



Guideline on procedural sedation

1. Purpose

- a). To promote uniform standards for high quality and safe administration of procedural sedation.
- b). To identify the competencies that sedationists¹ should possess.

2. Scope

This document is intended to apply to all health practitioners managing procedural sedation in all patients, including children, irrespective of the route of administration.

This document is not intended to apply to local anaesthesia or major regional anaesthesia, nor to analgesia when administered without sedation or when not associated with any procedure.

This document is not intended to apply to non-procedural sedation such as for the care of patients with acute behavioural disturbance, which is the subject of the Australian and New Zealand College of Anaesthetists (ANZCA) professional document PS63 *Guideline for safe care of patients sedated in healthcare facilities for acute behavioural disturbance*.

3. Background

Sedation is widely administered in a range of settings by health practitioners from a diverse group of disciplines and with differing training and skills. The ability for practitioners to provide safe procedural sedation is essential in order to preserve patient access to treatment.

In recognition of the diverse settings, individual needs, and variability in sedation techniques this guideline is not intended to direct or preference any techniques nor to instruct on how to administer sedation, but rather ensure that in all circumstances sedation services meet at least the minimum standard.

4. Principles

4.1 The aim of sedation is to facilitate patient comfort during the performance of their procedure, without resorting to general anaesthesia. In order to achieve this aim, a range of sedation options may be required during any one procedure, with a continuum from minimal sedation, through to deep sedation, which may inadvertently progress to general anaesthesia.

4.2 Risks of sedation require that sedationists are aware that transition from complete consciousness through the various levels of sedation to general anaesthesia is a continuum and not a set of discrete, well-defined stages. The margin of safety of medications used to achieve sedation varies widely between patients and loss of consciousness with its attendant risk of loss of protective reflexes may occur rapidly and unexpectedly.

The narrow therapeutic window of anaesthetic agents is such that inadvertent and unanticipated rapid progression to general anaesthesia may occur. For this reason, it is essential that when such agents are administered the sedationist is present and

¹ Refer to the glossary in Appendix V for definitions

retains sole responsibility for maintaining and managing sedation, including monitoring the depth of sedation, physiological variables, and the patient's condition. The sedationist is required to maintain all the requisite competencies and be able to provide any necessary rescue interventions.

5. Competencies

The safe procedural sedation competencies described in Appendix IV are designed to be attained by all sedationists managing procedural sedation. It is highly recommended that they be incorporated into any training curriculum where trainees are required to demonstrate competence in the provision of safe procedural sedation. They have been developed collaboratively by representatives from a range of medical, nursing, and dental colleges and societies.

It is expected that sedationists will incorporate activities relevant to procedural sedation into their continuing professional development programs, in order to maintain skills and competence.

6. Staffing

The minimum number of staff required to be present will be determined by the intended level of sedation.

Recognising the diverse settings and contexts of procedural sedation, practitioners present should clarify their roles and responsibilities with each other prior to commencement of the session.

It is essential that sedationists and assisting practitioners remain attentive to their patients throughout the duration of sedation. This will be determined by their patient's current conscious state, duration since administration of the last dose of sedative, and pharmacokinetics properties of the drugs used.

Practitioners singularly performing the dual role of sedationist and proceduralist may prescribe or direct administration of medications, and delegate monitoring and immediate rescue from any complications of sedation to the assisting practitioner. Both the sedationist and assisting practitioner should have the required competencies to recognise changes in conscious state or clinical deterioration and to respond effectively. However, the sedationist/proceduralist retains responsibility for managing sedation, including intervention if required.

Children undergoing minimal sedation using nitrous oxide/oxygen or a single dose of an oral anxiolytic may occasionally become distressed or may vomit, and the additional assistance of a third person may be required. Whilst it may be helpful to have a third person available, the need for this under minimal sedation should be considered in the context of the sedating environment, and child and family needs. Particularly anxious children undergoing minimal sedation because of anxiety can become overwhelmed with the presence of strangers. Conversely, some parents may become emotional and require support. Such issues should be considered when making decisions regarding staffing for paediatric sedation in any given setting.

Whilst vomiting is the commonest adverse effect of minimal sedation with nitrous oxide/oxygen, it may also be an indication that the child is not tolerating the procedure at this level of sedation. When the child is not tolerating the procedure at this level of sedation, in the best interest of the child, considering staff scope of practice, the sedating environment and its capability, referral for deep sedation or general anaesthesia in settings as per PS29, should be considered.

When using inhaled nitrous oxide or methoxyflurane in combination with other agents such as opioid analgesics, transition may occur unpredictably from minimal to moderate sedation. In these situations, engaging an assistant trained to monitor the patient and administer inhalational medication to maintain minimal sedation as directed by the sedationist is advisable. Under these circumstances, limits for acceptable vital signs should be confirmed and any digression beyond these limits reported to the sedationist. This offers the ability for sedationists to also be the proceduralist. However, the assisting practitioner should be able to provide basic airway support skills. If intervention is required, the sedationist/proceduralist is required to resume the primary role and responsibility for clinical care and safe recovery of the patient.

The availability of a third person is recommended for all cases of adult and paediatric sedation where the intended level of sedation exceeds minimal.

In the case of intentional deep sedation, there is a risk of sedation rapidly and unintentionally progressing to general anaesthesia, especially with intravenous administration of multiple medications with sedative effects. In these situations, it is strongly recommended that a fourth practitioner be in the room throughout the episode of sedation, available to immediately assist. Where deep sedation is targeted, it is advisable that the sedationist and proceduralist are separate individuals. However, where this is not the case and sedation is delegated to an assisting practitioner, it is essential this practitioner has at a minimum, advanced life support skills, including safe airway management skills.

