



# ACI Anaesthesia Perioperative Care Network Safe Procedural Sedation Project Phase 1 Diagnostic and Solution Design Report

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**Author:** Anaesthesia Perioperative Care Network

**Owner:** Agency for Clinical Innovation

Street address:  
Level 4, Sage Building  
67 Albert Avenue  
Chatswood NSW 2067

Postal address:  
Agency for Clinical  
Innovation  
PO Box 699  
Chatswood NSW 2057

**T** +61 2 9464 4666  
**F** +61 2 9464 4728  
info@aci.health.nsw.gov.au  
www.aci.health.nsw.gov.au

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Joanna Sutherland, Chair – Safe Sedation Working Group

Tracey Tay, inaugural Chair – Safe Sedation Working Group

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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](mailto:info@aci.nsw.gov.au) | [www.aci.health.nsw.gov.au](http://www.aci.health.nsw.gov.au)

Produced by: Anaesthesia Perioperative Care Network's Safe Sedation Working Group

Ph. +61 2 9464 4641  
Email. [Ellen.Rawstron@aci.health.nsw.gov.au](mailto:Ellen.Rawstron@aci.health.nsw.gov.au)

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# 1. Executive Summary

In NSW public hospitals there are ~300,000 episodes of procedural sedation<sup>1</sup> undertaken across numerous specialty areas each year. As a greater number of complex procedures move outside of the operating theatre, the use of sedation will continue to increase.

Therefore, 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 and also by safe medication use and access to life support skills. Anaesthetists are specifically trained to manage patients under sedation. However, in NSW public hospitals, there are a number of specialty areas where sedation is administered by non-anaesthetist clinicians.

One of the key priority areas of the Anaesthesia Perioperative Care Network is safe procedural sedation – more specifically, the Network has an interest on 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.

In 2013, the Network commenced a diagnostic of radiology, respiratory, gastroenterology and cardiology services to identify and explore the issues relating to procedural sedation where it is administered by a non-anaesthetist. The project team conducted over 35 interviews, which included visits to seven Local Health Districts (LHD), with feedback provided by an additional five LHDs. Overall, the survey results identified significant clinical variation across the system, LHDs and hospitals. Data searches and a literature review were also undertaken to confirm the findings. The results of the diagnostic were then categorised into key issues and barriers/enablers to inform the solution design phase of the project.

## Key Issues

- Variable patient assessment processes
- Pharmacology awareness and airway skills
- Monitoring
- Managing and escalating the deteriorating patient
- Recovery and discharge

## Barriers/Enablers

- Governance arrangements
- Access to anaesthetic support
- Access to skilled support
- Minimal formalised training
- Poor access to training
- Variable practice review
- PS09 – in the NSW Health context

The Network has identified three minimum standards that should be present in all episodes of safe sedation care:

- Assessment and triage of all patients receiving sedation
- A dedicated clinician, with appropriate skills and training, monitoring and managing the airway (who is not the proceduralist)
- 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 solutions, including guidelines and

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<sup>1</sup> Inpatient Statistics Collection, SaPHARI, 2013

tools, for implementation across the system. The solution development and implementation is being undertaken in collaboration with other ACI Networks, services and LHD clinicians and managers.

A second phase of the project looking at Emergency Departments, Burns Units and Blood and Marrow Transplant services will be commenced next.

## 2. Background

***Procedural sedation and/or analgesia*** implies that the patient is in a state of drug-induced tolerance of uncomfortable or painful diagnostic or interventional medical, dental or surgical procedures. Lack of memory for distressing events and/or analgesia are desired outcomes, but lack of response to painful stimulation is not assured.

- Australian and New Zealand College of Anaesthetists (ANZCA), PS09 – Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures, 2010: 1

More generally, 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 2010, at the request of the Department of Health, the Agency for Clinical Innovation's (ACI) Anaesthesia Perioperative Care Network developed a discussion paper regarding sedation practice by non-anaesthetist clinicians across NSW public hospitals. The report concluded that there was a need for better data collection, as well as an implementation plan to support the principles laid out in ANZCA's *PS09 Guidelines*.

