ACI NSW Agency for Clinical Innovation

Minimum Standards for Safe Procedural Sedation

This toolkit is designed for the non-operating theatre setting and is intended to support non-critical care clinicians

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Executive Summary

In NSW public hospitals there are ~300,000 episodes of procedural sedation[1] undertaken across numerous specialty areas each year. Procedural sedation involves the administration of **sedative or analgesic medications** which allow patients to tolerate painful or uncomfortable diagnostic or therapeutic procedures[2]. As a greater number of complex procedures move outside of operating theatres, it is anticipated that the need for procedural sedation will continue to increase.

While the majority of procedural sedation is administered to low risk patients and occurs without incident, there are consistent reports of poor patient outcomes from sedation and concern about failure to align the appropriate resources with patient need. This was highlighted by the two NSW Clinical Excellence Commission (CEC) reports which explored clinical incidents relating to the use of sedation and specifically Midazolam[3]. Complications in sedation episodes outside of operating theatres have also been identified as an area of interest for the Special Committee Investigating Deaths Under Anaesthesia (SCIDUA)[4].

It is widely accepted that patients at the highest risk of complications from procedural sedation should be referred to an anaesthetist. Currently in NSW public hospitals, procedural sedation is administered by a range of clinicians across a number of specialties. Whilst some health services have well developed processes to align resources and patient need, there is no consistent framework for the delivery of safe procedural sedation across the state, Local Health Districts (LHDs) or hospitals.

The adoption of these three standards and toolkit will support high quality care for patients receiving procedural sedation across NSW. This toolkit complies with the NSW Health Clinical Procedure Safety Policy PD2014_036 and the ANZCA *PS09 – Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures*.

Standard 1: Pre Procedure assessment and risk stratification of all patients receiving procedural sedation:

- Risk stratification is to be undertaken for every patient receiving sedation to ensure patient needs can be aligned with appropriate resources
- Local arrangements to refer higher risk patients to an anaesthetist.

Standard 2: Intra Procedure – The presence of a dedicated clinician, with appropriate skills and training in monitoring and managing the patient's airway and circulation, including bag mask ventilation skills:

- Access to appropriate pharmacology, monitoring and airway skills
- Presence of a clinician airway monitor who is not the proceduralist
- Presence of a clinician with bag mask ventilation skills
- The ability to recognise and manage a deteriorating patient.

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[1] Inpatient Statistics Collection, SaPHARI, 2013.
[2] Australian and New Zealand College of Anaesthetists, 2010. PS09 – Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures, 1.
[3] Clinical Excellence Commission, 2009. Clinical Focus Report from Review of IIMS Data: Use of Midazolam; Clinical Excellence Commission, 2009. Clinical Focus report from Review of RCAs and/or IIMS Data: Sedation / Excess Sedation as an Adverse Outcome.
[4] Clinical Excellence Commission (CEC), 2013. Activities of the Special Committee Investigating Deaths Under Anaesthesia, 2011-2012.

Standard 3: Post Procedure – Appropriate monitoring and application of discharge criteria:

- Monitoring requirements during the recovery phase
- Assessed appropriately for discharge and follow up arranged
- Discharge from the recovery area should be authorised by the clinician who prescribed the sedative and/or analgesic medications.

The **underpinning principles** outlined in this toolkit will support safe procedural sedation practice.

Introduction

In NSW public hospitals there are ~300,000 episodes of procedural sedation[5] undertaken across numerous specialty areas each year. As a greater number of complex procedures move outside of operating theatres, it is anticipated that the need for procedural sedation will increase.

Sedation and anaesthesia is a continuum of decreasing levels of consciousness, caused by the effect of sedative medications on the brain. At low doses, people may feel pleasantly relaxed, but with increasing doses, the parts of the brain that control the heart and breathing are depressed which can lead to severe adverse events.

Therefore, clinicians who administer and support procedural sedation must be appropriately trained to manage the complications of sedation. A safe environment for patient sedation is underpinned by patient risk assessment, risk stratification and management, and also by safe medication use and access to life support skills. Critical care specialists (anaesthetists, emergency physicians, intensivists) are specifically trained to manage patients under sedation – however, they are not required and/or available for every sedation episode, especially for low risk patients. In NSW public hospitals, there are a number of specialty areas where sedation is routinely administered by non-critical care clinicians.

Following anecdotal reports and feedback from clinicians working across a range of specialties, the Agency for Clinical Innovation (ACI) undertook to scope the extent of procedural sedation and/or analgesia across the NSW health system in order to identify challenges and innovations and make recommendations for supporting safe practice. Furthermore, the project aimed to facilitate a standardised approach to safe procedural sedation across the state, Local Health Districts (LHDs) or hospitals. In this toolkit, procedural sedation is defined as the administration of sedative and/or analgesic medications to facilitate patient tolerance of a procedure.

