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**Guidelines on Sedation and/or Analgesia for Diagnostic and
Interventional Medical, Dental or Surgical Procedures**

This document is intended to apply wherever procedural sedation and/or analgesia for diagnostic and interventional medical, dental and surgical procedures are administered, especially where sedation and/or analgesia may lead to general anaesthesia. The Australian and New Zealand College of Anaesthetists recognises that practitioners with diverse qualifications and training are administering a variety of medications to patients to allow such procedures to be performed. This document addresses pertinent issues for all practitioners involved in such activities.

1. DEFINITIONS

- 1.1 **Procedural sedation and/or analgesia** implies that the patient is in a state of drug-induced tolerance of uncomfortable or painful diagnostic or interventional medical, dental or surgical procedures. Lack of memory for distressing events

and/or analgesia are desired outcomes, but lack of response to painful stimulation is not assured.

1.1.1 **Conscious sedation** is defined as a drug-induced depression of consciousness during which patients are able to respond purposefully to verbal commands or light tactile stimulation. Only exceptionally will interventions be required to maintain a patent airway, spontaneous ventilation or cardiovascular function. Conscious sedation may be achieved by a wide variety of drugs including propofol, and may accompany adequate local anaesthesia. All conscious sedation techniques should provide a margin of safety that is wide enough to render loss of consciousness unlikely.

1.1.2 **Deep levels of sedation**, where consciousness is lost and patients only respond to painful stimulation, are associated with loss of the ability to maintain a patent airway, inadequate spontaneous ventilation and/or impaired cardiovascular function. Deep levels of sedation may have similar risks to general anaesthesia, and may require an equivalent level of care.

1.1.3 **Analgesia** is reduction or elimination of pain perception, usually induced by drugs which act locally (by interfering with nerve conduction) or generally (by depressing pain perception in the central nervous system).

1.2 **General anaesthesia** is a drug-induced state characterised by absence of purposeful response to any stimulus, loss of protective airway reflexes, depression of respiration and disturbance of circulatory reflexes. General anaesthesia is sometimes indicated during diagnostic or interventional medical or surgical procedures and requires the exclusive attention of an anaesthetist, or other appropriately trained and credentialled medical specialist within his/her scope of practice (see College professional document T1 *Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations*).

2. AIMS AND RISKS OF PROCEDURAL SEDATION AND/OR ANALGESIA

2.1 The aims of procedural sedation and/or analgesia are to ensure patient safety and comfort, and to facilitate completion of the planned procedure. In order to achieve these aims, a range of sedation options may be required during any one procedure, with a continuum from no medication, through conscious sedation and deep sedation, to general anaesthesia. While no sedation or conscious sedation with small doses of drugs such as benzodiazepines and opioids are options for some patients and proceduralists, many patients and proceduralists want deep levels of sedation or general anaesthesia to be an option during each procedure.

2.2 Practitioners authorised or credentialled to administer procedural sedation and/or analgesia should be aware that the transition from complete consciousness through the various depths of sedation to general anaesthesia is a continuum and not a set of discrete, well-defined stages. The margin of safety of drugs used to achieve sedation and/or analgesia varies widely between patients and loss of

consciousness with its attendant risk of loss of protective reflexes may occur rapidly and unexpectedly. Therefore practitioners who administer sedative or analgesic drugs that alter the conscious state of a patient must be prepared to manage the following potential risks:

- 2.2.1 Depression of protective airway reflexes and loss of airway patency.
 - 2.2.2 Depression of respiration.
 - 2.2.3 Depression of the cardiovascular system.
 - 2.2.4 Drug interactions or adverse reactions, including anaphylaxis.
 - 2.2.5 Individual variations in response to the drugs used, particularly in children, the elderly, and those with pre-existing medical disease.
 - 2.2.6 The possibility of deeper sedation or anaesthesia being used to compensate for inadequate analgesia or local anaesthesia.
 - 2.2.7 Risks inherent in the wide variety of procedures performed under procedural sedation and/or analgesia.
 - 2.2.8 Unexpected extreme sensitivity to the drugs used for procedural sedation and/or analgesia which may result in unintentional loss of consciousness, and respiratory or cardiovascular depression.
- 2.3 Over-sedation, airway obstruction, respiratory or cardiovascular complications may occur at any time. Therefore, to ensure high standards of patient care, the following guidelines are recommended.

