ACI NSW Agency for Clinical Innovation

Implementation Toolkit

Minimum Standards for Safe Procedural Sedation

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Contents

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Introduction

The Agency for Clinical Innovation undertook a project to scope the extent of intravenous procedural sedation and/or analgesia across the NSW health system in order to identify challenges and innovations and make recommendations for supporting safe practice. The project aimed to facilitate a standardised approach to safe procedural sedation across NSW Local Health Districts (LHDs) and hospitals. Three Standards were identified as essential to the practice of safe sedation:

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 staffing and resources align with their requirements
- Process for referral of higher risk patients to an anaesthetist to be established in every location offering 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.

- Clinician access to appropriate pharmacology, monitoring and airway skills training
- The clinician monitoring the airway must not be the proceduralist
- Clinician training to ensure their ability to recognise and manage a deteriorating patient.

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

- Monitoring of patient status during the recovery phase, including the ability to recognise and respond to patient instability, respiratory and cardiovascular status during the recovery phase
- Patient assessed appropriately for discharge and follow up arranged.

The Minimum Standards are in accordance with the NSW Health Clinical Procedural Safety Policy (PD2014_036).

1.1 The Case for Change

1. There are over 300,000 episodes of procedural sedation performed across NSW each year[1].
2. Significant variation of practice occurs, across the system, Local Health Districts, hospitals and specialty departments.
3. There are limited formal governance arrangements or oversight of procedural sedation practice across LHDs.
4. Adverse events relating to sedation care (either under or over sedation) are often not perceived as related to the procedural sedation itself or are otherwise not considered "adverse events". IIMS reviews identified significant underreporting of incidents relating to episodes of sedation care.

[1] Inpatient Statistics Collection, SaPHARI, 2013.

5. Sedation practice was highlighted by two Clinical Excellence Commission (CEC) reports which explored incidents relating to the use of intravenous sedation and specifically Midazolam.
6. There had been consistent anecdotal feedback from clinicians who identified that they did not feel they had the appropriate skills to support safe procedural sedation practice.

1.2 What can Implementation of the Minimum Standards Enhance?

- Reduction in clinical variation
- Reduction in adverse events or poor patient outcomes
- Improved patient experience
- Reduction in abandoned procedures
- Improved skill sets for staff involved in procedural sedation
- Improved staff satisfaction
- Improved efficiencies.

1.3 About the Implementation Toolkit

This implementation toolkit accompanies the Minimum Standards for Safe Procedural Sedation [the Minimum Standards]. It has been developed to support the successful implementation of the Minimum Standards and ensure the safe provision of procedural [intravenous] sedation to adult patients within NSW Health.

The toolkit includes three phases of implementation:

1. Plan
2. Assess
3. Operationalise.

1. Plan

The purpose of the project planning phase is to:

- obtain local sponsorship to support the implementation of the Minimum Standards
- define the key members of a project team and working group
- set a clear goal, objectives and scope.

1.1 Establish Sedation Governance/Project Sponsorship

It is essential that a member of the LHD Executive is identified as the project sponsor (this could be the Director of Clinical Governance). Due to the clinical nature of this project and the importance of risk stratification a Clinical Lead will also need to be identified (this could be the Head of the Anaesthetics Department, a nominated anaesthetist from the department or another nominated critical care specialist).

The role of project sponsor and Clinical Lead is not just to 'support' the project, but to:

- provide visible and active leadership and commitment to the project with all levels of staff
- align the project goals/objectives at an executive and strategic level in relation to the hospital and LHD operational plans
- govern escalated risks and assist in the resolution of issues/barriers escalated by the project manager and/or working group.

1.2 Identify a Project Manager

It is recommended that, for the implementation period, a member of the team is allocated the role of project manager. This will require dedicated project time.

The role of the project manager is to:

- lead the implementation within the agreed scope and budget of the project
- lead the project monitoring and evaluation process
- facilitate meetings and effectively communicate and engage staff and clinicians in the project
- escalate risks, issues and updates to the project steering committee and project sponsor.

1.3 Establish a Working Group

It is recommended that the working group is multidisciplinary and representative of the clinical and non-clinical teams that care for patients undergoing an episode of procedural sedation. The role of the working group is to:

- understand the case for change and how this applies to the local environment
- execute the implementation ensuring that agreed actions and project milestones are delivered
- effectively communicate and engage staff and clinicians in the project
- develop local solutions as needed
- monitor and evaluate project outcomes.

The working group should include membership from affected specialty departments (e.g. Cardiology, Respiratory, Radiology, Gastroenterology, Emergency, Burns, Blood and Marrow Transplantation), the Department of Anaesthesia, Clinical Governance and other clinicians and managers as needed. Both nursing and medical staff should be represented.

