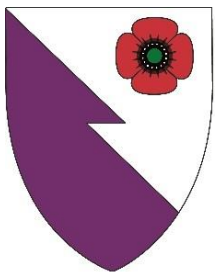


The Royal College of Emergency Medicine

Best Practice Guideline

**Pharmacological
Agents for Procedural
Sedation and Analgesia
in the Emergency
Department**



May 2016

Summary of recommendations

1. Every Emergency Department should have a procedural sedation policy that is regularly reviewed, and audited
2. The procedural sedation policy should provide guidelines for pharmacological agents that are routinely used in the Department
3. A pro-forma should be used for procedural sedation and analgesia (PSA) as a checklist and as an auditable record of the procedure
4. Adverse events should be reported using the SIVA reporting tool

Scope

This document provides guidelines for the use of common pharmacological agents in sedation in the Emergency Department in the UK. It provides guidelines for the use of these agents for adults and children (excluding neonates).

This guideline only applies to pharmacological agents used in sedation in the Emergency Department and is not intended to be used in any other setting. It does not set standards for safe sedation, these are set out in the "Safe Sedation of Adults in the Emergency Department" guideline developed by the Royal College of Anaesthetists and the College of Emergency Medicine in November 2012 (1) and NICE Clinical Guideline 112 "Sedation in children and young people" (2). This guideline is intended to be used as an adjunct to these guidelines.

It does not provide guidance for anaesthesia.

A [pro-forma template](#) has been developed for use as a checklist, for formal recording, for monitoring and for the purposes of audit (Appendix 1).

Reason for development

There are currently no recommended guidelines for the use of pharmacological agents in procedural sedation and anecdotally, practice varies widely. There are many sedation techniques available, this document provides guidance on common combinations of pharmacological agents and suggested drug doses.

Introduction

The practice of Emergency Medicine (EM) includes the performance of procedures that will cause pain and anxiety. The EM practitioner should always seek to minimise discomfort and apprehension with appropriate non-pharmacological and pharmacological interventions or techniques. Procedural sedation and analgesia (PSA) is an appropriate technique in some circumstances, using short-acting analgesics and sedative medicines to facilitate the effective performance of a procedure.

Current guidelines focus on procedural standards for delivering safe sedation in the Emergency Department. Some Emergency Departments have developed guidelines for PSA that include the use of pharmacological agents and suggested drug doses. Comprehensive guidelines for PSA in both adults and children that include detailed review of common pharmacological agent's properties, usage and side effects are available through the point of care resource, UpToDate® (3), (4). The American College of Emergency Physicians published an official Clinical Policy on procedural sedation and analgesia in 2014 (5). These guidelines have informed this document.

Audit of procedural sedation is on the Royal College of Emergency Medicine's national clinical audit cycle, first audit August 2015 – January 2016.

Preparing for Procedural Sedation and Analgesia

Effective procedural sedation requires:

Analgesia: Pain experienced by the patient should be treated with analgesia rather than sedation. Pain should be assessed and managed prior to starting sedation using the WHO pain ladder principles and the need for ongoing pain relief post-procedure considered. Where opiate pain relief has been given prior to PSA, doses of sedatives should be adjusted accordingly.

Anxiolysis: Non-pharmacological methods of reducing anxiety are often the most effective and include consideration of the environment and patient comfort. Environment is particularly important for children and patients with dementia or learning difficulties. Family members often provide invaluable support and distraction. Most painful procedures are best performed with the patient supine.

Sedation: The Joint Commission on Accreditation of Healthcare Organizations in the United States has attempted to define the levels of sedation (6) (see Appendix 2). For most procedures in the ED, the level of required sedation will be moderate to deep, this should be determined in advance.

Amnesia: A degree of amnesia will minimise unpleasant memories associated with the procedure.

In most circumstances a combination of short acting analgesics and sedatives are required as the only pharmacological agent that has the potential to provide analgesia, sedation, anxiolysis and amnesia is ketamine.