3. PATIENT PREPARATION

- 3.1 The patient should be provided with written information, where possible, which includes the nature and risks of the procedure, preparation instructions (including the importance of fasting), and what to expect during the immediate and longer term recovery period, including after discharge.
- 3.2 Informed consent for sedation and/or analgesia and for the procedure should be obtained according to applicable legislation (see College professional document *PS26 Guidelines on Consent for Anaesthesia or Sedation*).

4. PATIENT ASSESSMENT

- 4.1 All patients should be assessed before procedural sedation and/or analgesia. Assessment should include:
 - 4.1.1 Details of the current problem, co-existing and past medical and surgical history, history of previous sedation and anaesthesia, current medications

(including non-prescribed medications), allergies, fasting status, the presence of false, damaged or loose teeth, or other evidence of potential airway problems.

4.1.2 Examination, including that relevant to the current problem, of the airway, respiratory and cardiovascular status, and other systems as indicated by the history.

4.1.3 Results of relevant investigations.

4.2 This assessment should identify those patients at increased risk of cardiovascular, respiratory or airway compromise during procedural sedation and/or analgesia, as in such cases, an anaesthetist should be present to care for the patient. These patients include the elderly, those with severely limiting heart, cerebrovascular, lung, liver or renal disease, morbid obesity, significant obstructive sleep apnoea, or known or suspected difficult endotracheal intubation, acute gastrointestinal bleeding particularly with cardiovascular compromise or shock, severe anaemia, the potential for aspiration of stomach contents (which may necessitate endotracheal intubation), previous adverse events due to sedation, analgesia or anaesthesia, and patients in ASA Grades P 4-5 (see Appendix I and College professional document PS7 *Recommendations for the Pre-Anaesthesia Consultation*).

5. STAFFING

5.1 Except for very light conscious sedation and/or analgesic techniques such as inhaled nitrous oxide or low dose oral sedation, there must be a minimum of three appropriately trained staff present: the proceduralist, the medical or dental practitioner administering sedation and monitoring the patient, and at least one additional staff member to provide assistance to the proceduralist and/or the practitioner providing sedation as required.

5.2 The assistant to the medical or dental practitioner administering sedation/anaesthesia must be exclusively available to that practitioner at induction of and emergence from sedation/anaesthesia, and during the procedure as required. If general anaesthesia is intended, and especially in emergency situations where endotracheal intubation is planned, a fourth person to specifically assist the anaesthetist throughout the procedure is required (see College professional document PS8 *Recommendations on the Assistant for the Anaesthetist*).

5.3 The practitioner administering procedural sedation and/or analgesia requires sufficient training to be able to:

5.3.1 Understand the actions of the drugs being administered, and be able to modify the technique appropriately in patients of different ages, or in the case of concurrent drug therapy or disease processes.