This toolkit aims to meet the challenges of providing a quality sedation service, as aligned with the Institute of Medicine's six Aims for Improvement[6]:

- Safety – to ensure that every episode of procedural sedation in the NSW health system is as safe as possible. These standards and toolkit will highlight the risks of sedation and support health professionals and services to implement a safe sedation environment. When minimum standards cannot be met, procedures will need to be

[5] Inpatient Statistics Collection, SaPHARI, 2013.
[6] Institute of Medicine, 2011, accessed at http://www.ihi.org/knowledge/Pages/HowtoImprove/ScienceofImprovementSettingAims.aspx on 5 November 2013.

deferred until resources are adequate or patients are transferred to hospitals able to meet the minimum standards.

- Effective – due to healthcare innovations there is a trend of procedures moving from operating theatres to procedure rooms. This has been further highlighted by the need of health services to manage finite resources and more particularly to efficiently manage the appropriate use of operating theatres. This toolkit may assist services that have seen a significant increase in their procedure room caseload to appropriately support the provision of safe procedural sedation, which may occur in the absence of an anaesthetist.
- Patient-centred – providing patient-centred care is a key element in a successful patient journey. This toolkit provides guidance for health services to implement processes to improve awareness of the individual patient need when designing and providing a successful safe sedation journey. It will assist services to individualise the alignment for each patient (according to needs-based criteria) with the appropriate level of sedation provider.
- Timely – implementing the standards and toolkit will assist services to seek information to identify individual patient needs, especially for more complex patients, and assist in avoiding late referrals and cancellations on the day of the procedure.
- Efficient – this toolkit provides a range of resources, drawn from examples across the system that will assist services to streamline their local processes.
- Equitable – by establishing this minimum standard, this project aims to ensure that all patients receive a comparable sedation service no matter where in our health system they receive their care.

The ACI has identified and developed the minimum standards and an accompanying toolkit to assist hospitals and LHDs in implementing best practice for procedural sedation. This toolkit is designed for the non-operating theatre setting and is intended to support non-critical care clinicians.

These standards were identified following a detailed consultation process involving specialty procedural units across a range of hospitals in NSW and based on advice from the ACI's Anaesthesia Perioperative Care Network[7]. The findings were themed and categorised into issues and barriers/enablers:

<u>Key Issues</u>

- Variable patient assessment processes
- Pharmacology knowledge
- Airway skills
- Monitoring skills and practice
- Recognising, managing and escalating the deteriorating patient
- Recovery and discharge

<u>Barriers/Enablers</u>

- Governance arrangements
- Access to anaesthetic support
- Access to skilled specialist support
- Minimal formalised training
- Poor access to training
- Variable practice review
- Availability of skilled workforce
- Challenges for rural and remote facilities

These issues were highlighted by significant variation in practice and access, not only across LHDs and specialties, but across specialty departments within hospitals.

[7] Agency for Clinical Innovation, 2013. Safe Procedural Sedation Project: Phase 1 Diagnostic and Solution Design Report.

The toolkit will support LHDs in meeting the requirements outlined in the Clinical Procedure Safety Policy PD2014_036, particularly where it relates to (Level 3) procedures with sedation. Additionally, the standards follow the principles set out in the Australian and New Zealand College of Anaesthetists (ANZCA) *PS09 – Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures*. The Medical Board of Australia has identified that they expect PS09 to be followed where procedural sedation is being provided.

The aim of this toolkit is to assist clinicians to identify the key components of best practice for every episode of sedation that will support high quality patient care. These standards are intended to be adopted by all NSW hospitals – they do not apply to Intensive Care Units (ICU), High Dependency Units, Paediatrics, Dentistry or the management of patients with severe behavioural disturbance requiring restraint.

The Minimum Standards

The implementation of and adherence to these standards will help minimise clinical variation and improve patient outcomes by:

- Improving patient experience
- Improving service efficiency
- Reducing adverse outcomes.

The following are essential standards of care for a patient undergoing a procedure that requires procedural sedation:

