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Clinical Radiology
The Royal College of Radiologists

Sedation, analgesia and anaesthesia in the radiology department
second edition

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Contents

Foreword

This important guidance is an update of the 2003 guidance and has been undertaken by a multiprofessional working party led by Dr Matthew Gibson on behalf of the British Society of Interventional Radiology (BSIR).

The document builds on the previous guidance in line with the Academy of Medical Royal Colleges' (AoMRC) generic guidance on safe sedation (published in 2013), and the recommendation that individual specialties consider development of their own guidance and standards.[1]

Since 2003, the number of imaging and interventional procedures has increased exponentially, with interventions of increasing complexity and duration being undertaken 24/7 and increasingly being performed on patients who are elderly, neonates or children who may have multiple co-morbidities. Sedation techniques, together with good analgesia and sympathetic, supportive patient management can improve the patients' experience by minimising the negative effects of the intervention and optimising patient outcome. However, patients should not be exposed to unnecessary risk and patient safety must be preserved.

Safe and effective analgesia and sedation should be delivered by an appropriately trained and credentialed team with good access to anaesthetics, pre-procedure assessment, sedation plan and checklist, with appropriate monitoring and availability of resuscitation equipment and reversal agents.

Recommendations for multidisciplinary sedation committees in each institution administering sedation and analgesia, education, training and assessment of all staff groups as well as audit suggestions are included.

This document provides a detailed overview of the issues and will assist departments in reviewing their policies and those responsible for commissioning healthcare to ensure that safe practices are in place.

I would like to thank the members of the working party who prepared this document on behalf of the Faculty.

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Vice-President, Faculty of Clinical Radiology

Key points

1. Safe and effective sedation and analgesia is an essential part of radiological practice.
2. An appropriately trained and credentialed team should administer sedation and analgesia.
3. Patients requiring sedation should undergo pre-procedure assessment and have a sedation plan.
4. A World Health Organization (WHO) checklist should be used for every sedated patient.[2]
5. Sedated patients should be appropriately monitored.
6. Resuscitation equipment and reversal agents should be readily available.
7. A properly staffed recovery area and formalised communication are essential for safe after-care and discharge.
8. All sedation related complications should be recorded.
9. Regular audit of practice should be performed.
10. A multidisciplined sedation committee should exist in each institution administering sedation and analgesia.

1. Introduction

Interventional radiological (IR) procedures are an integral part of many patients' care with a multiplicity of interventions which are increasing in complexity and duration. These procedures can cause pain, anxiety, psychological and physical distress. These unwanted effects can usually be ameliorated by the use of sedation and analgesia. The goal of sedation and analgesia is to improve the patients' experience by minimising the negative effects of the intervention and to optimise patient outcome. To minimise complications associated with sedation and analgesia, they must be administered safely and tailored to individual patients' needs. IR procedures requiring sedation should be performed in an environment appropriate for the delivery of safe care.

Anxiety potentiates pain and vice versa. Sedation cannot be considered in isolation from analgesia as they are frequently used in conjunction. For this reason, this guidance covers the use of sedation and analgesia in diagnostic and interventional radiology procedures.

It is important to consider safe administration of sedation, not only during routine working hours, but also for those patients (who are often elderly, frail or clinically unstable) requiring radiological procedures out of hours as an emergency. For the majority of such procedures, staffing levels will be lower than if the case was performed during normal working hours. If there are complications related to the sedation or analgesia administered, this can compromise effective management.

The Royal College of Radiologists' (RCR) previous guidance in 2003 was well received and this document builds on this foundation.[3] Unfortunately, not all of the goals of the 2003 guidance have been realised and it is hoped that this updated guidance may help to address this. Following the publication of the Francis report, there is a renewed focus on standards, training, audit and organisation.[4]

The Francis report states *'No provider should provide, and there must be zero tolerance of, any service that does not comply with fundamental standards of service. Standards need to be formulated to promote the likelihood of the service being delivered safely and effectively, to be clear about what has to be done to comply, to be informed by an evidence base and to be effectively measurable.'*[4]

The recommendations outlined in this document are graded according to the integrated hierarchy of standards of service outlined in the Francis report.[4]

1. *Fundamental standards of minimum safety and quality, in respect of which non-compliance should not be tolerated. Failures leading to death or serious harm should remain offences for which organisations may be prosecuted. There should be a defined set of duties to maintain and operate an effective system to ensure compliance.*
2. *Enhanced quality standards, which set requirements higher than fundamental standards but which are discretionary matters for commissioners and subject to availability of resources.*
3. *Developmental standards, which set out longer-term goals for providers. These would aim to improve effectiveness and are more likely to be the focus of commissioners and progressive provider leadership than the regulator.*

As described in the Francis report and the Duty of Candour guidance, patients must be informed of the outcome of their procedure including complications.[4,5] The conversation with the patient should occur after the effects of sedation have worn off and the patient has the capacity to comprehend the information given.

The AoMRC's generic guidance on safe sedation, which should be read in conjunction with these guidelines, recommends that individual specialties consider development of their own guidance and standards.[1]

2. Basics of sedation and analgesia

- Sedation is a drug-induced state of depressed consciousness that allows tolerance of an uncomfortable or painful diagnostic or interventional procedure.
- Sedation is a continuum from minimal sedation to general anaesthesia. Some terminology around sedation is confusing and for clarity's sake this document uses the American Society of Anesthesiologists' (ASA)-defined levels of sedation (see Table 1).[6]

Table 1. Definition of level of sedation[6]

	Minimal sedation (anxiolysis)	Moderate sedation 'conscious sedation'	Deep sedation	General anaesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal/ tactile stimulation	Purposeful response to repeated/ painful stimuli	Unrousable even to painful stimuli
Airway	Unaffected	No intervention required	Intervention may be required	Intervention usually required
Spontaneous ventilation	Unaffected	Adequate	May be impaired; assistance may be required	Frequently impaired; assistance may be required
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

- Appropriately trained sedation teams should be able to safely induce a state of minimal or moderate sedation. Deep sedation and general anesthesia should remain the province of an anaesthetist. As the level of sedation increases, physiological responses become depressed and the likelihood of adverse events increases.
- A target level of sedation should be defined prior to the procedure. However a deeper level of sedation may be inadvertently produced and the sedation team should be able to rescue the patient by correcting the physiological consequences and returning the patient to the intended level of sedation.
- Analgesia and sedation are closely related. Anxiety potentiates pain and vice versa. Analgesia is therefore crucial and can be multimodality including local and regional anaesthesia and opioid and non-opioid drugs.

