

PG09(G)BP Guideline on procedural sedation Background Paper 2022

Short title: Sedation BP

1. Purpose of review

Sedation is commonly employed for medical, dental and surgical procedures by a range of health practitioners with diverse qualifications and training, including anaesthetists, other medical and nursing practitioners, and dental specialists.

The goal of the Australian and New Zealand College of Anaesthetists (ANZCA) professional document PG09(G) Guideline on procedural sedation is to optimise patient care in the management of procedural sedation by all duly qualified health practitioners in Australia and New Zealand. The document was last reviewed in 2014. The current review was undertaken under the process outlined in <u>CP24(G)</u> Policy for the development and review of professional documents. This background document was written to support the guideline.

2. Scope of this document

The accompanying professional document is intended to apply to all sedationists administering procedural sedation.

Discussion surrounding the clarity as to whom the accompanying guideline should apply revealed confusion and potential for misinterpretation with regard to the use of the term "practitioner". Alternatives to this were considered in the context of medical practitioners, nursing practitioners, allied health practitioners, dentists and dental specialists. To avoid such confusion, it was agreed that the simplest approach was for PG09(G) to apply to all sedationists, irrespective of their qualification, who are registered with their jurisdictional regulatory registration authority and working within their defined scope of clinical practice.

With the decision to include paediatric sedation, expert advice was sought from the Society of Paediatric Anaesthetists of New Zealand and Australia (SPANZA) and the Paediatric and Child Health Division (PCHD) of the Royal Australasian College of Physicians (RACP), in addition to the DDG expertise provided by members with paediatric anaesthesia/sedation experience.

The accompanying guideline is not intended to apply to local anaesthesia or major regional anaesthesia, or analgesia administered without targeting sedation, nor to general anaesthesia techniques, all of which are the subjects of other ANZCA professional documents (i.e. <u>PG37(A)</u> Guideline for health practitioners administering local anaesthesia, <u>PG03(A)</u> Guideline for the management of major regional analgesia and <u>PS55(A)</u> Position statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations). However, if local anaesthesia and/or major regional anaesthesia or analgesia are co-administered with sedation, then the associated guidelines apply.

The accompanying guideline is intended to apply to procedural sedation, and therefore, does not apply to nitrous oxide administered for pain relief in labour. However, if used in combination with local anaesthesia or other intravenously administered analgesic/hypnotics to induce sedation to facilitate any procedure such as forceps delivery or suturing an episiotomy, then the guideline will apply. When sedating pregnant women, the additional risks of aortocaval compression and aspiration of gastric contents should be addressed.

3. Process of review

The review followed the process outlined by ANZCA professional document CP24(G) Policy for the development and review of professional documents. Refer to items 5.4 and 5.7 of the policy as well as to items 4.3 and 5 of its accompanying background paper for details regarding the role of evidence and consensus. The first two meetings were held by videoconference instead of face-to-face due to Covid-19



restrictions. These meetings proved valuable in facilitating critical evaluation on the purpose and scope of PG09(G) and achieving consensus.

Most of the content review and further development was undertaken electronically via email.

An initial search of the literature for articles between 2008 and 2021 was conducted between 9th March 2021 and 10th April 2021. The search was assisted by the ANZCA Library as well as submissions received from stakeholders. Areas of specific interest included:

- Sedation safety in both anaesthetist and non-anaesthetist settings
- Paediatric sedation
- Models of delivery including physician-directed nurse administered sedation
- Post-sedation advice

There are numerous articles published in the literature describing the safety of a wide variety of techniques. However, there is a paucity of randomised trials. Nevertheless, recommendations presented in PG09(G) are guided by best available evidence, or consensus where this is lacking.

Articles applicable to PG09(G) have been identified and screened, and although not exhaustive, they are listed at the end of this background paper.

Given the recency of the development of the Safe Sedation Competencies that have been incorporated into PG09(G), the literature search undertaken as part of that project was not repeated.