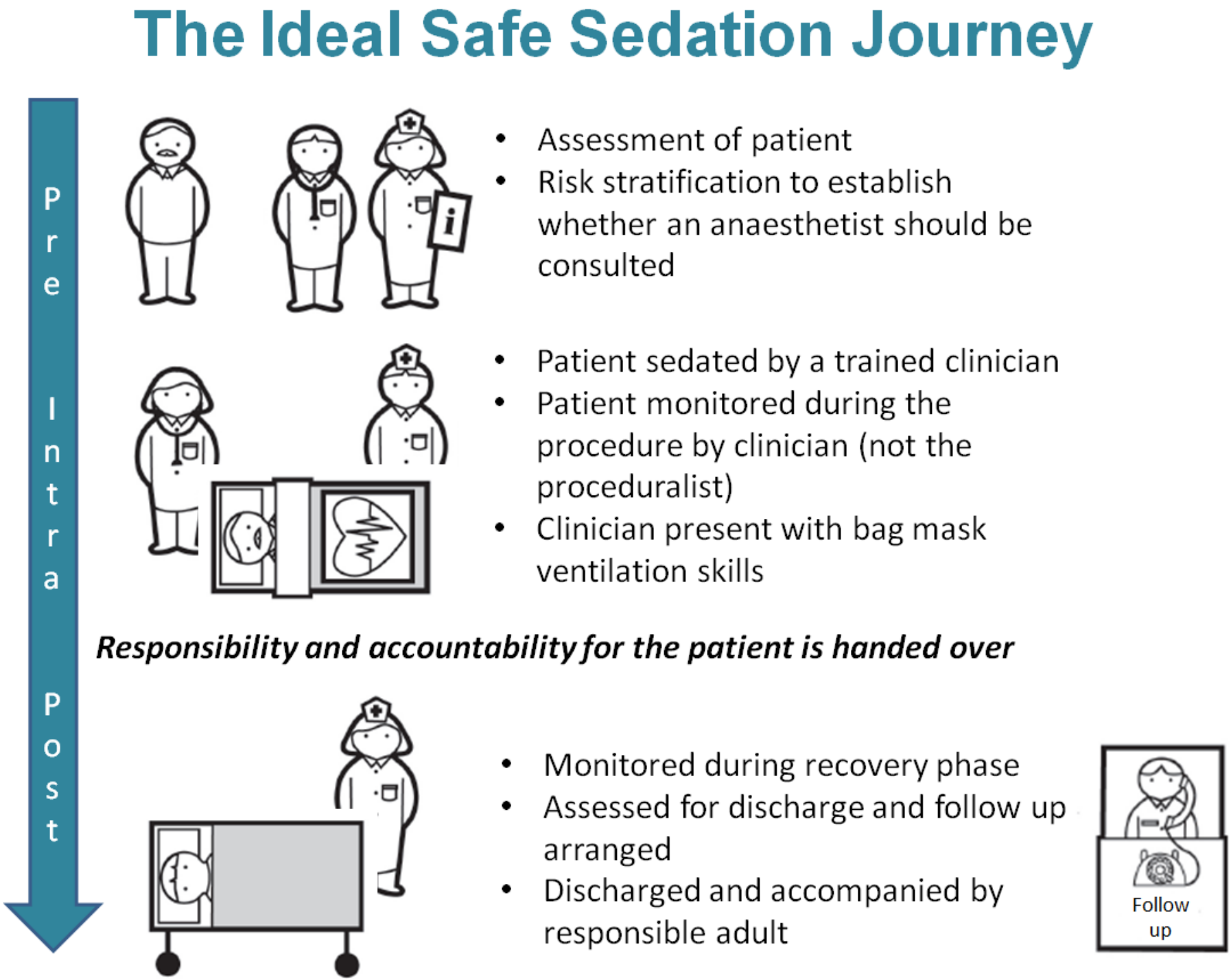
Standard 1: Pre Procedure assessment and risk stratification of all patients receiving procedural sedation.

Standard 2: Intra Procedure – The presence of a dedicated clinician, with appropriate skills and training in monitoring and managing the patient's airway and circulation, including bag mask ventilation skills.

Standard 3: Post Procedure – Appropriate monitoring and application of discharge criteria.

Example tools are available on the ACI Safe Sedation Resource page. These are provided as templates which can be adapted to support implementation of the minimum standards locally. The tools are not intended to be mandatory.

Figure 1.1: The standards can be represented by the following diagram.



Standard 1: Pre Procedure assessment and risk stratification of all patients receiving procedural sedation

Appropriate assessment and risk stratification of patients underpins safe sedation practice. Specialty units and departments should have locally agreed and supported protocols outlining which patients should and should not receive sedation from non-critical care sedation providers. The adequacy of local risk assessment and referral procedures should be informed by local audit and different triggers for consultation with the Department of Anaesthesia (or other service with sedation expertise) are likely to be required depending on the hospital, service and procedure. Some areas within hospitals (e.g. Emergency Departments) will have different levels of expertise routinely available, and may be able to manage higher risk patients.

1.1 Applying the Standard in Practice

The aim is to identify those patients at highest risk of adverse sedation-related events so that they can be referred to a more highly specialised sedation provider. Referral guidelines are most effective when locally developed within specialty units and in consultation with the procedural and anaesthetic teams.

Health care interpreters may be needed to facilitate communication between people who are not fluent in English and clinical staff. The use of interpreters allows clinicians to fulfil their duty of care, including obtaining valid consent[8].

Assessment

At a minimum, elements for pre procedure assessment should include:

1. Patient identification and age, and confirmation with patient and proceduralist that proposed procedure requires sedation
2. Previous anaesthesia/sedation experience, including family history and adverse events
3. Allergies and drug sensitivities
4. Fasting status (for solids and liquids)
5. Airway assessment including risk of airway obstruction during sedation
6. General health including exercise tolerance and cardiorespiratory status, current medications
7. Explicit discussion regarding intended depth of sedation and patient consent including safety and efficacy of procedural sedation[9].

As a minimum, procedural units should have a checklist (or protocol) that addresses the above listed criteria. An example pre procedure tool is provided on the **Safe Sedation Resource page** on the ACI website at http://www.aci.health.nsw.gov.au/resources/clinician-resources/safe-

[8] NSW Health, 2006. Interpreters – Standard Procedures for Working with Health Care Interpreters. PD2006_053, 1.
[9] National Clinical Guideline Centre, 2010. Sedation in Children and Young People, 68; Chatman, Sutherland et al. 2013. A survey of patient understanding and expectations of sedation/anaesthesia for colonoscopy. Anaesth Intensive Care. 41: 369-373.

sedation-resources. This tool is provided as a template which can be adapted to support implementation of the minimum standards locally. The tool is not intended to be mandatory.