1.4 Define the Goal, Objectives and Scope

A clear project goal, specific project objectives and a well-defined scope are important to ensure that the project team are working towards the same goal. As the project team is likely to include multiple specialty groups, it is important that that the project goal, objectives and scope are agreed upfront by all members of the working group.

GOAL	• The project goal is a high-level statement of what the project will achieve. • It is aspirational and focussed on the intended outcome.
OBJECTIVES	• Outline the specific outcomes that will need to be achieved by the implementation as part of the overall aim. • Include timeframes and targets that can be used to measure success.
SCOPE	• A well-defined scope will aid in establishing manageable and realistic work plans, budgets, schedules, and expectations. • Define what is both IN and OUT of scope.

1.5 Communication Plan

Well-planned communications with staff and stakeholders within the LHD will be essential to the success of the project. Planning includes:

- developing consistent key messages
- identifying and targeting communications to specific stakeholders
- scheduling communications to align with key time points during your project
- ensuring that feedback loops are in place for all communication.

1.6 Evaluation

Evaluation measures should be considered during project development and aligned to the project aims as they are critical to measuring success. Clear and measurable objectives will help you clarify what is to be evaluated.

The ACI is currently developing an evaluation tool which will shared with the LHDs.

2. Assess

The purpose of the assess phase is to collect and analyse data about current processes for the provision of procedural sedation.

2.1 Completing a Baseline Assessment

Collecting baseline data allows you to identify the key issues or gaps in current practice compared with the Minimum Standards. Understanding the current context will allow you to identify where improvements can be made to align with the Minimum Standards.

To determine your site's compliance with the Minimum Standards an example self assessment tool has been provided with this toolkit. A summary of the assessment questions can be seen at **Appendix 3**.

2.2 Identifying and Prioritising Issues

Upon completing the baseline assessment, you may have identified gaps and key issues that need to be addressed in order to align local practices with the Minimum Standards. These should be sequenced, addressing the easiest gaps/issues ahead of the larger, more complex ones. The working group can work through this process as part of a regular meeting ensuring that all key stakeholders are included.

2.3 Considering Human Factors when Implementing

How individuals make decisions in real life and how they are likely to respond when given options involves gaining behavioural insight. This insight provides the opportunity to tailor interventions to make the desired behaviour easier to do than the current behaviour. These interventions are often simple and cost effective. In developing these interventions there are four things to consider:

Make it EASY for people to do the right thing:

- reduce the 'hassle factor' for people changing to your proposed solution
- simplify messages in letters, forms, emails, phone calls and text messages.

Make it ATTRACTIVE in the first place and reward those desired behaviours:

- draw attention to what is important
- use personalised messages so people understand that you are communicating with them.

Make it SOCIAL as we are heavily influenced by other people:

- use social norms to emphasise that most people are already doing the desired behaviour.

Make it TIMELY as timing is everything;

- prompt people at the moment and place when they are likely to be most receptive
- build desired behaviours into daily routines and habits.

3. Operationalise

The purpose of the operationalise phase is to apply the Minimum Standards in a way that addresses the issues and gaps identified in the assess phase.

It is important for the executive sponsor, project manager and working group to provide support and guidance to staff members implementing changes as well as monitoring the success of the implementation of solutions.

Establish a timeline • The timeline should identify regular intervals for the project manager / working group to check in on project progress. • Implementing 'quick wins' at the start of the implementation phase may help to generate positive momentum for the project.	**Set roles and responsibilities** • Each solution should identify the staff member who will be responsible for implementing the change. • Ensure that changes are communicated effectively with all impacted staff. • Consider if these staff need specific support or up-skilling. • The executive sponsor must reinforce the behaviour required for the solutions.
Define measurements • Consider the data that you measured during the baseline assessment phase – using these measurements during and after the project implementation will allow you to measure improvements.	**Establish feedback and support loops** • It is essential to have a mechanism for stakeholders to provide feedback or suggestions for improvement as implementing change across multiple departments/specialty units will be complex. • Provide a support service where stakeholders can ask questions and clarify new procedures.

3.1 Project Assessment

As the operationalise phase continues, consider the progress so far. One way of doing this is using a tool (see below). It is suggested that the project manager / working group has an opportunity to provide honest and open feedback about the project progress which should be done in a "safe" environment. For example, this could be a first agenda item in a meeting to allow frustrations and concerns, key lessons and positive outcomes to be shared openly.