Following that report the Network formalised recommendations that a first component of a staged approach to the implementation of PS09 should include, as a minimum:

- Assessment and triage of all patients receiving sedation
- A dedicated clinician, with appropriate skills and training, monitoring and managing the airway (who is not the proceduralist)
- Bag-mask ventilation skills for at least one clinician present

For 2012/13, the ACI identified Safe Procedural Sedation as key priority area. The Network agreed to undertake the project in two phases – **Phase 1** [this report] which includes **gastroenterology, cardiology, respiratory** and **radiology services** and Phase 2 which would include Emergency Departments, Burns Units and Blood and Marrow Transplant Units. It was agreed that ICU/HDU, Ambulance, Dentistry and Paediatrics would be excluded from the project scope.

This report reflects the findings of the Phase 1 diagnostic conducted from January – April 2013.

## 3. Methodology

The project has recently completed the diagnostic phase of project development. As part of the diagnostic phase data, literature and reporting was reviewed and site visits were conducted.

To facilitate the site visit aspect of the diagnostic, the Safe Sedation Working Group developed a survey tool to guide the interviews. The survey covered key aspects of the patient journey, safety and quality.

In total, there were over 35 interviews and/or surveys completed, covering metropolitan, regional and rural areas, including:

- Site visits to seven Local Health Districts (LHD)
- Sponsored surveys at two LHDs
- Teleconferences held with an additional four LHDs.

Following the completion of the site visits, the results were collated, themed and circulated to all participants for feedback. The Safe Sedation Working Group were responsible for prioritising these issues for action.

## **4. Procedural Sedation in the Broader Context**

A review of relevant national and international literature was undertaken to identify broad themes relating to procedural sedation in the non-anaesthetic setting. These key themes included: the function of advanced practice roles; the role and applicability of guidelines; education and training programs and who should design them, complete them and have oversight of them; the importance of monitoring, equipment and training; and finally the key role of audit and governance in maintaining a culture of safe sedation practice within a health facility. Whilst reviewing the literature, it became clear that many of the challenges experienced in the NSW Health system are synonymous with those being experienced in health systems across the world.

Generally, procedural sedation practice has been directed by the guidelines of professional bodies. In 1986, the Australian and New Zealand College of Anaesthetists (ANZCA) published guidelines – PS09 – on the administration of sedation for diagnostic and interventional procedures. Over time, PS09 has been adapted to reflect current practice – and is presently co-signed by seven specialty colleges and/or societies (ANZCA, 2010: 1). Similar guidelines exist in the United States (ASA Task Force, 2002) and Europe (Knape et al, 2007). Nonetheless, there have been documented circumstances where specialty College guidance on the safe use of sedative agents has not been followed (Eason et al, 2011: 61).

Overall, there is a worldwide trend of procedures moving from operating theatres to procedural environments, which has subsequently meant a shift to the administration of sedation by non-anaesthetist clinicians (Waugh et al, 2011: 189; Heuss et al, 2012: 504-505; Metzner and Domino, 2010: 523). In fact, the use of anaesthetists in procedural disciplines such as endoscopy has dropped as low as 15% in Switzerland (Heuss et al, 2012: 507) and 29% in some parts of the United States (Metzner and Domino, 2010: 523).

There are a number of reasons for this trend, including the increasing inclination of practitioners to use sedation for certain types of procedures (Heuss et al, 2012: 509). In the Australian healthcare context, changes to sedation practice have also come about as a result of anaesthesia workforce shortages and a rise in demand for service (Jones et al, 2011: 116-117).

In response to these challenges and due to anecdotal concerns relating to patient safety, the nurse sedationist role was introduced as a pilot in South Australia in 2006. Before then, this

role had not existed in Australia, although it had been present in European and the United States healthcare settings since the 1990s (Jones et al, 2011: 116-117).

Candidates who take on advanced practice roles such as nurse sedationist must complete specific and comprehensive education and training, which should be validated by submission of a credentialing package and subsequent authority by the employing hospital/service to practice in the role. In the pilot undertaken in South Australia, the exact requirements were agreed upon by a multidisciplinary and multispecialty working group. In developing and agreeing upon these requirements, relationships with medical colleagues were crucial (Jones et al, 2011: 117, 121).

However, where advanced practice roles such as the nurse sedationist do not exist, appropriate education and training programs are also vital to ensuring the safe practice of procedural sedation by all non-anaesthetist clinicians (both nursing and medical).

Education and training programs should be interdisciplinary and include didactic education on pharmacology and side effects of sedative 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 (Metzner and Domino, 530)

In describing his own hospital's experience, Hurford (2013: 26-27) outlined that as the list of sedation providers was so broad, there was a need for a detailed and customised education credentialing program which met national requirements as well as complementing local policy. In addition to completing educational modules, medical officers also had to have demonstrated ability to rescue a patient from a deeper than intended level of sedation i.e. general anaesthesia. There was some controversy around the latter requirement (Hurford, 2013: 26-27).