4. Discussion

4.1 Scope of the document and sedationist competencies

After the extensive second round of consultation, it was decided to narrow the scope of PG09(G) to minimal and moderate sedation but exclude deep sedation. Managing patients under general anaesthesia is complex, high-risk and requires extensive training. As deep sedation can rapidly progress to, general anaesthesia, it is unreasonable to expect any practitioner who has not completed such training to manage general anaesthesia.

Recommendations in the accompanying guideline defer to any active local jurisdictional requirements issued by regulatory authorities.

The issue of managing sedation in emergent cases, which may preclude following some or even all of the recommendations was considered and is acknowledged. Nonetheless, managing sedation in the emergent context does not reduce the importance of the recommendations of the accompanying guideline. Rather, in time-critical situations where some recommendations may be precluded, it remains important to recognise and acknowledge the situational context. It also serves as an opportunity to note potential for future improvements.

Medical practitioners from many disciplines, nurses, dentists and dental specialists administer sedative/hypnotic medications. The purpose of PG09(G) is to optimise patient care in the management of procedural sedation by <u>all</u> sedationists. To this end, since the original promulgation of PS09 in 1984, ANZCA has engaged in a process of endorsement with other medical and dental colleges and specialist societies. In the current revised guideline ANZCA has engaged stakeholders to collaborate on the revision and to co-badge PG09(G).

4.2 Definitions

To avoid confusion and assist with clarity, definitions have been modified in this version to ensure that they are fit for purpose. A glossary has been developed and is attached as an appendix to the guideline. The glossary includes definitions of the roles associated with procedural sedation.

The glossary also includes definitions that differentiate guidelines, position statements, policies, and standards, which help to put the accompanying guideline into perspective. PG09(G) is a guideline and consequently, is an advisory document that provides recommendations that are evidence-based or consensus-based where evidence may be lacking or poor, and which if followed should have the effect of optimising patient care. This differentiates guidelines from training manuals which are detailed and prescriptive and from policies, which are mandatory and proscriptive based on regulations. The accompanying guideline should be read in this context.

4.3 Risks

Clinical management and patient outcomes centre around identification of risks and risk management. Consequently, these are highlighted as a separate section (5.2 in the guideline) and include consideration of both general and specific risks.

Cohorts with specific risks include indigenous communities, the frail and elderly, those with comorbidities that fall into ASA 3 and 4 categories, pregnant women, and children, especially prematurity and ex-preterm infants.⁽¹⁾

Discussion surrounding risks associated with ASA status suggested that risks are doubled for each advance in classification status, and that this becomes clinically significant with advancing from ASA 2 to ASA 3. The classification is based on physiological impairment and encroachment on functional reserves for which distinct definitions are provided. There is no splitting of the classification and consequently, it was advised that the concept of ASA 3 stable/unstable runs contrary to its intent. It was agreed that "ASA 3 stable" and associated risks is consistent with ASA 2, and that such patients would be assigned to ASA 2. Therefore, reference to stable/unstable has been removed in the Pilot version.

4.4 Recognising culture

The accompanying guideline spans Australia and New Zealand and recognises the principles that underpin cultural safety, which includes indigenous peoples as well as people from other cultures and countries.

The concept of health within First Nations communities is commonly understood as more than the care and management of physical manifestations of illness. Indigenous Health includes the social, spiritual, emotional and ecological wellbeing of the land, individuals and communities. The laws governing indigenous rights differs between Australia and New Zealand, and sedationists are directed to the respective regulatory authorities for specific details. ANZCA *PS62(G) Position statement on cultural competence* articulates ANZCA's position and provides recommendations in regard to cultural competence and cultural safety.

Practices are diverse, complex and inclusive. They are understood as holistic, cyclical care, and are maintained through intergenerational transmission of knowledge to people, places and objects.

4.5 Competencies

There was strong support for incorporating into PG09(G) the Safe Sedation Competencies, which were the result of a collaborative project undertaken by stakeholders, into PG09(G). The scope of the competencies originally specifically excluded paediatric sedation. With the ongoing inclusion of paediatric sedation in PG09(G) the competencies were reviewed to accommodate paediatric sedation and have been incorporated into the accompanying guideline in Appendix IV.