Choice of Sedation Agents

The appropriate choice of pharmacological agents for PSA depends on:

- 1) The nature of the procedure
- 2) The planned level of sedation
- 3) Training and familiarity of the sedating practitioner with potential pharmacological agents
- 4) Patient factors
- 5) The local environment

Appendix 6 discusses this in greater detail.

Pharmacological Agents for PSA

Commonly used pharmacological agents are described in Appendix 3. There are many variations in the combinations of pharmacological agents described in the literature and many different ways of delivering the pharmacological agents. The most common agents are described along with the routes and doses for which there is most supportive evidence.

Having selected the appropriate drugs for the needs of the patient, doses of the pharmacological agents need to be tailored to the individual patient to deliver the required effects. Great care should be used when administering sedatives because of:

- Slow and variable onset time
- Inter-patient variability in dose requirement
- Synergistic action between drugs

Table 1 provides information for common pharmacological agents for PSA for adult patients and Table 2 provides equivalent information for paediatric patients.

There is a paucity of evidence of superiority of any one agent over another, and similarly there is no evidence that any agent has greater safety. There is some limited evidence of higher procedural success rates for some procedures with easily titratable sedative drugs.

During Sedation

Adherence to the guidance "Safe Sedation of Adults in the Emergency Department" guideline developed by the Royal College of Anaesthetists and the College of Emergency Medicine in November 2012 is advocated (1).

Post Procedure Monitoring

Full monitoring post-procedure should continue in the same clinical area (with the same facilities available including staffing) until the patient meets the criteria for safe discharge:

- vital signs returned to normal levels
- the patient is awake with intact protective reflexes and no longer at risk of reduced level of consciousness
- nausea, vomiting and pain have been adequately addressed.

Post-Sedation Advice

All patients being discharged home should be discharged home in the care of a competent adult with verbal and written advice. Information and discharge advice for children who have had ketamine PSA is available on the College website at www.rcem.ac.uk/Shop-Floor/Clinical%20Guidelines/Local%20Guidelines/Default.asp?f=edit#Discharge. There is also generic post-discharge advice available at the same site.

Evidence

There is currently limited evidence on the safety of PSA in the UK both in adults and children (2). The American College of Emergency Physicians Clinical Policies Subcommittee on Procedural Sedation and Analgesia evaluated a number of clinical questions related to PSA including the safety of some common pharmacological agents and combinations of agents (6). The data from that clinical policy is included in this guideline (Appendix 4).

Adverse Event Reporting and Data Collection

A large prospective database of sedation cases including data on drugs, procedures, the depth of sedation and complications would help to clarify the safety of sedation and improve clinical practice. Recognising the wide variation in sedation practices and the importance of recording and tracking adverse events, The World Society for Intravenous Anaesthesia (World SIVA) International Sedation Task force has developed an event reporting tool for sedation-related adverse events. This tool is available as a web page through several organisations (e.g. <http://aesedationreporting.com/site/Register.aspx>), as a tick box form that could be incorporated into electronic patient record, or as a paper-based tool (8). This tool (Appendix 5) would complement the information collected on the PSA Checklist and Monitoring proforma (Appendix 2).

Table 1: Adult: Pharmacological Agents for Procedural Sedation and Analgesia

➤ [Download Table 1 and Table 2 as pdf](#)

Agent (references)	Role	Route	Initial dose - Adult	Repeat dose	Initial dose - Adult	Repeat dose	Initial onset time (min)	Peak effect time (min)
			Elderly		Adult			
Propofol (4)	Sedation/Amnesia	IV	10 - 20 mg (given slowly)	10 - 20 mg (given slowly)	0.5– 1.0 mg/kg	0.5mg/kg every 3-5mins	½ - 1	1 - 2
Midazolam (4)	Sedation/Amnesia	IV (over 1-2mins)	0.5mg	0.5mg	1 - 2 mg (max single dose 2.5mg)	After 2-5mins	1 - 2	3 - 4
Ketamine (9)	Sedation/Amnesia/Analgesia	IV (give over 30-60secs)	10 - 30 mg		1 mg/kg	0.25-0.5mg/kg every 5-10 mins	½ - 1	1 - 2
Ketamine (9)	Sedation/Amnesia/Analgesia	IM			4-5 mg/kg	2 – 2.5 mg/kg every 5-10 mins	½ - 1	1 - 2
Ketamine (4, 9)	Analgesia (sub-dissociative)	IV			0.3mg/kg		½ - 1	1 - 2
Fentanyl (4)	Analgesia with other sedatives	IV			Up to 0.5µg/kg	Up to 0.5µg/kg every 2 mins	1 - 2	3 - 5
Fentanyl (4)	Sedation/Analgesia	IV			Up to 0.5 to 1µg/kg	0.5 - 1.0µg/kg every 2 mins	1 - 2	3 - 5
Ketofol (ketamine and propofol) (6)	Sedation/Amnesia/Analgesia	IV			0.5mg/kg-0.75mg/kg of both agents		½ - 1	1-2

