Sedation Safety

in CCLHD Endoscopy Units

Learning package for Registered Nurses

PREREQUISITES FOR SUCCESSFULLY UNDERTAKING THE SEDATION SAFETY LEARNING PACKAGE

1. All participants must be registered nurses with at least 6 months post qualification experience.
2. Each participant must work in an area where there is a clinical need for this skill.
3. Participants must be accredited to administer intravenous medications.
4. Participants must be currently accredited in basic life support.

The learning package is a mixture of reading material and self-directed learning activities. The activities relate theoretical concepts to real life situations that you may encounter in your clinical practice. By working through the activities you will have the opportunity to consolidate your understanding of sedation safety, and related concepts such as patient assessment and monitoring which will improve your nursing practice.

Completion of this learning package will aid you in your clinical decision making in the workplace. If you need further assistance please seek out your Clinical Nurse Educator /Specialist, Clinical Nurse Consultant or Nurse Unit Manager.

DISCLAIMER

The contents of this package relate to the nursing care of adult patients only.

AIMS /EXPECTED LEARNING OUTCOMES

This learning package aims to enhance the clinical knowledge base and decision-making skills of registered nurses. This package aims to develop their management of the person who is undergoing a procedure either in a ward, speciality unit or dept utilising sedation (sometimes referred to as procedural sedation or 'conscious sedation').

On successful completion of this learning package, it is anticipated that the registered nurse will be able to[1]:

- Identify what equipment, is required before commencement of the procedure;
- Safely administer intravenous sedation agents under the direct supervision of the proceduralist

INTRODUCTION / BACKGROUND

A 2004 report in the United Kingdom (UK) by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), "Scoping our Practice" [2], found that there had been 1,818 deaths after therapeutic GI endoscopic procedures. NCEPOD advisors judged that the sedation given was inappropriate in 14% of cases, usually because an overdose of medications had been administered.

In the UK this has led to several recommendations that sedation and monitoring practices in endoscopy units should be audited and reviewed. That there should be national guidelines on the frequency and method of the recording of vital signs during the endoscopy and clear protocols for the administration of sedation should be available.

In the US over the last 15 years, it has become widely known that the administration of sedatives and analgesics for performance of procedures is a significant independent risk factor for morbidity and mortality both inside and outside the operating room[3]. Consequently, the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has recognized that inconsistent standards of care adversely affect patient safety and released the 'comparable care mandate" i.e. that there must be no decrease in the care delivered to patients during their entire continuum of care within the hospital.

In Australia the standards concerning administration of sedation in Australia are the Australian and New Zealand College of Anaesthetists (ANZCA) PS9: '*Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical or Surgical Procedures'*. [4] Sedation safety is a growing contemporary health care issue in Australia.

During the last decade there has been a movement of many patient procedures from the operating room to ambulatory care settings, -called the "out-patient revolution". Registered Nurses are finding their role expanding as the emphasis on minimally invasive procedures increases.

In the contemporary workplace Registered Nurses can be required to administer intravenous sedation for unpleasant procedures in a wide range of clinical areas. This is often with varying degrees of training in sedation. Intravenous sedation is potentially hazardous, as there is always the potential for patients to slip into deeper sedation than planned therefore it is important that is performed as safely as possible.

NURSING SCOPE OF PRACTICE IN SEDATION

Registered Nurses administering intravenous sedation for procedures are considered to do so under the direct supervision of the proceduralist. The Registered Nurse administers only non-anaesthetic inducing medication's for conscious sedation, unless they work in CCH critical care areas and have undertaken specialist accreditation. [5]

The Registered Nurse who is deemed independent in competency based assessment or demonstrates recognition of prior learning / experience of monitoring patients (in a critical care environment such as ICU /HDU/CCU, ED or theatres) who have undergone sedation can assist the medical officer in the sedation procedure. Assistance can be given by performing the monitor role or as an assistant to either the proceduralist or to the clinician (nursing or medical) attending the monitor role.

The sole monitoring of sedated patient is considered beyond the scope of practice of the endorsed enrolled nurse. There are several reasons for this: the extent of their educational preparation, the acuity of the sedated person, the amount of clinical judgement/ the level of technical skill required in sedation monitoring, the degree of registered nurse direction and supervision available, and the legislation in NSW which does not allow the enrolled nurse to administer schedule 8 medications.

WHAT IS CONSCIOUS /PROCEDURAL SEDATION?

Conscious Sedation (sometimes referred to as 'Procedural or Moderate Sedation/Analgesia'") has been defined as: "A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained"[6].

