



ACI NSW Agency
for Clinical
Innovation

ACI Anaesthesia Perioperative Care Network Safe Procedural Sedation Project Phase 2 Diagnostic Report

15
October
2012

January 2014

Acknowledgements

Joanna Sutherland, Chair – Safe Sedation Working Group

The members of the Safe Sedation Working Group / Anaesthesia Perioperative Care Network.

All those who took the time to participate in site visits and provide their expertise.

AGENCY FOR CLINICAL INNOVATION
Level 4, Sage Building
67 Albert Avenue
Chatswood NSW 2067

Agency for Clinical Innovation
PO Box 699 Chatswood NSW 2057
T +61 2 9464 4666 | F +61 2 9464 4728
E info@aci.nsw.gov.au | www.aci.health.nsw.gov.au

Produced by: Anaesthesia Perioperative Care Network's Safe Sedation Working Group
ACI TRIM Ref: D14/113

Ph. +61 2 9464 4641
Email. Ellen.Rawstron@aci.health.nsw.gov.au

Further copies of this publication can be obtained from:
Agency for Clinical Innovation website at: www.aci.health.nsw.gov.au

Disclaimer: Content within this publication was accurate at the time of publication. This work is copyright. It may be reproduced in whole or part for study or training purposes subject to the inclusion of an acknowledgment of the source.

It may not be reproduced for commercial usage or sale. Reproduction for purposes other than those indicated above, requires written permission from the Agency for Clinical Innovation.

© Agency for Clinical Innovation 2014

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY	2
2. BACKGROUND	3
3. METHODOLOGY	3
4. LITERATURE	3
5. THE NSW HEALTH EXPERIENCE	5
5.1 Context – the three services	5
5.2 Key Themes	5
5.2.1 Key Issues	5
5.2.2 Barriers and Enablers	8
6. SOLUTION DESIGN	9
7. RECOMMENDATIONS	9
8. REFERENCES	10
9. CONSULTATION LIST	11

1. Executive Summary

Clinicians who administer procedural sedation must be appropriately trained and supported. A safe environment for patient sedation is underpinned by appropriate patient risk assessment, risk stratification and management, safe medication use and access to life support skills.

Procedural sedation is one of the key priority areas of the Anaesthesia Perioperative Care Network – more specifically, the Network has an interest in procedural sedation in a setting where it is provided by a non-anaesthetist clinician. This is because sedation involves a decreased level of consciousness caused by the effect of sedative medications on the brain which can affect patient cardiac and respiratory function.

Following the phase one diagnostic and solution design process, the Network commenced a diagnostic of emergency departments, burns services and blood and marrow transplantation units to identify additional issues and innovations relating to procedural sedation. The project team conducted over 17 visits, to ten Local Health Districts (LHD). Many of the site visits endorsed the findings of the first phase and feedback was provided that a more structured – but not prescriptive – approach to procedural sedation would be useful.

As with phase one, there was significant variation across the system, LHDs and hospitals. An additional literature review – largely relating to sedation in emergency departments – was also undertaken to confirm the findings.

Key Issues

- Variable patient assessment processes
- Pharmacology awareness and airway skills
- Monitoring skills and practice
- Recognising, managing and escalating the deteriorating patient
- Recovery and discharge
- PS09 – in the NSW Health context

Barriers/Enablers

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

There was good support for the identified three minimum standards that should be present in all episodes of safe sedation care:

- Assessment and risk stratification of all patients receiving sedation
- A dedicated clinician (who is not the proceduralist), with appropriate skills and training, whose primary responsibility is to monitor and manage the patient's airway
- Bag-mask ventilation skills for at least one clinician present

In addition to identifying issues, some LHDs and/or hospitals provided detailed advice on initiatives that had been undertaken to support safe procedural sedation practice. These resources have been used to inform the development of the Minimum Standards and Toolkit. This process has been undertaken in collaboration with other ACI Networks, services and LHD clinicians and managers.

2. Background

Sedation/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. 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.