3. Pre-procedural assessment

Inadequate pre-procedural assessment is a factor in sedation related adverse events. Patients should be assessed to identify those that may not tolerate sedation and require anaesthetic input. Pre-procedural assessment should also address consent, patient expectation and post-procedural instruction and care.

Timing

- Patients requiring sedation for elective procedures should be assessed within 30 days of the procedure and this should be updated within 24 hours of the procedure. *Development standard.*
- Emergency cases should be assessed prior to procedure. *Fundamental standard.*

Format

- The format of the assessment can be adapted locally. Models include telephone assessment, written proforma, IR clinic, nurse-led clinics or the pre-existing preoperative assessment service.
- The assessment could be combined with the consent process.
- The assessment and resultant pre-procedure plan (including sedation, anticoagulation, medication and so on) should be documented and available at time of procedure. The format should be agreed locally and could be incorporated into the safety checklist. *Fundamental standard.*

Medical history

- A medical history and a systems survey should be obtained to identify co-morbidities and disease control issues.
- Factors that may indicate sensitivity to sedation, for example, sleep apnoea, chronic obstructive pulmonary disease (COPD), smoking, alcohol abuse, obesity and renal or hepatic impairment should be identified.
- ASA level (see table 2) should be assessed.[6] *Fundamental standard.*

Table 2. ASA physical status classification[6]

	Patient characteristic	Example
Class I	A normal healthy patient	Non-smoker, minimal drinker, healthy
Class II	A patient with a mild system disease	Smoker, well controlled hypertension/diabetes, mild lung disease, moderate drinking
Class III	A patient with a severe system disease	Distant history of myocardial infarction (MI), cerebrovascular accident (CVA), cardiac stent, end stage renal disease (ESRF), pacemaker, ejection fraction <40%
Class IV	A patient with severe systemic disease that is a constant threat to life	Recent MI, CVA, transient ischemic attack (TIA), ongoing cardiac ischaemia, ejection fraction <28%
Class V	A moribund patient who is not expected to survive without the procedure	Ruptured abdominal aortic aneurysm (AAA), bowel ischaemia

Anaesthetic consultation for Class III–V should be considered.

Drug history and allergies

- A list of current medication must be obtained.
  Fundamental standard.
- Local anticoagulation, anti-platelet therapy and glycaemic control protocols should be implemented.
  Fundamental standard.
- Links with the anaesthetic lead for perioperative medicine should be established to ensure that preoperative advice is uniform through the organisation.
- Opiate usage and chronic pain predict higher sedation requirements and anaesthetic input should be considered.
- Regular analgesics should be taken on the procedural day to ensure comfortable positioning.
- Patients already taking narcotic analgesia including patches and patient controlled analgesia (PCA) pumps are often habituated to opiates but vulnerable to overdose and should be identified.

- Allergies to most sedative agents or local anaesthesia are rare, but all allergies should be documented.
  Fundamental standard.

Anaesthetic history

- The anaesthetic history may highlight previous difficult intubations or an event, which may indicate the need for experienced anaesthetic input.
- The airway should be assessed, this may include the Mallampati airway score, jaw protrusion, neck flexion and extension neck issues.[7] If potential airway problems that may compromise airway management and the ability to ventilate are identified, anaesthetic input should be sought.

Positioning

- Patients should be assessed to ensure they can lie flat and still for the requisite time.

Examination

- A set of preoperative observations (heart rate, blood pressure, oxygen saturation and respiratory rate) should be documented.
  Fundamental standard.
- Height and weight should be measured to aid dose calculation.
  Fundamental standard.

Patient information

- Fasting advice should be given (see Section 4. Immediate pre-procedure care).
  Fundamental standard.
- Patients should receive written (available in a variety of languages) or visual information detailing what to expect from the sedation and the procedure.
  Fundamental standard.
- Adequate aftercare (accompanying adult, transport) must be ensured and written post-procedure instructions (for example, no driving for 24 hours) given at the pre-assessment visit.
  Fundamental standard.

4. Immediate pre-procedure preparation

Fasting

- The need for fasting with moderate sedation has been questioned. However, as there is the possibility of inadvertent over-sedation, fasting should be instituted to reduce risk of aspiration.
- Many institutions have their own fasting guidelines for elective cases (often the same as those for general anaesthesia). Adult patients can have food up until six hours before the procedure and clear fluid (including black tea and coffee) until two hours before. There are specific recommendations for paediatric patients (see Section 13. Paediatric sedation and reference 8).[8]

- Patients should not be over-fasted. Wards and so on should be kept informed of procedure start times.
- In emergent non-fasted cases that cannot be delayed, intravenous therapy (such as metocloperamide and H2 blocker) to promote gastric emptying, neutralise gastric acid and reduce chance of aspiration or even general anaesthesia and intubation should be considered.[9]
- Fasting is unnecessary for inhaled nitrous oxide and oxygen (Entonox).

Medication

- In general, regular medications, including analgesia and cardiovascular, should be continued.
- There are specific perioperative guidelines for patients with diabetes (covering such topics such as when procedures should be postponed and how to manage perioperative hyperglycaemia).[10] A local policy, incorporating this guidance, for the management of diabetes (with advice on fasting, medication [including insulin] dose and timing and intravenous substitution) should be developed in conjunction with local diabetes and endocrinology services and adhered to.
  Fundamental standard.

Communication

- Good communication and a sympathetic manner with patients is an essential adjunct to sedation and improves the patient experience.
- A WHO checklist, adapted to the radiology environment and procedure should always be used.[2,11]
  Fundamental standard.

Miscellaneous

- Reliable intravenous cannula – preferably 20 Gauge (G) or above (except inhaled or minimal oral sedation) should be available.
  Fundamental standard.
- For every case, formal confirmation that all appropriate equipment is available, working and the team know its location. This includes, but is not limited to oxygen (O_2) supply, suction, intravenous fluids and resuscitation equipment (including defibrillator and intubation equipment).
  Fundamental standard.