Within the same hospital context, Ehrhardt and Staubach (2013: 35) outlined development of nursing programs, emphasising that education needed to offer flexibility, the opportunity to study independently and meaningful evaluation. Failure to complete the online course modules and pass each subsequent quiz meant nursing staff were not permitted to monitor patients undergoing procedural sedation. To ensure continuity for hospital services, all staff in all areas doing procedural sedation were required to complete the education program (Ehrhardt and Staubach, 2013: 35-36). Nursing staff were also required to demonstrate competency in airway management and monitoring (Ehrhardt and Staubach, 2013: 38). Skills renewal was expected of both nursing and medical staff (Hurford, 2013: 26; Ehrhardt and Staubach, 2013: 38).

A customised program may not work in every setting. In looking at nurse-administered sedation in the cardiac catheterisation laboratory (CCL), Conway et al (2011, 1021) also identified that educating CCL staff to an advanced practice level and assessing their competence arguably assisted in a lower complication rate – indeed their specialised skill set, combined with vigilance is fundamental in non-anaesthetist sedation to ensure patient safety. However, Conway et al (2011: 1022) argued that instead of relying on individual institutions, there needs to be a standardised set of educational objectives.

It is not just pharmacology, sedation administration and airway skills that make up the skill set for procedural sedation – patient monitoring is also critical for patient safety.

Although most standards outline the minimum necessary monitoring requirements, including heart rate and pulse oximetry, Waugh et al (2011: 194) noted that these requirements can often be non-specific. Irrespective of the monitoring equipment used, Maurer et al (2010: 89) emphasised that this aspect of the procedure must be closely considered and addressed and the staff responsible for monitoring the patient must be appropriately trained and have access to the right equipment.

One area of discussion throughout the literature related to the use of capnography. A number of studies found that adverse respiratory events were more likely to be captured with the presence of capnography monitoring and that it was more accurate than oximetry in detecting adverse changes relating to ventilation (Waugh et al, 2011: 192-194; Heuss et al, 2012: 509; Maurer et al, 2010: 88). Waugh et al (2011: 194) emphasised that both methods should be used. Although most studies were done in the endoscopy and emergency setting, it was suggested it should be used in other procedural disciplines as well (Metzner and Domino, 2010: 529; Conway et al, 2011, 1017, 1019-21). In the Australian context, ANZCA states in PS09 that capnography may be required depending on the clinical status of the patient (2010: 7-8).

One area of weakness identified across the literature related to audit and data. Although the risks and adverse outcomes of operating rooms are well documented, this is less true for sedation-related morbidity and mortality, especially respiratory depression, in the non-theatre setting (Metzner and Domino, 2010: 524).

In response to discoveries of poor auditing practice within their own facility, Ehrhardt and Staubach (2013: 39) outlined how requirements to audit at least 10% of all cases of procedural sedation were built into the local policy. Until that time data on procedural sedation had not been collected at an organisational level. Since the introduction of this requirement, regular reporting has occurred and complications and use of reversal agents are reviewed to ensure practice complied with the relevant standards (Ehrhardt and Staubach, 2013: 41).

In addressing safe sedation practice, oversight is crucial and all services must be organised under the direction of someone qualified (who does not necessarily need to be an anaesthetist) (Hurford, 2013: 24). Hurford (2013: 25) identified that there was need to create an oversight committee that met the needs of busy clinicians and engaged medical directors as issues arose that involved their units specifically. Ultimately, to be successful, the safe sedation process needed to be owned by the staff (Hurford, 2013: 25).

## **5. NSW Health – Data Review**

Within the NSW Health system, a number of potential sources of data were identified for investigation, including inpatient data, the Incident Information Management System (IIMS), Health Care Complaints Commission (HCCC), Special Committee Investigating Deaths Under Anaesthesia and Sedation (SCIDUA) and hospital pharmacy data. Finding usable, relevant data proved difficult and on the whole, the numbers of reported incidents were quite low.