Many procedural units have developed specific checklists which guide staff through the pre procedure assessment process. Some units have combined all elements of the procedure on the same form, which provides all the relevant details, including observations, relating to the patient's procedure. Examples collected during the diagnostic phase are available under Procedure Tools on the Safe Sedation Resource page.

For elective (outpatient) cases, the assessment process should occur in advance of the day of the planned procedure, so that patient needs can be identified, appropriate instructions provided or if required, an appropriate referral to an anaesthetist can be organised and undertaken in a timely fashion.

Risk Stratification

The aim of risk assessment and risk stratification is to identify those patients at highest risk of adverse sedation-related events so that they can be referred to a more highly specialised sedation provider. A screener is crucial to the provision of a safe and efficient procedural service. The screener will apply the agreed protocols and alert clinical staff when patients do not meet the agreed criteria for non-anaesthetist procedural sedation administration.

"Red flags" in the assessment process will alert staff to higher risk patients. These should be followed up with a nominated contact within the Department of Anaesthesia for advice and consideration given to referral. Clinical features which predispose patients to adverse sedation-related outcomes can include:

- Prior sedation or anaesthesia related adverse events
- Obstructive sleep apnoea
- Morbid obesity
- Patients with limited functional reserve
- Frailty
- Age.

Examples of specific tools – e.g. for sleep apnoea – can be found under Other Resources on the Safe Sedation Resource page.

The ASA Score is a global tool for classifying the physical status of the patient. It is sometimes referred to as ASA-PS.

- **ASA 1** – A normal healthy patient
- **ASA 2 –** A patient with mild systemic disease
- **ASA 3** – A patient with severe systemic disease
- **ASA 4** – A patient with severe systemic disease that is a constant threat to life
- **ASA 5** – A patient who is not expected to survive[10].

[10] American Society of Anesthesiologists. Accessed at http://www.anzjsurg.com/view/0/ASAscore.html on 17 December 2013.

1.2 Evidence Base^

It is essential that a target level of sedation is identified pre operatively[11]. As part of this process, it is vital that the patient's weight is recorded. In a report into patient outcomes in UK endoscopy services, it was found that only 24% of cases – in a study of 1818 patients – had the patient's weight recorded, which is key to judging the sedation dosage[12].

In that same report, it was identified that in many cases the appropriate investigations were not carried out before procedures. This is important when considering that only 5% of patients did not have a co-existing medical condition[13].

Patients at increased risk of adverse sedation-related events should be referred to an anaesthetist[14]. Liu et al considered that referral to an anaesthetist for endoscopy sedation for patients ASA 3 and greater was consistent with appropriate and justified use of anaesthesia services for higher risk patients[15].

Chung et al in their systematic review confirmed that patients with obstructive sleep apnoea are at greater risk of adverse perioperative events, particularly respiratory complications, and that for these patients anaesthetist-directed sedation may allow more judicious choice and doses of drugs[16].

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[11] McQuaid, K., Laine, L., 2008. A systematic review and meta-analysis of randomized, controlled trials of moderate sedation for routine endoscopic procedures. Gastrointestinal Endoscopy, Volume 67, No. 6, 910-923.

[12] National Confidential Enquiry into Patient Outcome and Death (NCEPOD), 2004. Scoping our Practice – The 2004 Report of the National Confidential Enquiry into Patient Outcome and Death, 10.

[13] National Confidential Enquiry into Patient Outcome and Death (NCEPOD). 2004. 10.

[14] Australian and New Zealand College of Anaesthetists, 2010. 4.

[15] Liu, H., Waxman, D., Main, R., Mattke, S., 2012. Utilization of Anesthesia Services During Outpatient Endoscopies and Colonoscopies and Associated Spending in 2003-2009. Journal of the American Medical Association, March 21, 2012 – Vol 307, No.11, 1178-84.

[16] Chung, S., Yuan, H., Chung, F., 2008. A Systemic Review of Obstructive Sleep Apnea and Its Implications for Anesthesiologists. Anesthesia and Analgesia, 2008, Nov, Vol 107, No. 5, 1543-63.

Standard 2: Intra Procedure – The presence of a dedicated clinician with appropriate skills and training, to monitor and manage the patient's airway and circulation, including bag mask ventilation skills

The sedation/anaesthesia continuum describes a dose related depression of the patient's level of consciousness and cardiorespiratory systems. After discussion with the patient and considering the complexity and likely discomfort of the intended procedure, a target level of sedation should be nominated and planned in advance of the procedure. Doses of sedative and/or analgesic medications should be kept at the minimum level required for patient comfort.