Discussions centred around the priority of competence rather than the discipline or specialty background of sedationists. The skills and competencies of specialists working in critical care settings such as intensive care physicians, emergency department physicians, and anaesthetists equip them to manage deep levels of sedation and were highlighted as exceeding those of sedationists from other disciplines. Consequently, one view proposed was that PG09(G) should not include deep sedation as this may be outside the competencies of sedationists not engaged in critical care settings.

A contrary view was that transient brief periods of deep sedation may be required in specific settings such as cardiological procedures requiring defibrillation or the initial stage of upper gastrointestinal endoscopy. These types of procedures are normally performed in hospitals where medical emergency teams are available to respond in the rare event that resuscitation is required. Consensus was reached that while the need for deep sedation in such specific circumstances is acknowledged, the accompanying guideline would not provide guidance as this is provided elsewhere. Refer to ANZCA *PG29(A) Guideline for the provision of anaesthesia care to children* for deep sedation in children and to *CSANZ Position Statement on Sedation for Cardiovascular Procedures* for cardiological procedures requiring transient brief periods of deep sedation.⁽²⁾

The applicable competencies and skills outlined in Appendix IV are based on the risks associated with depth of sedation as well as patient comorbidities. The skills needed to manage minimal sedation



using either a single dose of oral anxiolytic or nitrous oxide/oxygen or methoxyflurane as the sole agent in patients of American Society of Anesthesiologists (ASA) 1 or 2 are quite different from those required to manage sedation in ASA 3 and 4 patients. A summary of the competencies and skills recommended for sedationists and assisting practitioners is presented in Table 1 of the accompanying guideline.

PG09(G) supports the view that the competencies should be incorporated into sedation training curricula, the delivery of which may be operated by stakeholder colleges, societies, or institutions.

The accompanying guideline encourages close cooperation with nominated anaesthetists or anaesthesia departments, to promote the potential benefits of such cooperation, including facilitating sedationists to acquire rescue skills, and ensuring the availability of backup in case of need.

4.6 Personnel for sedation

This was a topic of major discussion in relation to minimum staffing recommendations to support safe procedural sedation. Numerous issues were considered including:

- The impact on viability of procedural services in the diverse settings of procedural sedation given the availability of staff possessing the requisite skills.
- Acknowledging that although sedation is not without risk, the level of risk is closely related to depth of sedation, patient age and health status, competence and skillset of sedationists and assisting practitioners, and facility support services.
- The considerable variability in procedures, settings, and locations and the specific needs applicable to individual circumstances.

Limitations of access to sedation and potential unintended consequences were considered in these discussions. A summary of staffing requirements is depicted in Appendix III of the accompanying guideline.

4.7 The use of propofol for sedation

Propofol is the drug of choice of anaesthetists who administer sedation for endoscopy in Australia and New Zealand.⁽³⁾ Propofol is also in widespread use by non-anaesthetist medical practitioners, dentists and dental specialists. There is a paucity of high-level evidence that demonstrates any significant difference in outcomes when propofol is used for sedation by either anaesthetists or non-anaesthetists, although there are numerous studies with lower level evidence that support similar outcomes. One single-centre study using a non-validated method to measure recovery after propofol suggests that cognitive outcomes are no different when non-anaesthetists administer propofol rather than benzodiazepines for sedation.⁽⁴⁾ However, PG09(G) advises that the use of propofol in non-anaesthetic doses by non-anaesthetists should occur only under an agreed set of principles:

- 4.7.1 Where propofol is administered by the proceduralist who also assumes the role of sedationist, the presence of two additional staff member is essential, one of whom, the assisting practitioner has the requisite skills and competencies.
- 4.7.2 Use of propofol by non-anaesthetist practitioners is acceptable only if the requisite number of staff with the applicable skills and competencies is present, or if targeting only minimal sedation.
- 4.7.3 It is essential that non-anaesthetist practitioners who wish to administer propofol sedation are trained in sedation consistent with the competencies described in Appendix IV.