5.3.2 Monitor the patient's level of consciousness and cardiorespiratory status.

- 5.3.3 Detect and manage appropriately any complications arising from sedation.
- 5.4 A medical or dental practitioner who is skilled in airway management and cardiopulmonary resuscitation must be present whenever procedural sedation and/or analgesia are administered.
- 5.5 Techniques intended to produce deep sedation or general anaesthesia must not be used unless there is present an anaesthetist, or other appropriately trained and credentialled medical specialist within his/her scope of practice (see College professional documents PS1 *Recommendations on Essential Training for Rural General Practitioners in Australia Proposing to Administer Anaesthesia*, PS2 *Statement on Credentialling and Defining the Scope of Clinical Practice in Anaesthesia*, PS8 *Recommendations on the Assistant for the Anaesthetist*, PS16 *Statement on the Standards of Practice of a Specialist Anaesthetist*, TE3 *Policy on Supervision of Clinical Experience for Trainees in Anaesthesia*, T1 *Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations*).
- 5.6 In situations other than those when an anaesthetist must be present (noted in 4.2 and 5.5), administration of sedation and/or analgesia and monitoring of the patient should be performed by another appropriately trained medical or dental practitioner working with the proceduralist.
- 5.7 If such an appropriately trained medical or dental practitioner is not present solely to administer sedation and/or analgesia and monitor the patient, there must be an assistant to the proceduralist present during the procedure, who is appropriately trained in observation and monitoring of sedated patients, and in resuscitation, and whose primary duty is to monitor the level of consciousness and cardiorespiratory status of the patient, and who must be immediately available to manage the patient should there be any need. This person may, if appropriately trained, administer sedative and/or analgesic drugs under the direct supervision of the proceduralist, who must have advanced life support skills and training (see 5.4). Propofol, thiopentone and other anaesthetic agents must not be used in these circumstances. If loss of consciousness, airway obstruction or cardiorespiratory insufficiency occur at any time, all staff must devote their entire attention to monitoring and treating the patient until recovery, or until such time as another medical or dental practitioner becomes available to take responsibility for the patient's care.

6. FACILITIES AND EQUIPMENT

The procedure must be performed in a location which is adequate in size, and staffed and equipped to deal with a cardiopulmonary emergency. These facilities and equipment must be sufficient to maintain basic life support until more specialised help, equipment and drugs become available. At a minimum this must include:

- 6.1 Adequate room to perform resuscitation should this prove necessary.

- 6.2 Appropriate lighting.
- 6.3 An operating table, trolley or chair which can be tilted head down readily is preferable but not mandatory.
- 6.4 An adequate suction source, catheters and handpiece.
- 6.5 A supply of oxygen and suitable devices for the administration of oxygen to a spontaneously breathing patient.
- 6.6 A means of inflating the lungs with oxygen (e.g. a self-inflating bag and mask) together with ready access to a range of equipment for advanced airway management (e.g. masks, oropharyngeal airways, laryngeal mask airways, laryngoscopes, endotracheal tubes).
- 6.7 Appropriate drugs for cardiopulmonary resuscitation and a range of intravenous equipment and fluids including drugs for reversal of benzodiazepines and opioids (See Appendix II).
- 6.8 A pulse oximeter.
- 6.9 A sphygmomanometer or other device for measuring blood pressure.
- 6.10 Ready access to an ECG and a defibrillator.
- 6.11 A means of summoning emergency assistance.
- 6.12 Within the facility there should be access to devices for measuring expired carbon dioxide.

(See College professional documents T1 *Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations*, PS15 *Recommendations for the Perioperative Care of Patients Selected for Day Care Surgery*.)

7. SPECIALISED EQUIPMENT FOR INHALATIONAL SEDATION

When inhalational agents such as nitrous oxide or methoxyflurane are being used to provide sedation, risks of chronic exposure should be considered, and the following special requirements must be satisfied:

- 7.1 The patient breathing circuit should be of lightweight construction, should have a reservoir bag for inspired gases, and must provide low resistance to normal gas flows.
- 7.2 Installation and maintenance of any piped gas system must be according to appropriate standards.

- 7.3 Servicing of equipment and piped gases must occur on a regular basis and at least annually.
- 7.4 There must be a non-return valve to prevent re-breathing.
- 7.5 An appropriate method for scavenging of expired gases must be in use.
- 7.6 When nitrous oxide is used there must be a minimum oxygen flow of 3 litres/minute with a maximum combined flow of 10 litres/minute, or, in machines so calibrated, a minimum of 30% oxygen. The circuit must include an anti-hypoxic device which cuts off nitrous oxide flow in the event of an oxygen supply failure, and opens the system to allow the patient to breathe room air.
- 7.7 There must be the capacity for the administration of 100% oxygen.
- 7.8 There must be a low gas flow alarm.