Recognising children have a diminished functional reserve compared to adults, where deep sedation is targeted for children, it is preferable that a sedationist with age-appropriate experience and skills is in attendance as a separate individual to the proceduralist.

- 6.1** The staff present for all sedation techniques, excluding those targeting minimal sedation, will normally consist of the following:
- the proceduralist
 - an additional practitioner who may be either:
 - the sedationist, or
 - the assisting practitioner tasked with administering sedation medications and monitoring the patient under the direction of the proceduralist, and who possesses the designated competencies. In this case, the proceduralist is the one fulfilling both roles as sedationist and proceduralist.
 - at least one additional staff member to provide assistance to both as required.

All staff present should be clear on their roles and responsibilities prior to commencement of the session.

- 6.2** An assistant to the sedationist should be exclusively available at induction of, and emergence from sedation, and as required during the procedure.

- 6.3** Sedationists require sufficient training to:

- 6.3.1 Fulfil the knowledge and skills outlined in Appendix 4 Competencies.
- 6.3.2 Monitor levels of consciousness and cardiorespiratory status.
- 6.3.3 Detect and manage any complications arising from sedation.
- 6.3.4 Communicate effectively with proceduralists

- 6.4 It is essential that a practitioner with the required airway and life support skills is immediately available for all procedural sedation. This can be the proceduralist only if they are able to immediately stop the procedure to perform rescue manoeuvres as required. This will be BLS for minimal sedation and age-appropriate ALS for deeper levels of sedation for children and adults (see competencies section).
- 6.5 Where the proceduralist is also the sedationist, an assistant may assume the role of assisting practitioner, on condition they are trained in observation and possess basic life support skills. The primary duty of assisting practitioners is to monitor and record the level of consciousness and cardiorespiratory status and be immediately available to manage complications should the need arise. Assisting practitioners may, if trained to do so, administer sedative medications under the direct supervision of proceduralists, who should, at a minimum, have advanced life support skills and training (see Appendix IV) if providing moderate to deep sedation. Propofol, thiopentone and other anaesthetic agents are not to be used in these circumstances, unless the proceduralist is able to immediately interrupt the procedure, or a practitioner with those skills is immediately available. In circumstance of paediatric sedation with anaesthetic agents, a separate sedationist practitioner with age-appropriate skills and experience is essential.

If loss of consciousness, airway obstruction, hypoxaemia, or cardiorespiratory insufficiency occur at any time, all available staff are required to devote their attention to treating and monitoring their patient until recovery, or until such time as another medical or dental practitioner becomes available to take responsibility for the patient's care.

7. Facilities and equipment

Procedural sedation should be performed only in locations that are of adequate size, with staff and equipment to deal with any cardiopulmonary emergency. This includes easy access to location by ambulance services should the need arise. Adequate facilities and equipment to suit the age and condition of patients need to be ensured so that, if required, basic life support may be maintained until more specialised help, equipment and medications become available. Some of the recommendations in this section may be moderated in instances where minimal sedation is achieved by the sole use of a single dose of orally administered anxiolytic or nitrous oxide/oxygen. In all other cases, the minimum facilities and equipment include:

- 7.1 Adequate room to perform resuscitation.
- 7.2 Adequate lighting.
- 7.3 Operating tables, trolleys or (dental) chairs that can be tilted head down readily are preferable but not mandatory.
- 7.4 Suction and associated suction attachments and suction catheters, suitable for intra-oral and intranasal clearance of secretions
- 7.5 Adequate supply of oxygen and suitable devices for its administration to spontaneously breathing patients.
- 7.6 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 such as face masks, oropharyngeal airways, laryngeal mask airways, laryngoscopes, endotracheal tubes).

For children there should be a separate suite of equipment with a range of airway equipment that allows selection for one size larger and one size smaller than the estimated size.

- 7.7 Medications for cardiopulmonary resuscitation and for reversal of benzodiazepines and opioids (See Appendix II).as well as a range of intravenous equipment and fluids.

In facilities providing sedation services to children there should be a paediatric compendium or paediatric emergency drug protocol to facilitate accurate dosing based on weight or size. In larger facilities, this may take the form of a specific drug dosing book or a Broselow Tape.

- 7.8 A pulse oximeter.
- 7.9 A sphygmomanometer or other device for measuring blood pressure.
- 7.10 Ready access to an electrocardiograph (ECG) and a defibrillator.
- 7.11 A means of summoning emergency assistance.
- 7.12 Within the facility there should be access to devices for measuring expired carbon dioxide. Use of waveform capnography is strongly recommended.
- 7.13 Adequate access throughout the facility to allow the patient to be transported easily and safely.
- 7.14 A written and ideally, practised escalation plan or clinical emergency response plan in the event of clinical deterioration.
- 7.15 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.

7.15.1 The following special requirements should be satisfied:

- Capacity for the administration of 100% oxygen.
- Installation and maintenance of any piped gas system that complies with relevant standards including servicing of such piped gas systems on a regular basis and at least annually.
- An accepted method for scavenging of expired gases within the room.

7.15.2 When nitrous oxide is used:

- Patient breathing circuits should be of lightweight construction, have a reservoir bag for inspired gases and have low resistance to normal gas flows.
- Rebreathing is to be prevented by use of either non-return valves or other mechanisms (such as a T-piece flow connection).
- Use of sufficient gas flow rates and inclusion of anti-hypoxic devices are necessary.
- Low gas flow alarms are recommended, however, where they are not incorporated into the delivery device then:
 - An interlink style device (or the modern equivalent) that prevents the delivery of an hypoxic mix of gas (< 21% oxygen) is essential.