5. Intra-procedure monitoring and management

Monitoring

- Continuous monitoring of pulse oximetry, respiratory rate and electrocardiogram (ECG).
  Fundamental standard.
- Blood pressure measured at least every five minutes.
  Fundamental standard.
- Sedation and pain level monitored at least every ten minutes.
  Fundamental standard.

- Temperature measured before, during and after procedure, especially with prolonged procedures.
  Developmental quality standard.
- Blood glucose should be measured before, during and after procedure in patients with diabetes.
  Fundamental standard.
- Capnography – advocated for early detection of apnoea (prior to desaturation) and indirect monitoring of cardiac output but not considered essential.[12]
  Developmental standard.
- The use of bispectral index monitoring (BIS) to measure and quantify sedation level is controversial without sufficient agreement to allow this to be a standard.[13]

In-procedure patient care

- Intravenous (IV) access maintained.
  Fundamental standard.
- Record of all drugs given with doses, times, route.
  Fundamental standard.
- Preserve normothermia.
  Fundamental standard.
- Prevent pressure and position related injuries, make comfortable and support painful joints and so on to allow lying still for longer.
  Fundamental standard.

6. Recovery and discharge post-procedure

- Patients transferred from the procedural room to recovery area should be handed over to a named member of staff.
  Fundamental standard.
- The recovery area and staff should provide monitoring and resuscitative levels to the same standard as the procedural room.
  Fundamental standard.
- Monitoring including sedation level, heart rate, blood pressure, oxygen saturation, respiratory rate, pain score, nausea and vomiting scores (where appropriate) should be recorded on a chart with calculated warning scores.
  Fundamental standard.
- Time to discharge should also be recorded. Procedures should use appropriate sedation levels and analgesia aiming for early mobility and discharge.
- Patients receiving general anaesthetic should be recovered until return of airway reflexes by an anaesthetist, anaesthetic assistant or trained recovery staff as per Association of Anaesthetists of Great Britain and Ireland (AAGBI) recommendations.[14]
  Fundamental standard.
- Patients can be discharged home when:
  - They have returned to their pre-procedural consciousness level
  - Their vital signs are stable or returned to pre-procedural levels

  - They have a responsible adult at home
  - Pain and/or nausea or vomiting is controlled.
  - They have and understand written post-procedure instructions including contact details (including for out of hours). A hard copy of the discharge summary documenting the procedure and sedation and discharge medication should be given to patient.
    Fundamental standard.
- Patients may be transferred from the recovery area to the ward with a similar level of care and staffing if required. Patients should be handed over to both nursing and medical staff using the situation, background, assessment and recommendation (SBAR) format covering the procedure, sedation and post- procedural care.

7. Equipment

- Resuscitation/emergency cart with back-up power, defibrillator, equipment for intubation and ventilation immediately available with regular documented checks.
  Fundamental standard.
- Oxygen supply – portable or fixed source with back-up supply.
  Fundamental standard.
- Airway maintenance and oxygen delivery equipment – such as nasal cannulae, face masks (including one capable of delivering 100% oxygen), oral airways, endotracheal tubes/supraglottic airways for example, laryngeal mask airways, laryngoscopes, Ambubag.
  Fundamental standard.
- Suction equipment (capable of producing continuous suction at 150 millimeter mercury [mmHg]) and suction catheters, regularly checked and immediately available.
  Fundamental standard.
- Monitoring equipment – pulse oximetry, blood pressure, heart rate, cardiac rhythm, respiratory rate.
  Fundamental standard.
- Pressure related and position related injury prevention equipment (such as straps and gel pads).
  Fundamental standard.
- Anaphylaxis pack – usually as separate pack (often in emergency cart) containing adrenaline 1 in 1,000 for intramuscular (IM) injection, chlorphenamine and hydrocortisone and blood tubes for tryptase (recommended by National Institute of Health and Care Excellence [NICE] for all case of anaphylaxis to confirm diagnosis).[15]
  Fundamental standard.
- Readily available, clearly displayed emergency response plans (possibly wall charts) for cardiovascular collapse, over-sedation/reversal and anaphylaxis.
  Fundamental standard.
- Magnetic resonance imaging (MRI) appropriate equipment for sedation in MRI scanner – see section **14. Cross-sectional imaging**.
- Support for X-ray table (if needed) for resuscitation.
  Fundamental standard.

- Venous thromboembolism (VTE) prophylaxis equipment as per locally developed protocol.
  Fundamental standard.
- Homeothermia preserving equipment (such as space blankets or forced air warming system).
  Fundamental standard.

8. Personnel

Sedation and analgesia should be administered by a competent and well-trained sedation team and oversight provided by a sedation committee within the institution.

Sedation team members

Performing clinician

- Should be at least intermediate life support (ILS) trained.
  Fundamental standard.
- Understands the indications and objective of sedation/analgesia.
- Obtains consent for analgesia/sedation.
- Prescribes medication in advance.
- Identifies potential synergism with other medications
- Can identify side-effects and complications of sedation/analgesia.
- Can administer reversal agents.

Primary sedation practitioner

- Should be at least ILS trained.
  Fundamental standard.
- Administers sedation/analgesia.
- Monitors the patient and records the results.
- May be a doctor, nurse or other appropriately trained healthcare professional.
- Determines correct dosage of medications.
- Communicates any concerns to other team members.
- Identifies side-effects and complications of sedation/analgesia.
- Can administer reversal agents.

Secondary sedation practitioner

- At least basic life support (BLS) trained.
  Fundamental standard.
- Assists primary sedation practitioner (and, as circumstances dictate, the performing clinician).
- Usually a nurse, nurse practitioner or healthcare assistant.