ENVIRONMENT FOR SEDATION

The staff and equipment to initiate rescue measures should be immediately available

due to the unpredictable nature of sedation and individual responses to it, a deeper level of sedation should always be anticipated. The location, in which the patient is having the procedure and sedation, must be appropriately sized to allow for resuscitation if needed, and **must** be equipped with the following [4]:

- Adequate lighting and floor space to be appropriate for resuscitation if needed
- An adequate oxygen supply with suitable devices for means of delivering oxygen to a spontaneously breathing patient
- Functional suction supply and suction equipment
- Pulse oximeter with audible alarms
- Non invasive Blood pressure monitor
- A means of summoning hospitals medical emergency team (MET) by phoning 77 (excluding emergency depts)
- Emergency electricity supply

And **must** have:

- Drugs for the reversal of benzodiazepines and opioids
- Ready access to an ECG Monitor
- Ready access to a hospital standard resuscitation trolley with a defibrillator and a positive pressure breathing device

The following **should** be available within the facility [4]:

- End tidal carbon dioxide monitoring (capnography)

ACTIVITY 1

Read: Australian and New Zealand College of Anaesthetists PS9: '*Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical or Surgical Procedures***.**

Then complete the table below:

SUGGESTED EQUIPMENT FOR PROCEDURAL SEDATION AND ANALGESIA	
EQUIPMENT	**RATIONALE**
High-flow oxygen source	
Suction source with large-bore catheters	
Intravenous access equipment	
Airway-management equipment	
Monitoring equipment	
Pulse oximeter	
Blood pressure	
Resuscitation drugs	
Reversal agents (appropriate to drugs being used*)	
Adequate staff for monitoring and documentation	How many staff?
Electrocardiography	
Capnography	

Table 1.Suggested equipment for sedation procedures

STAFFING FOR SEDATION

The ANZCA PS9 describes a minimum standard for staffing during sedation assisted invasive procedures. Having now read the document, please reflect and complete the questions in the activity below.

ACTIVITY 2

1) When administering procedural sedation how many appropriately trained staff should be present?

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2) Define each staff member's role.

PRE-SEDATION: PATIENT ASSESSMENT

Patients must be assessed by the medical officer as to whether they are suitable to receive intravenous sedation. Sedation should be avoided or used with extreme caution if the patient cannot lie flat or if the patient is breathless at rest. The medical officer as part of the patient assessment will consider the following factors in the pre-procedure period [4,6,7].

SEDATION RISK FACTORS[7]:	
Advanced age	• Sedation in the elderly involves additional hazards compared with sedation in younger adults. • A good history of the patient's functionality is required in order to make an accurate assessment of risk. • A reduced dosage of sedative drugs is recommended.
Airway	• Mouth opening< 2 finger breadths • Bull neck • Receding chin • Buck teeth
Adequate Fasting As a guide:	• Food within the last six hours • Clear fluids with the last four hours ***N.B. please refer to unit based protocols for fasting instructions***
Cardiovascular	• Unstable angina • Symptomatic heart failure • Aortic Stenosis • Haemodynamically unstable
Gastrointestinal	• Significant gastro-oesophageal reflux • Morbid obesity
Medication / Allergy risks	• Known drug allergy • Previous adverse reaction to sedation /anaesthesia • List of medications taken- including herbs or alternative medications
Respiratory	• Unable to maintain Sa02>95% with 02 6lts via face mask prior to sedation • Unable to lie flat (on one pillow) • Upper airway obstruction
Renal	• Renal impairment sufficient to interfere with drug clearance

Table 2.Sedation risk factors

Based on the information gained in the initial patient assessment the American Society of Anaesthesiology (ASA) patient classification status[7] (table 3) is often used as a guide by medical officers as to whether patient should have sedation by a proceduralist or whether an anaesthetist should be present.

ASA Classification of Patient	Comments	Medical Description
P 1	No known systemic disease A normal healthy patient	May have conscious sedation without other consultation
P 2	Mild or well-controlled systemic disease	
P 3	Multiple or moderate controlled systemic disease(s)	
P 4	Poorly controlled systemic diseases(s) that is a constant threat to life	Mandatory involvement of anaesthesiology department
P 5	Moribund patient who is not expected to survive without the operation	
E	Patient requires emergency procedure	

Table 3. American Society of Anaesthesiology patient classification status[7,8]

FOCUSED PATIENT ASSESSMENT: AIRWAY

Fig.1. Risky airway?

