

CLINICAL UPDATE

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

Sedation

Review PS9 (2008)
Incorporating PS 24 (Review 2004)



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Digestive Health Foundation

The Digestive Health Foundation (DHF) is an educational body committed to promoting better health for all Australians by promoting education and community health programs related to the digestive system.

The DHF is the educational arm of the Gastroenterological Society of Australia, the professional body representing the specialty of gastrointestinal and liver disease in Australia. Members of the Society are drawn from physicians, surgeons, scientists and other medical specialties with an interest in GI disorders.

Since its establishment in 1990 the DHF has been involved in the development of programs to improve community awareness and the understanding of digestive diseases.

Research and education into gastrointestinal disease are essential to contain the effects of these disorders on all Australians.

Guidelines for General Practitioners and patient leaflets are available on a range of topics related to GI disorders. Copies are available on the GESA website or by contacting the Secretari at at the address below.

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INTRODUCTION

This document is intended to apply wherever procedural sedation and/or analgesia for diagnostic and interventional medical 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 permissiveness of uncomfortable or painful diagnostic or interventional medical or surgical procedures. Lack of memory of 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. No interventions are usually required to maintain a patent airway, spontaneous ventilation or cardiovascular function. Conscious sedation may be achieved by a wide variety of techniques 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 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 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 (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

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. Practitioners authorised or credentialed 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:

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

3 PATIENT PREPARATION

- 3.1 The patient should be provided with written information 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 (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 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). See also College Professional Document PS7 – Recommendations on the Pre-Anaesthesia Consultation.

5 STAFFING

- 5.1 There must be a minimum of three appropriately trained staff present: 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/anaesthesia must be exclusively available to the 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 practitioner throughout the procedure is required. (See College Professional Document PS8 Guidelines on the Assistant to the Anaesthetist)
- 5.3 The practitioner administering procedural sedation and 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 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 an anaesthetist is present (see College Professional Documents PS1 Recommendations on Essential Training for Rural General Practitioners in Australia Proposing to Administer Anaesthesia, PS2 Statement on Credentialing in Anaesthesia, PS8 Guidelines on the Assistant to 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 an appropriately trained medical practitioner other than the proceduralist.
- 5.7 If an appropriately trained medical 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 sole duty is to monitor the level of consciousness and cardiorespiratory status of the patient. 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). 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 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.

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.
- 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) together with 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 (See Appendix II).
- 6.8 Drugs for reversal of benzodiazepines and opioids.
- 6.9 A pulse oximeter.
- 6.10 A sphygmomanometer, or other device for measuring blood pressure.
- 6.11 Ready access to an ECG and a defibrillator.
- 6.12 A means of summoning emergency assistance.
- 6.13 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 TECHNIQUE AND MONITORING

- 7.1 Reliable venous access should be in place for all procedures when procedural sedation and/or analgesia are used.
- 7.2 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.
- 7.3 Monitoring of the patient's response to verbal commands must be routine. Loss of patient response to verbal commands indicates that loss of airway reflexes, respiratory and/or cardiovascular depression are likely.
- 7.4 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.
- 7.5 There must be regular recording of pulse rate, oxygen saturation and blood pressure throughout the procedure in all patients.
- 7.6 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).

8 OXYGENATION

Hypoxaemia may occur during procedural sedation and/or analgesia without oxygen supplementation. Oxygen administration diminishes hypoxaemia during procedures carried out under sedation /or analgesia, and must be used in all patients. Pulse oximetry enables the degree of tissue oxygenation to be monitored and must be used in all patients during procedural sedation and/or analgesia.

9 MEDICATIONS

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. Intravenous anaesthetic agents such as propofol must only be used by a second medical practitioner trained in their use, because of the risk of unintentional loss of consciousness. These agents must not be administered by the proceduralist.

10 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 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 the College Professional Document PS6 Recommendations on the Recording of an Episode of Anaesthesia Care.

11 RECOVERY AND DISCHARGE

11.1 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).

11.2 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.

11.3 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.

11.4 A system should be in place to enable safe transfer of the patient to appropriate medical care should the need arise.

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

It is recommended that non-anaesthetist medical practitioners wishing to provide procedural sedation/analgesia should have received a minimum of 3 months full time equivalent supervised training in procedural sedation and/or analgesia and anaesthesia. They should participate in a process of In-Training and Competency Assessment. Training should include completion of a crisis resource management simulation centre course. It is recognised that there will be non-anaesthetist medical 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. Credentialling, training and clinical support of such medical practitioners should receive close cooperation from nominated anaesthetists in the hospital or centre. Annual certification in advanced cardiac and life support, and evidence of relevant Continuing Professional Development, are required for credentialling.

