	Moderate Sedation/Analgesia ('Conscious Sedation')	Deep Sedation/ Analgesia
Monitoring	Dictated by co- morbidity	Verbal responsiveness. $SaO_2$ . NIBP. Use of ECG and $ETCO_2$ are Developmental Standards and already recommended by one authority <sup>33-34</sup>	Response to repeated/painful stimulus, SaO <sub>2</sub> , ECG, NIBP, ETCO <sub>2</sub>
Availability of resuscitation skills	BLS – as defined by RC(UK) <sup>4°</sup>	ILS – as defined by RC(UK)	ALS – as defined by RC(UK)
Specific airway skills required	Basic airway manoeuvres	Competency in the use of basic airway manoeuvres, airway adjuncts, supraglottic devices, and bag and mask ventilation	
Environment and facilities	ASA 1 and 2 patients are suitable for treatment in primary and secondary care	Where anaesthetic drug techniques (with or without opioid) are used, trained personnel must be immediately available to assist with the resuscitation of a collapsed patient so that the patient's airway, breathing and circulation are supported fully <b>without delay</b>	NHS Acute Trust setting or equivalent**

#### Notes accompanying Table 2

- \* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.
- \*\* See page 27.
- S The use of opioid/midazolam combinations for dental procedures. For those patients requiring conscious sedation for dentistry, the majority of procedures can be undertaken using inhalational sedation (O<sub>2</sub>/N<sub>2</sub>O), or sedation using a benzodiazepine (midazolam) as a single drug. Analgesia for painful procedures is provided by means of effective local anaesthesia in conjunction with behavioural management strategies. A small number of patients may require the use of systemic analgesia to facilitate administration of local anaesthesia, for example, if multi-quadrant dental treatment is planned. For these patients it may be appropriate to administer a single dose of a short-acting opioid, e.g. fentanyl, waiting a period of time for it to take full effect and only then titrating midazolam to effect. Due to the unpredictability of titrating multiple drugs to effect, the addition of a subsequent dose of opioid should be avoided. There should be no reliance on systemic analgesia to undertake the procedure itself. If the procedure and consider an alternative technique of pain and anxiety management.
- S An appropriately trained healthcare professional possessing equivalent competencies, i.e. those required for the safe administration of deep sedation and the prompt recognition and rescue management of potential complications, including general anaesthesia. Such an individual must be proficient in airway management and life support.

### Supplementary doses of opioids

Supplementary doses of opioids may be required in prolonged uncomfortable procedures such as colonoscopy for which local anaesthesia is not appropriate.

### Setting

\*\*It is important to recognise the limitations of working in the relative isolation of the non-theatre or non-hospital setting.

Irrespective of the setting, where multiple drug/anaesthetic drug techniques are used to provide conscious sedation, the sedation team should have immediate access to the same range of skills and facilities as would be found in an acute NHS Trust, for the prompt recognition and immediate management of adverse events.

Patient selection in advance of the procedure will determine whether the setting meets the requirements of the patient, intended procedure and proposed sedation technique. Staffing and equipment must meet the needs of both the technique (including monitoring) and its possible complications. Appropriate recovery facilities and discharge criteria relevant to the patient's destination are necessary. Resuscitation equipment must be checked, maintained and include all the drugs necessary for life support.

The management of sedation-related complications and medical emergencies should be regularly rehearsed as a team.