There was considerable discussion and representation regarding physician-directed, nurse administered propofol sedation as a safe technique. In the context that administration of any medication carries risk of adverse effects it is inappropriate to deem any technique safe. However, safety can be considered in terms of degree of risk and the safety of any technique in terms of how well those risks are mitigated. From this perspective it was agreed that models of propofol sedation by non-anaesthetists, such as endoscopist directed nurse administered propofol sedation (EDNAPS) or dental sedation by dentists or dental specialists endorsed for sedation, may be acceptable models subject to complying with the recommendations on competencies of sedationists and presence of the requisite support personnel and systems, as depicted in Appendix III.

Intravenous propofol can be administered as either intermittent boluses or as an infusion. A strong view was presented that there are advantages to using specialised pumps in circumstances where

propofol is administered by infusion. There are a number of target-controlled infusion (TCI) pumps on the market with algorithms that can target either plasma levels or effect-site levels. Use of such devices has advantages but requires an understanding of the pharmacology and pharmacokinetics of propofol as well as the pharmacokinetic models used by the pumps.

Patients classified as ASA 3 or 4 presenting for cardiological procedures under moderate sedation may require a brief period of deep sedation for their procedure. Often their cardiological morbidity is the reason for their ASA classification and the indication for their procedure. It is recognised that cardiologists are physicians with detailed understanding of cardiovascular physiology and specialise in the treatment of cardiovascular disease. The Cardiac Society of Australia and New Zealand (CSANZ) position statement on sedation reflects its awareness of the risks of sedation and provides sensible guidance.⁽²⁾ Cardiological procedures requiring deep sedation are generally undertaken in larger hospitals supported by the availability of ALS teams, and patient cardiorespiratory variables are closely monitored throughout. The staffing personnel and requirements are depicted in Appendix III.

5. Patient assessment and selection

The section dealing with patient assessment is commensurate with *PG07(A)* Guideline on the preanaesthesia consultation.

5.1 Assessment:

The extent of any assessment will be determined by the targeted level of sedation and proposed procedure. For example, for patients classified as ASA 1 or 2 in whom sedation is to be achieved solely by administration of nitrous oxide/oxygen or single dose of oral administered anxiolytic or methoxyflurane for a short procedure will differ from those targeted for deeper levels or patients with comorbidities.

Special attention should be paid to identifying patients with complex pain syndromes and/or frequent use of opioid analgesics, as such patients may demonstrate tolerance to analgesics and require higher doses of sedatives or opioids, which then renders them at risk of hypoventilation, nausea, and unexpectedly deep levels of sedation. Special attention should be paid to potential airway problems including any history of airway difficulties. In Australia, difficult airway alert documents are being developed¹ to facilitate recording and documenting events for patients having presented airway challenges. As part of the airway assessment, such documents should be consulted where available.

Issues specific to procedural sedation for children include age and those where children present with a history of sleep disordered breathing or obstructive sleep apnoea; a history of anaesthesia-related problems; history of difficult airway or syndromes associated with difficult airways such as Pierre-Robin or Treacher-Collins syndrome. Some syndromes, such as Down Syndrome are associated with obstructive sleep apnoea and cardiac lesions.

Furthermore, paediatric procedural sedation necessitates drawing attention to the importance of accurate calculations for drug dosing. These calculations are usually based upon weight. An important 'vital sign' to document for paediatric sedation is weight. If it is not possible to weight the child, for example if sedation is required in emergency setting^(5, 6), Broselow tapes are a means of estimating the weight of children from their length (height). Generally accurate within a normal weight distribution, they may be inaccurate at extremes of obesity and underweight. Pre-calculation of drug doses is particularly relevant to guide accurate dosing in sedation to ensure effective dosage, avoid overdosing and consequent unintended deep sedation. Pre-calculation of emergency medications is recommended. Reputable weight-based, printable guides are also available on the internet, such as the Paediatric Emergency Medication Book.⁽⁷⁾

¹ For example, Queensland Health Difficult Airway Alert Document <u>https://clinicalexcellence.qld.gov.au/sites/default/files/docs/clinical-networks/difficult-airway-alert.pdf</u> In the emergency or urgent care setting, patterns of injury consistent with the possibility of nonaccidental injury should be borne in mind as these are occasionally overlooked. Discussion with, or assessment by, a paediatrician is recommended in such cases.