Airway obstruction is a major concern because it is perhaps the chief cause of respiratory adverse events that occur during sedation. Identification of patients who are likely to suffer airway obstruction is an essential part of the pre-procedure care.

Mask-ventilation is a primary rescue action when serious, life-threatening airway obstruction or respiratory depression is encountered. Across the literature, few studies evaluate factors contributing to difficult mask-ventilation. However, several risk factors for predicting difficult mask ventilation have been identified. [, 10]:

These include[, 10]

- High body mass index (BMI) (> 26 kg/m^2);
- Presence of a beard;
- Lack of teeth;
- Age older than 55 years
- History of snoring

The patient undergoing conscious sedation should have a thorough airway assessment focusing on[, 10]:

- airway class
- mouth opening
- thyromental distance (distance from chin to thyroid)
- range of motion of the neck

Analysing all of these factors will enable an assessment as to whether it is safe to continue with conscious / procedural sedation.

Airway Class[, 10]

Class I = visualization of the soft palate, fauces, uvula, anterior and posterior pillars.
Class II = visualization of the soft palate, fauces and uvula.
Class III = visualization of the soft palate and the base of the uvula.
Class IV = soft palate is not visible at all.

To perform the Mallampati examination, the provider has the patient sit facing the examiner and asks the patient to open the mouth as wide as possible. The patient is classified as Mallampati I if you can see down to the tonsillar pillars, class II if the examiner can visualize just the full uvula, class III if only the soft palate can be seen, and class IV if the hard palate is all that is visualized.

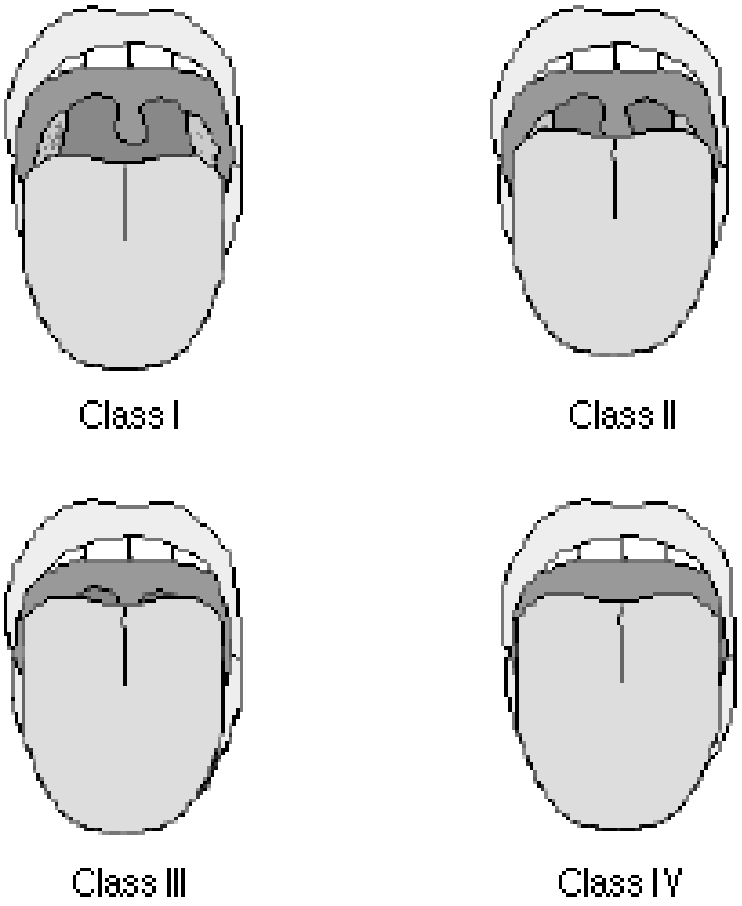


Fig.2.Mallampati classification[11]:

The picture illustrates the Mallampati Classification of airways. In a class one airway the entire uvula and tonsillar pillars are seen. This individual should be easy to mask ventilate or to intubate with a laryngoscope and endotracheal tube. In a Mallampati Class Three airway none of the uvula or tonsillar pillars are seen. This individual may hard to mask ventilate, and quite difficult to intubate. This examination (which classifies the relative size of the tongue in the mouth) may be used as a trigger for referring a patient for "expert" sedation[10]:

Thyromental distance

Fig.2 .Thyromental distance
Image courtesy of Ann Willemsen-Dunlap[12]:

This image is representative of an extremely short thyromental distance. This finding may indicate possible difficulty establishing a satisfactory mask seal, and potential difficulty in tracheal intubation.