8. TECHNIQUE AND MONITORING

- 8.1 Reliable venous access should be in place for all procedures when procedural sedation and/or analgesia are used. It is acknowledged that this may not be practical in some patients receiving non-intravenous sedation (e.g. small children, intellectually disabled patients), in which case a note should be made in the medical record.
- 8.2 As most complications of sedation are cardiorespiratory, doses of sedative and analgesic drugs should be kept to the minimum required for patient comfort, particularly for those patients at increased risk.
- 8.3 Monitoring of the depth of sedation, typically by assessing the patient's response to verbal commands or stimulation must be routine. Loss of patient response to stimulation or verbal commands indicates that loss of airway reflexes, respiratory and/or cardiovascular depression are likely, and sedation should be lightened accordingly. It is recognised that monitoring of verbal response may be difficult in some patients (e.g. small children, patients with intellectual disabilities or language difficulties).
- 8.4 All patients undergoing procedural sedation and/or analgesia must be monitored continuously with pulse oximetry and this equipment must alarm when appropriate limits are transgressed.
- 8.5 In all patients there must be regular recording of pulse rate, oxygen saturation and blood pressure throughout the procedure. It is acknowledged that monitoring prior to commencement of sedation may not be practical in some patients (e.g. small children, patients with intellectual disabilities), in which case a note should be made in the medical record.

- 8.6 According to the clinical status of the patient, other monitors such as ECG or capnography may be required (see College professional document PS18 *Recommendations on Monitoring During Anaesthesia*).

9. OXYGENATION

- 9.1 Hypoxaemia may occur during procedural sedation and/or analgesia without oxygen supplementation. Oxygen administration diminishes hypoxaemia during procedures carried out under sedation and/or analgesia, and must be used in all patients for as much of the procedure as possible. It is acknowledged that oxygen administration prior to commencement of sedation may not be practical in some patients (e.g. small children, patients with intellectual disabilities), in which case a note should be made in the medical record.
- 9.2 Pulse oximetry enables the degree of tissue oxygenation to be monitored and must be used in all patients during procedural sedation and/or analgesia. If hypoxaemia is detected staff should devote their whole attention to correcting this situation which may include ceasing the procedure until the hypoxaemia is corrected.

10. MEDICATIONS

- 10.1 A variety of drugs and techniques are available for procedural sedation and/or analgesia. The most common intravenous agents used are benzodiazepines (such as midazolam) for sedation and opioids (such as fentanyl) for analgesia. Even small doses of these drugs may result in loss of consciousness in some patients. Special care is required when local anaesthesia of the larynx and/or pharynx has been administered to facilitate the procedure.
- 10.2 **Intravenous anaesthetic agents such as propofol must only be used by a second medical or dental practitioner trained in their use because of the risk of unintentional loss of consciousness. These agents must not be administered by the proceduralist.**

11. DOCUMENTATION

The clinical record should include the names of staff performing sedation and/or analgesia, with documentation of the history, examination and investigation findings. A written record of the dosages of drugs and the timing of their administration must be kept as a part of the patient's records. Such entries should be made as near to the time of administration of the drugs as possible. This record should also note the regular readings from the monitored variables, including those in the recovery phase, and should contain other information as indicated in College professional document PS6 *Recommendations on the Recording of an Episode of Anaesthesia Care*.

12. RECOVERY AND DISCHARGE

- 12.1 Recovery should take place under appropriate supervision in a properly equipped and staffed area (see College professional document PS4 *Recommendations for the Post-Anaesthesia Recovery Room*).
- 12.2 Adequate staffing and facilities must be available in the recovery area for managing patients who have become unconscious or who have suffered complications during the procedure.
- 12.3 Discharge of the patient should be authorised by the practitioner who administered the drugs, or another appropriately qualified practitioner. The patient should be discharged into the care of a responsible adult to whom written instructions should be given, including advice about eating and drinking, pain relief, and resumption of normal activities, as well as about making legally-binding decisions, driving, or operating machinery.
- 12.4 A system should be in place to enable safe transfer of the patient to appropriate medical care should the need arise.