- An oxygen analyser, if not already present in the system, is advisable, or alternatively, confirmation that the system has been checked for correct plumbing and certified.

7.15.3 When methoxyflurane is used, the facility should have a guideline for the recognition and emergency management of malignant hyperthermia.

8. Patient preparation

8.1 Patient assessment:

All patients should be assessed and consulted as part of the normal management of procedural sedation. Pre-procedural assessment and application of selection criteria should be performed in all non-emergency cases. The nature of the procedure should be considered. This consideration should include duration of the procedure, likelihood of pain, the need for immobility and the need for different levels of alertness. These factors will dictate the aims of sedation in each case.

8.1.1 Assessment should include past medical and surgical histories, noting anatomical, access or physical abnormalities that may impact on the ability to perform the proposed procedure at the level of intended sedation. Particular note should be taken of any history of known airway or anaesthesia difficulties, obstructive sleep apnoea or complaints of excessive, loud snoring from family members or partner. These patients are at significantly higher risk of increased sensitivity to sedatives, and adverse events from associated unpredicted difficult airway. Consequently, these patients should be referred for medical assessment or considered for anaesthesia assessment to determine suitability for sedation in the proposed sedating environment and context. These remarks apply equally to children, adolescents and adults.

Further assessment is based upon the level of sedation targeted. Given that targeting immobility and its intended duration in children brings about its own risks of unintended deep sedation it is essential to ascertain that any procedure is achievable at the anticipated depth of sedation. Where there is a level of uncertainty proceduralists should be prepared to refer for general anaesthesia or sedation in any hospital setting staffed and equipped with age-appropriate practitioner competencies and physical resources.

For paediatric sedation, the history should aim to identify children at higher risk of sedation complications. This includes laryngospasm, which may arise in the presence of recent or intercurrent URTI; or children at risk of airway obstruction associated with excessive sedation in the case of obstructive sleep apnoea or sleep disordered breathing; ex-premature birth; and syndromes associated with airway difficulties or early obstruction. Such children should be referred for specialist anaesthesia opinion.

On occasions children may present for urgent or emergency procedures with injuries consistent with non-accidental injuries, the possibility of which should always be borne in mind. Where this is suspected it should be discussed with or assessed by a paediatrician.

Patients of all ages, with known chronic diseases such as cardiac, respiratory, severe gastro-oesophageal reflux, chronic aspiration, neuromuscular or metabolic and rare syndromes are at higher risk of sedation complications and should be referred for medical or anaesthesia opinion.

8.1.2 In addition to the above, for Minimal sedation, assessment should include:
- Allergies

- Fasting guided by nature of the procedure and depth of intended sedation
- Medications including regular opioids
- Complex pain syndromes
- Other medical co-morbidities or psychiatric illness. Patients who have medical co-morbidities such as heart problems, epilepsy, vascular disease, or diabetes; or patients or patients with psychiatric disorders should be evaluated by a medical practitioner before embarking on sedation.
- ASA classification and documentation

8.1.3 For moderate and deep sedation, a comprehensive medical-sedation assessment should be performed including:

- Details of any current problems, past and present medical and surgical history noting abnormalities of major organ systems and how these may affect the patient's response to sedation should be considered.
- History of previous sedation and anaesthesia
- Potential for difficult airway issues including
 - History of difficult airway²
 - Dental – presence of dentures or loose teeth
 - Difficulty swallowing in cases where gastroscopy or transoesophageal echocardiography will be performed
- Current medications including non-prescribed medications that may interact with sedation medications. Alcohol and tobacco should also be noted.
- Allergies and any adverse drug reactions.
- Ascertaining exercise tolerance or functional status to gain an understanding of their functional reserve
- Fasting status
- Physical examination applicable to medical status, proposed procedure, and risks associated with sedation.
- Examination of the airway including range of neck movement, range of mouth opening; respiratory and cardiovascular system; and other systems as indicated by the history, including that relevant to the current problem.
- Recording of baseline vital signs including, for all paediatric patients, their weight and if applicable, their height.

In paediatric and generalist critical care settings, deep paediatric sedation is conducted within the capability of the healthcare facility and the scope of practice of practitioners. The history should be targeted at identifying children at higher risk of sedation complications. It is important to identify children at higher risk of laryngospasm, which may arise in the presence of recent or intercurrent URTI; or children at risk of airway obstruction associated with excessive sedation in the case of obstructive sleep apnoea or sleep disordered breathing; and syndromes associated with airway difficulties.

For children, age is an independent risk factor for requiring deep sedation, as well as an increased risk of adverse events. Children younger than 12 months are at particularly high risk of adverse events. Children younger than 6 years are more likely to require increased depth of sedation and at risk of adverse airway events.

Children with known chronic diseases such as cardiac, respiratory, severe gastro-oesophageal reflux, chronic aspiration, neuromuscular or metabolic

² Airway Alert Document

syndromes should be referred for specialist anaesthesia opinion. Children with an ASA physical status of 3 are three times more likely to have an adverse event compared to ASA 1 patients.

Non-accidental injuries in children presenting for procedures in EDs should be borne in mind, and if suspected should be discussed with or assessed by a paediatrician.

