

## Australian and New Zealand College of Anaesthetists (ANZCA)

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### Faculty of Pain Medicine

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*The following organisations have endorsed this document:*

**Gastroenterological Society of Australia**  
**Royal Australasian College of Surgeons**  
**Australasian College for Emergency Medicine**  
**College of Intensive Care Medicine of Australia and New Zealand**  
**Royal Australian and New Zealand College of Radiologists**  
**Royal Australian and New Zealand College of Psychiatrists**

## 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, but excludes situations where sedation is used for longer term management of patients such as in intensive care units or for psychiatrically disturbed patients. The Australian and New Zealand College of Anaesthetists (ANZCA) and all co-signing colleges/societies recognise 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** imply 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 of distressing events and/or analgesia may be 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. Interventions to maintain a patent airway, spontaneous ventilation or cardiovascular function may, in exceptional situations, be required. Conscious sedation may be achieved by a wide variety of drugs including propofol, and may accompany 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 **Deeper sedation** is characterised by depression of consciousness that can readily progress to the point where consciousness is lost and patients respond only to painful stimulation. It is associated with loss of the ability to maintain a patent airway, inadequate spontaneous ventilation and/or impaired cardiovascular function, and has similar risks to general anaesthesia, requiring an equivalent level of care.
- 1.1.3 **Analgesia** is reduction or elimination of pain perception, usually induced by drugs that act locally (by interfering with nerve conduction) or generally (by depressing pain perception in the central nervous system). This may be achieved by a wide range of drugs including methoxyflurane and nitrous oxide.
- 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 trained and credentialed medical practitioner within his/her scope of practice (see ANZCA professional documents *PS01 Recommendations on Essential Training for Rural General Practitioners in Australia Proposing to Administer Anaesthesia*, *PS02 Statement on Credentialing and Defining the Scope of Clinical Practice in Anaesthesia*, *PS08 Recommendations on the Assistant for the Anaesthetist*, *PS16 Statement on the Standards of Practice of a Specialist Anaesthetist*, *PS55 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 enhance patient comfort whilst facilitating 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 deeper levels of sedation or general anaesthesia to be an option during the procedure.
- 2.2 Practitioners who 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, and those who supervise recovery from sedation, 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 Unexpectedly high sensitivity to the drugs used for procedural sedation and/or analgesia which may result in unintentional loss of consciousness, and respiratory or cardiovascular depression.
  - 2.2.6 Individual variations in response to the drugs used, particularly in children, the elderly, and those with pre-existing disease.
  - 2.2.7 The possibility of deeper sedation or anaesthesia being used to compensate for inadequate analgesia or local anaesthesia.
  - 2.2.8 Risks inherent in the wide variety of procedures performed under procedural sedation and/or analgesia.
- 2.3 Over-sedation, airway obstruction, respiratory or cardiovascular complications may occur at any time. Therefore, to ensure patient safety, the following guidelines should be followed.

### 3. PATIENT PREPARATION

- 3.1 Informed consent for sedation and/or analgesia and for the procedure should be obtained from the patient, or a person entitled to give consent on behalf of the patient, according to applicable legislation (see ANZCA professional document *PS26 Guidelines on Consent for Anaesthesia or Sedation*).
- 3.2 The proceduralist or other suitable person should provide the patient, or their carer, with written information, where possible, which includes the nature and risks of the procedure, preparation instructions (including the importance of fasting – see ANZCA professional document *PS15 Guidelines for the Perioperative Care of Patients Selected for Day Care Surgery*), and what to expect during the immediate and longer term recovery period, including after discharge.

### 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, and the patient's exercise tolerance or functional status.
  - 4.1.2 Examination of the airway, respiratory and cardiovascular status, and other systems as indicated by the history, including that relevant to the current problem.
  - 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, or other trained and credentialed medical practitioner within his/her scope of practice, should be

present to care for the patient. These patients include all children less than 2 years of age, the elderly, those with severely limiting heart, cerebrovascular, lung, liver or renal disease, morbid obesity, significant obstructive sleep apnoea, 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 1 and ANZCA professional document *PS07 Recommendations for the Pre-Anaesthesia Consultation*).