### References

- 1 Implementing and ensuring safe sedation practice for healthcare procedures in adults. *AoMRC*, London 2001:1–21 (<u>www.rcoa.ac.uk/node/2270</u>).
- 2 Executive summary of the report of the Mid-Staffordshire NHS Foundation Trust Public Enquiry. Chaired by Robert Francis QC, February 2013 (<u>www.midstaffspublicinquiry.com/sites/default/files/</u>report/Executive%20summary.pdf).
- 3 Daneshmend TK, Bell GD, Logan RF. Sedation for upper gastrointestinal endoscopy: results of a nationwide survey. *Gut* 1991;**32(1)**:12–15.
- 4 Quine MA et al. Prospective audit of upper gastrointestinal endoscopy in two regions of England: safety, staffing, and sedation methods. *Gut* 1995;**36(3)**:462–467.
- 5 Conscious sedation in the provision of dental care. Report of an expert group on sedation for dentistry. Standing Dental Advisory Committee. DH, London 2003;1:1–36 (http://www.dh.gov.uk/prod\_consum\_dh/groups/dh\_digitalassets/@dh/@en/documents/ digitalasset/dh\_4074705.pdf).
- 6 Guidelines on safety and sedation during endoscopic procedures. *BSG*, London 2003 (<u>www.bsg.</u> org.uk/clinical-guidelines/endoscopy/guidelines-on-safety-and-sedation-during-endoscopicprocedures.html).
- 7 Safe sedation, analgesia and anaesthesia within the radiology department. *RCR*, London 2003;**1**;1–8. (www.rcr.ac.uk/publications.aspx?PageID=310&PublicationID=186).
- 8 Scoping our practice. NCEPOD, London 2004 (<u>www.ncepod.org.uk/2004sop.htm</u>).
- 9 Standards for dental professionals. *GDC*, London 2005 (<u>www.gdc-uk.org/dentalprofessionals/</u> <u>standards/pages/default.aspx</u>).
- 10 Reducing risk of overdose with midazolam injection in adults. Rapid Response Report (and supporting information). *NPSA*, London 2008 (<u>www.nrls.npsa.nhs.uk/</u> <u>resources/?entryid45=59896</u>).
- 11 Sedation in children and young people: sedation for diagnostic and therapeutic procedures in children and young people (CG112). *NICE*, London 2012 (<u>http://publications.nice.org.uk/sedation-in-children-and-young-people-cg112</u>).
- Standards for conscious sedation in dentistry: alternative techniques. A report from the Standing Committee on Sedation for Dentistry. *RCoA* and *RCS Eng*, London 2007 (<u>www.rcoa.ac.uk/</u><u>node/2283</u>).
- 13 Guidelines for the appointment of dentists with a special interest (DwSI) in conscious sedation (Gateway Ref: 9102). *DH* and *FGDP*, London 2007 (<u>www.fgdp.org.uk/\_assets/pdf/dentists%20</u> with%20special%20interests/dwsi\_cons\_sed.pdf).
- 14 Conscious sedation in dentistry: standards for postgraduate education. *DSTG* 2008 (<u>www.dstg</u>. <u>co.uk/wp-content/uploads/2012/09/dstg-pg-standards.pdf</u>).
- 15 Safe sedation of adults in the Emergency Department. *RCoA* and *CEM*, London 2012 (<u>www.rcoa</u>. <u>ac.uk/node/10214</u>).