8.2 Patient selection:

8.2.1 Procedural sedation is not usually recommended for children 2 years or under. It is recommended that young children and babies who may require procedural sedation are assessed by a credentialled paediatrician and anaesthetist working within their scope of practice and managed in a hospital setting that offers the skill-mix, competency, and experience to manage small children. Specialist advice from paediatric anaesthesia, critical care, or retrieval services is recommended if there is a need to sedate an infant 12 months and younger.

8.2.2 Children at risk of complications of sedation should not undergo moderate or deep levels of sedation outside a hospital setting. It is suggested that practitioners carefully evaluate the severity of obstructive sleep apnoea or sleep disordered breathing, including treatment, before undertaking minimal sedation.

8.2.3 The following are relative contraindications or barriers to be addressed prior to provision of intravenous sedation:

- Language barriers or other factors preventing effective communication with patients, parents or carers.
- Previous difficulty with sedation or anaesthesia
- Allergy to medications
- Poorly controlled medical conditions where treatment of these will optimise outcomes
- Old age or frailty
- The presence of obstructive sleep apnoea

8.3 Informed consent

8.3.1 Informed consent for sedation 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 *Guideline on consent for anaesthesia or sedation* item 5.2).

8.3.2 When older adolescents are to undergo sedation, informed consent may be sought from patients who have the mental capacity to consent ("Gillick competent minors"). Mindful of variations in maturity, family arrangements and care relationships, minors providing consent should be encouraged to share decision-making with their parent(s). Notwithstanding parental consent, it is strongly recommended all teenagers and children, are given developmentally applicable information for the purpose of seeking their assent to the procedure. Relevant information for parents should include the purpose and likely outcome of the procedure, as well as the intended level of sedation and alternatives to sedation taking into consideration the sedating environment and capability of the healthcare facility, including staffing skill mix and availability.

8.3.3 Sedationists should ensure that processes are in place that confirm patients understand and adhere to preparation and fasting.

Patients should be prepared for the procedure with information about their likely experience and expected degree of sedation. This may be incorporated into the procedural consent.

8.4 Management of fasting

Patients should be fasted for the circumstances and targeted level of sedation. (To be decided by the DDG).

9. Technique and monitoring

9.1 Technique

The following considerations should be borne in mind when embarking on any sedation technique:

9.1.1 Reliable venous access is desirable; however, consideration may be given to proceeding without venous access for procedures under minimal sedation. Nonetheless, for deeper levels of sedation venous access is strongly recommended.

9.1.2 Where venous access is to be gained in children this should be performed by trained practitioners skilled in use of equipment suited to age and size. In special circumstances those skills may include venous access via the intra-osseous route.

9.1.3 As most complications of sedation are cardiorespiratory, doses of sedative and analgesic medications should be kept to the minimum required for patient comfort, particularly for those patients at increased risk.

9.1.4 It is important, when selecting agents, to consider their duration of action to ensure that they are commensurate with the required duration of sedation. To avoid the potential for prolonged effects of sedation at home, it is recommended that paediatric sedation is achieved with short acting agents rather than long acting ones.

9.1.5 Medications:

The narrow therapeutic window of anaesthetic agents is such that inadvertent and unanticipated rapid progression to deep sedation or general anaesthesia may occur.

- For this reason, it is essential that when such agents are administered there is one healthcare practitioner present who is responsible solely for maintaining and monitoring the depth of sedation, physiological variables, and the patient's condition. The sedationist is required to maintain all the requisite competencies and be able to provide any necessary rescue interventions.
- Sedationists should select the routes of administration of medications appropriate to the intended level of sedation as rates of absorption and onset of effects vary markedly.
- Regardless of the route of administration, constant vigilance is required where combinations of medications are used, due to their synergistic interactions. Also, for early detection and management in cases of unanticipated sensitivities. Particular care is required when topical local anaesthetic of the larynx or pharynx is employed.
- Intravenous anaesthetic agents, such as ketamine and propofol should be used only by sedationists trained and competent in their use. This includes an understanding of the nature of these medications along with their actions, pharmacology, and dose range. Unintentional general anaesthesia may occur in patients who are unwell or otherwise sensitive to their effects. An anaesthetic consultation is advisable if these concerns are present.

- All sedative medications should be managed according to local jurisdictional regulations. In Australia, healthcare facilities and providers are required to follow NSQHS Standard 4: medication safety standard. Available from: <https://www.safetyandquality.gov.au/standards/nsqhs-standards/medication-safety-standard>

9.2 Monitoring

Routine monitoring of the depth of sedation and changes in depth, is essential. Purposeful response to verbal commands or tactile stimulation is an early and sensitive guide. Loss of patient response to stimulation or verbal commands heralds loss of airway reflexes, respiratory and/or cardiovascular depression are likely, and sedation should be adjusted accordingly. Monitoring of verbal response may be difficult in patients with intellectual disabilities or language difficulties, or small children.

While it is advised that all sedated patients are monitored, the following recommended monitoring may be modified in circumstances where minimal sedation is achieved with a single dose of oral anxiolytic, or with nitrous oxide alone.

- 9.2.1 Continuous monitoring of oxygen saturation with pulse oximetry that alarms when pre-set limits are transgressed is essential in all patients undergoing procedural sedation. When alarms are triggered signifying presence of hypoxaemia then staff should devote their whole attention to correcting this situation, which may include ceasing the procedure until the hypoxaemia is corrected.
- 9.2.2 Continuous waveform capnography is recommended for sedation where verbal contact is lost or difficult to monitor. Capnography is strongly advised for moderate and deep sedation in children.
- 9.2.3 Regular monitoring of pulse rate, oxygen saturation and blood pressure throughout the procedure and recovery phase, using equipment suited to patient size, is essential. For those patients in whom monitoring prior to commencement of sedation may not be practical, such as small children or patients with intellectual disabilities, regular monitoring should continue throughout the episode of sedation and the early recovery phase of care.
- 9.2.4 According to the clinical status of the patient, other monitors such as ECG may be required (see College professional document *PS18 Guideline on monitoring during anaesthesia*).