Anaesthetist

- A trained anaesthetist, with a special interest in radiology and familiarity with the diagnostic and IR environments and procedures, can be very helpful and often essential.
- Deep sedation or anaesthesia should not proceed without dedicated anaesthetic support.[16]
- Dedicated anaesthetic support should be considered in:
  - Procedures involving confused, frail or elderly patients
  - Patients with multiple co-morbidities
  - Patients who are already on opiates who may require increased sedation or alternative agents for example Propofol
  - Patients with a suspected difficult airway
  - Patients with previous general anaesthetic problems or allergies to sedation drugs
  - Complex cases or long procedural times
  - Any case where an unexpected peri-procedural complication significantly changes the pre-procedural expectations
  - Emergency or unpredictable procedures
  - Patients who are, or are likely to become, unstable.

Sedation team composition

- The minimal sedation team for IR should be the performing clinician and a primary sedation practitioner.
  Fundamental standard.
- Ideally the sedation team should be the performing clinician, primary sedation practitioner and secondary sedation practitioner.
  Development standard.
- The AoRMC guidance notes that 'current guidance for endoscopic procedures allows for an "operator-sedationist" (who both administers sedation and performs the procedure) with the presence of two endoscopy assistants, of whom at least one is a qualified nurse.'[1,17] However we believe the 'operator-sedationist' model should be avoided, as it may not be possible for this individual to be in full control of the patient's condition.
- While we acknowledging the challenges of providing a comprehensive IR service out of hours, we recommend the same standards apply as in hours, as this environment may pose increased risk due to emergent patient group and reduced availability of *ad hoc* support.
- Any member of the sedation team has the authority to stop the procedure if they feel that the patient is at risk.
  Fundamental standard.
- The primary sedation practitioner should continue to monitor the patient and stay with them at all times until full recovery or formalised handover.

- Ideally the original sedation team should remain in place throughout the procedure, but this is not always possible. Any change to team requires approval of the performing clinician and appropriate handover.

9. Therapeutic agents

- Drugs should be targeted at the anticipated problem – usually pain or anxiety. It is recognised that anxiety and pain are inter-related.
- In general the IV route is preferred to oral or IM as the unpredictable bioavailability makes titration of dose versus effect difficult. However, oral medication may have role in cross-sectional imaging such as prior to MRI in claustrophobic patients.
- The initial dose of medication will be determined by the clinician based on pre-procedure assessment including size, age, co-morbidities and so on.
- Subsequent doses should be titrated against effect and pre-determined sedation target level.
- The elderly are much more sensitive to sedative effects of and paradoxical reactions to drugs (especially benzodiazepines) than younger patients and doses should be adjusted accordingly.
  Fundamental standard.
- Adequate time should be allowed for drugs to take effect (with intravenous medication at least two minutes) before another dose or second drug is given.
  Fundamental standard.
- Combination therapy (sedation and analgesia) is often used in IR. The sedative effects of opiates and benzodiazepines are synergistic rather than additive (such as a benzodiazepine and opiate with equal sedative effect given together have an eight fold increase in sedative effect rather than double). A reduced dose of opiate should be given first. The sedative effect should be assessed after at least two minutes before an appropriately reduced dose of benzodiazepine is given.
  Fundamental standard.
- Non-pharmacological measures such as empathetic staff, own music, video games and hypnosis can compliment other measures.
- If there is any doubt or clinical concern, anaesthetic involvement should be considered.

Sedatives

Benzodiazepines

- Benzodiazepines are the most commonly used sedative agents possessing both anxiolytic and amnesia properties.
- Midazolam is the benzodiazepine of choice because of its rapid onset of action and short elimination half-life (1–4 hours). Other benzodiazepines are available but none have any significant advantages over midazolam and some have significant disadvantages. A typical dose of midazolam is 1–2.5 miligrams (mg) given over two minutes.

- Differing strengths of the preparation can lead to the incorrect dose being administered and therefore it is strongly recommended that only the 1 mg/millilitre (ml) strength should be used.
- This is reflected in the NHS 2015/16 list of 'never events' which highlights complications of the use of higher strength preparations for 'conscious sedation'.[18]

Other sedatives

Propofol

- Given as an IV infusion, propofol has a rapid onset of effect, fast recovery and ease of titration but it has a narrow therapeutic range and can impair respiration and airway reflexes.
- Few sedation teams have sufficient experience and expertise to use propofol and at present this should remain an 'anaesthetist only' drug.

Ketamine

- Induces a dissociative state and analgesia and causes only minimal respiratory depression but can cause hypertonus, movement, bronchodilation and sympathetic stimulation (hypertension and tachycardia although sometimes the reverse in critically ill patients).
- Therefore it is suggested that ketamine should be an 'anaesthetist only' drug.

Analgesics

Opioids

Opioids are the most commonly used intra-procedural systemic analgesic.

Fentanyl

- Is the opioid of choice due to its rapid onset of action, short half-life and fewer side-effects compared to other opioids such as morphine, diamorphine or pethidine.
- A typical dose is 25–100 micrograms (µg) titrated to effect, usually given in 25 µg increments.
- Rarely, fentanyl can cause skeletal muscle rigidity resulting in 'stiff chest syndrome' which may require succinylcholine administration and airway intubation.

Patient controlled analgesia (PCA) using opioids (usually fentanyl) can be used successfully for many IR procedures, particularly solid organ embolisation.

Oral opioids can be used but usually for analgesia after a procedure.

Non-opioids

- These include paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) and are typically used after procedures or as outpatient medication (although intravenous paracetamol can be useful intra-procedurally).
- Combining non-opioids with opioids can improve effectiveness of analgesia without increasing the opioid related risks.

Other drugs

- 50% nitrous oxide and 50% oxygen (Entonox) can be used as a patient activated inhaled form of analgesia. Rapid onset of action with minimal side-effects means it is suited to use in the IR setting.
- Entonox has approximately the same analgesic effect as 100 µg of fentanyl and few significant side-effects.
- Local policy for the use of Entonox, documenting details such as suitable patients, should be in place.
- An Entonox champion who overseas training, cylinder availability and so on is advised.

Local anaesthesia

Topical

- Topical local anaesthetics can be applied as creams, sprays, jellies and so on, and can be useful for needle phobic patients prior to intravenous catheter insertion or prior to infiltration of local anaesthetic.
- The most widely used is Emla cream (2.5% lidocaine/2.5% prilocaine) applied to the desired location under an occlusive dressing one hour prior to procedure.