MEDICATIONS USED IN SEDATION PROCEDURES:

The medications used during sedation typically have additional beneficial effects, as important as sedation. These actions include the following[13]

- Anxiolysis - Relief of trepidation / agitation with minimal alteration of sensorium
- Amnesia - Lapse in memory for a period of time
- Analgesia - Relief of pain without an altered sensorium

Sedatives typically have more than one of these actions, although one action may be dominant[13]: The ideal sedative would exhibit all of the above qualities; as most do not, it is common practice to co administer medications with different qualities to compensate for any shortcomings.

An example is midazolam which is primarily an anxiolytic with some amnestic qualities and fentanyl primarily an analgesic[13]: When drugs are used together, decreasing the dose of each respective drug is important, as the medications may act synergistically and this will decrease the incidence of side effects.

It is recommended that you familiarise yourself with the prescribing information available for sedation medications used in endoscopic procedures.

COMMON MEDICATIONS USED FOR SEDATION PROCEDURES

ACTIVITY 3:

Read relevant sections in the MIMS and complete the blanks in the common sedation medication table:

COMMON SEDATION MEDICATIONS[14]					
MEDICATION NAME	**DOSING GUIDELINE**	**TYPE OF AGENT**	**ONSET, PEAK EFFECT, AND DURATION OF ACTION**	**ADVERSE DRUG REACTIONS**	**REVERSAL**
Midazolam			Onset: 1- 3 min Peak Effect: 5 -7 min Duration of Action: 20 - 30 min		
Lignocaine spray					
Naloxone					
Pethidine					
Fentanyl		Opiate			
Flumazenil					

Table 4.Common sedation medications

SAFE MEDICATION USE - PEARLS FOR PRACTICE (courtesy of Ann Willemsen-Dunlap) [12]

- Drugs administered for conscious sedation should allow a patient to be calm, comfortable and cooperative.
- Clinical endpoints for conscious sedation may include a respiratory rate of 10-12 in an adult and a slurring of speech.
- A drug should be allowed to exert its full effect before administering additional doses or another drug.
- When combining opioids and sedatives, administer the opioids first to ensure the patient receives analgesia prior to painful stimulation.

REMEMBER WHAT YOU ARE TRYING TO ACHIEVE:

- ☑ Analgesia
- ☑ Amnesia
- ☑ Cooperation
- ☑ Maintenance of all protective reflexes
- ☑ Safety

CLINICAL MONITORING

Patients receiving procedural sedation require continuous monitoring and assessment throughout the procedure and the recovery phase. The patient must have supplemental oxygen in place both during the procedure and in the post procedure phase [4]. Oxygen saturations should be as close as possible to 100% throughout the procedure.

ACTIVITY 4

The ANZCA PS9 describes a minimum standard for staffing during sedation assisted invasive procedures. Having now read the document, please reflect and complete the questions in the activity below.

1. Document below the minium requirement of monitoring is for sedation procedures in CCLHD endoscopy units.

_____
_____
_____
_____

2. What other types of monitoring may be considered for higher risk patients for example with known cardiovascular or respiratory disease.

_____
_____
_____

ASSESSMENT OF CONCIOUS LEVEL [17]:

Conscious Sedation Scale	Deep Sedation	General Anaesthesia
Due to the unpredictable nature of sedation and individual responses to it a deeper level of sedation should always be anticipated		
• Relaxed • Restful • Drowsy • Appropriate response to commands • Protective reflexes present • Occasional vocalisation • Pulse change <10% • SaO2 change <5%	• Not easily roused • Partial loss of protective reflexes • Partial or complete inability to protect airway (< GCS 9) • No purposeful response to stimuli or commands	• Controlled unconsciousness • Loss of protective reflexes • No response to physical stimuli or verbal command

Table 5.Sedation continuum

MODIFIED RAMSEY SEDATION SCALE[, 8]

The six-category Ramsay scale, developed in the early 1970s. It has faced criticism for being subjective and not the ideal tool for assessing levels of consciousness. However it is considered appropriate for use in areas where sedation / analgesia are used for short term diagnostic and therapeutic procedures[8].