Table 2: Paediatric: Pharmacological Agents for Procedural Sedation and Analgesia

Agent (reference)	Role	Route	Age	Initial dose - Paediatric	Maximum dose	Repeat dose	Maximum dose	Initial onset time (min)	Peak effect time (min)
Propofol (5)	Sedation/Amnesia	IV	6months – 2 years	1mg/kg-2mg/kg*		0.5mg/kg every 3-5mins*	3mg/kg*	½ - 1	1 - 2
			> 2 years	0.5 – 1.0 mg/kg*					
Midazolam (5)	Sedation/Amnesia	IV	6months - 5yrs	0.05-0.1mg/kg	2mg (single dose)	Up to 0.2mg/kg after 2-5 mins	Total 6mg	1 - 2	3 - 4
			6 – 12 yrs	0.025-0.05mg/kg	2mg (single dose)	0.1mg/kg	Total 10mg		
IM Ketamine (9)	Sedation/Amnesia/Analgesia	IM	➤ 3months only	4-5mg/kg		2-2.5mg/kg IM after 5-10mins		½ - 1	1 - 2
IV Ketamine (9)	Sedation/Amnesia/Analgesia	IV (over 30-60secs)	➤ 3 months only	1.5-2mg/kg		0.5 – 1.0 mg/kg IV after 5-10mins		½ - 1	1 - 2
Ketofol (ketamine and propofol) (5, 6)	Sedation/Amnesia/Analgesia	IV	➤ 3 months only	0.5mg/kg propofol and ketamine				½ - 1	1-2

*reduce dose significantly in patients who are debilitated or have decreased cardiac function

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Dr Dominic Janssen (consultant anaesthetist) kindly reviewed this guideline. Dr Tim Godfrey provided advice on content and layout of the proforma. The Best Practice Committee advised on the presentation of this document.

Review

Usually within three years or sooner if important information becomes available.

Conflicts of Interest

None

Disclaimers

The College recognises that patients, their situations, Emergency Departments and staff all vary. This guideline cannot cover all possible scenarios. The ultimate responsibility for the interpretation and application of this guideline, the use of current information and a patient's overall care and wellbeing resides with the treating clinician.

Research Recommendations

There is a need for research into the safety of combinations of drugs, for example sub-dissociative doses of ketamine and propofol(4). There is also a need to develop a comprehensive database of PSA methodology and outcomes.

Audit standards

There should be documentation that allows the regular audit of the use of pharmacological agents in Procedural Sedation and Analgesia and the outcomes of their use in PSA.

Key words for search

Medline search performed for all publications in English after 2010 including the terms "procedural sedation" and "emergency department".