10. Oxygenation and airway patency

- 10.1 Airway patency is crucial to maintenance of oxygenation. Effective breathing requires an open airway, and airway patency may be impaired even in the presence of intact airway reflexes as witnessed in laryngospasm or alternatively, due to loss of pharyngeal muscle tone and consequent airway obstruction at deeper levels of sedation.
- 10.2 Apnoea or hypoventilation may occur during moderate and deep procedural sedation and lead to hypoxaemia in the absence of oxygen supplementation. Oxygen administration diminishes the risk of hypoxaemia and should be administered for as much of the procedure as possible.

Although desirable, oxygen administration prior to commencement of sedation may not benefit all patients and may not be achievable in some patients such as small children or patients with intellectual disabilities.
- 10.3 Pulse oximetry enables tissue oxygenation to be monitored, which is essential in all patients during procedural sedation.

11. Documentation

The clinical record should include the names of staff performing sedation, as well as documentation of the history, examination and investigation findings. A written record of the dosages of medications and the timing of their administration should be kept as a part of the record. Such entries should be made as near to the time of administration of the medications as possible. This record should also note the regular readings of monitored variables, including those during the recovery phase, and should contain other information as indicated in ANZCA professional document *PS06 Guideline on the anaesthesia record*.

12. Recovery and discharge

12.1 Where deep sedation has been achieved recovery should take place under supervision of postanesthesia care unit (PACU) trained nurses, in a properly equipped and staffed area, which may be the area where the procedure was performed (see ANZCA professional document *PS04 Statement on the post-anaesthesia care unit*).

12.2 If the recovery area is not where the procedure occurred then availability of adequate and safe patient transfer facilities is essential.

12.3 It is essential that staffing is adequate, and facilities are available in the recovery area for managing patients who have become unconscious or who have suffered complications during their procedure.

12.4 Discharge of patients should be authorised by the practitioner responsible for managing sedation, or another qualified practitioner working within their scope of practice. Patients 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 Systems should be in place to enable safe transfer of patients to escalated medical care should the need arise.

13. Training in procedural sedation for non-anaesthetist practitioners

13.1 It is essential that sedationists undergo training with recognised training providers capable of meeting the Safe Sedation Competencies contained in Appendix 4.

13.2 Training and clinical support of sedationists may be assisted by close cooperation with nominated anaesthetists, or for remote or rural practitioners, with anaesthetists in any major centre, particularly when intravenous or intramuscular sedation is practised. Such cooperation facilitates sedationist training in rescue skills, as well as availability of backup

13.3 Regular certification in cardiopulmonary resuscitation relevant to the clinician's practice, as well as evidence of relevant continuing professional development, are requirements for credentialling.

14. Audit

14.1 It is strongly recommended that sedationists undertake regular and effective audit of their sedation practice and comply with local jurisdictional requirements.

- 14.2 Any unit where sedation services are provided is expected to have an established system for audit of outcomes related to sedation and include these audited outcomes 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 Sedationists are required to be aware of their jurisdictional obligations 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

PS02 *Statement on credentialling and defining the scope of clinical practice in anaesthesia*

PS04 *Statement on the post-anaesthesia care unit*

PS06 *Guideline on the anaesthesia record*

PS07 *Guideline on pre-anaesthesia consultation and patient preparation*

PS08 *Position statement on the assistant for the anaesthetist*

PS15 *Guideline for the perioperative care of patients selected for day stay procedures*

PS18 *Guideline on monitoring during anaesthesia*

PS26 *Position statement on informed consent for anaesthesia or sedation*

PS29 *Guideline for the provision of anaesthesia care to children*

PS55 *Position statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations*

APPENDIX I

The American Society of Anesthesiologists classification of physical status:

- P 1 A normal healthy patient
 Healthy with good exercise tolerance – no organic or physiologic disturbances
- P 2 A patient with mild systemic disease
 Well-controlled disease of one body system with no functional limitations.
 Includes controlled hypertension or diabetes without systemic effects, mild obesity, pregnancy.
- P 3 A patient with severe systemic disease
 Controlled disease of more than one body system or one major system and with some functional limitation but no immediate danger of death. Includes stable angina, old infarct, controlled congestive cardiac failure, poorly controlled hypertension, chronic renal failure.
- P 4 A patient with severe systemic disease that is a constant threat to life
 Poorly controlled or end stage of at least one severe disease and possible risk of death. Includes unstable angina, hepatorenal failure, symptomatic congestive cardiac failure, symptomatic chronic obstructive lung disease.
- P 5 A moribund patient who is not expected to survive without the operation
 Not expected to survive more than 24 hours without surgery and imminent risk of death. Includes. Multiorgan failure, sepsis syndrome with haemodynamic instability, hypothermia, poorly controlled coagulopathy
- 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 medications should include at least the following:

	Sedation modes			
	Opioids	Benzodiazepines	Ketamine	Propofol
Medication				
Epinephrine/adrenaline	√	√	√	√
Atropine	√			√
Naloxone	√			
Flumazenil		√		
Portable oxygen supply	√	√	√	√
Crystalloid solution	√	√	√	√

Lidocaine 1% topical to break laryngospasm in children
Dextrose to treat hypoglycaemia:

- 50% for intravenous administration in adults
- 10% for intravenous administration in children at a recommended dose of 2.5mL.Kg⁻¹
Oral glucose is a suitable alternative for children undergoing minimal sedation.