### **5.1 Incident Information Management System**

Following an initial key word search and subsequent reviews, 68 relevant IIMS reports from 2011/12 were identified and analysed. A number of key themes were identified and the

incidents ranged across a significant number of hospital (and non-hospital) services. The key themes included:

- **Administration** incidents – e.g. where drug protocols were not followed or staff made errors in administering the agent
- **Dosage** incidents – e.g. wrong dose or wrong concentration used
- **Assessment** incidents – e.g. sedation was administered without an assessment or patient sedated despite their level of risk
- **Medication** errors – e.g. incorrect agent was prescribed or administered.
- **Under Reporting** - A significant aspect of the IIMS review was that over sedation of patients was not generally reported unless this led to a sentinel event. The only mention of over sedation was related to a medication error and not the over sedation.

## 5.2 Other sources

Data was provided by the Health Care Complaints Commission for the 2011/12 year in which they received and reviewed 14 complaints. Most cases related to patient complaints of under sedation during a procedure. One complaint related to the lack of appropriate sedation staff members in the procedure room.

The Special Committee Investigating Deaths Under Anaesthesia provided feedback that there have been 13 notifications of a death under, as a result of, or within 24 hours following sedation. This data dates from September 2012 when the Public Health Act 2010 came into effect. No data was available regarding the practitioners involved – in other words, whether these reportable incidents involved anaesthetist or non-anaesthetist practitioners.

Using their local IIMS system, one hospital pharmacy department reviewed how many incidents had been reported to IIMS regarding the use of reversal agents as a result of over sedation – in a time period of 2011 to present, there were four.

## 5.3 Conclusions

Overall, the availability of useable data was suboptimal. It appears that adverse events relating to sedation care (either under or over sedation) are often not related to the procedural sedation itself or otherwise are not considered “adverse events”. This raises several questions about the perceived ‘normality’ of this practice, reporting culture and how the system defines an adverse event.

These issues, challenges and questions are not isolated to the NSW Health system. Numerous studies summarised in the international literature have identified data quality as an area of concern.

# 6. The NSW Health Experience

## 6.1 Context – the four services

In NSW Health, there are a range of procedures undertaken across the four services that may involve the use of procedural sedation:

- **Radiology** – interventional and non interventional including MRI, CT, angiography and fluoroscopy.

- **Gastroenterology** – colonoscopy, upper GI endoscopy, endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP).
- **Respiratory** – bronchoscopy and endobronchial ultrasound (EBUS).
- **Cardiology** – transoesophageal echocardiography (TOE), coronary angiography, angioplasty, device implants, cardioversions.

## 6.2 Key Themes

The qualitative results of the site visits have been categorised into themes and separated into two groups – issues and barriers/enablers. Although many services have well developed processes, these themes were identified by services as the areas of significant variation or concern.

### PS09 – Is it appropriate for the NSW Health context?

Throughout the diagnostic, the project team sought feedback on applicability of PS09. Although there was good awareness of the guideline and the principles broadly supported, there were a number of concerns including:

- It is difficult to implement/apply as it is too long and detailed
- Interaction with other professional guidelines can be complex
- Proceduralist discontent with PS09 due to a lack of (perceived) consultation with professional groups/societies
- Does not cover nurse administered sedation

PS09 does not acknowledge the challenges of providing a service in the public health system, particularly in rural and regional areas. It also does not cover all relevant specialties and there has been limited engagement from ANZCA in seeking LHDs Executive support.

### 6.2.1 Key Issues

The key issues have been listed in the order in which they have been prioritised by the Safe Sedation Working Group.

#### 1. Patient Triage / Risk Assessment

It was emphasised that patients should be afforded the same standard of risk assessment as those being admitted for surgery. Although most services have triage processes in place, these are generally ad hoc. Challenges relating to patient assessment include:

- Often no checklists/questionnaires for staff to use
- Lack of resources (e.g. staff time) to undertake screening prior to on the day
- Limited (or no) access to the pre-anaesthetic clinic (particularly relevant in rural areas - ? role for telehealth)
- No clear parameters on which patients should be referred to the pre-anaesthetic clinic
- Differences between outpatient and inpatient processes: assessment of outpatients is usually started by the proceduralist but inpatients can often be limited to an informal discussion with the referring team. On the day, the review of patient status is largely left to unit nurses to determine.
- Patients, especially those with complex co-morbidities, are frequently reviewed on the day – this can sometimes mean failed/cancelled procedures.

- Accessing ad hoc anaesthetic support on the day can be difficult as services “go in the queue” and it can lead to procedure delays.