In 2012/13, the ACI identified Safe Procedural Sedation as a key priority area. Following the completion of the diagnostic for phase one – involving gastroenterology, cardiology, respiratory and radiology services – of the project (see phase one report), the Network commenced the **Phase Two** diagnostic [this report] which included **Emergency Departments (ED), Burns Units** and **Blood and Marrow Transplant Units (BMT)**. ICU/HDU, Ambulance, Dentistry and Paediatrics remain out of scope for this project.

This report reflects the findings of the Phase Two diagnostic conducted from September 2013 – January 2014.

3. Methodology

In phase one, data and literature searches undertaken as well as site visits across NSW LHDs. For more information, see section three of the Phase One Report.

Phase two included a review of relevant literature and site visits. In total, there were 17 interviews and/or surveys completed, covering metropolitan, regional and rural areas, including:

- Site visits to eight Local Health Districts (LHD)
- Videoconference/teleconferences with an additional two LHDs.

Due to the limited number of sites where those specialties are based, the two adult burns units were visited and three BMT units were identified by the ACI Blood and Marrow Transplant Network Executive. The remaining visits were to emergency departments.

4. Literature

There is a significant amount of literature relating broadly to procedural sedation in the ED and considering the safety and efficacy of such procedures. As with other procedural areas, the prevalence of sedation in EDs has increased as more procedures take place outside of operating theatres. As a result of this trend, practice in EDs has evolved and the Australasian College of Emergency Medicine has been closely involved in the reviews of PS09 (ANZCA, 2010: 1).

There are unique challenges for emergency departments in structuring a procedural sedation service – for instance, there is a balance between the need to complete the procedure expediently and the requirement to wait until the patient is adequately fasted (Molina et al, 2010: 75-76) according to guidelines for standard anaesthesia management, most commonly produced for elective surgery (Molina et al, 2012: 75-76; ANZCA). This is not easy to resolve, particularly when considering the relationship between fasting status and prevention of complications. Therefore, it is incumbent upon the physician to remain upskilled, particularly in skills and techniques related to airway management and protection, so that they may, on a case by case basis, determine the trade-off between timeliness and caution (Molina et al, 2010: 78; Green and Krauss, 2002: 39-40).

This is underpinned by an evolution in emergency medicine that appropriate relief of procedural pain and anxiety is an ethical imperative (Green et al, 2007: 455). Although much of the literature outlines that the need for following fasting guidelines is arguable and open to interpretation, fasting status must be assessed carefully, as part of patient risk assessment, together with assessment of procedure urgency and identification of the desired target level of sedation (prior to the procedure) (Green et al, 2007: 459).

The emergency medicine specialty has worked to ensure its fellows and trainees have the requisite knowledge, skills and capacities to manage procedural sedation (Bell et al, 2011: 459; Green and Krauss, 2002: 40). Case studies into particular sites emphasised that adherence to guidelines, knowledge of drugs and airway management are all of the utmost importance when providing procedural sedation (Wenzel-Smith and Schweitzer, 2011: 6).

Although there was a theme in some literature that sedation related events are common, but rarely result in an adverse outcome, it was highlighted that competency in managing these events is needed, as is conducting a proper risk assessment prior (Taylor et al, 2011: 468, 471). Use of available monitoring technology should be maximised to reduce potential risks, including where needed, capnography (Green and Krauss, 2002: 40).

One study found that there was an increased rate of complications in the late evening or at night and although there was no specific factors identified for this, it does highlight then need for EDs where sedation is practised to have a doctor on site who is trained and experienced in emergency medicine (Jacques et al, 2011: 1040).

Performance of sedation in the ED does not only have implications for patient care, but can also serve to minimise hospital admissions (and theatre time and resources) for procedures that can now be safely undertaken in environments outside of operating theatres (Harvey et al, 2011: 43).

The American College of Emergency Physicians recommends the need for credentialing but emphasises that it should be locally determined and tailored to the needs of the institution and the skills of the local practitioners (O'Connor et al, 2011).

Sedation is also important in the supporting burns procedures. The aim is to reduce patient anxiety, improve analgesia and ensure immobilisation when required. However, sedation for a burns procedure can be made more challenging due to patient response to regular doses of sedative agents. Therefore, the need is emphasised for a trained practitioner (who is not the proceduralist) to manage the patient's sedation, including managing their airway in the event of a complication (Gregoretti et al, 2008: 2427).