Subcutaneous Lidocaine

- Is the most widely used infiltrative local anaesthetic, usually in 1 or 2% formulation with typical onset of one to two minutes, duration of 30–60 minutes with a maximum dose of 4 mg/kilogram (kg) (typically 30 ml of 1% and 15 ml of 2%).

Bupivacaine, mepivaciane and ropivacaine are longer acting and have slightly different side-effects.

- Infiltration of local anaesthetic causes transient pain.
- This can be reduced by injecting slowly, prior topical local anaesthetic, pinching the skin prior to injection and alkalinisation using 8.4% sodium bicarbonate (typical ratio 1:10 sodium bicarbonate:lidocaine).
- Guiding the local anaesthetic needle using ultrasound (for example, immediately adjacent to the liver or renal capsule or the vessel wall) and giving a sufficient dose improves effectiveness of local anaesthetic.

Local anaesthetic systemic toxicity (LAST) can occur when an excessive dose of local anaesthetic is infiltrated or injected in the wrong location (such as intravascular).

This results in a wide range of symptoms from metallic taste, mouth numbness and light-headedness through to seizures and cardiac arrest. Urgent anaesthetic assistance should be sought to assist with airway management and cardiovascular support. Intravenous lipid can be used for LAST especially in unresponsive cardiac arrest. Every department giving infiltrative local anaesthetic should have local policy for management of LAST (which may include use of IV lipid).[19,20]
Fundamental standard.

Regional anaesthesia

Local anaesthetic can be infiltrated around nerves to produce larger areas of anaesthesia. These areas of anaesthesia can be very effective and may make otherwise intolerable procedures pain free. They include various arm and shoulder blocks for haemodialysis

dialysis fistula intervention, intercostal or celiac plexus blocks for biliary procedures and superior hypogastric nerve block for uterine embolisation. Regional anaesthesia is typically administered by anaesthetists but, with appropriate training and support, is within the capability of most IRs.

Reversal agents

The effects of opioids and benzodiazepines can be reversed. However with safe sedation practice, reversal is rarely needed and thus sedation teams may become unfamiliar with drug doses and so on.

A clear reversal protocol should be developed and prominently displayed wherever sedation or analgesia is used.
Fundamental standard.

Audit of reversal agent usage may reveal over usage indicating suboptimal sedation practice.

Naloxone

Naloxone blocks and reverses the effect of opioids. It reverses the respiratory depression but also the analgesic effects. Thus its administration can cause pain, anxiety and agitation. Therefore it should be administered in incremental doses with full-dose reversal reserved for life-threatening respiratory depression. 0.1–0.2 mg should be given at two to three minute intervals until respiratory depression is reversed.

Its half-life is less than 90 minutes so repeated doses or even an infusion may be required (although less likely to be needed with shorter acting opioids such as fentanyl).

Flumazenil

Flumazenil blocks the sedative and amnesic effects of benzodiazepines and reverses benzodiazepine induced respiratory depression within two minutes of administration. Reversal dose is 0.01 mg/kg. Typically given in 0.1–0.2 mg increments for partial reversal and 0.4–1 mg for complete reversal. Its short half-life may necessitate repeated administration. Flumazenil may cause agitation, anxiety and tremors.

10. Complications

Treatment should be directed at the specific complication and reversal of sedation should be considered.

Some complications can be easily managed by the sedation team but there should be clear local policy for summoning assistance both in and out of hours. Complications of sedation should be recorded as part of departmental morbidity and mortality (M&M) data.
Fundamental standard.

- Agitation
  - Paradoxical agitation can occur, especially with children, adolescents and the elderly. Giving more sedation may exacerbate the situation and rescheduling the procedure with anaesthetic assistance should be strongly considered.

- Hypotension
  - Hypotension can be due to sedation or analgesia but other causes such as sepsis and blood loss need to be considered.
  - IV fluid should be readily available.
    Fundamental standard.
  - Summoning anaesthetic assistance and vasopressors should be considered.
- Nausea and vomiting
  - Suction must be available in case vomitus compromises the airway.
    Fundamental standard.
  - Anti-emetics (for example, ondansetron typically 4 mg IV over two minutes) should be given to relieve nausea.
- Respiratory depression
  - Supplemental oxygen should always be given with sedation.
    Fundamental standard.
  - The airway can be protected by manoeuvres such as chin lift, jaw thrust and suction but intubation may be required.
  - Robust local policy to allow this, such as training members of the sedation team or a policy for summoning urgent anaesthetic assistance should be in place.
    Fundamental standard.

11. Training and audit

Structured training of the sedation team and radiology trainees in sedation and analgesia and life support is essential.

Continuing professional development for the sedation team needs to be implemented and formalised.

Audit and incident reporting is essential for quality assurance.

Education and assessment for radiologists in training

- The clinical radiology curriculum (2016) includes knowledge and skills required to safely prescribe, administer and monitor the use of sedation and analgesia.[21]
- The IR curriculum should to be used in conjunction with this document.[22]
- Trainees in IR should be competent in:
  - Prescribing drugs used for sedation and analgesia including drug interactions and patient-specific factors affecting administration
  - Management of adverse reactions, including anaphylaxis, resuscitation and cardiac arrest
  - Knowledge of reversal agents
  - Advanced life support (ALS), to recognise and treat the deteriorating patient using a structured airways, breathing, circulation, disability, exposure (ABCDE) approach.
- Assessment of these competencies should include:
  - Assessment of the knowledge component of the core curriculum during the FRCR Part 2A examination

  - Recording peri-procedural sedation routinely in trainee log books which could form part of future workplace-based assessment (WpBA) assessments or curricula. *Development standard.*
- The appropriate use of anaesthesia and sedation should be specifically addressed when undertaking WpBAs for trainees and should be considered as part of any overall summative assessment of competence in a procedure.
- Formal examination of competency in sedation and analgesia is included within the European Board of Interventional Radiology examination.[23] This qualification is optional for UK trainees but may be helpful in demonstrating competencies in this field.

Additional training in sedation

Additional knowledge and experience in sedation might be obtained from a range of sources including:

- Formal knowledge and skills training, possibly delivered in conjunction with anaesthetists
- Clinical experience in other departments using sedation (for example endoscopy)
- E-learning resources relating to sedation generally and specifically within IR (for example, Radiology Integrated Training Initiative [R-ITI])
- Simulation training involving sedation or complications of sedation.[24]

Training and assessment for nursing staff

Several models for delivering procedural sedation exist within current UK practice.