APPENDIX III
Personnel for procedural sedation

Scenario 1: Minimal sedation by proceduralist (single dose of oral anxiolytic or nitrous oxide/oxygen only)



- Proceduralist/sedationist with requisite competencies for minimal sedation
- Assistant
- Suitable for adults
- For children a third person may be advisable
- ASA 1-2 patients

Scenario 2: Minimal sedation by sedationist



- Proceduralist
- Sedationist with requisite competencies for minimal sedation
- Assistant to both
- ASA 1-2
- Either adults or children

Scenario 3: Moderate sedation



- Proceduralist/sedationist with requisite competencies and skills
- Assisting practitioner with requisite skills
- Assistant to assist both
- ASA 1-2
- Moderate sedation not recommended for children

Scenario 4: Deep sedation



- Proceduralist/sedationist with requisite competencies for deep sedation
- Assisting practitioner with requisite ALS skills
- Assistant to each
- Healthcare facility with onsite medical emergency availability

Scenario 5: Deep sedation



- Proceduralist/sedationist with requisite competencies for deep sedation
- Assisting practitioner with requisite ALS skills
- Assistant to each
- Suitable for children
- Suitable for ASA 1-2
- Healthcare facility with no onsite medical emergency availability

Scenario 6: Deep sedation/anaesthesia by anaesthetist



- Proceduralist
- Anaesthetist
- Assistant to assist both
- ASA 1-4
- Adults and children
- All approved anaesthetic medications may be used



Appendix IV

Safe procedural sedation competencies

Introduction

For clarity and for the purposes of the development and use of curriculum competencies, this appendix is intended to ensure that:

- 1) Procedural sedation can be provided safely to patients of all ages, and by any routes of administration including use of intravenously administered medications.
- 2) All levels of sedation from minimal to deep as defined above can be safely managed.
- 3) Practitioners responsible for sedation (sedationists) are familiar with jurisdictional regulations/requirements for facilities.

It is understood that sedation may be required for therapeutic or interventional purposes. The use of the terms “procedure” or “procedural” in this document encompasses diagnostic and interventional procedures.

The risks associated with procedural sedation are proportional to the depth of sedation. Consequently, a graded approach to skills, staffing and technique may be appropriate. For example, basic life support skills suffice for minimal sedation achieved solely by a single oral dose of an anxiolytic or alternatively by the sole administration of nitrous oxide/oxygen. However, where multiple sedative agents are administered or for deeper levels of sedation where the risks are greater the higher skills of advanced life support are necessary.

While the following competencies are intended to apply to all depths of procedural sedation, the guidance items for each competency below may reasonably be moderated for minimal sedation achieved by sole use of an orally administered anxiolytic or nitrous oxide/oxygen.

As a general principle, when sedating children, practitioners require competencies that include an understanding of normal child development; anatomical and physiological differences at different ages; knowledge of how children respond to anxiety, fear, and pain; and pharmacological effects of sedation within the proposed scope of practice. Practitioners should also have age-specific experience and technical skills to rescue physiological deterioration. In addition, they should have knowledge about the facility and environment in the context of sedation as well as its capability to support sedation for different age groups.

Incorporating the competencies into a curriculum

These competencies represent the **minimum** requirements for practitioners to be deemed competent to deliver safe procedural sedation. The competencies were developed to suit a wide range of professional groups and it is understood that individual colleges and other organisations may need to adapt the format of the competencies to match the format of their specific curriculum.

Non-bolded items provide essential guidance for the main competency statement in bold text, helping to articulate its intentions.

The competencies

By the end of training, the trainee sedationist will be able to:

- 1. Describe the goals of sedation.**

This is particularly relevant for paediatric sedation as children cannot advocate for themselves. It is incumbent on healthcare professionals to look after the welfare of children first and foremost. Parental (or anyone else's) convenience or request does not alleviate the healthcare practitioner's first duty under their legal obligations to look to the welfare of the child first.

The goals of paediatric sedation include:

- Guarding patient safety and wellbeing
- Minimising discomfort and pain
- Controlling anxiety and minimising psychological trauma
- Modifying behaviour and or movement to facilitate successful completion of the procedure.

2. Conduct a thorough pre-sedation assessment, identifying clinical features, pre-existing conditions and medications that predisposes them to adverse sedation-related events.

- Describe the rationale for assessment for sedation.
- Discuss the elements of pre-sedation assessment and the importance of each, including but not limited to:
 - Patient identification and age
 - Previous anaesthesia/sedation history
 - Allergies and drug sensitivities
 - Aspiration risk assessment, including expected fasting status and pre-sedation instructions
 - Airway assessment, including risk of airway obstruction during sedation
 - Specific attention should be paid to ascertaining the existence of any written airway alerts.
 - General health, including exercise tolerance, cardiorespiratory status and current medications
- Outline the 'red flags' in the assessment process (and use assessment tools to identify those patients at risk) including but not limited to:
 - Prior sedation or anaesthesia related adverse events/complications
 - Obstructive sleep apnoea
 - Morbid obesity
 - Patients with limited functional reserve
 - Frailty
 - Age

2.1 Paediatric pre-sedation assessment:

- Recall and describe normal childhood development
- Understand and describe the use of common non-pharmacological tools such as distraction or commonly used communication techniques suitable for children of different ages.
- Describe the anatomical and physiological changes as children grow from infancy to adolescence including usual range of acceptable vital signs at different ages.
- Describe how children respond to anxiety, fear and pain; and analyse how these impact on the pharmacological effects and dose requirements of sedation.
- Outline the 'red flags' for paediatric sedation:
 - Age

- obstructive sleep apnoea or sleep disordered breathing
- Adeno-tonsillar hypertrophy
- Upper respiratory tract infection (URTI)
- Croup, including history of recent episode of croup
- Lower-respiratory tract infection including bronchiolitis
- Chronic disease: cardiac, respiratory, neuromuscular, metabolic, rare syndromes, severe gastro-oesophageal reflux.