- 16 Gavin DR et al. The national colonoscopy audit: a nationwide assessment of the quality and safety of colonoscopy in the UK. *Gut* 2013;**62(2)**:242–249.
- 17 The 'Never Events' list 2012/2013. *DH*, London 2012 (<u>www.gov.uk/government/uploads/system/</u><u>uploads/attachment\_data/file/142013/Never\_events\_201213.pdf</u>).
- 18 Continuum of depth of sedation: definition of general anaesthesia and levels of sedation/analgesia. ASA, USA 2009 (<u>http://bit.ly/11iGlax</u>).
- 19 Wylie DWD. The Wylie Report 1978;**1**:1–21.
- 20 Gray A, Bell DG. Elderly patients vulnerable because of excessive doses of sedatives. *NPSA*, London 2006 (www.ncepod.org.uk/pdf/current/NPSA%20sedation%20article.pdf).
- 21 Lord DA et al. Sedation for Gastrointestinal Endoscopic Procedures in the Elderly: Getting Safer but Still Not Nearly Safe Enough. BSG, London 2006;19:1–14 (www.bsg.org.uk/pdf\_word\_docs/ sedation\_elderly.pdf)
- 22 Bhananker SM et al. Injury and liability associated with monitored anesthesia care. A closed claims analysis. *Anesthesiol* 2006;**104**:228–234.
- 23 Hug CCJ. MAC should stand for maximum anesthesia caution, not minimal anesthesiology care. *Anesthesiol* 2006;**104(2)**:221–223.
- 24 Thorpe RJ, Benger J. Pre-procedural fasting in emergency sedation. *Emerg Med J* 2010;**27(4)**:254–261.
- 25 Reference guide to consent for examination or treatment. *DH*, London 2009 (<u>www.gov.uk/</u> government/uploads/system/uploads/attachment\_data/file/138296/dh\_103653\_1\_.pdf).
- 26 Mulady DK. The effect of intravenously administered diazepam, midazolam and flumazenil on the sensitivity of upper airway reflexes. *Anaesth* 1994;**49(2)**:105–110.
- 27 Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: an updated report by the American Society of Anesthesiologists Committee on Standards and Practice Parameters. *Anesthesiol* 2011; **7(114)**:495–511.
- 28 Clinical practice guideline: Perioperative fasting in adults and children (full). *RCN*, London 2005 (www.rcn.org.uk/\_\_data/assets/pdf\_file/0009/78678/002800.pdf).
- 29 Ben-Schlomo I et al. Midazolam acts synergistically with fentanyl for induction of anaesthesia. *Br J Anaesth* 1990;**64(1)**:45–47.
- 30 Dumonceau JM et al. Non-anaesthesiologist administration of propofol for GI endoscopy. ESGE-ESGENA-ESA guideline. *Endoscopy* 2010;**42**:960–974 (<u>www.esge.com/assets/downloads/pdfs/</u> guidelines/2010\_non\_anesthesiologist\_admin\_propofol\_gi\_endo.pdf).
- 31 Perel A. Non-anaesthesiologists should not be allowed to administer propofol for procedural sedation. *EJA* 2011;**28(8)**:580–584.
- 32 Guidance for the use of propofol sedation for adult patients undergoing Endoscopic Retrograde Cholangiopancreatography (ERCP) and other complex upper GI endoscopic procedures. *RCoA* and *BSG*, London 2011 (www.rcoa.ac.uk/node/2266).

- 33 Recommendations for standards of monitoring during anaesthesia and recovery (4th Edition). AAGBI, London 2007 (www.aagbi.org/sites/default/files/standardsofmonitoring07.pdf).
- 34 The use of capnography outside the operating theatre. Safety Statement. *AAGBI*, London 2011 (www.aagbi.org/sites/default/files/Capnographyaagbio90711AJH%5B1%5D\_1.pdf).
- 35 Major complications of airway management in the UK. Results of the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 2: intensive care and emergency departments. *Br J Anaesth* 2011;**106(5)**:632–642.
- 36 WHO Surgical Safety Check list. January 2009 (<u>www.nrls.npsa.nhs.uk/alerts/?entryid45=59860</u>).
- 37 Management of a patient with suspected anaphylaxis during anaesthesia. Safety drill. *AAGBI*, London 2009 (www.aagbi.org/sites/default/files/ana\_web\_laminate\_final.pdf).
- 38 CCT in Anaesthetics Basic Level Training (Annex B). *RCoA*, London 2010 (<u>www.rcoa.ac.uk/</u> <u>node/1411</u>).
- 39 CCT in Anaesthetics Intermediate Level Training (Annex C). RCoA, London 2010 (<u>www.rcoa.</u> ac.uk/node/1434).
- 40 Resuscitation Guidelines. Resuscitation Council (UK), 2010 (<u>www.resus.org.uk/pages/GL2010.pdf</u>).

## Appendix 1: Exemplar core curriculum for the safe use of conscious sedation

## Core curriculum for the safe use of conscious sedation techniques for diagnostic and therapeutic healthcare procedures

Conscious sedation techniques are increasingly being used to render potentially uncomfortable diagnostic and therapeutic procedures more pleasant for patients. Nevertheless, they are not without risk and have the potential to cause life-threatening complications. It is essential that trainees understand what is meant by conscious sedation ('A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation') and how it is administered safely.