13. TRAINING IN PROCEDURAL SEDATION AND/OR ANALGESIA FOR NON-ANAESTHETIST MEDICAL PRACTITIONERS

- 13.1 It is recommended that non-anaesthetist medical or dental practitioners wishing to provide procedural sedation and/or analgesia should have received a minimum of 3 months full time equivalent supervised training in procedural sedation and/or analgesia and anaesthesia or similar approved course. They should participate in a process of In-Training and Competency Assessment. Training should include completion of a crisis resource management simulation centre course.
- 13.2 It is recognised that there will be non-anaesthetist medical or dental practitioners who have had many years experience in procedural sedation and/or analgesia, but who may not have had a period of formal supervised training as described. Such longstanding clinical experience may be deemed equivalent to a formal period of training as described.
- 13.3 Credentialling, training and clinical support of such medical or dental practitioners should be achieved by close cooperation from nominated anaesthetists in the hospital or procedural centre, or for remote or rural practitioners with anaesthetists in a major centre particularly when intravenous or intramuscular sedation is practiced.
- 13.4 Regular certification in cardiopulmonary resuscitation, and evidence of relevant continuing professional development, are required for credentialling.

RELATED ANZCA DOCUMENTS

All College professional documents must be complied with, but particular note should be taken of the following:

- PS1 *Recommendations on Essential Training for Rural General Practitioners in Australia Proposing to Administer Anaesthesia*
- PS2 *Statement on Credentialling and Defining the Scope of Clinical Practice in Anaesthesia*
- PS4 *Recommendations for the Post-Anaesthesia Recovery Room*
- PS6 *The Anaesthesia Record. Recommendations on the Recording of an Episode of Anaesthesia Care*
- PS7 *Recommendations for the Pre-Anaesthesia Consultation*
- PS8 *Recommendations on the Assistant for the Anaesthetist*
- PS15 *Recommendations for the Perioperative Care of Patients Selected for Day Care Surgery*
- PS16 *Statement on the Standards of Practice of a Specialist Anaesthetist*
- PS18 *Recommendations on Monitoring During Anaesthesia*
- PS26 *Guidelines on Consent for Anaesthesia or Sedation*
- T1 *Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations*
- TE3 *Policy on Supervision of Clinical Experience for Vocational Trainees in Anaesthesia*

FURTHER READING

The following references provide evidence to support the recommendations made in this document.

American College of Radiology. ACR practice guideline for adult sedation/analgesia. 2005.

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Qadeer MA, Vargo JJ, Khandwala F, Lopez R, Zuccaro G. Propofol versus traditional sedative agents for gastrointestinal endoscopy: a meta-analysis. *Clin Gastroenterol Hepatol* 2005;3(11):1049-56.

Rex DK. Review article: moderate sedation for endoscopy: sedation regimens for non-anaesthesiologists. *Aliment Pharmacol Ther* 2006;24(2):163-71.

Scottish Intercollegiate Guidelines Network. SIGN Guideline 58: safe sedation of children undergoing diagnostic and therapeutic procedures. *Paediatr Anaesth* 2008;18(1):11-2.

Vargo JJ, Ahmad AS, Aslanian HR, Buscaglia JM, Das AM, Desilets DJ, et al. Training in patient monitoring and sedation and analgesia. *Gastrointest Endosc* 2007;66(1):7-10.

APPENDIX I

The American Society of Anesthesiologists' classification of physical status:

- P 1 A normal healthy patient
- P 2 A patient with mild systemic disease
- P 3 A patient with severe systemic disease
- P 4 A patient with severe systemic disease that is a constant threat to life
- P 5 A moribund patient who is not expected to survive without the operation
- P 6 A declared brain-dead patient whose organs are being removed for donor purposes

- E Patient requires emergency procedure

Excerpted from American Society of Anesthesiologists Manual for Anesthesia Department Organization and Management 2007. A copy of the full text can be obtained from ASA, 520 N Northwest Highway, Park Ridge, Illinois 60068-2573.