3. Stratify patients according to risk.

Patients at high risk of adverse sedation-related events should be referred to a specialist anaesthetist.

See section 8 Patient Preparation above for details applicable to paediatric sedation. Specifically, the ability to rescue and manage general anaesthesia if administering deep sedation to children. (Refer ANZCA PS29 *Guideline for the provision of anaesthesia care to children*).

4. Determine the suitability of and requirements for the targeted level of sedation.

This should take into account the complexity of the procedure, duration of immobility required, tolerance of the procedure for movement, and likely discomfort of the procedure.

Prolonged immobility for children unable to be satisfactorily positioned using minimal sedation, or any procedure with no tolerance for movement is an indication for general anaesthesia. Although deep sedation may be used, it is likely that most children will slip into a state of general anaesthesia.

5. Clearly communicate the risks of procedural sedation to the patient or parent/carer to obtain valid informed consent and address patient expectations.

See section 8 Patient Preparation above for details of consent as well as ANZCA PS26 *Statement on informed consent for anaesthesia or sedation*.

6. Describe key safety features when conducting a risk assessment of the facility capability and proposed sedating environment.

Paediatric sedationists should be able to assess the suitability of any sedating environment, capability of any healthcare facility including assisting staff to support safe paediatric sedation for the intended level of sedation and describe the similarities and differences for the different age groups.

Sedationists intending to administer moderate or deep sedation intravenously or intramuscularly to children under 3 years of age, are advised to consult with a paediatrician, paediatric experienced critical care specialist or anaesthetist. Where intended sedation levels for young children are beyond minimal, then ANZCA PS29 provides guidance on the competencies required to rescue deeper levels of sedation which may encroach on general anaesthesia for procedures demanding movement control.

7. Prepare for an episode of procedural sedation ensuring that:

- equipment for monitoring and for emergencies is available and functional in both the procedure and recovery areas³
 - at least the minimum recommended number of staff⁴ are present during the procedure and in the recovery area, all of whom have current age-appropriate basic life support skills
 - at least one practitioner present is current in age-appropriate advanced life support skills and can stop what they are doing immediately in the event of an emergency
 - medications for sedation and for emergencies are immediately available
 - all team members have a shared understanding of their responsibilities and the patient care plan, including escalation plans and emergency protocols.
- 8. Administer sedation medications, titrating them to effect, taking into consideration the differing onset times, doses, peak effects and duration, to ensure completion of the entire procedure.**
- Discuss the pharmacology of medications used intravenously for procedural sedation and variations in response with age.
 - Discuss the pharmacology of medications administered by different routes of administration including oral, inhalational, intra-nasal, and rectal.
 - Analyse and recognise the importance of alternative routes of sedation for children
 - Describe how the use of multiple medications administered by different routes may produce synergistic or antagonistic effects.
 - Describe and recognise the levels of sedation and understand that depth of sedation is a continuum between minimal through to deep sedation and even to general anaesthesia.
 - Describe the pharmacology of reversal /antagonist agents, and medications used for the management of medical emergencies, including indications, their duration of action and risks of use.
- 9. Continually⁵ monitor patient comfort and record regular observations, according to local guidelines.**
- Understand the need to be continuously⁶ present during the procedure and continually monitor the patient's status, to the exclusion of all other duties.
- 10. Recognise age-applicable key features of patient deterioration, initiate management or rescue and call for help if required.**
- Key factors include:
- Airway obstruction or abnormal breathing
 - Hypoventilation or apnoea
 - Aspiration
 - Oxygen desaturation: clinical observation or by use of age-appropriate oximetry where indicated.
 - Changes to waveform capnography where it is indicated for use.
 - Changes in depth of sedation
 - Heart rate and heart rhythm changes if conducting IV sedation or moderate – deep sedation.
 - Blood pressure changes if conducting intravenous sedation or moderate to deep sedation.

³ Refer to sections 8, 9, 10 of the guideline above

⁴ Refer to *Appendix III* above

⁵ “Continually” means “regularly and intermittently”

⁶ “Continuously” means “in an uninterrupted way”

- Allergic reactions and anaphylaxis
- Complaints of chest pain or shortness of breath

Initiation of management and rescue include:

- Basic Life support: Age-appropriate technical skills and recency of practice or requalification of basic airway opening manoeuvres, age-appropriate use of suction and age-appropriate CPR
- Advanced Life support: Age-appropriate technical skills:
 - Recency of practice or requalification of basic airway opening manoeuvres,
 - Use of suction to clear the airway
 - Use of airway adjuncts such as sizing and insertion of oropharyngeal airways, Laryngeal mask airways
 - Effective Bag-valve mask positive pressure ventilation
- Age-appropriate management of anaphylaxis

11. Ensure patients are safe to be transferred to a recovery area and complete a formal handover of care, along with documentation of the sedation and plan for ongoing care.