In contrast, many units have developed comprehensive processes for patient assessment. In one cardiology unit, nursing resources are available to call each patient prior to the day of procedure and run through a pre-procedure checklist. If necessary, they can then refer the patient for anaesthetic review. This process is supported by an education and competency package. The process has been successfully used for a number of years and ensures a low cancellation rate. Informal discussion, ad hoc arrangements and more formalised plans arising from clinical incidents is a common thread with many rural services.

## 2. Pharmacology Awareness

Across units and services, there was variation in dosage and method of administration (Midazolam and Fentanyl were the agents of choice by the units surveyed. Only one unit uses Propofol). Limited knowledge of the sedative agents and reversal agents were listed as a key priority and the need for education was highlighted by a majority of surveyed units. This has been supported by patient feedback relating to under sedation. Data (IIMS) also indicated that adverse events relating to over sedation do occur, although most units reported infrequent/rare use of reversal agents.

Some LHDs and/or hospitals have taken steps to develop specific education programs or provide resources that outline key information on the relevant sedative medications.

## 3. Airway Skills

Further to this, consistent access, completion and renewal of relevant airway skills was emphasised as fundamental. Indeed, airway and resuscitation skills are mandated for all NSW Health clinical staff under PD2005\_083.

Generally, there were concerns over a lack of continuity as to who has what airway skills – in particular, the skills [or lack thereof] of experienced procedural staff were raised.

Feedback was also provided that there needs to be education on “triggers for action during a procedure and that this should be taught as part of a learning package and/or listed on forms/tools used during the procedure.

Again, some or hospitals have identified local options for ensuring staff have the relevant skills. For example, in one LHD, an online education program (with practical skills) has been developed that addresses basic principles of safe sedation, pharmacology and airway skills and is applicable across all relevant specialties. In some circumstances hospitals or individual units have developed more specific education programs or competency packages which meet the need of the specific discipline. In one hospital, the Department of Anaesthesia has taken over a unit specific program and broadened it for applicability to other units.

## 4. Monitoring

There is generally good access to and use of monitoring equipment during procedures. There are issues in accessing training in using this equipment and it was queried whether monitoring equipment should be standardised.

One particular challenge with monitoring related to staffing – in other words, **who** should be the clinician airway monitor and what other roles are they playing during the procedure. In providing feedback on this issue, units reported that:

- Staff resources/time can be limited – some units cannot always have a dedicated monitor (the number of staff in the room is often dictated by the type of procedure being undertaken).
- Sometimes one staff member is expected to have multiple roles concurrently.
- Staff often have to be pulled from “elsewhere” to be the monitor
- As the complexity of a procedure increases, proceduralists do not want to be left managing all aspects of the procedure and the sedation – i.e. staffing needs to match the procedure.

It was queried whether monitoring should “be everyone in the room’s responsibility”?

#### 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. As such, the project team sought information on what resources and processes units had in place to manage these situations when they arise. In discussing this, some clinical staff reported that they have been in situations where they were expected to manage issues that they felt were beyond their skill level.

On the whole there was variation across services and LHDs and the escalation plan included options such as:

- Managed by the proceduralist
- MET/PACE/RRT calls
- Anaesthetics (or ICU) are based nearby and can offer timely support

However, some units reported that they do not sit within their hospital’s MET/PACE area and must rely on their own skills. One large anaesthetics department noted that in the event of an emergency they are always able to provide support, but this may not be the case in smaller metropolitan or rural hospitals where there are not as many resources.

#### 6. Recovery

Overall, 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). There is often limited supervision of patients due to staffing challenges and indeed one service reported that they often rely on their recovery nurse to come into the procedure room as the clinician airway monitor. It was also noted that the physical environment often provides a significant difference for the service in managing patient recovery.

#### 7. Discharge

As with recovery, there are limited formal processes and tools in managing this phase of the patient journey. Most services keep patients for a minimum period of time (four hours) until their condition meets certain parameters they will not be released without an escort home.

There is also limited post-discharge follow up and use of post procedure patient surveys. Those services that have implemented this process highlighted it as a key audit tool for the unit. Travel is an ongoing issue in rural areas with no access to trains, buses, cabs, etc – there is a reliance on community transport services which are limited and may or may not be

available. The escorts in this instance are usually older able bodied retirees who adopt a 'duty of care' for what can be quite a long journey. Elderly people who live alone are often deemed at risk, which necessitates their hospitalization overnight for some minor procedures.

Another key issue in rural communities is the lack of medication or scripts dispensed with the patient on discharge following some procedures e.g. analgesia, which sees them re-present at the local health facility afterhours for assessment and treatment by a GP/VMO.