Appendix 1: Procedural Sedation and Analgesia (PSA) Checklist and Monitoring Proforma

➤ [Download in excel \(see all sheets\)](#)

Date	<input type="text"/>	Patient name		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time	<input type="text"/>	Date of birth	<input type="text"/>	affix label	<input type="text"/>	<input type="text"/>	<input type="text"/>
		Hospital number	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Planned procedure:		<input type="text"/>					
Planned sedation level:		minimal	<input type="text"/>				
		moderate sedation	<input type="text"/>				
		deep sedation	<input type="text"/>				
		dissociative sedation	<input type="text"/>				
Patient factors:							
Age:	<input type="text"/>	yrs	<input type="text"/>	Weight	<input type="text"/>	Kg	<input type="text"/>
Pregnant:	Yes <input type="text"/>	No	<input type="text"/>				
Relevant co-morbidities	IHD	COPD/asthma		Obese		<input type="text"/>	<input type="text"/>
	Schizophrenia	other:		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Allergies	<input type="text"/>						
Normal Medications	<input type="text"/>						
Acute Medications	<input type="text"/>						
Recreational drugs or alcohol	<input type="text"/>						
Previous anaesthetic	Yes	<input type="text"/>	No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Anaesthetic complications	<input type="text"/>						
Date and time of last food	<input type="text"/>						
Date and time of last oral fluid intake	<input type="text"/>						
ASA grade (please circle)	ASA I	A normal healthy patient					
	ASA II	A patient with mild systemic disease					
	ASA III	A patient with severe systemic disease					
	ASA IV	A patient with severe systemic disease that is a constant threat to life					
	ASA V	A moribund patient who is not expected to survive without the operation					
Difficult Airway?	no concern/ mild concern/significant concern						
Features to consider:							
BMV ventilation:	beard, no teeth, obesity, trauma, cachexia						
LMA:	Look for characteristics of difficult intubation, Evaluate mouth opening and						
Laryngoscopy:	thyromental distance, assess Mallampati score, look for Obstruction, assess Neck						
Crithyroidotomy:	mobility. (LEMON) Check front of neck.						
Consent: sedation	verbal	<input type="text"/>	written	<input type="text"/>	lacks capacity	<input type="text"/>	<input type="text"/>
procedure	verbal	<input type="text"/>	written	<input type="text"/>	lacks capacity	<input type="text"/>	<input type="text"/>
Preprocedural ECG:	Y	<input type="text"/>	N	<input type="text"/>			
Pain before procedure	mild (0-3)	<input type="text"/>	moderate (4-6)	<input type="text"/>	severe (7-10)	<input type="text"/>	<input type="text"/>
Pain post-procedure	mild (0-3)	<input type="text"/>	moderate (4-6)	<input type="text"/>	severe (7-10)	<input type="text"/>	<input type="text"/>

		Name	Grade	Speciality	Patient Information													
Sedating Practitioner					Name:													
Procedural Assistant					Hosp No:		Affix patient label:											
Nursing staff																		
Location for procedure		Resus	Y <input type="checkbox"/>	N <input type="checkbox"/>	Other (details)													
Date:																		
Time:																		
Respiratory rate (bpm)																		
SpO2 %																		
Oxygen delivered (l/min or %)																		
Et CO2																		
Blood pressure: Systolic/ Diastolic (mmHg)	240																	
	230																	
	220																	
	210																	
	200																	
	190																	
	180																	
	170																	
	160																	
	150																	
Heart Rate (bpm)	140																	
	130																	
	120																	
	110																	
	100																	
	90																	
	80																	
	70																	
	60																	
	50																	
40																		
30																		
Drugs	Units																	
GCS/ Sedation level																		
Level of sedation achieved:		minimal sedation	<input type="checkbox"/>															
		moderate sedation	<input type="checkbox"/>															
		deep sedation	<input type="checkbox"/>															
		dissociative sedation	<input type="checkbox"/>															
		anaesthesia	<input type="checkbox"/>															
Interventions needed:		none	<input type="checkbox"/>															
		hypotension rx	<input type="checkbox"/>															
		BMV	<input type="checkbox"/>															
		LMA	<input type="checkbox"/>															
		ETT	<input type="checkbox"/>															
		reversal agent	<input type="checkbox"/>															
		other	<input type="checkbox"/>															
Adverse events:		none	<input type="checkbox"/>															
		hypoxia	<input type="checkbox"/>															
		hypotension	<input type="checkbox"/>															
		adverse reaction	<input type="checkbox"/>															
		vomiting	<input type="checkbox"/>															
		cardiac arrest	<input type="checkbox"/>															
		aspiration	<input type="checkbox"/>															
		death	<input type="checkbox"/>															
Return to baseline	yes	<input type="checkbox"/>		no	<input type="checkbox"/>			Eating/ drinki	yes	<input type="checkbox"/>		no	<input type="checkbox"/>					
Ambulant	yes	<input type="checkbox"/>		no	<input type="checkbox"/>													
Procedure Successful:	yes	<input type="checkbox"/>		no	<input type="checkbox"/>													
Discharge Advice given:	verbal	<input type="checkbox"/>		written	<input type="checkbox"/>			Sedating Practitioner signature:										
Patient satisfaction with procedure:		/10																