As some procedures may require the patient to be turned regularly, the use of patient controlled sedation and sedative agents that allow the patient to maintain spontaneous breathing are commonly used in burns (Gregoretti et al, 2008: 2427; Nilsson et al, 2008: 929). In particular, patient controlled sedation has been successful not only from a patient perspective, but from a safety and resource perspective (Nilsson et al, 2008: 929, 933).

There is conflict in the literature between findings where patients preferred intravenous sedation and instances where they were satisfied undergoing the procedure with local anaesthetic. In the latter, there that was a slight tendency towards sedation for those patients who were having a repeat biopsy (Mainwaring et al, 1996: 285; Giannoutsos et al, 2004: 201). A later study found that inhaled sedatives provided an effective, safe alternative to intravenous sedation and was acceptable for both staff and patients (Gudgin et al, 2008: 65-67).

5. The NSW Health Experience

5.1 Context – the three services

In NSW Health, there is a range of procedures undertaken across the three services surveyed as part of this phase which may involve the use of procedural sedation:

- **Burns** – dressing changes and physiotherapy.
- **Blood and Marrow Transplantation** – bone marrow biopsies.
- **Emergency Departments** – fracture or dislocation reductions, suturing of lacerations, dressings, other.

5.2 Key Themes

The feedback from the site visits has been collated and categorised into themes. As part of the phase two site visits, the key findings from phase one were shared with interviewees. Most participants echoed those findings and outlined a number of additional areas of concern.

Use of Inhalants

A number of services use inhaled sedatives to partially, or wholly, meet the needs of their local sedation service. This method has been introduced successfully at these sites and although a number of challenges were identified, inhalants are not within the scope of this project. Nonetheless, it is important for any sedation practice to have underpinning processes to ensure it is appropriately structured and resourced. Interviewees emphasised that a key element of making the service function well related to patient education, not only for their preparation, but also in ensuring the patient has an understanding of how conscious sedation will work.

No Sedation Service

At those units where a sedation service is not available (outside of limited theatre access), it may be useful to liaise with other sites/LHDs [within the specialty]. It is recommended that the relevant Executive Committees address this within their Networks.

Awareness and Acceptance of PS09

Throughout the diagnostic, the project team sought feedback on the feasibility and applicability of PS09. Although there was some awareness of the guideline and the principles broadly supported, particularly within EDs, PS09 does not appear to be widely recognised within units specialising in burns and blood and marrow transplantation. The reason is likely because the Royal Australasian College of Physicians (RACP) has not co-badged the document. PS09 is well accepted and practiced by specialist ED physicians. In smaller rural departments, where specialist emergency physicians may not have a presence, there may not be a high level of awareness of PS09.

5.2.1 Key Issues

1. Patient Triage / Risk Assessment

In the smaller, specialised services assessment is often ad hoc and informal but generally individual patients and their histories are well known to staff.

Due to the nature of emergency department presentations, fasting status can often determine type of sedation and agent, as well as post procedure recovery time. Airway

assessment is well practiced in EDs particularly by specialist ED physicians who have been trained. It is sometimes a challenge at smaller [rural] sites with a more transient staff or after hours when fewer staff are available.

Most EDs indicated they generally do not need to seek support from Anaesthetics Departments for an assessment. Occasionally, the ideal scenario may be for a patient to be referred to anaesthetics/theatres, but this is not always possible given resource restrictions. The procedure may instead need to go ahead in the ED. In those circumstances, feedback received indicated that a process for a detailed risk assessment is not only helpful, but also creates an evidence base for the procedure going ahead.

For some smaller rural and remote EDs, procedural sedation is managed exclusively by the anaesthetics service, except in extenuating or limited circumstances. In these scenarios, scope of practice is designated by a LHD/hospital committee with appropriate authority.

2. Pharmacology Awareness

There was variation in dosage and method of administration (a wide range of agents are used, including Midazolam, Fentanyl, Ketamine, Propofol). Practice varied within specialty and across LHDs.