LEVEL OF CONCIOUSNESS / SEDATION SCORE		ASSESSMENT CUES	OTHER ASSESSMENT CLUES
0	No sedation, patient is awake and alert	Patient is alert, responsive and obeys commands.	■ Sedation Level 0 = Patient unimpaired. ■ Sedation Level 1 = slightly decreased level of consciousness and verbal response; no other impairments. ■ Sedation Level 2 = Altered level of consciousness; patient maintains patent airway and haemodynamic performance. ■ Sedation Level 3 = Poorly responsive patient with decreased airway patency and respiratory drive; at risk for compromised cardiovascular performance. Little or no response to painful stimuli; absolute airway compromise; possible impaired haemodynamics. (courtesy of Ann Willemsen-Dunlap) [, 12]
S	Sleepy, but normal to rouse	Patient is sleepy but wakes easily. Opens eyes to speech. Responds to verbal commands.	
1	Mild sedation, occasionally sleepy, easy to rouse	Patient is sleepy but wakes easily. Responds to calling of his /her name loudly.	
2	Moderate sedation, frequently drowsy	Patient is asleep or more heavily sedated. Patient may be snoring. Patient is slow to respond to calling of his /her name loudly. Stimuli may need to be repeated before patient responds.	
3	Severe or deep sedation, somnolent, difficult to rouse	Patient is unresponsive. Patient may be snoring. May not responsive to painful stimuli	

Table 5.Sedationscale and assessment cues

DOCUMENTATION STANDARDS

The clinical record should include the names of staff performing sedation and/or analgesia, with documentation of the history, examination and investigation findings. A written record of the dosages of drugs and the timing of their administration must be kept as a part of the patient's records, on their medication chart,[4,15] including the inspired concentrations of inhalation sedation agents and oxygen and the duration of administration shall be documented [8]. Ideally any sedation activity should be accompanied by a time-based record that includes the name, route, site, time, dosage, and patient effect of administered sedation drugs. Adverse events shall be documented.

Such entries should be made as near the time of administration of the drugs as possible. This record should also note the regular readings from the monitored variables, including those in the recovery phase. [4,15]

RECOVERY FROM SEDATION

Place patient in an appropriate "recovery" position- for some patients this may be lying on left lateral and for others they may be better sitting up, seek advice from proceduralist if unsure.

Oxygenation levels and respiratory rates should be monitored until patients are considered fully recovered from the sedation, (minimum of one hour) but monitoring / close observation may need to continue for up to 2 hrs if the patient is elderly or the patient is slow to recover from the sedation agents[8].

The 'Sedation Period" is considered over when the patient meets the following criteria[7]:

- Aldrete score [(15)] is 8-9 *(this will be explained in discharge instructions section)*
- Fasting status- Unit based protocols will need to be followed for patients who have received local anaesthetic spray to their larynx and / or pharynx to facilitate their procedure.

TROUBLESHOOTING

ACTIVITY 5

Please complete the nursing actions in the table below:

TROUBLESHOOTING GUIDE		
CLINICAL SCENARIO	**VARIABLES**	**NURSING ACTION**
Low blood pressure	Sedation related- medication side effect	
Prolonged or excessive sedation post procedure	Sedation related- this is a high risk time after the stimulus of the procedure is over.	
Respiratory depression e.g. respiratory rate less than 12 during procedure	Over sedation	
Not enough staff available to assist with procedure	Procedure is non urgent	
Patient aggression	Paradoxical reaction to the midazolam	
Equipment failure- O2 sats machine not working	Intra-procedure	
Hypothermia	Post procedure	
Pain	Intra-procedure	
Persistent low oxygen saturations	Intra procedure	
Day case procedure has no way to get home	Patient wants to drive self home	
Failed cannula	Intra procedure	

Table. 7. Sedation troubleshooting

ACTIVITY 6

QUICK QUIZ (CIRCLE YOUR ANSWER)

1) During sedation procedures, which of the following should be immediately available?

a. Defibrillator

b. Intubation equipment

c. Anaesthetist

d. A and B

2) During moderate sedation vital signs must be documented every:

a. Once

b. 10 minutes

c. 30 minutes

d. 5 minutes

3) The following drug is used to reverse midazolam:

a. flumazenil

b. naloxone

c. diphenhydramine

c. ampicillin

4) Moderate Sedation is defined as a drug induced depression of consciousness in which the patient retains the ability to:

a. Maintain spontaneous ventilation

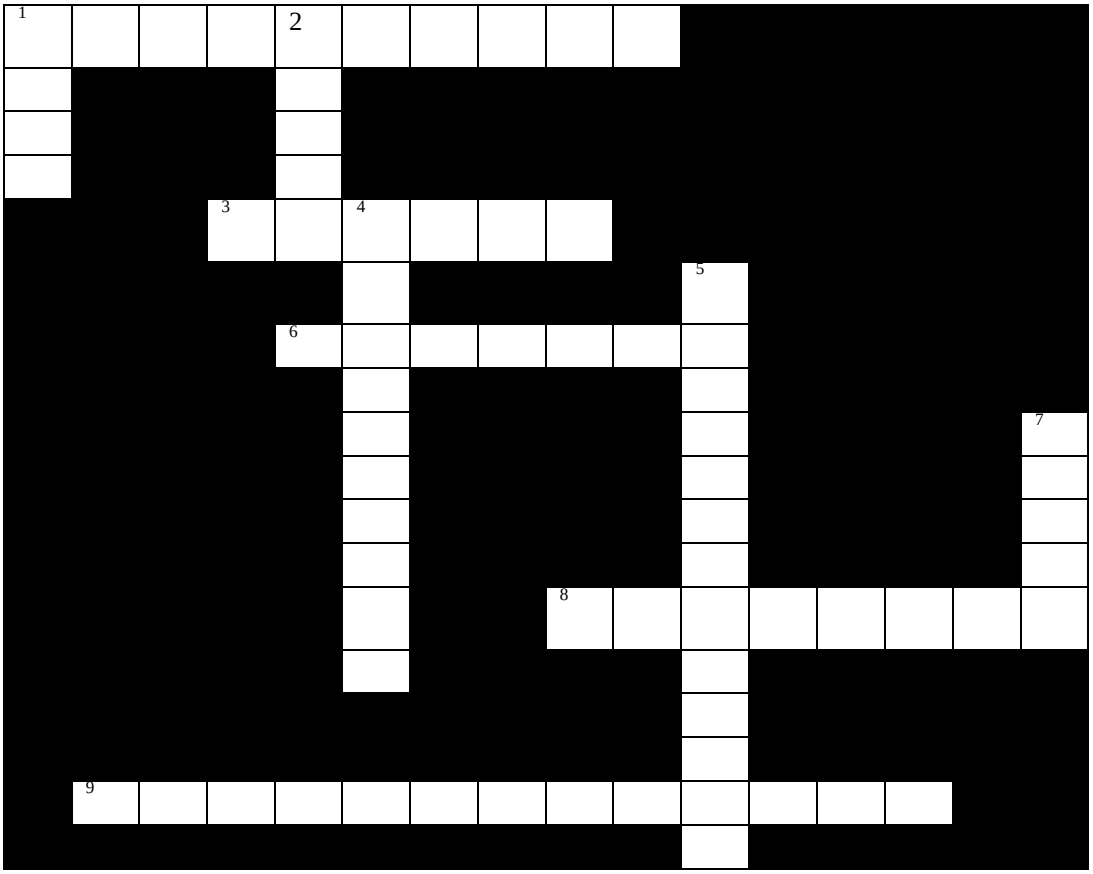
b. Maintain an unobstructed airway

c. Respond purposefully to verbal commands

d. All the above

5) 1 mg. of intravenous midazolam can cause respiratory depression or hypotension in the elderly or compromised patient.

True False



ACROSS

1. Reversal agent for bendzodiazapines
3. Name of CCH sedation scale
6. Recovery assessment scale
8. Reversal agent for opiates
9. Emergency team (2 words)

DOWN

1. Minimum minutely frequency to record vital signs-intraprocedure
2. Governing body for sedation standards in Australia
4. Airway assessment scale
5. Equipment that should be immediately available for sedation procedures
7. Minimum number of staff present for sedation procedures

CONCLUSION[21]

Congratulations on completing this self-directed learning package and evaluation. We trust that this has been a valuable learning experience for you and that it provides you with confidence in providing competent nursing care for those patients receiving procedural/ conscious sedation.

Expectations are that having completed this package and achieving a satisfactory assessment you will maintain a competent standard of nursing practice for yourself and continually review the standard of nursing practice in your unit /ward. Reassessment is by way of ongoing peer review, literature review and reflection on your own practice.

Records will be kept in your Division database.

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Self Directed Learning Program and Materials Evaluation Form

Name……..**Payroll number**……

Hospital……. **Date returned**…… **Minutes to complete?** .....

Name of what you did: ……

	strongly agree	agree	not sure	disagree	strongly disagree
Overall I found the information to be beneficial to my learning needs.	1	2	3	4	5
I will use the information to guide my clinical practice.	1	2	3	4	5
Was this revision information for you? Or new information?					

Thank you for your time and effort in completing this form and now please return it to your CNE or CNC to receive your certificate of participation.