## 5. STAFFING

- 5.1 Except for techniques such as inhaled nitrous oxide, inhaled methoxyflurane or low dose oral sedation (see scenario 0, appendix 3), there must be a minimum of three appropriately trained staff present (see scenarios 1-2, appendix 3): the proceduralist, the 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 practitioner administering sedation must be exclusively available to that practitioner at induction of and emergence from sedation, and during the procedure as required. If general anaesthesia is intended, and especially in emergency situations where endotracheal intubation is planned, a person to specifically assist the anaesthetist, or other trained and credentialed medical practitioner within his/her scope of practice, is required throughout the procedure (see ANZCA professional document *PS08 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 appropriately manage any complications arising from sedation.
- 5.4 A medical or dental practitioner who is skilled in airway management and cardiopulmonary resuscitation, relevant to the patient's age and condition, must be present whenever procedural sedation and/or analgesia are administered.
- 5.5 Techniques intended to produce deeper sedation or general anaesthesia must not be used unless an anaesthetist, or other trained and credentialed medical practitioner within his/her scope of practice, is present.
- 5.6 In situations other than those when an anaesthetist, or other trained and credentialed medical practitioner within his/her scope of practice, 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 practitioner working with the proceduralist and whose training complies with the requirements outlined in section 13. 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 another health practitioner present during the procedure, who is trained in observation and monitoring of sedated patients and in resuscitation. The **primary** responsibility of this other practitioner is to monitor the level of consciousness and cardiorespiratory status of the patient. This practitioner 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 item 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 treating and monitoring 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 of an adequate size, and is staffed and equipped to deal with a cardiopulmonary emergency. These facilities and equipment must be sufficient and appropriate for the age and condition of the patient so that, if required, basic life support may be maintained 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 (for example, a self-inflating bag and mask) together with ready access to a range of equipment for advanced airway management (for example, 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 2).
- 6.8 A pulse oximeter.
- 6.9 A sphygmomanometer or other device for measuring blood pressure.
- 6.10 Ready access to an electrocardiograph (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.
- 6.13 Adequate access throughout the facility to allow the patient to be transported easily and safely.

6.14 A clinical emergency response plan to manage potential clinical deterioration.

(See ANZCA professional documents *PS55 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 AND/OR ANALGESIA**

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

- 7.1 There must be the capacity for the administration of 100 per cent oxygen.
- 7.2 Installation and maintenance of any piped gas system must comply with relevant standards. Servicing of such piped gases must occur on a regular basis and at least annually.
- 7.3 An appropriate method for scavenging of expired gases within the room must be in use.
- 7.4 When nitrous oxide is used:
  - 7.4.1 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.
  - 7.4.2 There must be a non-return valve or other mechanism (such as a T-piece flow connection) to prevent re-breathing.
  - 7.4.3 Gas flow rates must be adequate and the circuit must include an anti-hypoxic device.
  - 7.4.4 There must be a low gas flow alarm except when a demand-flow system is used.
- 7.5 When methoxyflurane is used, the facility should have a guideline for the recognition and emergency management of malignant hyperthermia.

## **8. TECHNIQUE AND MONITORING**

- 8.1 Reliable venous access should be in place for all procedural sedation and/or analgesia except when low doses of inhaled or oral agents are used. This may not be practical in some patients receiving non-intravenous sedation (for example, small children, intellectually disabled patients).
- 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. Monitoring of verbal response may be difficult in some patients (for

example, 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 monitoring of pulse rate, oxygen saturation and blood pressure throughout the procedure. Monitoring prior to commencement of sedation may not be practical in some patients (for example, small children, patients with intellectual disabilities).
- 8.6 According to the clinical status of the patient, other monitors such as ECG or capnography may be required (see ANZCA 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 should be considered for, and available for, use in all patients for as much of the procedure as possible. Oxygen administration prior to commencement of sedation may not benefit all patients, and may not be practical in some patients (for example, small children, patients with intellectual disabilities).
- 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 Sedation may be administered by a number of different routes including oral, intra-nasal, rectal, sub-cutaneous, intramuscular, intravenous and inhaled. Rates of absorption will differ markedly between these various routes of administration, and practitioners must be aware of these differences particularly when using a less familiar route to administer the sedation.
- 10.2 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. Because there is usually synergism between such drugs, 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.
- 10.3 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, details of any major resuscitation or rescue interventions, complications, etc., and should contain other information as indicated in ANZCA professional document *PS06 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 which may be the area where the procedure was performed (see ANZCA professional document *PS04 Recommendations for the Post-Anaesthesia Recovery Room*).
- 12.2 If the recovery area is not where the procedure occurred then there must be adequate and safe patient transfer facilities available.
- 12.3 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.
- 12.4 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.
- 12.5 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 Non-anaesthetist practitioners wishing to provide low dose analgesia should have received adequate supervised training in the technique to be used. Those medical or dental practitioners wishing to provide procedural sedation and/or analgesia should have received a minimum of three 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 There are non-anaesthetist medical or dental practitioners who have had many years experience in procedural sedation and/or analgesia, yet 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 Credentialing, training and clinical support of such medical or dental practitioners should be achieved by close cooperation with nominated anaesthetists, 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 relevant to the clinician's practice, and evidence of relevant continuing professional development, are required for credentialing.
- 13.5 Medical, dental or healthcare facilities are responsible for the safe administration of sedation within their institutions. This responsibility includes establishing the scope of practice and credentialing of practitioners administering sedation. Institutions must ensure that such practitioners are trained, and that their scope of practice remains valid with relevant ongoing professional development.