Patients requiring moderate to deep sedation, who are identified at higher risk for procedural sedation, warrant a more comprehensive assessment. Of particular note is the presence of cardiac and respiratory disease including obstructive sleep apnoea or a history of snoring. Note should also be made of any bleeding abnormalities or history of embolic events. The presence of hepatic and renal disease should be considered in relation to the metabolism of drugs. The presence of severe arthritis may cause difficulty in patient positioning and analgesia. The presence of active psychiatric illness or cognitive impairment also has an important effect on response to sedation. Patients with neurological or neuromuscular disease adversely affecting airway protection or respiratory function require special consideration. The presence of diabetes should be noted, and a plan made for diabetes management during the procedure.

- Physical examination to be undertaken includes examination of the cardiac and respiratory systems, assessment of the airway and assessment of vasculature where it is required for procedural access. If there is a risk of emergency airway intervention, note should be made if the neck is short, if there is limited extension, hyoid-mental distance of less than 3cm, or deformities of the neck. Note should be made if the mouth opening is small (less than 3cm), macroglossia is present or there are other restrictions within the oral cavity. A Mallampati score may be used. The teeth should be examined, and mobile teeth, the presence of removable dentures and/or expensive dental treatment noted. The patient's height and weight should be measured along with baseline blood pressure, oxygen saturation and heart rate.
- Unstable medical conditions including angina, uncontrolled hypertension, cardiac failure, thyrotoxicosis or poorly controlled diabetes should be stabilised prior to an elective procedure.
- Patients with suspected limiting respiratory disease should undergo spirometry or formal lung function testing pre-operatively where possible.
- For longer and more complex elective procedures and when there is suspected systemic disease, relevant pathology tests should be performed to quantify renal dysfunction, liver disease, electrolyte abnormalities, thyroid dysfunction, anaemia or coagulation abnormalities before intravenous sedation is undertaken. An electrocardiogram may also be required in these cases.

The following are relative contraindications or barriers that require consideration prior to provision of intravenous sedation.

- Language barrier or other factors preventing effective communication with the patient.
- Previous difficulty with sedation or difficulty with anaesthesia.
- Allergy to sedative medications.
- Uncontrolled medical conditions in elective cases where these conditions may be appropriately treated prior to cardiac intravenous sedation.
- The presence of obstructive sleep apnoea

In some jurisdictions where nurse administered sedation is being trialled or supported, patient selection is limited to those of ASA 1 or 2 status, which demands that the ASA status assessment and documentation is included as part of the pre-sedation assessment.

5.2 Selection:

Most children under the age of three are likely, for developmental and communication reasons, to require general anaesthesia or dissociative anaesthesia for uncomfortable or prolonged procedures requiring immobility. Older children are more amenable to sedation, although those under 6 years of age are at risk of requiring deeper sedation than intended.

The impact of stressful experiences associated with medical treatments in children is increasingly becoming recognised. An expanding body of empirical paediatric literature documents a significant population burden of persisting anxiety including post-traumatic stress disorder related to medical or procedural treatment. This may persist into adulthood and include requests for deeper than required levels of procedural sedation or even general anaesthesia for minor office procedures.

A trauma-informed, trauma prevention approach to paediatric procedural sedation for children encompasses pharmacological and non-pharmacological techniques such as developmentally appropriate explanation, communication and calming language including suitable distractions. Mindful of each child's previous experiences, these techniques may help sooth a child's fear and allay the sense of threat related to a procedure. Taken together, non-pharmacological and pharmacological techniques are tools to alleviate procedural anxiety or fear, real or imagined, enhance co-operation and reduce movement.

5.3 Informed consent:

Informed consent is required by law in both Australia and New Zealand. ANZCA and is addressed in <u>PS26(A)</u> Position statement on informed consent for anaesthesia or sedation. The issue of capacity to consent is relevant, especially in the case of children. The landmark decision in medical law applicable to consent in children is the Gillick decision,⁽⁸⁾ which addresses the ability of children to provide consent.