## **6.2.2 Barriers and Enablers**

### Governance Arrangements

Largely, there are limited formal governance arrangements for sedation practice within hospitals – most services rely on accepted informal processes and clinical pathways within their departments. Governance varies across LHDs (and even within LHDs and hospitals) – and may include Clinical Governance, Anaesthetics or Divisions of Medicine, Surgery (or other relevant service). It is important to note that many Departments of Anaesthesia do not have an oversight role in the hospital's sedation care.

However, 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. One LHD appointed a multi-specialty, multi-disciplinary committee to develop a local policy and education program. This process has allowed engagement with all key groups which has helped with acceptance and uptake of requirements for safe sedation.

### Access to Anaesthetic Support

Although there is some reticence from anaesthetic services, procedural units generally reported good relationships with and support from their Departments of Anaesthesia. The greatest 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. Rural services reported that they frequently rely on goodwill from their anaesthetic services just to be able to provide a service (and the Department of Anaesthesia is often stretched to capacity themselves).

Other concerns relating to access to anaesthetic support included:

- Where sedation support is provided by Departments of Anaesthesia it may lead to a skills vacuum for procedural advanced trainees (this was raised in a service where sedation care has returned to being fully supported by Anaesthetic services).
- Some large hospitals report that there is a culture where "anaesthesia support is readily available so there is less need for procedural staff to have airway skills"
- Funding for Anaesthetic services to cover all procedures
- Anaesthetic advanced trainees supervising sedation in procedural rooms – who is supervising the trainee?

### Formalised Training and Access

There is significant variation in available skills training and education programs – this includes what training is available to staff, who the training provider is, who is accessing the

training and whether it is didactic or practical training (or a mixture of the both). Other issues include:

- Who has what skills? Which staff are skilled/unskilled and how can this be known and staff assigned tasks appropriate to their skill level?
- Level/type of training does not necessarily match the sedation undertaken or the role that the staff member needs to perform
- Concern that some training programs over simplify a complex process
- Even where training programs exist, additional training was suggested as the practical often “falls short”
- Format of education programs must meet the need – in other words, online learning
- How can we ensure access and should there be a requirement to participate in assessment and competency based learning (credentialing)

In addition to challenges with existing programs, there are a number of services that reported that they struggle to access training at all. In providing this feedback, a number of matters were raised for consideration:

- Some skills cannot be adequately practiced or kept up to date once they are acquired (e.g. airway skills)
- How often should skills be renewed/checked etc?
- There is a culture of relying on “on the job” training
- Lack of medical practitioner (proceduralist/surgeon) “buy in” to sedation training programs/processes/policies

In some circumstances, these challenges have been addressed by formalising the education programs at a hospital or LHD level. This has allowed governance structures to be used to support the education program.

### Audit and Review

Audit and review has capacity for improvement. Although many units reported use of the IIMS system and regular discussion at local MDT or M&M meetings, there is seemingly a culture of under reporting for adverse events/critical incidents. This was also highlighted in the review of IIMS reports. It could be that adverse events that may relate to sedation care are not viewed or defined as such. On the other hand, some services, particularly radiology reported that due to the nature of the service, the feedback loop is limited and therefore audit is difficult to undertake.

Although there has been some patient feedback due to under sedation, one unit identified that this could be due to a lack of understanding of what is meant by *conscious sedation*.

## 7. Next Steps and Solution Design

The key issues and barriers/enablers were presented to the Safe Sedation Working Group for discussion. The group reviewed the information and developed a list of priorities for action (which are reflected by the order in which the issues are outlined in section six).

As a next step, on 13 August 2013, a workshop was held for members of the working group to identify potential solutions. In order to maximise output from the workshop, four of the identified issues were explored in more detail:

- Patient Management
- Monitoring Standards Post Procedure
- Safe Drug Delivery
- Governance of Safe Procedural Sedation

A range of brainstorming techniques were used to facilitate broad discussion and stimulate new ideas. The results of the solution design workshop are outlined below under each issue heading. These suggestions reflect the discussion at the workshop and are not necessarily recommended solutions.

### 7.1 Patient monitoring (during the procedure)

In considering this issue participants were asked to consider the skills required, governance, equipment, monitoring and escalation. The suggested solutions focussed predominantly on the skill set of the various team members, particularly the clinician airway monitor, but also addressed aspects of local process and governance.