Some patients may be particularly susceptible to the effects of sedative or analgesic medications and medications have different margins of safety. Sedative and analgesic medicines work synergistically – i.e. one drug may exacerbate the intended and adverse effects of the other. Transition from sedation to deep unconsciousness "with its attendant risk of loss of protective reflexes may occur rapidly and unexpectedly"[17].

Clinicians who administer sedative or analgesic drugs that alter the conscious state of a patient, and those who supervise recovery from sedation, must be prepared to manage the following potential risks:

1. Depression of protective airway reflexes and loss of airway patency
2. Depression of respiration
3. Depression of the cardiovascular system
4. Drug interactions or adverse reactions, including anaphylaxis
5. Unexpectedly extreme sensitivity to the drugs used for procedural sedation and/or analgesia resulting in unintentional loss of consciousness, and respiratory or cardiovascular depression[18].

If undertaking the procedure outside of a designated and detached procedure room, the proceduralist may need to give consideration to the location and minimise any distractions for the clinical team.

[17] Australian and New Zealand College of Anaesthetists, 2010. 3.
[18] Australian and New Zealand College of Anaesthetists, 2010. 3.

2.1 Applying the Standard in Practice

There are a number of aspects underpinning the implementation of this standard, including:

- Identifying a target level of sedation and/or analgesia
- Pharmacology knowledge
- Airway skills and training, including bag mask ventilation
- Monitoring requirements and equipment.

Identifying a Target Level of Sedation

In most procedural departments, it is anticipated that sedation providers will target a level of conscious sedation along the continuum. Lack of memory and/or analgesia may also be desired outcomes.

The level of sedation and other outcomes should be discussed between the patient, sedation provider and/or proceduralist. This must be undertaken in order to appropriately set expectations. On occasion, a patient's inability to accept or tolerate a procedure with conscious sedation may necessitate referral to the Anaesthetic Department.

Pharmacology Knowledge

Clinicians who administer sedation and/or monitor sedated patients need a working knowledge of the pharmacology underpinning the actions, interactions and adverse effects arising from commonly used medications.

At a minimum, this knowledge will involve the pharmacology of commonly used medications, including benzodiazepines and opioid drugs, as well as reversal agents.

Whilst generic pharmacological information is provided on the Safe Sedation Resource page, it is advised that procedural units also provide information on:

- their local preferred sedative agents
- standard dosing arrangements
- maximum dosing arrangements
- reversal agents.

This should be further emphasised by a summary sheet readily available in and around the unit. Prior to commencing the sedation, the sedation plan should be discussed with the clinical team including agent, dosage, potential issues and the plan for escalation.

Where possible, clinical staff should have access to a locally supported credentialing or knowledge program. A number of procedural units have successfully developed and implemented credentialing programs for pharmacology awareness. Examples of these can be found under Learning Packages on the Safe Sedation Resource page.

Airway Skills and Training

It is a NSW Health requirement that all clinical staff should complete basic resuscitation skills (*Resuscitation Equipment and Training* PD2005_083) but this should be supplemented by more detailed training and support for those clinicians working in a setting with procedural sedation.

Clinicians who administer sedation must have adequate knowledge and skills to detect serious adverse effects of procedural sedation and manage these events accordingly.

The two most common serious adverse effects of procedural sedation and the necessary skills needed are:	
Airway compromise (obstruction)	Ability to detect an obstructed or partially obstructed airway with the ability to overcome airway obstruction including chin lift, jaw thrust and/or use of airway devices such as Guedel's airways or laryngeal mask airways
Respiratory depression (reduced respiratory rate and respiratory arrest)	Ability to provide bag-mask ventilation.

Clinicians should have access to an appropriate airway skills training and credentialing program. A number of procedural units have successfully developed and implemented credentialing programs for airway skills. Across hospitals and LHDs, this training has been supported by a range of senior clinicians from Anaesthetic, ICU or Emergency Departments.

Monitoring Requirements and Equipment

All patients receiving intravenous procedural sedation must have:

- continuous pulse oximetry with identified appropriate audible patient alarms
- regular monitoring of blood pressure throughout the procedure
- reliable intravenous access
- ECG and capnography may be required and should be available for selected high risk patients.

Regular observations (including level of sedation) should be taken and recorded on an appropriate (sedation) record. An example intra procedure sedation record is provided on the Safe Sedation Resource page. This tool is provided as a template which can be adapted to support implementation of the minimum standards locally. It is not intended to be mandatory.

The minimum equipment required for an episode of procedural sedation includes:

- Pulse oximeter
- Non invasive blood pressure
- Cannulation equipment
- Oxygen
- High suction
- Emergency equipment, including a defibrillator and drugs utilised for cardiac arrest
- A means to inflate the lungs with 100% oxygen
- Equipment to assist in airway maintenance e.g. Guedel's and/or nasopharyngeal airways, laryngeal mask airways, a range of laryngoscopes and endotracheal tubes.

Recognising and Managing the Deteriorating Patient

Red flags for action within the team should include:

- unexpected reduction in the patient's conscious state beyond the target sedation level
- partial or complete airway obstruction
- snoring and/or noisy breathing (this can rapidly progress to complete obstruction)
- unexpected patient agitation
- hypotension.