Appendix 2: Definitions of Sedation Level

The Joint Commission on Accreditation of Healthcare Organizations in the United States has attempted to define the levels of sedation, which range from minimal sedation to general anaesthesia(3):

- Analgesia; Relief of pain without intentionally producing a sedated state. Altered mental status may occur as a secondary effect of medications administered for analgesia.
- Minimal sedation (anxiolysis); The patient responds normally to verbal commands. Cognitive function and coordination may be impaired, but ventilatory and cardiovascular functions are unaffected.
- Moderate sedation and analgesia; The patient responds purposefully to verbal commands alone or when accompanied by light touch. Protective airway reflexes and adequate ventilation are maintained without intervention. Cardiovascular function remains stable.
- Deep sedation and analgesia; The patient cannot be easily aroused, but responds purposefully to noxious stimulation. Assistance may be needed to ensure the airway is protected and adequate ventilation maintained. Cardiovascular function is usually stable.
- General anaesthesia; The patient cannot be aroused and often requires assistance to protect the airway and maintain ventilation. Cardiovascular function may be impaired.
- Dissociative sedation; Dissociative sedation is a trance-like cataleptic state in which the patient experiences profound analgesia and amnesia, but retains airway protective reflexes, spontaneous respirations, and cardiopulmonary stability. Ketamine is the pharmacologic agent used for procedural sedation that produces this state (see 'Ketamine' Appendix 2).

Sedation exists on a continuum, and is difficult to divide into discrete clinical stages. Many sedatives can cause rapid changes in the depth of sedation. Dissociative sedation is considered to be separate from the continuum of sedation.

Appendix 3: Pharmacological Agents for PSA

Entonox:

Properties: Entonox is a gaseous 1:1 mixture of nitrous oxide and oxygen (to prevent hypoxaemia) that is inhaled. It has a rapid onset (30secs) and short duration of action (1 min). Thought to act by binding to opiate receptors in the CNS.

Uses: Sedation, anxiolysis and minor analgesic properties.

Administration: Inhaled but requires patient to be able to hold the inhaler, does not require venous access.

Side effects: Requires a well ventilated room to prevent exposure of clinician, can cause vomiting, contraindicated in head injury, pneumothorax, bowel obstruction, sinus disease.

Propofol:

Properties: Phenol derivative, highly lipophilic, crosses blood brain barrier rapidly. Action thought to be through positive modulation of GABA inhibitory neurotransmission. Used widely for induction and maintenance of anaesthesia.

Uses: Sedation and amnesia.

Administration: Much smaller doses are required for sedation than for general anaesthesia, with initial doses as low as 10 mg in the elderly or those with significant co-morbidities although the initial action may be seen within 30 s, the peak effect may take 2 min or more, particularly in the elderly. An alternative technique is to use a computer-controlled infusion, which estimates the administration profile required for a target plasma concentration, normally 0.5-1.5 µg/ml for sedation.

Children: Propofol is not licensed for use in sedation in children, however the NICE Guideline Development Group recommend off-license use of propofol for sedation in children(2).

Side effects: Hypotension, respiratory depression, pain at site of injection

Allergens: soya and egg lecithin in formulation

Evidence: American College of Emergency Physicians Clinical Policy level of evidence of safety for use in PSA in the emergency department: Level A for paediatrics, Level A for adults.

Midazolam:

Properties: Short-acting benzodiazepine metabolised in the liver commonly used for sedation, it is also a powerful amnesic.