Underpinning shared decision-making is the assumption that patients have sufficient understanding of discussions and risks, and that resulting decisions are consistent with any patient's cultural or Indigenous background.

5.4 Fasting:

Fasting should be commensurate with the risk of aspiration, which is determined by the nature of the procedure and the depth of sedation. For procedures under minimal sedation fasting may not be required, however a large or substantive meal should not be ingested prior to planned treatment.

5.5 Depth of sedation

The continuum of sedative/hypnotic drug effect extends from minimal sedation through deep sedation to general anaesthesia.⁽⁹⁾ These risks include airway obstruction, respiratory depression and cardiovascular instability. If general anaesthesia is desired or required, then this should be done only by anaesthetists, or other trained and credentialled medical specialists within their scope of practice.

A variety of drugs and techniques is available for procedural sedation with, or without analgesia. Sedationists should be mindful that, regardless of the route of administration, sedative medications have additive and synergistic effects, and combinations of medications are more likely to increase the depth of sedation, or cause loss of consciousness with small incremental doses. Some patients are very sensitive to these effects and may experience respiratory depression or loss of airway reflexes. Special care is required when topical local anaesthesia of the larynx and/or pharynx has been administered because the protective cough reflex or co-ordinated swallowing may be impaired until sensation has returned to normal.

5.6 Patient co-morbidity

Patients with significant co-morbidities, such as those classified as ASA physical status 3, are at higher risk of complications during sedation than healthier patients.⁽⁹⁾ In addition, these patients may transition from conscious sedation to deeper levels of sedation or general anaesthesia after lower doses of sedative drugs than healthier patients. For this reason, the exclusive presence of a suitably trained and credentialed medical practitioner is essential to manage sedation for these patients. In addition, the exclusive availability of an assistant to this practitioner is recommended. For patients at high risk, such as those with severely limiting co-morbidities (who are commonly classified as ASA physical status 4-5) and those requiring endotracheal intubation to prevent aspiration of gastric contents, the presence of an anaesthetist or other trained and credentialled medical specialist working within their defined clinical scope of practice is essential.

6. Facilities and equipment

Instances were cited where patients requiring transfer by ambulance were hampered by the healthcare facility's inaccessibility to ambulance services. It is incumbent on sedationists to ensure that facilities meet the local jurisdictional registration standards and that there is ease of access to ambulance services should the need arise (see competency 6 in Appendix IV).

Nitrous oxide is a commonly used analgesic/sedative. It is an insoluble gas that displaces oxygen in the lungs and results in hypoxaemia unless it is administered as a mixture with oxygen. At 50% maximum delivery of nitrous oxide/oxygen, there is a margin of safety if there is air entrainment (which dilutes the

inspired O2), Where nitrous oxide/oxygen delivery systems do not come with an oxygen analyser, one should be added to the circuit or device outflow to confirm the integrity of the system and detect any leak with significant air entrainment. Alternatively, it is essential that the delivery system has been checked and certified for correct plumbing immediately after its installation and again after any works on the pipeline system. This was highlighted in the Bankstown-Lidcombe incident.⁽¹⁰⁾

The need for routine use of waveform capnography was discussed. It is strongly recommended for moderate and deep sedation in both children and adults.⁽¹¹⁾ It is not essential in patients undergoing minimal sedation with either nitrous oxide/oxygen or a single dose of oral anxiolytic or methoxyflurane as the sole means of achieving minimal sedation. However, when targeting minimal sedation with intravenous anaesthetic agents then waveform capnography is recommended unless verbal contact can be maintained.

7. Summary

Sedation is commonly employed for medical, dental and surgical procedures by medical practitioners, dentists and dental specialists. The goal of this revised document is to optimise patient care for procedural sedation managed by medical practitioners, nurses, and dentists in Australia and New Zealand.

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Further reading

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

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Related ANZCA documents

- PG03(A) Guideline for the management of major regional analgesia
- PG09(G) Guideline on procedural sedation
- PG18(A) Guideline on monitoring during anaesthesia
- PS26(A) Position statement on informed consent for anaesthesia or sedation
- PG29(A) Guideline for the provision of anaesthesia care to children.
- PS55(A) Position statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations

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