The clinician monitoring the airway should be adequately trained to recognise patient deterioration. They must therefore also be capable of activating the local clinical emergency response system (CERS) in the event that the sedated patient deteriorates.

In NSW, the need for emergency assistance should align with the NSW Health Standard Observation Charts and local Clinical Emergency Response Systems as outlined within PD2013_049. If there is a need for variations to these emergency trigger observation levels, these should be documented in advance of the procedure, and with specific agreement between members of the procedural teams, including the proceduralist and the clinician airway monitor.

Any patient deterioration outside prescribed or agreed limits will trigger the local CERS. All team members must be made aware that the procedure must be stopped in the event of patient deterioration, and the team member with bag-mask ventilation skills will attend the patient's airway until the arrival of the CERS team. The process for escalating to the CERS should be determined by local standard operating procedures.

2.2 Clinical Roles

As a minimum requirement, the following roles are required to be in the same room as the patient for every episode of sedation:

- Nominated sedation practitioner (who is responsible for prescribing sedation medication)
- Clinician airway monitor (this person must not be the proceduralist)
- Clinician with airway skills.

These roles may be undertaken by (three) different clinicians, or a minimum of two clinicians may fill multiple roles. Clinicians include nursing and medical staff.

The names of the clinicians undertaking each of these roles should be clearly recorded on the procedure record. Where a clinician undertakes multiple roles, their name should be recorded each time.

Nominated Sedation Practitioner

The clinician who prescribes and is responsible for the administration of the sedative and/or analgesic medications is the nominated sedation practitioner. This clinician may also be the proceduralist. The name of the sedation practitioner must be recorded.

Clinician Airway Monitor

An appropriately trained clinician whose principal task is to monitor and manage the patient's airway and cardiovascular system during the episode of procedural sedation must be nominated. This clinician must not be the proceduralist. The name of the nominated clinician must be recorded.

The clinician airway monitor is responsible for:

- ensuring the patency of the patient's airway, and respiratory and haemodynamic status until the procedure is complete; **and**
- completing clinical handover to an appropriate staff member who is able to manage the patient's recovery phase.

This clinician should regularly monitor the patient's conscious state by assessment of response to verbal commands and stimulation. If the patient enters a deeper level of sedation than planned or intended, or if the patient's airway, respiratory or cardiovascular systems become compromised, the clinician airway monitor must alert the procedural team immediately.

The clinician airway monitor must have access to appropriate assistance if/when required e.g. when the patient condition deteriorates and more skilled support is needed. This should include being able to identify who the nominated clinician with airway skills is, as well as a good understanding of the local CERS for the unit/hospital/LHD.

Clinician with Airway Skills

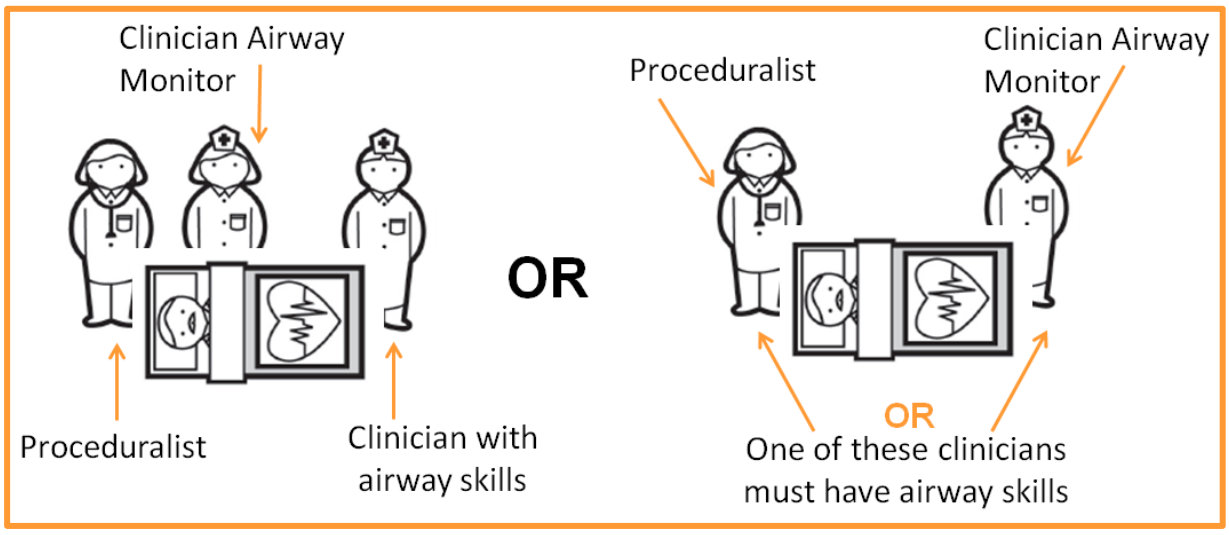
A clinician who is proficient in providing bag-mask ventilation must be present in the room where the episode of procedural sedation is occurring[19]. This person may be the proceduralist, although this may require that the procedure be stopped immediately in the event that airway support is required. It is preferable that the clinician airway monitor has the appropriate airway skills. The name of the nominated clinician must be recorded.