Uses: Sedation and amnesia

Administration: Can be administered orally, buccally or as an IV infusion.

Children: Midazolam is not licensed for use in children under 6 months or for sedation either via the oral or buccal route in children. There is no UK marketing authority currently for oral or intranasal midazolam use in sedation.

Side effects: respiratory depression, hypotension, paradoxical disinhibition and agitation at low doses in children. Accumulates in adipose tissue, which can significantly prolong sedation. The elderly, obese and patients with hepatic or renal disease are at risk of prolonged sedation.

Ketamine:

Properties: Phencyclidine derivative that produces a dissociative state and profound analgesia with superficial sleep. Ketamine does not display a dose-response continuum as seen with other analgesic and sedative agents. There is a threshold dose for dissociation after which additional doses are required only to maintain the dissociative state. Sub-dissociative doses provide analgesia with disorientation rather than dissociation.

Uses:

1. dissociative state, amnesia and analgesia
2. analgesia

Administration: Can be administered in IV boluses, as an IV infusion or intramuscularly.

Side effects: tachycardia, hypertension, laryngospasm, unpleasant hallucinations (reduced by pre-medication with a benzodiazepine), nausea and vomiting, hyper-salivation, increased intracranial and intraocular pressure.

Contraindications: Absolute contraindications: age less than 3 months, known or suspected schizophrenia. Relative contraindications: active pulmonary disease or infection, known or suspected cardiovascular disease (including angina, hypertension and heart failure), CNS masses, abnormalities or hydrocephalus, globe injury or glaucoma (9).

Coadministered pharmacological agents(9):

1. Prophylactic anticholinergics have been used in the past to reduce hyper-salivation; however there is no support in the literature to any benefit of prophylactic co-administration.
2. Benzodiazepines (primarily midazolam) have been recommended in the past to minimize recovery reactions. The literature is not supportive of prophylactic use of midazolam in children but there may be benefit in adults (single controlled study). Benzodiazepines can be used, when required to treat unpleasant reactions if they occur.
3. Anti-emetics are not considered mandatory, a trial using ondansetron showed a significant decrease in emesis (8%) in children; however this evidence was not considered strong enough to mandate the use of anti-emetics.

Evidence: American College of Emergency Physicians Clinical Policy level of evidence of safety for use in PSA in the emergency department: Level A for paediatrics, Level C for adults.

Ketofol

Properties: Combination of ketamine and propofol used at a 1:1 ratio in the same syringe in the belief that the lower doses reduce side-effects (hypotension and vomiting and emergence phenomena respectively) of the agents and that the agents act synergistically.

Uses: sedation, amnesia and analgesia

Administration: 1:1 mixture in the same syringe.

Side effects: as for propofol and ketamine

Evidence: American College of Emergency Physicians Clinical Policy level of evidence of safety for use in PSA in the emergency department: Level B for paediatrics, Level B for adults.

Fentanyl

Properties: A synthetic opioid with 72-125x potency of morphine. Rapid onset (2-3 minutes) duration of effect 30-60mins.

Uses: analgesia and sedation

Administration: Best given a few minutes before sedation to maximise analgesic effect. Doses of no more than 0.5 mcg/kg with other sedation agents.

Side effects: Respiratory depression potentiated by sedatives (e.g. propofol). Patients with renal or hepatic disease and the elderly may experience more profound or prolonged effects.

Appendix 4: Methodology

Where possible, appropriate evidence has been sought and appraised using standard appraisal methods. High quality evidence is not always available to inform recommendations. Best Practice Guidelines rely heavily on the consensus of senior emergency physicians and invited experts.

American College of Emergency Physicians Definitions of Evidence Levels

American College of Emergency Physicians Clinical Policy: level of evidence of safety for use in PSA in the emergency department (6)

Agent	Children	Adults
Ketamine	Level A	Level C
Propofol	Level A	Level A
Ketofol	Level B	Level B

A = Generally accepted principles of patient care based on evidence from 1 or more randomised control trials/ meta-analysis or multiple non-randomised control trials.

B = Recommendations for patient care based on 1 or more non-randomised control trials or multiple case series or reports.