Learning outcomes:

- To gain a fundamental understanding of what is meant by conscious sedation and the risks associated with deeper levels of sedation.
- To be able to describe the differences between conscious sedation and deeper levels of sedation, with its attendant potential risks to patient safety.
- To gain a fundamental understanding that loss of verbal responsiveness/deep sedation requires the same level of skills and care as for general anaesthesia.
- To recognise the important principle of minimum intervention, where the simplest and safest technique which is likely to be effective is used to achieve the clinical goal.
- To gain a fundamental understanding of the particular dangers associated with the use of multiple sedative drugs, especially in the elderly and young children.
- To be able to safely deliver pharmacological sedation to appropriate patients and recognise the limits of their competency and experience.
- To be able to discuss where and when deeper levels of sedation or anaesthesia may be indicated.
- To be able to manage sedation-related side effects in a timely manner, ensuring patient safety is of paramount consideration at all times.
- To gain a fundamental understanding that for all but brief and simple procedures, undertaken on fit patients, serious consideration must be given to the use of a trained dedicated sedationist, whose sole responsibility is to administer sedation, monitor the patient and address any sedation-related issues and that if a dedicated sedationist is not used the operator-sedationist must be prepared to justify the decision.

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Knowledge			
Competence	Description	Suggested Assessment Methods	GMP
CS_K_01	<ul> <li>Can explain:</li> <li>What is meant by conscious sedation and why understanding the definition is crucial to patient safety.</li> <li>The differences between conscious sedation, deep sedation and general anaesthesia.</li> <li>The fundamental differences in techniques/drugs used/risks to patient safety.</li> </ul>	A,D,E	1,2,3
	<ul> <li>The potential significant risks to patient safety associated with sedation techniques that requires meticulous attention to detail by a dedicated suitably trained sedationist with responsibility for patient safety, safe monitoring and contemporaneous record keeping.</li> </ul>		
CS_K_02	Describes the indications for the use of conscious sedation.	A,C,E	1,2
CS_K_03	Describes the rationale for the use of single drug, multiple drug and inhalation techniques.	A,C,E	1,2
CS_K_04	Describes the risks associated with conscious sedation including [but not exclusively] those affecting the respiratory and cardiovascular systems.	A,C,E	1,2
CS_K_05	Describes the importance of thorough pre-operative assessment and preparation of patients, focusing on medical, social and psychological assessment and evaluation of risk, taking into consideration the limitations of the location. This should include being able to take an appropriate history (e.g. including sleep apnoea and history of problematic airway management during anaesthesia).	A,C,E	1,2,3
CS_K_06	Describes the pharmacology of drugs commonly used to produce sedation and their antagonists.	A,C,E	1
CS_K_07	Explains the need for and means of monitoring the sedated patient including the use of commonly used sedation scoring systems.	A,C,E	1,2

CS_K_08	Describes how drugs should be titrated to effect and how the use of multiple drugs with synergistic actions can reduce the therapeutic index and hence the margin of safety.	A,C,E	1,2
CS_K_09	Describes the importance of considering the demands of the procedure being undertaken, particularly whether it is painful or not, in determining the drugs used, appreciating that painful procedures require the administration of a specific analgesic agent.	A,C,E	1,2
CS_K_10	<ul> <li>Describes the importance of recognising the following when multiple drug techniques are employed:</li> <li>Increased potential for adverse outcomes when two or more sedating/analgesic drugs are administered.</li> <li>The importance of titrating multiple drugs to effect whilst recognising that the possibility of differing times of onset, peak effect and duration, can result in an unpredictable response.</li> </ul>	A,C,E	1,2,3
	<ul> <li>Knowledge of each drug's time of onset, peak effect, duration of action and potential for synergism.</li> </ul>		
CS_K_11	Discusses the place of infusions compared to bolus doses of sedative agents.	A,C	1
CS_K_12	Can explain the minimal monitoring required during pharmacological sedation.	A,C,E	1
CS_K_13	Describes the risks implicit in the administration of sedative drugs to the elderly frail patient and young children and how sedation techniques should be modified accordingly.	A,C,E	1,2,3
CS_K_14	Describes the indications for the use of reversal agents and potential problems associated with their use.	A,C,E	1,2
CS_K_15	Explains the need for robust recovery and discharge criteria when conscious sedation is used for out-patient procedures and the importance of ensuring appropriate escort arrangements are in place.	A,C,E	1,2,3