Patients should be able to maintain a patent airway with no more than minimal support.

12. Ensure continual observation and monitoring of patients in the recovery area until they meet pre-defined criteria for discharge.

- Describe the criteria required for safe discharge of patients after procedural sedation.

13. Ensure written discharge information is provided for all patients before they leave the facility with their carer, including instructions for steps to take in the event of an emergency.

Competencies applicable to Assisting practitioners administering sedation under the direction of proceduralists or sedationists include the following.

By the end of training, the trainee assisting practitioner will be able to:

- Apply age-appropriate techniques of communication with children to alleviate anxiety and minimise the use of sedative medications.
- Discuss the use of age-appropriate non-pharmacological techniques of procedural management or conduct in order to minimise the use of sedative medications.
- Perform age appropriate BLS, ALS and contribute to anaphylaxis management

Further reading:

Safe Sedation Practice for Healthcare Procedures: Standards and Guidance
(Academy of Medical Royal Colleges, Oct 2013).

Communicating procedures to children. Safer Care Victoria. NSW Agency for Innovation. Clinical Excellence QLD. [Internet; Updated June 2021] Available from: https://www.rch.org.au/clinicalguide/guideline_index/Communicating_procedures_to_children/

APPENDIX V

Glossary:

General anaesthesia: A drug-induced state of unconsciousness characterised by absence of purposeful response to any stimulus, loss of protective airway reflexes, depression of ventilation and disturbance of circulatory reflexes.

Paediatrics: Relating to any person under the age of 18 as defined by jurisdictional authorities.

However, in recognition of the considerable physiological and mental disparity between children and adolescents as well as their responses to sedative medications and procedural interventions, this document refers specifically to children.

For the purposes of this document, children are considered as those 12 years of age or younger, while the 13 to 18 age group are considered adolescents.

Practitioner: Any members of the medical or nursing professions who are registered with their jurisdictional regulatory registration authority, or specialist dentists or dentists who are registered with their jurisdictional regulatory registration authority.

Assisting practitioner: Any healthcare practitioner with defined and annually certified competencies as outlined in Appendix 4, who under the direction of a sedationist is tasked with administering medications, patient observation and monitoring. Assisting practitioners should have basic resuscitation skills as a minimum.

For dental procedures performed under minimal sedation that is achieved solely by a single dose of orally administered anxiolytic or nitrous oxide/oxygen, this role may be supported by dental assistants under the direct supervision of the sedationist who maintains primary responsibility for managing sedation and any complications.

Procedural sedation: a state of drug-induced relief of anxiety or tolerance of uncomfortable diagnostic or interventional medical, dental, or surgical procedures.

Lack of memory of distressing events may be desired outcomes, but lack of response to painful stimulation is not assured. This is of particular relevance to paediatric patients in whom absence of movement may be difficult to achieve in the absence of deeper levels of sedation.

Sedation is a continuum, and wide interpatient variability exists. Further, the conduct of procedural sedation is a dynamic and rapidly changing process, requiring ongoing assessment and monitoring. It is essential that management and rescue plans be prepared prior to commencement of sedation, should deeper than intended levels of sedation occur, or airway, respiratory or cardiovascular interventions become necessary.

Children undergoing sedation are more prone to laryngospasm than adults demanding that sedationists caring for children understand the periods of risk and can manage laryngospasm.

Proceduralist: Any practitioner performing surgical, diagnostic, or dental procedures,

This practitioner may also perform the role of sedationist if they meet the requirements of sedationists, listed below. Where proceduralists assume both roles the presence of an

additional assisting practitioner working strictly under their direction, is essential for the purpose of patient observation and monitoring, and administration of medications.

Sedation

Minimal: A drug-induced state, during which patients respond purposefully to verbal commands or light tactile stimulation.

Features of minimal sedation include maintenance of airway patency and reflexes, as well as ventilatory and cardiovascular function, although there may be some reduction in cognition and physical dexterity.

Moderate: A drug-induced state of depressed consciousness during which patients retain the ability to respond purposefully to verbal commands and tactile stimulation.

Features of moderate sedation include maintenance of airway patency and reflexes, as well as ventilation and cardiovascular function. However, minimal interventions to maintain airway patency, spontaneous ventilation or cardiovascular function may, be required. Moderate sedation offers a margin of safety that is wide enough to render loss of consciousness unlikely.

This level of sedation is normally not used for children due to the heightened risk of laryngospasm associated with this plane.

Deep: A drug-induced state of depressed consciousness during which patients are not easily roused and may respond only to noxious stimulation.

Features of deep sedation may be difficult to distinguish from general anaesthesia and include impaired ability to maintain an airway, inadequate spontaneous ventilation and/or impaired cardiovascular function. Deep sedation can readily and rapidly progress to general anaesthesia with onset of unconsciousness and inability to maintain an airway. For this reason, providers of deep sedation should possess a level of skill and training commensurate with these risks. Advanced airway and life support skills are necessary when deep sedation is practised. Similarly, the environment in which deep sedation is administered should be suitable for the management of the inherent risks of this technique.

Sedationist: Any practitioner responsible for the administration, management, and conduct of sedation working within their scope of practice.

This practitioner is expected to have completed training relevant to sedation and have attained and maintained the competencies outlined in Appendix 4 of this guideline.

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Promulgated (as P9): 1984

Reviewed: 1986, 1991, 1996, 2001, 2005, 2007, 2008, 2010, 2014

Date of current document: Oct 2021

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