C = Recommendations for patient care based on case series or reports and/ or expert consensus.

Appendix 5: World SIVA adverse sedation event-reporting tool

World SIVA adverse sedation event reporting tool

World SIVA adverse sedation event recording tool configured for a web page or paper form. Completion of this tool requires execution of all five steps. Responses to each step will often occupy different columns.

Step 1: Was there one or more adverse events associated with this sedation encounter?

No, this form is now complete. Yes, fill out remainder of form below.

Step 2: Please DESCRIBE the adverse events(s). Check all that apply.

<i>Minimal risk descriptors</i>	<i>Minor risk descriptors</i>	<i>Sentinel risk descriptors</i>	
<input type="radio"/> Vomiting / Retching	<input type="radio"/> Oxygen desaturation (75–90%) for <60 s	<input type="radio"/> Oxygen desaturation, severe (<75% at any time) or prolonged (<90% for >60 s)	<input type="radio"/> Other, specify below
<input type="radio"/> Subclinical respiratory depression ^a	<input type="radio"/> Apnoea, not prolonged	<input type="radio"/> Apnoea, prolonged (>60 s)	
<input type="radio"/> Muscle rigidity, myoclonus	<input type="radio"/> Airway obstruction		
<input type="radio"/> Hypersalivation	<input type="radio"/> Failed sedation ^e		
<input type="radio"/> Paradoxical response ^b	<input type="radio"/> Allergic reaction without anaphylaxis	<input type="radio"/> Cardiovascular collapse/shock ^g	
<input type="radio"/> Recovery agitation ^c	<input type="radio"/> Bradycardia ^f	<input type="radio"/> Cardiac arrest/absent pulse	
<input type="radio"/> Prolonged recovery ^d	<input type="radio"/> Tachycardia ^f		
	<input type="radio"/> Hypotension ^f		
	<input type="radio"/> Hypertension ^f		
	<input type="radio"/> Seizure		

Step 3: Please note the INTERVENTIONS performed to treat the adverse events(s). Check all that apply.

<i>Minimal risk</i>	<i>Minor risk</i>	<i>Moderate risk</i>	<i>Sentinel intervention</i>	
<input type="radio"/> No intervention performed	<input type="radio"/> Airway repositioning	<input type="radio"/> Bag valve mask-assisted ventilation	<input type="radio"/> Chest compressions	<input type="radio"/> Other, specify below
Administration of:	<input type="radio"/> Tactile stimulation or the administration of:	<input type="radio"/> Laryngeal mask airway	<input type="radio"/> Tracheal intubation or the administration of:	
<input type="radio"/> Additional sedative(s)	<input type="radio"/> Supplemental oxygen, new or increased	<input type="radio"/> Oral/nasal airway	<input type="radio"/> Neuromuscular block	
<input type="radio"/> Antiemetic	<input type="radio"/> Antisialagogue	<input type="radio"/> CPAP	<input type="radio"/> Pressor / epinephrine	
<input type="radio"/> Antihistamine		or the administration of:	<input type="radio"/> Atropine to treat bradycardia	
		<input type="radio"/> Reversal agents		
		<input type="radio"/> Rapid i.v. fluids		
		<input type="radio"/> Anticonvulsant i.v.		

Step 4: Please note the OUTCOME of the adverse events(s). Check all that apply.

<i>Minimal risk outcome</i>	<i>Moderate risk outcome</i>	<i>Sentinel outcome</i>	
<input type="radio"/> No adverse outcome	<input type="radio"/> Unplanned hospitalisation or escalation of care ^h	<input type="radio"/> Death	<input type="radio"/> Other, specify below
		<input type="radio"/> Permanent neurological deficit	
		<input type="radio"/> Pulmonary aspiration syndrome ⁱ	

Step 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.

- If there are any options checked in the Sentinel columns above, then this is a Sentinel^l adverse event.
- If the most serious option(s) checked above are Moderate risk, then this is a Moderate^k risk adverse event.
- If the most serious option(s) checked above are Minor risk, then this is a Minor^l risk adverse event.
- If the most serious option(s) checked above are Minimal risk, then this is a Minimal^m risk adverse event.