#### **14. AUDIT**

- 14.1 Practitioners carrying out sedation and/or analgesia should be subject to regular and effective audit of sedation administration complying with local jurisdictional requirements.
- 14.2 Each unit where sedation services are provided must have an established system for audit of the outcomes related to sedation, and include these audited outcomes, and any complications, in quality assurance and peer review processes. Local audit results should inform ongoing training, education and support of all team members involved in the care of patients who receive sedation.
- 14.3 Practitioners who administer sedation must be aware of their jurisdictional requirements to report morbidity and mortality related to sedation. These requirements are particularly important where an intended sedation episode has inadvertently resulted in general anaesthesia, with an adverse outcome.

#### **RELATED ANZCA DOCUMENTS**

PS01 Recommendations on Essential Training for Rural General Practitioners in Australia Proposing to Administer Anaesthesia

PS02 Statement on Credentialing and Defining the Scope of Clinical Practice in Anaesthesia

PS04 Recommendations for the Post-Anaesthesia Recovery Room

PS06 The Anaesthesia Record. Recommendations on the Recording of an Episode of Anaesthesia Care

PS07 Recommendations for the Pre-Anaesthesia Consultation

PS08 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

PS55 Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations

#### FURTHER READING

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

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## APPENDIX 1: 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

Adapted from: American Society of Anesthesiologists. ASA physical status classification system [Internet]. n.d. From: <http://www.asahq.org/For-Members/Clinical-Information/ASA-Physical-Status-Classification-System.aspx>. Accessed 31 July 2014.

## APPENDIX 2: EMERGENCY DRUGS

Emergency drugs and supplies should include at least the following:

adrenaline

atropine

dextrose 50 per cent

lignocaine

naloxone

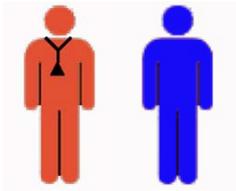
flumazenil

portable emergency O<sub>2</sub> supply

Ringer's or Hartmann's solutions or isotonic saline solution

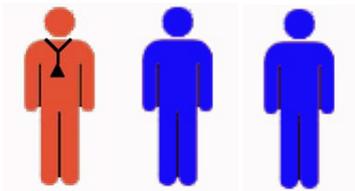
### APPENDIX 3: PERSONNEL FOR PROCEDURAL SEDATION AND ANALGESIA

Scenario 0: Two personnel – sedation by proceduralist



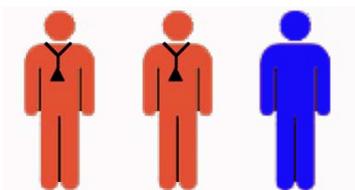
- Medical or dental practitioner proceduralist with airway and resuscitation skills, and training in nitrous oxide, methoxyflurane or low dose oral sedation techniques
- Assistant with training in monitoring sedation
- Conscious sedation using nitrous oxide or methoxyflurane alone, and/or low dose oral 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



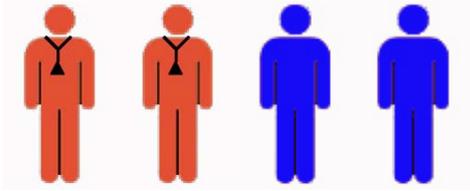
- Medical or dental practitioner proceduralist with airway and resuscitation skills, and training in sedation
- Assistant with training in monitoring sedation whose primary responsibility is to monitor the patient
- Assistant to assist both
- Conscious sedation in ASA P 1-2 patients
- Propofol, thiopentone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

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



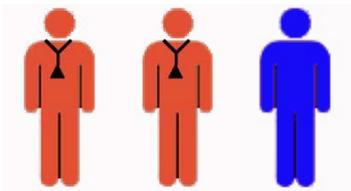
- Proceduralist
- Medical or dental practitioner with airway and resuscitation skills, and training in sedation whose primary responsibility is to monitor the patient and administer sedation
- Assistant to assist both
- Conscious sedation in ASA P 1-3 patients
- Propofol, thiopentone and other intravenous anaesthetic agents may only be used by a medical or dental practitioner trained in their use

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



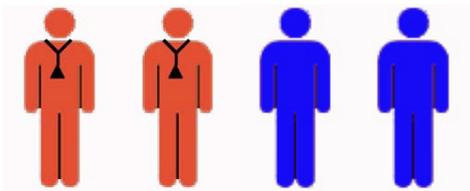
- Proceduralist
- Medical or dental practitioner with airway and resuscitation skills, and training in sedation whose primary responsibility is to monitor the patient and administer sedation
- Assistant to assist **each**\*
- Conscious sedation in ASA P 1-3 patients #
- Propofol, thiopentone and other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

Scenario 4: Three personnel – sedation by anaesthetist, or other trained and credentialed medical practitioner within his/her scope of practice



- Proceduralist
- Anaesthetist, or other trained and credentialed medical practitioner within his/her scope of practice
- 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, or other trained and credentialed medical practitioner within his/her scope of practice



- Proceduralist
- Anaesthetist, or other trained and credentialed medical practitioner within his/her scope of practice
- 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 (for example, complex or emergency patients)*

# *Please refer to section 4.2*

*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*

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