The performing physician and primary sedating practitioner model is the most commonly used and primary and secondary sedating practitioners should be appropriately trained in sedation.

- Intermediate life support (ILS) training should be undertaken. *Fundamental standard.*
- Administering and monitoring sedation should not be undertaken by anyone without appropriate training and experience, the level of which should be formally determined within each department. *Fundamental standard.*
- There is a need for formalised training, review and appraisal procedures. *Fundamental standard.*

Continuing professional development

Maintaining current knowledge and skills for safe sedation should also be regarded as part of continuing fitness to practise, and therefore be included in the annual appraisal and revalidation processes for consultants, nurses and trainees in IR.
Development standard.

Quality and practice improvement

The safe and appropriate use of sedation forms an important element of the clinical risk profile of IR and as such should be part of any departmental clinical governance and audit programme.

All departments where sedation is used should have the following in place.

- A clearly defined pathway for elective patients who might require sedation, including minimum requirements for pre-assessment, peri- and intra-procedural monitoring and immediate postoperative care.
- Written advice for patients who have received sedation for a procedure, given in advance of admission.
- Mechanisms for ensuring that all staff involved in administering or monitoring sedation are appropriately trained.
- Local links between radiology recovery area and theatre recovery to enable education and training.
- Defined pathways for managing and recording events of inadvertent deep sedation.

Audit

Regular audit should assess and ensure standards of practice.
Fundamental standard.

Outcomes measures, which should be audited
Fundamental standard.

- 100% of complications related to sedation recorded on computerised incident reporting system.
- 100% of 'never events' relating to sedation (currently overdose due to the selection of high-strength midazolam [5 mg/ml or 2 mg/ml] rather than the 1 mg/ml preparation) recorded and investigated.

Outcomes measures, which could be audited: one per year per institution as a recommended minimum
Fundamental standard.

- Cases of sustained SaO_2 of <90%.
- Failure to give supplemental oxygen in response to decreased oxygen saturation (although it is recommended that supplemental oxygen is given to all sedated patients).
- The need for use of reversal agents.
- Proportion of procedures carried out under sedation.
- Unplanned admissions following sedation.
- Unplanned requirement for ventilation.
- 30-day mortality.

An audit template is included as Appendix 1.

12. Organisation

In line with the Francis report, every institution should have sedation standards that are robust and infer safe practice at all times.[4] Organisational support within every institution is required to ensure adherence to these standards while allowing a framework in which to instigate enhanced standards with tailoring of services at a departmental level.

- A sedation committee should be formed within every institution using sedation to ensure appropriate governance.
  Developmental standard.
- Members of the committee with a nominated clinical lead for sedation could include:
  - Members of key clinical teams using sedation
  - Anaesthetist
  - Specialist in pain control
  - Pharmacology representation
  - Nurse specialist with an interest in sedation
  - Risk manager
  - Lay member.
- The sedation committee should ensure high standards of care across an institution and provide a framework for continuous improvement.
  - This can be achieved through:
    - Education and training
    - Support for formal training of sedation teams
    - Continued professional development to ensure safe practice
    - Assessment of clinical competency.
  - Audit
    - Measure performance at trust and local level
    - Compare performance to national standards.
  - Clinical effectiveness
    - Develop sedation standards for implementation
    - Encourage research and scientific review to improve practice.
  - Risk management
    - Computerised record of clinical incidents related to sedation
    - Local investigation of all clinical incidents
    - Reporting of all 'never events' to the National Reporting and Learning System.[25]
  - Systems and process
    - Continuous monitoring of risk
    - Encourage learning from mistakes.
  - Liaising with professional bodies
    - Royal Colleges
    - National/international societies.

13. Paediatric sedation

A paediatric sedation practice requires a multidisciplinary approach. A local multidisciplinary sedation committee should be formed to define local sedation practices, age limits, review practice, learn from audit cycles and report critical incidents to the appropriate national body.[26]
Fundamental standard.

The paediatric sedation team should work in close collaboration with the paediatric anaesthetic department.

It should be possible to achieve a high success rate for sedation in children undergoing radiological imaging. Repeated failure should prompt a review of the sedation service and changes must be implemented before the service is resumed.

General points

Children undergoing radiological examinations and procedures need a deeper level of sedation than adults. Sedation should provide anxiety relief and control of pain and excessive movement.

Sedation may be required to control behaviour.[27] A child's ability to control their behaviour and cooperate is dependent on their chronological and developmental age. Generally, healthy children over the age of six years can co-operate with non-invasive studies. Those younger than four months can successfully complete diagnostic imaging procedures with a feed and wrap technique.

Sedation should produce central nervous system (CNS) depression, such that the child is not easily roused by painless stimuli such as noise or movement, but does not impair breathing reflexes or the airway. Levels of sedation in paediatrics are the same as those in adults.[6]

No airway intervention should be required, although the paediatric sedation team should be trained in advanced airway management and life support to rescue the child from a deeper than anticipated level of sedation.[26,28]
Fundamental standard.

Sedation should be administered by a healthcare professional who is not directly involved in the procedure – a primary sedation practitioner (See **Section 8. Personnel**).
Fundamental standard.

The primary sedation practitioner should be trained in advanced paediatric life support.
Fundamental standard.

Failure of sedation results in a crying, struggling, distressed child, who may also require significant restraint. This causes unwanted stress (for child and parents), adverse procedural outcomes and less effective care for future investigations/procedures.[29]

For procedures likely to be painful or to induce unpleasant autonomic reflexes, general anaesthesia should be considered.

In older children, the administration of pre- and peri-procedural analgesia can produce good results without the need for a general anaesthetic.

For older and co-operative children, other modalities, including hypnosis, distraction, guided imagery, parental presence and the use of topical local anaesthesia may reduce the need for and depth of sedation.

Individual MRI examinations should be tailored to allow diagnostic images to be acquired in the shortest possible time. Short acquisition times using single-shot fast spin echo and volumetric gradient echo sequences which reduce artefacts and improve image quality should be considered.[30]

1. Pre-assessment

Pre-assessment prior to sedation is mandatory.
Fundamental standard.