Additional details (including 'other' entries):

Footnotes:

- a. "Subclinical respiratory depression" is defined as capnographic abnormalities suggesting respiratory depression that do not manifest clinically.
- b. "Paradoxical response" is defined as unanticipated restlessness or agitation in response to sedatives.
- c. "Recovery agitation" is defined as abnormal patient affect or behaviors during the recovery phase that can include crying, agitation, delirium, dysphoria, hallucinations, or nightmares.
- d. "Prolonged recovery" is defined as failure to return to baseline clinical status within 2 hours.
- e. "Failed sedation" is defined as inability to attain suitable conditions to humanely perform the procedure.
- f. Alteration in vital signs (bradycardia, tachycardia, hypotension, hypertension) is defined as a change of >25% from baseline.
- g. "Cardiovascular collapse/shock" is defined as clinical evidence of inadequate perfusion.
- h. Examples of "escalation of care" include transfer from ward to intensive care, and prolonged hospitalisation.
- i. "Pulmonary aspiration syndrome" is defined as known or suspected inhalation of foreign material such as gastric contents into the respiratory tract associated with new or worsening respiratory signs.
- j. "Sentinel" adverse events are those critical enough to represent real or serious imminent risk of serious and major patient injury. Once recognized, they warrant immediate and aggressive rescue interventions. Once clinically concluded, they warrant immediate reporting within sedation care systems, and the highest level of peer scrutiny for continuous quality improvement.
- k. "Moderate" adverse events are those that, while not sentinel, are serious enough to quickly endanger the patient if not promptly managed. Once clinically concluded, they warrant timely reporting within sedation care systems, and periodic peer scrutiny for continuous quality improvement.
- l. "Minor" adverse events are those encountered periodically in most sedation settings, and that pose little threat given appropriate sedationist skills and monitoring.
- m. "Minimal" adverse events are those that alone present no danger of permanent harm to the patient.

Appendix 6

Procedure: The degree of pain and anxiety caused by the procedure and the length of time for the procedure.

Planned level of sedation and analgesia: The planned level of sedation should be decided prior to the procedure and any deviation from the planned level, whether intentionally or unintentionally should be recorded.

Practitioner Training and Familiarity: The sedating practitioner should have familiarity with using the pharmacological agent(s) chosen for the procedure.

Patient factors/ pre-sedation assessment:

Paediatric patients: Both pharmacological and non-pharmacological approaches that are developmentally appropriate should be considered to address anxiety and pain to optimise the success of PSA. Relative contraindications to PSA in paediatric patients include difficult airway or significant co-morbidities, sleep apnoea, special needs, and decreased GI motility (5).

Pregnant patients: Additional considerations include positioning, oxygenation, foetal monitoring and pre-procedural medication. In late second and third trimester, left lateral displacement of the uterus will reduce risk of hypotension and foetal hypoxaemia. Oxygenation should be provided. Pre-procedural administration of antacid and anti-emetic such as metoclopramide should be considered.

Older patients: Older patients may be at increased risk of complications with PSA particularly when deeply sedated (7).

Patients with significant co-morbidities: Co-morbidities such as anaemia, heart failure, COPD, dehydration and neuromuscular disease make patients more susceptible to the cardiorespiratory side effects of sedatives.

For older patients and those with significant co-morbidities, it is recommended that lower starting doses with slower rates of administration and repeated doses at less frequent intervals are employed (4).

Other factors: anaesthetic complications, allergies, weight, normal medications, acute medications, recreational drugs including alcohol, anxiety should be assessed.

Fasting: The current recommendation is that PSA in the ED should not be delayed in adults or in paediatrics based on fasting time as there is no demonstrated reduction in risk of vomiting or aspiration (Level B evidence) (6).

Weight: Accurate weight should be recorded and used to calculate appropriate doses.

Environment: Time of day, availability of appropriate staff and facilities, availability of alternative approaches (theatre) should be a strong consideration in deciding what level of PSA should be performed.



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