Most units described a good understanding of the pharmacological agents involved, but emphasised that it would be useful to have standardised information about dosages. This was raised particularly by ED staff as there is regular changeover of staff and limited staff available after hours. Some units e.g. burns have put standard dosages in place, and allow variation based on extraordinary individual needs.

As outlined in the phase one report, data (IIMS) also indicated that adverse events relating to over sedation do occur, although most units reported infrequent/rare use of reversal agents.

3. Airway Skills

Consistent access, completion and renewal of relevant airway skills was emphasised as fundamental.

For specialist ED medical staff, airway skills are a key, everyday skill. There were some concerns over the continuity of which airway skills are available – in particular, the skills [or lack thereof] of locums [and some non-specialist staff] in rural emergency departments. In many instances, feedback was provided that nursing staff are often the most reliable source of basic airway skills, as they are a more stable workforce in some rural areas.

Those units that are part of a critical care department are able to access airway skills training (ie ALS) as it is a requirement of day to day clinical care. For services such as burns, nursing staff are usually also required to have experience in theatres/critical care/ICU and complete specific training for the management of burns. In the emergency departments nursing staff are often required to have worked in critical care/ED for a period of time before they are able to work in resuscitation and/or support an episode of procedural sedation.

For BMT staff, access to airway skills training can be difficult as the specialty does not fall within critical care.

4. Monitoring

Formal monitoring varies across services but for the most part there is consistent practice, although it not necessarily formalised or protocolised. There is good access to and use of monitoring equipment during procedures.

As with phase one, one challenge relates to staffing. Some units cannot always have a dedicated clinician monitor (the number of staff in the room is often dictated by the type of procedure being undertaken). This can mean that the patient is monitored but observations are not recorded during the procedure. However, observations are always recorded before and after a procedure.

As noted above, procedures take place in a range of different environments, including outpatient clinics, on wards, in shower rooms and resuscitation bays. The majority of these locations have access to appropriate monitoring equipment, as well as oxygen, suction and other key items needed for managing the patient for the duration of the procedural sedation.

In many circumstances, post procedure monitoring is not formalised. However, these services will generally leave a staff member to monitor the patient until they are awake and ready to be discharged. Most services managed this in an ad hoc way and did not have formal discharge criteria and/or a checklist.

5. Managing and Escalating the Deteriorating Patient

Due to the nature of sedative medications, there is always a risk that the patient may deteriorate during a procedure. There was variation across services and LHDs and the escalation plan includes options such as:

- Management by the specialist medical officer
- MET/PACE/RRT calls
- Anaesthetics/ICU/ED are based nearby and can offer timely support

At those EDs with specialist ED physicians, there is usually already appropriate expertise available to manage an airway in the event of a deteriorating patient. However, in many smaller facilities the staffing is limited after hours and the medical officer on duty may be responsible (as the rapid response team) for the whole hospital – this is particularly the case in EDs.

6. Recovery

Overall, as with phase one, there needs to be more education in managing patients in this phase of their journey and the need for formalised tools (rather than ad hoc practices), particularly with regard to post procedure observations.

Some ED staff indicated that ensuring a patient is given an appropriate time to recover can be difficult to manage due to the needs of the service (e.g. need for resuscitation bays, NEAT).

7. Discharge

Where it is day only procedures, many services have processes in place to manage the process of discharge, but it is predominantly not formalised. Most services keep patients for a minimum period of time and/or until their condition meets certain parameters. Most services will not release the patient without an escort home and will provide them with post-discharge instructions following an episode of procedural sedation e.g. not driving until the next day.

There is limited post-discharge follow up. In the smaller services, patients and their individual circumstances are well known to clinical staff and are often in consistent contact with the patients.

These issues can be particularly difficult to manage in small rural sites where staff, resources and beds are all limited.

5.2.2 Barriers and Enablers

Governance Arrangements

As with phase two, governance arrangements are limited across these services - most services rely on accepted informal processes and clinical pathways within their departments.