In the event of airway support being required, the nominated clinician must be immediately available to support the patient's airway until:

- at a minimum, the level of sedation lightens and/or the patient's airway can be safely maintained without support; **or**
- emergency assistance arrives via the local CERS.

Successful airway skills training models are generally supported by senior clinicians from Anaesthetic, ICU or Emergency Departments.

Figure 1.2: Clinical roles – there must be a minimum of two clinicians present



[19] If the procedure requires staff to be outside the procedural room for their own safety (e.g. radiation exposure risk), the clinician with airway skills must be immediately available outside the room.

2.3 Evidence Base

Education and training programs should be interdisciplinary and include didactic education on pharmacology and side effects of sedative and/or analgesic agents, as well as airway skills (including simulation training) and specific monitoring techniques. There also needs to be preparation for clinicians to be able to rescue a patient from a deeper than intended state of sedation[20]. Regular skills renewal is expected of both nursing and medical staff[21].

Educating staff to an advanced practice level and assessing their competence arguably assists in a lower complication rate – indeed their specialised skill set, combined with vigilance is fundamental to ensure patient safety[22].

The staff responsible for monitoring the patient must be appropriately trained in using monitoring equipment[23].

Pooled analysis for patients undergoing endoscopy demonstrated hypoxaemia in 6-20% of cases, and this was the most commonly reported serious adverse event[24]. Patients with a history of obstructive sleep apnoea are at particular risk of adverse events[25].

Anaesthetists can play an important role in the development of protocols, training programs and quality assurance programs[26].

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[20] Metzner and Domino, 2010. 530; Hurford, W., 2013. Controversies and Considerations in Formulating a Hospital Policy for Procedural Sedation. International Anesthesiology Clinics, vol. 51, no. 2, 23-32: 26-27; Australian and New Zealand College of Anaesthetists, 2010. 4-5.

[21] Hurford, 2013: 26; Ehrhardt, S. and Staubach, K. 2013. A Program for Education, Competency, and Quality in Procedural Sedation. International Anesthesiology Clinics, vol. 51, no.2, 33-42: 38

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[26] Hession, P., Joshi, G., 2010. Sedation: Not Quite That Simple. Anesthesiology Clin 28 (2010) 281-294, 294.

Standard 3: Post Procedure – Appropriate monitoring and application of discharge criteria

At the end of the procedure, and especially with the removal of procedural stimulus in the context of a still-sedated patient, there will be an ongoing need for close patient respiratory and cardiovascular monitoring. Airway obstruction remains a significant risk and continued assessment of the level of consciousness is required. Monitoring includes the presence of appropriately trained staff, and the ability to detect and respond to patient instability and/or deterioration.

Discharge from the recovery area should be authorised by the clinician who prescribed the sedative and/or analgesic medications. The patient should be discharged into the care of a responsible adult and should be given written instructions including eating, drinking, pain relief and resumption of normal activities. The patient and/or carer should be actively engaged by the clinical team when determining a plan and timeline for discharge.

The patient and carer should be given instructions and contact details in the event of any deterioration after discharge. There should be a locally agreed plan should the need arise to transfer the patient to a higher level of care.

3.1 Applying the Standard in Practice

Recovery from sedation should occur in an appropriately supervised, staffed and equipped area[27].

- Designated area
- Monitoring requirements
- Staff with adequate training and support
- Discharge planning and arrangements.

Designated Area

- The area where the patient recovers may be the procedural area, or if not, should be designated as a “recovery” area or space or be a formal post anaesthesia recovery room
- If it is the latter, the area should be close to the procedural area.

Monitoring Requirements

- Precise requirements will vary according to the clinical context
- Continuous pulse oximetry will be required until the patient is conscious and easily rousable
- Oxygen may be required and should be available.

An example post procedure tool is provided on the Safe Sedation Resource page. This tool is provided as a template which can be adapted to support implementation of the minimum

[27] Australian and New Zealand College of Anaesthetists, 2010.

standards locally. The tool is not intended to be mandatory. Other examples are also available on this webpage.

Staff with Adequate Training and Support

- The staff responsible for caring for patients recovering from sedation should be appropriately trained
- There should be ready access to supervising medical staff when needed.

If patients have become unconscious or suffered other complications during the procedure, adequate staffing and facilities must be available. For more information, see ANZCA's PS04[28].

Discharge Planning and Arrangements

- Discharge should only be arranged when the clinician authorising the discharge and the patient and/or carer feel the patient is ready
- The discharge of the patient should be authorised by the clinician who prescribed the sedative and/or analgesic drugs
- Discharge criteria are often useful, and should be developed locally, ideally with co-operation between procedural teams and Departments of Anaesthesia.
- Local departments should develop instructions to provide to patients when they are discharged.

An example post procedure tool is provided on the Safe Sedation Resource page. This tool is provided as a template which can be adapted to support implementation of the minimum standards locally. The tool is not intended to be mandatory. Other examples are also available on this webpage.