- Pre procedure assessment of the patient by an appropriate person with the intention of triaging patients appropriately for sedation.
- Adequate resuscitation and airway skills
- Ensuring patients are appropriately monitored (at an appropriate level for the sedation) and including as a minimum pulse oximetry, cardiac monitoring and blood pressure.
- Designated and dedicated, trained clinician who has the appropriate skill level to monitor the patient's airway and vitals – doctor or nurse – and to respond to the monitoring (as needed).
- Credentialing process for dedicated and designated “clinician airway monitor”.
- Role awareness particularly about the “monitor” by all in room and a culture of respecting that role. In other words, not expecting them to take on other roles/tasks.
- Person present with skills to identify and manage an obstructed airway and bag mask ventilate

### 7.2 Monitoring standards post procedure

In considering this issue participants were asked to consider the skill set and processes for post procedure monitoring, including recovery and discharge. The suggestions largely focussed on the physical environment as well as clear processes and tools to guide the post procedure process.

- Post procedure monitoring must be defined by the pre procedure assessment – in other words, more complex patients require closer and more skilled post procedure monitoring. Each patient's care needs to be planned ahead so that it can be individualised.

- There needs to be “actual” monitoring during the post procedure phase with continuous monitoring of the patient’s vital signs.
- The patient needs to be recovered in a safe physical environment that:
  - Is in an appropriate location
  - Includes close access to the equipment including suction and airway equipment
  - Includes ability to call for help/escalate – ie PACE/MET call button.
  - Is in close proximity to the procedure room and proceduralist
- Standards for recovery areas should cover all recovery areas in the hospital equally.
- There needs to be an explicit identification of the recovery phase. This needs to include recovery and discharge criteria and a clear handover of care. Nursing staff should not accept the patient if they are not comfortable.
- Need to keep patient with skilled staff – recovery staff need skills and awareness to match the patient’s needs. Staff also need to have the ability to critically analyse monitoring data and respond appropriately.
- Discharge criteria – expand on ‘awake’ in context of reversal agents and co-morbidities. Non-anaesthetists should have different criteria that need to be met.
- Need to ensure the patient has a safe environment to be discharged to – i.e. sent home with a responsible adult, or if this is not an option, should remain under the care of staff until such time as they are deemed able to be discharged safely as per appropriate criteria.

### **7.3 Safe drug delivery**

The participants were asked to think more critically regarding the pharmacological aspects of the patient journey, particularly in regards to specific sedative agents and delivery as well as staff training and accreditation. A number of solutions also related to process aspects of the patient journey.

- Pharmacological knowledge – this should include half life of sedative agents and the relevant antidotes. A knowledge test on basic drug information including sedative and reversal agents to be completed each year (ideally online).
- Access to simulation lab to practice scenarios with the team, including complications.
- Mandatory training/accreditation in order to be allowed to administer sedation.
- Cheat sheet/one pager on all common sedative drugs, interactions, contraindications and reversal agents that is readily available in the “sedation environment”.
- While Propofol would be the most appropriate choice for many patients, its use would depend on the experience and skill set of the clinician prescribing and using it. There needs to be a range of drugs available to suit the full range of patients and the variation in skill level of the clinician administering the sedation.
- Patient should always be assessed for suitability to be sedated.
- It should be a single person managing drug administration, monitoring and airway management. This would allow for a “closed loop”.
- Support and engagement with rescue team and understanding who they are – ICU, ED, Anaesthetics?
- Possibly a roaming/mobile sedation team to cover the hospital/facility.
- Governance around the use of the pharmaceutical agents. For example, audit of reversal agents - high use could be used as a global trigger tool.

### **7.4 Governance of safe procedural sedation**

The participants were asked to consider potential governance arrangements including the key stakeholders, how it should be structured and what the outcomes should be. Following

the brainstorming, the group looked at the issue of governance in more detail with a view to exploring strategies in more detail whilst also acknowledging the key barriers.