CS_K_16	Discusses the limitations imposed by working in the isolation of the remote/non-hospital environment including:	A,C,E	1,2,3
	The need to ensure that each component of the premises, e.g. waiting room, surgery, recovery area, is appropriate to the sedation technique(s) used.		
	<ul> <li>The importance of robust patient selection including that it be undertaken in advance of actual treatment and include a valid consent process.</li> </ul>		
	<ul> <li>Awareness that staff and equipment available must meet the needs of both the technique (including monitoring) and its possible complications; awareness of the need to ensure that resuscitation equipment is regularly checked, maintained and includes all the drugs and equipment necessary for advanced life support.</li> </ul>		
CS_K_17	Explains the need to ensure that, irrespective of the setting, where multiple drug/anaesthetic drug techniques are used to provide conscious sedation, the sedation team should have immediate access to the same range of skills and facilities as would be found in an acute NHS trust setting, for the prompt recognition and immediate management of adverse events.	A,C,E	1,2
Skills			
Competence	Description	Suggested Assessment Method	GMP
CS_S_01	Demonstrates the ability to undertake a thorough pre-operative assessment, taking into account the patient's age, frailty and any significant co-morbidities, in determining an appropriate management plan and identifying the 'at-risk' patient. This should include airway assessment, to identify features associated with increased risk of difficulty maintaining the airway and/or ventilation.	A,C,D	1,2,3
CS_S_02	Demonstrates the ability to recognise limits of their competency and experience and when to refer patients for further assessment and possibly the use of an alternative management technique.	A,C,D	1,2
CS_S_03	Demonstrates the ability to explain sedation to patients and to obtain consent.	A,D	1,2,3

CS_S_04	<ul> <li>Demonstrates the ability to consider the following when considering the choice of sedation technique:</li> <li>That no one technique is suitable for all patients and that the most appropriate technique is based on the principal of minimum intervention, using the simplest and safest effective technique, based on patient assessment and clinical need.</li> <li>That techniques using multiple drugs/anaesthetic drugs should only be considered where there is a clear clinical justification, having excluded simpler techniques.</li> </ul>	A,C,E	1,2
CS_S_05	Demonstrates the ability to take into consideration the demands of the procedure being undertaken, particularly whether it is painful or not, in choosing a suitable technique.	A,C,E	1,2
CS_S_06	Demonstrates the ability to administer and monitor inhalational sedation to patients for clinical procedures.	A,D	1,2,3
CS_S_07	Demonstrates the ability to administer and monitor intravenous sedation to patients for clinical procedures.	A,D	1,2,3
CS_S_08	Demonstrates the ability to select sedation techniques appropriate to management in patients of all ages, including those with significant co-morbidities.	A,C	1,2
CS_S_o9	Demonstrates the ability to recognise the limitations of conscious sedation techniques and where and when deeper levels of sedation or general anaesthesia may be indicated.	A,C,D	1,2
CS_S_10	Demonstrates the ability to recognise and manage the complications of sedation techniques promptly and appropriately, including recognition and correct management of loss of verbal responsiveness. This includes the possession of advanced life support skills, including the management of the unconscious patient through possession of deployable airway skills, including, basic airway manoeuvres, use of airway adjuncts, e.g. oropharyngeal airway, supraglottic devices, e.g. iGel/ LMA, and the ability to administer positive pressure ventilation (bag-mask-valve ventilation) when indicated.	A,D	1,2,3

#### Assessment Method Decode

- A Anaesthesia Clinical Evaluation Exercise (A-CEX)
- C Case-based discussion (CBD)
- D Direct observation of clinical skills (DOPS)
- E Examination

#### **GMC** Domains

Domain 1	Knowledge, skills and performance
Domain 2	Safety and quality
Domain 3	Communication, partnership and teamwork
Domain 4	Maintaining trust

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