It should include evaluation of current medical condition, growth assessment, past medical problems (particularly related to sedation or anaesthesia), medication history, and physical status including airway problems, psychological and developmental status.

The preferences of the child and parents should be taken into account.

If any of the following apply, an anaesthetic review is needed, as it may be safer for the procedure to be performed under general anaesthesia:[289]

- Potential airway or respiratory problem
- ASA grade 3 or greater
- Neonate or infant
- Neurological impairment
- Global developmental delay
- Behavioural disturbance.

Other relative contraindications to sedation include:

- Raised intracranial pressure
- Uncontrolled grand mal epilepsy
- Risk of pulmonary aspiration of gastric contents
- Severe renal or hepatic failure.

When assessing a child it should be decided how much patient motion can be tolerated. Although many radiology procedures require the patient to be motionless, this is not always necessary. In these cases, a lighter level of sedation may be sufficient.

Radiology investigations/procedures requiring breath-holds for children who are too young to comply will mandate the use of general anaesthesia to reliably and safely facilitate a controlled apnoea.[31]

2. Consent

Written consent for all procedures performed under sedation should be obtained.
Fundamental standard.

The proposed sedation technique and alternatives to sedation should be discussed with the child (if Gillick/Fraser competent) and the parents or carers.[32,33]
Fundamental standard.

The child should be psychologically prepared by ensuring the following information is discussed with them in a way appropriate to the cognitive stage of development.

- Clear and full explanation of the procedure.
- What will be expected of them.
- How to cope with the procedure, including reassurance on elements of the procedure of which they may be fearful.

- Explanation of sensations that they may feel during the procedure, such as the contrast injection, cannula/needle insertion or numbness.

3. Environment

The type of hospital where the sedation is undertaken is an important safety consideration. It is of key importance that the entire team involved is familiar with caring for sedated children undergoing imaging studies. This is not something that can be undertaken as occasional practice. When an established and experienced team is not available, early consideration should be given to transferring the child to a specialist paediatric hospital.

There are differences in sedation practice in a specialist children's hospital compared to a district hospital setting, for example lower age limits defined for general anaesthetic practice in a specialist children's hospital.

The facilities should be safe, secure and child-friendly and separate from adult services.

The child should be sedated within or close to the imaging department.

Transportation of sedated children over long distances is undesirable.

Gaining access to the child if they deteriorate can be difficult (especially during MRI). The rescue and resuscitation of a child in this setting should be documented in local sedation guidelines.

Deep sedation outside a hospital environment is potentially hazardous and is not recommended.[26]
Fundamental standard.

The staff undertaking sedation should be competent in airway management. Notably, training in advanced paediatric life support (APLS) or the equivalent is not sufficient for care of sedated children.[26] Staff should be appropriately trained and regularly assessed in the recognition and management of airway complications.[28]
Fundamental standard.

4. Equipment

The availability of age and size appropriate equipment is mandatory.
Fundamental standard.

For moderate sedation the following should be continuously monitored.[27]
Fundamental standard.

- Respiratory rate.
- Oxygen saturation.
- Heart rate.
- Depth of sedation.
- Pain.
- Coping.
- Signs of distress.
- Three lead electrocardiogram.
- Blood pressure.

With deep sedation there should also be continuous monitoring of end tidal CO_2 (capnography).[28]
Fundamental standard.

Staff must be trained to monitor, interpret and respond to changes in the child's condition throughout the investigation/procedure and recovery until the patient is easily rousable with a stable airway and protective airway/respiratory reflexes.

5. Fasting guidelines

Neonates and young infants will often sleep through an imaging procedure with a feed and wrap technique.

All children should be fasted for procedures requiring sedation or general anaesthesia.

NICE guidance advises that fasting is not required for minimal sedation, Entonox and moderate sedation during which the child will maintain verbal contact.[26] However caution is advised with moderate sedation as it has the risk of inadvertent over-sedation.

Recommended fasting times are:

- Two hours for clear fluids (includes dilute iodinated contrast for bowel opacification in CT)
- Four hours for breast milk
- Six hours for solids.

It is important that children do not undergo unnecessary prolonged fasting as this can cause significant distress and affect the efficacy of sedation.

The decision to sedate a child for an emergency procedure when they have not been fasted should be based on the urgency of the procedure and the target depth of sedation required.

6. Technique

This will depend on the procedure and the required depth of sedation. Numerous drugs have been used and these have been given by various routes including oral, intra-nasal and intravenous. There is no perfect sedative agent in children and all drug regimens have a failure rate.

Selecting a sedative drug will depend on local expertise, patient cohort and the type of imaging study. The following are examples of drugs that could be considered. These might be used in isolation or combination. This list is by no means exhaustive. The choice of sedative may be less important than the personnel, protocols and environment used to deliver it.

Chloral hydrate is given in a single dose orally. Dose ranges from 30–100 mg/kg up to 1 g. It is used in infants and children >45 weeks post-menstrual age (PMA) and <15 kg. The main disadvantage is gastric irritation, which can lead to vomiting. At higher doses respiratory depression has been reported.

Midazolam can be administered by a variety of routes; orally, intranasally or intravenously. It has a rapid onset and produces anxiolysis and amnesia, which may be useful. Paradoxical agitation occurs in up to 15% of patients. Children must be closely observed for signs of respiratory depression, especially if it is used in conjunction with an opioid.

Dexmedetomidine has been introduced into British paediatric clinical practice relatively recently. It is a highly selective Alpha 2 agonist that has sedative and analgesic effects. It has been safely used as an intravenous infusion for paediatric MRI. Dose ranges are wide and being explored. A notable side-effect is bradycardia.

Nitrous oxide (Entonox or 'laughing gas') is administered via a mask or mouthpiece with oxygen. It produces analgesia and a degree of sedation. It maybe useful for older children undergoing brief painful procedures for example renal biopsy. It does not reliably produce adequate procedural conditions. It can cause nausea and euphoria.

7. General anaesthesia and deep sedation

General anaesthesia will produce the best conditions for operating and acquiring images. It ensures the child is comfortable, motionless and can facilitate breath holds as needed.