At a broader level, there is good coordination of all three services at a statewide level. The Emergency Care Institute has undertaken comprehensive work to assist in standardising practice, but has also provided guidance on individual clinician accreditation. Further, the ACI is closely involved in the Burns and BMT Networks and as these services are both specialised and limited to a relatively small number of sites, works with them to facilitate best practice across the specialty.

That said, as outlined in phase one, some LHDs have developed local policies and formed oversight groups. Critical incidents have often been a driver for hospitals/LHDs to encourage more interaction from CGU / Anaesthetics (or other units) and in developing more formal processes in managing the hospital's sedation processes. A key governance aspect which should be addressed as part of both phase one and phase two is the need to formalise local sedation practices to ensure continuity of practice both now and in the future (with staff changeover).

Access to Anaesthetic Support

Although most Departments of Anaesthesia has developed relationships with Burns and BMT services, for the most part EDs manage their own sedation practice. Where needed many sites reported that advice from Anaesthetics Departments is available if needed, but that assistance is rarely sought for airway support. The exception to this is in some rural EDs where staffing arrangements after hours and/or lack of specialist ED support means that assistance may need to be sought from the on call anaesthetist.

Throughout the site visits, some EDs noted that occasionally a patient should ideally be treated in theatres and supported by the anaesthetics team. However, this is not always possible due to a range of factors including theatre availability and anaesthetist availability. This can mean that the procedure may need to proceed in the emergency department. Feedback from these units was that it would be useful for the Minimum Standards and Toolkit to provide a structure to demonstrate the justification for the procedure to have gone ahead in the ED.

As with phase one, the key challenge was in accessing anaesthetic services at the "last minute". Similarly, Departments of Anaesthesia reported difficulties in identifying solutions to best manage the stream of ad hoc requests for support. Another highlighted challenge was the desire for consistent anaesthetic support without understanding the necessary cost implications upon the Department.

Formalised Training and Access

There is significant variation in available skills training and education programs – however, in comparison to phase one, access to training is significantly better, at least for those services that are part of critical care. In addition to ALS staff have access to more specialised programs such as FLECC and Emergency Management of Severe Burns (EMSB).

Credentialing and scope of practice

Some rural LHDs have established arrangements to restrict sedation practice unless an anaesthetist or a credentialed physician (with a defined scope of practice) is present. These systems are managed by LHD committee and were introduced following critical incidents. Clinicians who operate under this system reported that it has provided a structure to provide safe patient care and also support staff, particularly where there is high staff turnover.

6. Solution Design

Many of the key issues and barriers/enablers outlined in this phase have reflected those of the phase one diagnostic. In consultation with the Working Group/s, it was agreed that the minimum standards and toolkit should be drafted to include all seven scoped services.

7. Recommendations

It is recommended that:

- The second phase services be encompassed in under the recommendations of the phase one report, that is the Minimum Standards and Toolkit for Safe Procedural Sedation.
- The Standards be reviewed to take into account key aspects outlined in this report, including:
 - Geographical challenges for rural and remote NSW
 - Availability of skilled workforce
 - Continuity of staffing arrangements (eg locums)
- Network Executive Committees facilitate links between units that do not have a sedation service (outside of limited theatre access) and those that do.