Project Process	**Exceeding project aims and timelines**	**Meeting project aims and timelines**	**Meeting project aims and timelines** **Some assistance would be beneficial**	**Having difficulties in meeting project aims and timelines** **Would like some assistance**	**Not meeting project aims and timelines** **Need assistance**
Escalation Avenue	No escalation needed	No escalation needed	Discussion with working group	Discussion with working group	Discussion and plan with executive sponsor

3.2 Evaluation

The purpose of evaluation is to assess the success of the implementation of the Minimum Standards. It is important to measure the outcomes of your project to:

- determine if there has been any improvement in practice to align with the Minimum Standards
- identify any solutions which are not working and require reassessment
- satisfy accountability requirements
- enable more informed decisions in regards to future improvement planning.

Reassess your Baseline

During the baseline assessment phase, you will have collected data through a number of methods – redoing this assessment after the operationalise phase will allow you to measure change or improvements in practice.

Sustainable Implementation

Remember that the implementation project end date is not really the end. The implementation of solutions to align practice with the Minimum Standards is ongoing.

The project manager / working group should plan to review the provision of safe procedural sedation at regular intervals. These may be quarterly, half-yearly or yearly depending on the extent of changes that occurred as part of the implementation project.

Communicating your Success

By this point in the implementation project many staff and other stakeholders will be familiar with the project and may have contributed to it in some way.

It is important to recognise and celebrate the contribution of the project manager, working group, staff and the stakeholders that have been involved in the implementation of the Minimum Standards at your site. Communicate the outcomes of the reassessment, particularly if there is significant improvement.

Appendix 1 – Frequently Asked Questions

1. What is sedation?

Sedation is part of a continuum of decreasing levels of consciousness, caused by the effect of sedative medications on the brain. With increasing doses, the parts of the brain that control the heart and breathing are depressed and in some patients, breathing and blood pressure may be adversely affected.

2. Why were the Minimum Standards developed when there is PS09?

The Australian and New Zealand College of Anaesthetists (ANZCA) developed PS09 – Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures which have been adopted by a number of specialty medical colleges. Although there was good awareness and the principles are well accepted by clinicians across NSW, many sites have felt that the guidelines are too detailed and prescriptive and therefore difficult to implement in public hospitals. Also, some specialty medical colleges were not co-signatories to PS09 and some areas where procedural sedation is used are not covered by PS09 as no college is represented (e.g. some smaller emergency departments). Therefore, the ACI identified three minimum standards required for an episode of safe procedural sedation. These standards align with the principles set out in PS09.

3. Why is Safe Procedural Sedation an issue?

Sedation involves the use of medications which can affect the parts of the brain which control the patient's breathing and circulation. A safe environment for sedation is underpinned by risk stratification, safe medication use and access to life support skills. Therefore, clinicians who administer sedation must have the appropriate skills, including airway training. Some specialists, such as anaesthetists are specially trained to manage patients under sedation. However, there is currently no standardised way in which procedural sedation is managed across NSW.

4. Why is there so much variation in practice?

There has been a worldwide trend of procedures moving from operating theatres to procedural environments, which has been mirrored across NSW. As the number of procedures occurring in procedural rooms have increased, so too has the rise of sedation provision by non-critical care specialists. This change has been largely informal and has meant that most sedation services have been developed through "on the job" training. As part of this, relationships with anaesthetic departments (or other specialist services) have been managed on an ad hoc basis. This has led to the variation in practice, not only across LHDs, but within hospitals and even within specialty departments.

5. Do all patients need to be treated according to the Minimum Standards?

Yes. These Standards have been identified and confirmed as MINIMUM requirements for an episode of safe sedation care. However, the Standards do allow flexibility so that hospitals/specialty departments may adapt them to suit their local context.

6. How do the minimum standards apply to rural and regional NSW?

As part of the project diagnostic, site visits were undertaken to a range of rural sites to ensure that the key issues were well understood and addressed as part of developing the

Minimum Standards. It was acknowledged that there are challenges specific to rural and regional NSW, especially relating to availability of skilled workforce. It has been emphasised in the Standards that where a site cannot meet Minimum Standards, the procedure should be deferred until resources are adequate.

Appendix 2 – Procedural Sedation Record Example

EXAMPLE – PROCEDURAL SEDATION – PRE PROCEDURE

Insert logo and LHD/hospital name here	
Insert name of tool	

Surname:	MRN:
Given Name(s):	Male ☐ Female ☐
D.O.B:	M.O:
Address:	
Location/ward:	

Affix label here

Preferred Language	Interpreter Booked
	YES ☐ NO ☐ N/A ☐

Procedure:	
Date / Location	
Indication for procedure	

Fasting Status	Date	Time
Solids:		
Fluids:		