#### 7.4.1 Governance Arrangements

- Every patient should receive the same standard of care – “treated as a VIP” – need to address the current inequities of service/experience between public/private/rural/metropolitan.
- Consultation with consumers and non-anaesthetist clinicians – ask them what they need. After all, they are the key stakeholders. All parties/perspectives need to be considered and “given a seat at the table”.
- Keep it simple and avoid unnecessary risk – single point of accountability but a group approach to governance/ownership for each group (proceduralists, nurses, patients). In other words, consistent leadership and roles.
- Overall, clinicians need to see the benefit in changes in sedation policy/practice – that it is about improving the standard of sedation care and not just “changing for change sake”. Therefore, recommendations need to be evidence based and underpinned by data that supports improving clinical experience and outcomes.
- Guidelines/policy must meet the need or people are forced to go outside them
- There needs to be a governing body for each hospital and a statewide body to oversee audits and outcomes.
- There also needs to be a designated person in each unit who takes responsibility for staff accessing training, staff awareness, communication (both up and down).
- Criteria/accreditation/minimum standards of care
- Hospital/LHD management must be engaged in supporting safe sedation care.
- There needs to be flexibility in governance – sedation group to provide oversight and middle layer between managers and clinicians.
- Access to a clinician with a higher level of skill to resuscitate if needed e.g. intubation
- The local process should be well understood and should include how to deal with sedation further along the continuum.
- Equipment maintenance including a checklist and someone to take responsibility for the process of checking the equipment.
- Leadership and governance and accountability for delivery of sedation service
- An evaluation and audit process.
- Human resources – in other words, there needs to be enough staff to fulfil these key roles. Operating theatres abide by ACORN, but there does not appear to be an equivalent standard which is adhered to for sedation.

In addition, there were also a number of suggestions relating to technology and resources:

- Smart phones – use app technology for monitoring. Standards set on the device to alarm when vitals are outside parameters. Data could also be downloaded centrally to allow data collecting on the service as a whole.
- Check lists for each stage of the patient journey
- Easily accessible cheat sheets

The group identified that achieving the buy in of key stakeholders who provide sedation locally is fundamental to identifying and implementing solutions relating to governance. This could be achieved by:

- Gaining consensus on statewide minimum standards
- Including local facility providers of sedation in a state level governance group.
- Seeking executive leadership and heads of department buy in

- Asking each specialty to nominate a representative - ideally this would be a doctor, nurse and manager for each department. This should also be a role for trainees. This will ensure the message crosses all relevant specialties and staff.
- Engaging those who work predominantly in private who may not necessarily be interested/understand the local processes in the public hospital.
- Identifying local clinical champions who can be drivers for change.
- Engaging the professional Colleges as they set the professional standards for each craft group.
- Recording and maintaining accreditation and skill maintenance of relevant staff.
- Learning the lessons of previous projects e.g. Time out. Ideally, Safe Sedation to have similar profile and acceptance.
- Using a range of levers to support change – including policy, accountability structure, paying staff, job descriptions and accreditation.
- Key performance indicators – clinical indicators could be identified and reported against
- AHPRA – PS09 endorsement

#### 7.4.2 Barriers

In discussing the potential solutions, the group was also asked to identify those key barriers they felt would need to be acknowledged and addressed:

- VMO workforce – the public hospital is not necessarily their main focus, time, or interest.
- Staff across NSW Health are still not convinced that sedation (outside of theatres) can be dangerous. Awareness is a key barrier.
- Sensitivity – clinicians and other staff do not have the impression that they are not doing it the right way – cultural change and getting people to change is difficult.
- Anaesthetic Departments – some have a lack of capacity or a lack of willingness to support units – getting them on board is a challenge.
- Financial – human resources to support safe sedation, as well as monitoring equipment.
- Marketing to managers and executive leadership teams.

## 8. Recommendations

It is recommended that:

- A guideline and accompanying toolkit be developed as part of the process for implementing solutions to support safe procedural sedation practice across NSW public hospitals.
- The guideline and toolkit provide guidance on safe sedation processes for each stage of the patient journey and include:
  - Minimum standards for safe procedural sedation
  - Checklists for each aspect of the patient journey e.g.:
    - Pre procedure assessment
    - Monitoring requirements including necessary staff skill sets
    - “Red flags” during the procedure.
  - Examples of resources from existing radiology, respiratory, cardiology and gastroenterology units.
  - Links to key references e.g. PS09, Between the Flags etc.
  - Education and skills competencies (minimum and/or recommended requirements).
  - Links to existing education programs that meet the necessary standard.
  - Example audit tool and recommended audit process.
  - Proposed governance structures (for hospitals/LHDs/NSW Health).

- The role (if any) of the ACI Safe Sedation Working Group.
- The ACI should also investigate the feasibility of a policy directive to underpin the guideline and toolkit.

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## 10. Consultation List

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- Northern NSW LHD
- Northern Sydney LHD
- South Eastern Sydney LHD
- St Vincent's Health Network
- Sydney LHD
- Western Sydney LHD