8. References

- Agency for Clinical Innovation, 2014. Minimum Standards for Safe Procedural Sedation.
- Agency for Clinical Innovation, 2013. Safe Procedural Sedation Project: Phase 1 Diagnostic and Solution Design Report.
- American Society of Anesthesiologists Task Force, 2002. Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology*, 96, 1004-1017.
- Australian and New Zealand College of Anaesthetists. Fasting Guidelines. Accessed at <http://www.anzca.edu.au/patients/frequently-asked-questions/fasting.html/?searchterm=fasting%20guidelines> on 11 February 2014.
- Australian and New Zealand College of Anaesthetists, 2010, PS09 – Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures. <http://www.anzca.edu.au/communications/Other%20publications/policy-quality-and-accreditation-2010/ps9-2013-guidelines-on-sedation-and-or-analgesia-for-diagnostic-and-interventional-medical-dental-or-surgical-procedures>
- Bell, A., Taylor, D., Holdgate, A., MacBean, C., Huynh, T., Thom, O., Augello, M., Millar, R., Day, R., Williams, A., Ritchie, P., Pasco, J., 2011. Procedural sedation practices in Australian Emergency Departments. *Emergency Medicine Australasia*, 23, 458-465.
- Giannoutsos, I., Grech, H., Maboreke, T., Morgenstern, G., 2004. Performing bone marrow biopsies with or without sedation: a comparison. *Clinical and Laboratory Haematology*, Volume 26, Issue 3, 201-204.
- Green, S., Krauss, B., 2002. Pulmonary Aspiration Risk during Emergency Department Procedural Sedation – An examination of the Role of Fasting and Sedation Depth. *Academic Emergency Medicine*, Volume 9. Number 1. 35-42.
- Green, S., Roback, M., Miner, J., Burton, J., Krauss, B., 2007. Fasting and emergency department procedural sedation and analgesia: A consensus-based clinical practice advisory. *Annals of Emergency Medicine*, 49, 454-461.
- Gregoretto, C., Decaroli, D., Piacevoli, Q., Mistretta, A., Barzaghi, N., Luxardo, N., Toseti, I., Tedeschi, L., Burbi, L., Navalesi, P., Azzeri, F., 2008. Analgo-sedation of patients with burns outside the operating room. *Drugs*, 68 (17), 2427-43.
- Gudgin, E., Besser, M., Craig, J., 2008. Entonox as a sedative for bone marrow aspiration and biopsy. *International Journal of Laboratory Haematology*, Volume 30, Issue 1, 65-67.
- Harvey, M., Cave, G., Betham, C., 2011. Contemporary sedation practice in a large New Zealand emergency department. *New Zealand Medical Journal*, Vol 124, No 1344, 36-45.
- Jacques, K., Dewar, A., Gray A., Kerslake, D., Leal, A., Lees, F., 2011. Procedural sedation and analgesia in a large UK Emergency Department: factors associated with complications. *Emergency Medicine Journal*, 28, 1036-1040.
- Mainwaring, C., Wong, C., Lush, R., Smith, J., Singer, C. 1996. The role of midazolam-induced sedation in bone marrow aspiration/trephine biopsies. *Clinical and Laboratory Haematology*, Volume 18, Issue 4, 285-288.
- Molina, J., Lobo, C., Goh, H., Seow, E., Heng, B., 2010. Review of studies and guidelines on fasting and procedural sedation at the emergency department. *International Journal of Evidenced Based Healthcare*, 8, 75-78.

Nilsson, A., Steinvall, I., Bak, Z., Sjoberg, F., 2008. Patient controlled sedation using a standard protocol for dressing changes in burns: Patient's preference, procedural details and a preliminary safety evaluation. *Burns*, Volume 38, Issue 7, 929-934.

O'Connor, R., Sama, A., Burton, J., Callaham, M., House, H., Jaquis, W., Tibbles, P., Bromley, M., Green, S., 2011. Procedural Sedation and Analgesia in the Emergency Department: Recommendations for Physician Credentialing, Privileging and Practice.

Taylor, DMcD., Bell, A., Holdgate, A., MacBean, C., Huynh, T., Thom, O., Augello, M., Millar, R., Day, R., Williams, A., Ritchie, P., Pasco, J., 2011. Risk factors for sedation-related events during procedural sedation in the emergency department. *Emergency Medicine Australasia*, 23, 466-473.

Wenzel-Smith, G., Schweitzer, B., 2011. Safety and efficacy of procedural sedation and analgesia (PSA) conducted by medical officers in a level 1 hospital in Cape Town. *South African Medical Journal*, Vol 101, No 12.

9. Consultation List

We would like to thank staff from the following LHDs for providing their time and expertise during the diagnostic for phase two of the project:

- Central Coast LHD
- Far West LHD
- Hunter New England LHD
- Mid North Coast LHD
- Murrumbidgee LHD
- Northern NSW LHD
- Northern Sydney LHD
- South Western Sydney LHD
- Southern NSW LHD
- Sydney LHD