Consent completed	YES ☐ NO ☐	Weight		Height	BMI

Flags for Increased Sedation Risk	Yes/No
PRESENCE of any of these flags may indicate need for referral to anaesthetic department. Local policies should be developed for detailed agreed definitions.	
Previous anaesthesia/sedation complication including family history	
Previous failed sedation	
Sleep apnoea/severe snoring	
Unstable heart disease	
Alcohol >50 g/day	
Morbid obesity BMI>35	
Limited functional reserve (see below)	
Increased Oxygen requirement at rest	
Frail elderly	
Poorly controlled oesophageal reflux	
Other flags as agreed locally (e.g. IV drug use)	

Allergies / Adverse Events / Medications	Yes/No
Allergies:	
Adverse drug reactions / Drug sensitivities	
Medications:	**Last taken**

Comments:

Patient's ASA Score	
ASA Score – Physical Status	
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	

Physical Examination-flags for increased risk of adverse events as agreed locally	
Airway flags (e.g. obese, bearded, reduced mouth opening, neck mobility)	YES ☐ NO ☐
Cardiovascular flags	YES ☐ NO ☐
Intended sedation - Conscious Sedation - Discussed with patient	 YES ☐ NO ☐ YES ☐ NO ☐
Does this patient meet *locally agreed* criteria for referral to the Anaesthetic Department – if yes, DO NOT PROCEED.	YES ☐ NO ☐

Functional Reserve	
Can the patient walk up a set of stairs without becoming short of breath?	YES ☐ NO ☐

Do they have someone to escort them home?	YES ☐ NO ☐

Form completed by (name and position):		Signature:	

EXAMPLE – PROCEDURAL SEDATION – INTRA PROCEDURE

Insert logo and LHD/hospital name here	Surname:		MRN:
	Given Name(s):		Male ☐ Female ☐
	D.O.B:		M.O:
Insert name of tool	Address:		
	Location/ward:		

Affix label here

Procedure:	
Time of arrival in room	
Time out completed	YES ☐ NO ☐
Time procedure completed	

Monitoring	Pulse Oximetry ☐	Automated BP ☐
	Capnography ☐	ECG ☐
Oxygen ___ L/Min		

Attending Staff	
Proceduralist	
Sedationist	
Clinician Airway Monitor	
Procedure Nurse	
Other staff:	

< Use National Inpatient Medication Chart or other appropriate chart for Medications>

<Use a NSW Health Standard Observation Chart for Observations>

Sed. Score						
Time						
Sedation Score:	1 = Alert	2 = Responds to Verbal		3 = Responds to Pain		4 = Unresponsive

EXAMPLE – PROCEDURAL SEDATION – POST PROCEDURE

Procedure:		Oxygen Therapy	
Time of arrival in room:		Pulse Oximetry	
Received by:		IV therapy	

<Use a NSW Health Standard Observation Chart for Observations>

Sed. Score						
Time						
Sedation Score:	1 = Alert	2 = Responds to Verbal		3 = Responds to Pain		4 = Unresponsive

Discharge / Transfer of Care

Item	Yes/No/NA	Notes
IV Cannula removed	N/A	
Tolerating fluid?	N/A	
Seen by proceduralist / sedationist	N/A	
Medical Certificate	N/A	
Personal items returned	N/A	
Post procedure information given	N/A	
Follow up arranged	N/A	
Escort Home/back to ward	N/A	

Vital Signs

Vital signs reviewed	YES ☐ NO ☐

Time Discharged:
Discharged by:

2/

These tools are reproduced here from the Minimum Standards.

Appendix 3 – Self Assessment Tool Summary

Safe Procedural Sedation

	Service/Unit/Department:	
	Assessment Domains	
	Standard 1: Pre Procedure Assessment	
1	Is there a documented process of pre procedure assessment (risk stratification) for EVERY patient undergoing procedural sedation?	
2	Is anaesthetic (or other critical care service) advice available when it is sought by your unit?	
3	Does the pre procedure assessment include an airway assessment for EVERY patient undergoing procedural sedation?	
	Standard 2: Intra Procedure	
4	Is there a clinician airway monitor - who is not the proceduralist - present for the entire procedure for every episode of procedural sedation?	
5	Is there a clinician with airway skills present for the entire procedure for every episode of procedural sedation?	
	Standard 3: Post Procedure	
6	Is there a clinician monitor present during the recovery phase for every episode of procedural sedation?	
7	Are there demonstrated criteria for the transfer of the patient post procedure?	

	Underpinning Frameworks	
8	Is there an agreement with the Anaesthetic Department to provide ongoing, structured support to your unit?	
9	Are there clear governance structures in place for your hospital and/or LHD for the support of safe procedural sedation practice?	
10	Is there a monitoring and/or review process for outcomes of procedural sedation (both positive and negative)?	

This is a summary only. The full self assessment tool may be found in the accompanying excel spreadsheet – *Self Assessment Tool – Minimum Standards and Toolkit for Safe Procedural Sedation.*