APPENDIX II

Emergency drugs should include at least the following:

- adrenaline
- atropine
- dextrose 50%
- lignocaine
- naloxone
- flumazenil
- portable emergency O₂ supply

APPENDIX III

Personnel for procedural sedation and analgesia

Scenario 0: Two personnel – sedation by proceduralist



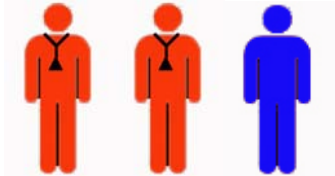
- Medical or dental practitioner proceduralist with airway and resuscitation skills, and training in nitrous oxide or low dose oral sedation techniques
- Assistant with training in monitoring sedation
- Conscious sedation using nitrous oxide alone and/or low dose oral sedation alone in ASA P 1-2 patients
- Heavy oral sedation and intramuscular or intravenous sedative/anaesthetic/analgesic agents must not be used

Scenario 1: Three personnel – sedation by proceduralist



- Medical or dental practitioner proceduralist with airway and resuscitation skills, and training in sedation
- Assistant with training in monitoring sedation
- Assistant to assist both
- Conscious sedation in ASA P 1-2 patients
- Propofol, thiopentone and other intravenous anaesthetic agents must not be used

Scenario 2: Three personnel – sedation by medical or dental practitioner



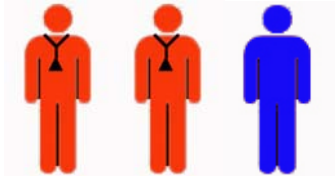
- Proceduralist
- Medical or dental practitioner with airway and resuscitation skills, and training in sedation
- Assistant to assist both
- Conscious sedation in ASA P 1-2 patients
- Propofol, thiopentone and other intravenous anaesthetic agents may only be used by a medical or dental practitioner trained in their use

Scenario 3: Four personnel – sedation by medical or dental practitioner



- Proceduralist
- Medical or dental practitioner with airway and resuscitation skills, and training in sedation
- Assistant to assist *each**
- Conscious sedation in ASA P 1-3 patients #
- Propofol, thiopentone and other intravenous anaesthetic agents may only be used by a medical or dental practitioner trained in their use

Scenario 4: Three personnel – sedation by anaesthetist



- Proceduralist
- Anaesthetist
- Assistant to assist both
- Conscious, deep sedation or general anaesthesia in all patients
- All approved anaesthetic drugs may be used

Scenario 5: Four personnel – sedation by anaesthetist



- Proceduralist
- Anaesthetist
- Assistant to assist *each**
- Conscious sedation, deep sedation or general anaesthesia in all patients
- All approved anaesthetic drugs may be used

* *Recommended if assistance is likely to be required for the majority of the case (e.g. complex or emergency patients)*

Please refer to Section 4.2

COLLEGE PROFESSIONAL DOCUMENTS

College professional documents are progressively being coded as follows:

<i>TE</i>	<i>Training and Educational</i>
<i>EX</i>	<i>Examinations</i>
<i>PS</i>	<i>Professional Standards</i>
<i>T</i>	<i>Technical</i>

POLICY – defined as ‘a course of action adopted and pursued by the College’. These are matters coming within the authority and control of the College.

RECOMMENDATIONS – defined as ‘advisable courses of action’.

GUIDELINES – defined as ‘a document offering advice’. These may be clinical (in which case they will eventually be evidence-based), or non-clinical.

STATEMENTS – defined as ‘a communication setting out information’.

Professional documents of the Australian and New Zealand College of Anaesthetists (ANZCA) are intended to apply wherever anaesthesia is administered and perioperative medicine practised within Australia and New Zealand. It is the responsibility of each practitioner to have express regard to the particular circumstances of each case, and the application of these ANZCA documents in each case. It is recognised that there may be exceptional situations (e.g. some emergencies) in which the interests of patients override the requirement for compliance with some or all of these ANZCA documents.

ANZCA professional documents are reviewed from time to time, and it is the responsibility of each practitioner to ensure that he or she has obtained the current version which is available from the College website (www.anzca.edu.au/). Each document is prepared in the context of the entire body of the College's professional documents, and should be interpreted in this way. These professional documents have been prepared having regard to the information available at the time of their preparation, and practitioners should therefore take into account any information that may have been published or become available subsequently.

Whilst ANZCA endeavours to ensure that its professional documents are as current as possible at the time of their preparation, it takes no responsibility for matters arising from changed circumstances or information or material which may have become available subsequently.

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RACDS Website: <http://www.racds.org/>
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