General anaesthetics agents and sedative drugs in sufficient quantities to cause unconsciousness should be administered by an anaesthetist. This should be done by anaesthetic teams that have expertise in caring for children.

Induction of anaesthesia may be inhalational, usually with sevoflurane or intravenous, usually with propofol. A variety of other agents are available including ketamine and thiopentone. These may be used for specific clinical reasons.

Delivery of a balanced anaesthetic will ensure optimal operating conditions and a quick and painless recovery for the child. The risk of anaesthesia in healthy children is minimal. In children with co-morbidity, general anaesthesia is often safer than sedation.

8. Analgesia

Simple analgesics including paracetamol and non-steroidals may be effective for children having diagnostic studies. When children are undergoing painful procedures, analgesia should be titrated to ensure they are comfortable peri- and post-operatively. Occasionally local anaesthetic to a puncture site will be enough, but often an opiate such as fentanyl is required.

9. Recovery, transfer and discharge (including postoperative instructions)

Vital signs must return to pre-sedation values before discharge.
Fundamental standard.

The child must be awake (or have returned to their baseline level of consciousness) with no risk of further reduced level of consciousness.
Fundamental standard.

Symptoms resulting from sedation/anaesthesia (nausea or vomiting) or from the procedure (pain) must be adequately managed.
Fundamental standard.

The parent/carer must receive clear and relevant instructions on aftercare prior to discharge from hospital.
Fundamental standard.

10. Paediatric interventional radiology

Improved patient satisfaction and procedural conditions result when general anaesthesia is used for painful procedures in children.[30] Therefore sedation has a limited role in paediatric IR.

It is inappropriate to perform anything other than the briefest interventional radiology procedure under sedation in a young child.

In co-operative children, short, painful procedures can be undertaken using preoperative topical analgesia, with a local anaesthetic agent infiltrated into the incision site at the time of the procedure.

For children requiring a minimal to moderate level of sedation for a short invasive procedure, such as a renal biopsy or chest tube removal, midazolam and/or Entonox should be considered.

Entonox is a potent analgesic, anxiolytic and sedative. It causes depressed consciousness and therefore is self-administered under the supervision of an appropriately trained healthcare professional (familiar with administration, side-effects, contraindications and trained in paediatric basic life support). Entonox is contraindicated in conditions where air may be trapped in body cavities (for example, pneumothorax, intestinal obstruction, severe bullous emphysema, maxillofacial injuries, air embolism), head injury with depressed consciousness and poor nutritional status.[31]

Midazolam (oral or intranasal) can produce moderate sedation, although the stimulating effects of a painful procedure may counteract its sedative action. Caution is advised with oral usage due to the difficulty titrating dose to effect.

Intravenous agents can be considered for painful procedures where Entonox and/or midazolam are unsuitable. These should only be administered under the direction and supervision of an anaesthetist.

14. Cross-sectional imaging

Cross-sectional imaging rarely requires sedation or analgesia although there are notable exceptions.

MRI claustrophobia

- Often successfully treated with minimal (oral) anxiolysis or sedation, re-assurance and pre-scan visit.

Patients unable to co-operate

- Confusion, dementia and involuntarily movement can compromise ability to image patients. Varying levels of sedation or general anaesthesia are required according to severity of underlying problem.
- Appropriate consent should be sought and in many cases anaesthetic input will be needed.
- For patients who are unable to lie still due to pain, sedation and analgesia can be helpful.

Critically ill patients

- Transfer to and from radiology should be rigorously planned and local protocols developed and adhered to.
  Fundamental standard.
- Ideally the patients should be stable before transfer but in certain circumstances this is not possible, for example where CT is needed to elucidate the cause of blood loss.
- The patient should be accompanied and fully monitored by an anaesthetist +/- appropriate team during the transfer and imaging.
  Fundamental standard.
- There should be minimal delay while the patient is in the radiology department for the investigation to be performed.

Environment

- Both CT and MRI suites are challenging environments in which to perform sedation and general anaesthesia.
- Limited access to the patient, exposure to radiation and magnetic fields are some of the challenges.
- Liaison with the anaesthetic department is essential to ensure several anaesthetists and ancillary personnel are familiar with the radiological environment.
- Written protocols for these environments should be produced. These should include emergency evacuation of the patient from the scanner and location of resuscitation area.
  Fundamental standard.

MRI compatible equipment

- All equipment used in the MRI scanning room must be MRI compatible and clearly labelled as such.
  Fundamental standard.

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Appendix 1. Audit of sedation, analgesia and anaesthesia in radiology

Descriptor

Tool for assessing the safety and efficacy of sedation and analgesia in the setting of radiological procedures.

Background

This tool is designed to be used in conjunction with *Sedation, analgesia and anaesthesia in the radiology department, second edition*.

Cycle

Standards:

1. An appropriately trained and credentialed team should administer sedation and analgesia.
2. Patients requiring sedation should undergo pre-procedure assessment and have a sedation plan.
3. A World Health Organization (WHO) checklist should be used for every sedated case.[2]
4. Sedated patients should be appropriately monitored.
5. Resuscitation equipment and reversal agents should be readily available.
6. A properly staffed recovery area and formalised communication are essential for safe after-care and discharge.

Target:

100% of these criteria should be met.

Assess local practice

Indicators:

1. The person administering sedation to the patient should have appropriate and current training in line with local and national guidance.
2. Documented pre-procedure assessment and sedation plan should be available in the notes.
3. A completed WHO checklist including sign-in and sign-out should be available for every case.
4. Appropriate monitoring should be used for all cases. The observations monitored should be recorded in a legible way, with an appropriate frequency of measurement.
5. Resuscitation trolley and drug inventory should be checked daily and signed for.
6. Documented hand over after the procedure and written discharge information should be available for every patient.

Data items to be collected:

A retrospective audit of 10–20 consecutive radiology cases having sedation should be undertaken, with each one of the above indicators assessed for each case.

Where the target is not met, action should be taken promptly to ensure the target is achieved and a repeat audit undertaken. If the targets are achieved, then a routine audit should be undertaken annually to ensure safe standards of practice are maintained.

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