3.2 Evidence Base

Patient recovery must be appropriately monitored by skilled staff. Staff experience and training should be comparable with those staff assisting a procedure. Those patients who have received a reversal agent require extended monitoring as there is a risk of re-sedation[29].

Discharge scoring criteria are valid and safe, and are an important part of providing safe clinical care[30].

[28] Australian and New Zealand College of Anaesthetists, 2006. PS04 – Recommendations for the Post Anaesthesia Recovery Room.
[29] Cohen L., et al. 2007. AGA Institute Review of Endoscopic Sedation. Gastroenterology. 2007, 133, 675-701, 677.
[30] Trevisani, L., Cifala, V., Gilli, G., Matarese, V., Zelante, A., Sartori, S. 2013. Post- Anaesthetic Discharge Scoring System to assess patient recovery and discharge after colonoscopy. World Journal of Gastrointestinal Endoscopy. 2013 October 16, 5(10): 502-507.

Underpinning Principles and Frameworks

1.1 Governance

1.1.1 Unit, hospital and LHD governance

It is important that all units, hospitals and LHDs have governance and reporting processes in place to support the sedation service. This is in accordance with the requirements in the Clinical Procedure Safety Policy PD2014_036. Additionally, hospitals and LHDs must ensure that units are provided with the appropriate resourcing to support safe procedural sedation practice. This may include facilitating and developing relationships between procedural departments and anaesthetic departments or other departments with expertise in sedation practice.

In establishing a governance process, scope of practice for clinicians (medical and nursing) should be determined locally in collaboration with procedural units and the anaesthetics department (where such a department exists) and where necessary, credentialing requirements should be identified, documented and implemented. Examples of local credentialing programs are provided on the Safe Sedation Resource page.

Safe procedural sedation practice must then be supported by the following key accountabilities:

- Clinicians are responsible for pre procedure assessment, maintenance of skills, addressing standards, leading responses to and reporting on critical events
- Unit managers for ensuring appropriate staffing, equipment and space are available
- The manager/department head is responsible for ensuring that the processes to support safe procedural sedation are followed.

1.1.2 Audit and Review

Units and teams who regularly administer procedural sedation should have regular and effective audit of sedation related outcomes. LHDs should review compliance with local policy, procedures and identified outcomes using one percent of procedures undertaken each month.

Data reporting for sedation-related morbidity and mortality, especially respiratory depression, in the non-theatre setting, as opposed to operating rooms, is not well documented[31].

A significant aspect of information sourced from the NSW Incident Information Management System (IIMS) review was the under reporting of serious adverse events leading to sedation.

Reporting of all adverse outcomes relating to the procedural sedation must occur through the IIMS process. This includes, but is not limited to:

- airway compromise requiring intervention
- abandoned procedures
- the need for emergency assistance (rapid response) including need for ventilation and/or emergency medications such as vasopressors, inotropes etc.
- unplanned overnight admission/unplanned admission to ICU/HDU
- use of reversal agents.

[31] Metzner and Domino, 2010: 524.

Local audit could include the above as well as patient complaints.

In particular, high use of reversal agents should be reviewed as an indicator of poor quality sedation[32].

The results of such audits should be discussed within the procedural team and inform ongoing training, education and support for all members of the multi-disciplinary team involved in procedural sedation administration and care of sedated patients.

Effective audit and feedback should also involve oversight by and communication with an appropriate department, for example the Clinical Governance Unit.

1.1.3 Reporting Requirements

Clinicians who administer sedation must be aware of their jurisdictional requirements to report all deaths occurring while under, as a result of, or within 24 hours after the administration of sedation.

Information and the form for reporting to the Special Committee Investigating Deaths Under Anaesthesia (SCIDUA) can be found at http://www.cec.health.nsw.gov.au/programs/scidua.

1.2 Access to Skilled Support

Units and departments with well-functioning procedural sedation services usually have collaborative relationships with their local Department of Anaesthesia (where a department exists). It may be useful to have a nominated “procedural sedation” contact person within the Department of Anaesthesia (or other department with specialised skills) who can assist with the development and updating of triage and risk assessment processes, and development of locally agreed referral criteria.

If this contact person is not the Head of the Department of Anaesthesia, the explicit support of the Department Head is essential.

1.3 Access to Training

Where non-anaesthetist sedation is regularly administered, units and departments will require access to high quality training in order to best support the monitoring and management of sedated patients. The most commonly required skills relate to pharmacological awareness and airway management.

In many hospitals, this skills training is often provided by Departments of Anaesthesia by:

- using simulation-based training and/or
- regular rotation of staff to operating theatres and/or recovery units.

If Anaesthetic Departments are unable to provide this training it may potentially be provided by other critical care teams e.g. from ED or ICU.

[32] National Patient Safety Agency. 2008. Rapid Response Report: NSPA/2008/RRR011: Reducing risk of overdose with Midazolam injection in adults. 3.

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^ Much of the evidence in this area relates to procedural sedation for endoscopy and is sourced from the USA and Europe. It is unclear how this data pertains to sedation for non-endoscopy procedures, nor how it should be translated to non-USA non-European settings, as models of care may be different.