13 REFERENCES

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

AGA Institute (Cohen LB et al.). AGA Institute review of endoscopic sedation. *Gastroenterology* 2007; 133: 675-701

American College of Radiology (Towbin et al.). ACR practice guideline for adult sedation/analgesia. <www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/iv/adult_sedation.aspx> 2005

American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists (Gross JB et al.). Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology* 2002; 96: 1004-1017

American Society of Anesthesiologists. Statement on granting privileges for administration of moderate sedation to practitioners who are non anaesthesia professionals. <www.asahq.org/publicationsAndServices/standards/40.pdf> 2006

American Society for Gastrointestinal Endoscopy (Chutkan R et al.). Training guideline for use of propofol in gastrointestinal endoscopy. *Gastrointestinal Endoscopy* 2004; 60: 167-172

American Society for Gastrointestinal Endoscopy (Vargo JJ et al.). Training in patient monitoring and sedation and analgesia. *Gastrointestinal Endoscopy* 2007; 66: 7-10

Clarke AC, Chiragakis L, Hillman LC, Kaye GL. Sedation for endoscopy: the safe use of propofol by general practitioner sedationists. *Medical Journal of Australia* 2002; 176: 159-162

Faigel DO, Pike IM, et al. Quality indicators for gastrointestinal endoscopic procedures: an introduction. *Gastrointestinal Endoscopy* 2006; 63 (4 Suppl.): S3-S9

Qadeer MA, Vargo JJ, Khandwala F, Lopez R, Zuccaro G. Propofol versus traditional sedative agents for gastrointestinal endoscopy: a meta-analysis. *Clinical Gastroenterology & Hepatology* 2005; 3: 1049-1056

Rex DK. Review article: moderate sedation for endoscopy: sedation regimens for nonanaesthesiologists. *Alimentary Pharmacology & Therapeutics* 2006; 24: 163-171

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 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 on the Pre-Anaesthesia Consultation
- PS8 Guidelines on the Assistant to 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

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 2003-04. A copy of the full text can be obtained from ASA, 520 N Northwest Highway, Park Ridge, Illinois 60068-2573

APPENDIX II

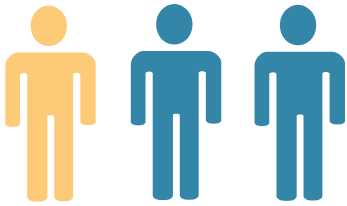
Emergency drugs should include at least the following:

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

APPENDIX III

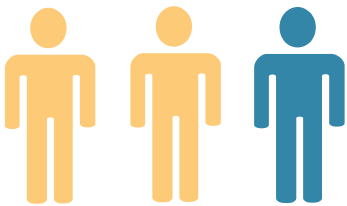
Personnel for Procedural Sedation and Analgesia

Scenario 1: Three practitioners – Sedation by Proceduralist



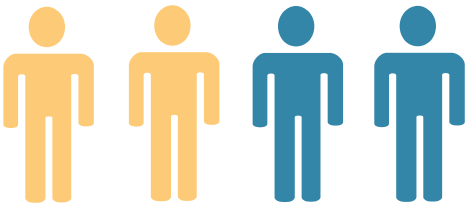
- Medical practitioner proceduralist with airway and resuscitation skills, and training in sedation
- Practitioner with training in monitoring sedation
- Assistant to assist both
- Conscious sedation in ASA P 1-2 patients
- Propofol, thiopentone and other intravenous anaesthetic agents must not be used

Scenario 2: Three practitioners – Sedation by Medical Practitioner



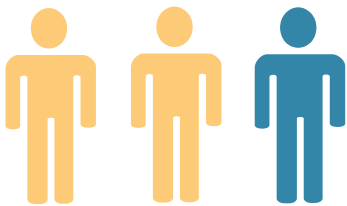
- Proceduralist
- Medical practitioner with airway and resuscitation skills, and training in sedation
- Assistant to assist both
- Conscious sedation in ASA P 1-2 patients
- Propofol, thiopentone and other intravenous anaesthetic agents may only be used by a medical practitioner trained in their use

Scenario 3: Four practitioners – Sedation by Medical Practitioner



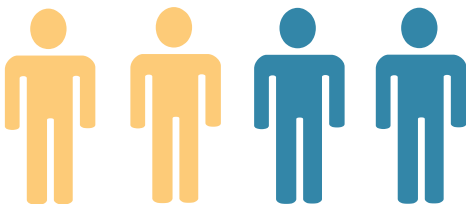
- Proceduralist
- Medical practitioner with airway and resuscitation skills, and training in sedation
- Assistant to assist each*
- Conscious sedation in ASA P 1-3 patients#
- Propofol, thiopentone and other intravenous anaesthetic agents may only be used by a medical practitioner trained in their use

Scenario 4: Three practitioners – 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 practitioners – 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

14 COLLEGE PROFESSIONAL DOCUMENTS

College Professional Documents are progressively being coded as follows:

TE	Training and Educational
EX	Examinations
PS	Professional Standards
T	Technical

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 nonclinical.

STATEMENTS - defined as 'a communication setting out information'. This document has been prepared having regard to general circumstances, and it is the responsibility of the practitioner to have express regard to the particular circumstances of each case, and the application of this document in each case.

Professional documents are reviewed from time to time, and it is the responsibility of the practitioner to ensure that the practitioner has obtained the current version. Professional documents have been prepared having regard to the information available at the time of their preparation, and the practitioner should therefore have regard to any information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that 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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