The Royal College of Emergency Medicine

CLINICAL AUDIT 2017/2018
Procedural Sedation in Adults
Clinical Audit Information

INTRODUCTION AND BACKGROUND

The administration of sedative drugs to promote calm or sleep for a medical procedure is common practice in Emergency Departments (ED). Sedation is an important topic as it can lead to adverse effects if incorrectly undertaken. Studies by NCEPOD[1] and NPSA[2] have reported avoidable overdose and deaths.

As a result of occasional unpredictable pharmacokinetics and pharmacodynamics, drugs given for sedation can sometimes result in progression between levels of sedation irrespective of the practitioner's intention. Sedation is mostly not a life-saving procedure and safety in its practice is paramount. The provider must be equipped with the necessary skills, support, resources and monitoring to manage this continuum and any possible complications. This is reflected in our standards set out for this audit which is as much for addressing safety before, during and after the procedure as it is for monitoring the effects of medication.

Inappropriately delivered and monitored sedation can cause unintended loss of consciousness and dangerous hypoxia[3]. However, if administered safely, it can enhance the patient's experience and care by reducing pain and procedure time. It may also benefit the hospital by reducing admissions. It is an ideal audit topic as structure, process and outcomes can all be measured.

The AoMRC 'Safe sedation practice for healthcare procedures' guidance[4] states *"There should be audit of the process and outcome of procedures performed under sedation, particularly the incidence of major complications (e.g. cardiopulmonary arrest, unexpected admission to intensive care and delayed hospital discharge)."*

The joint guideline from the RCoA and RCEM (2012)[5], AoMRC guidance (2013)[4] and NICE CG112[3] are used as the basis for standards and audit measures.

Aims and objectives

The purpose of the audit is:

1. To benchmark current performance in EDs against RCEM/RCoA and AoMRC clinical guidance
2. To allow comparison nationally and between peers
3. To identify areas in need of improvement
4. To compare against previous performance

METHODOLOGY

Inclusion criteria

- Adult patients past their 16th birthday
- Patients undergoing procedural sedation at all levels (minimal, conscious, moderate, dissociative and deep)

Exclusion criteria

- Patients aged 15 or under.
- Patients receiving:
  - Entonox (50% nitrous oxide/oxygen) only
  - Opiates only
  - Entonox and opiates in combination

Search Terms
The ICD 10 codes below can be used to help initially identify potential cases. This is not an exhaustive list; other search terms can be used but all potential patients should then be reviewed to check they meet the definitions & selection criteria before inclusion in the audit.

ECDS codes to support case identification

Related Audit Q	DATA GROUP	DATA ITEM NAME	ICD10	SNOMED	DM&D	UDDA v 3	ECDS	CDS_Code mapping used for HRG Grouping	PbR_ Category	NOTES
Q2	EMERGENCY CARE ATTENDANCE ACTIVITY CHARACTERISTICS	EMERGENCY CARE ARRIVAL DATE	-	-	As per CDS 6.2 Type 010	-	-	-	-	Exclude all BEFORE 01/01/2017
Q2	EMERGENCY CARE ATTENDANCE ACTIVITY CHARACTERISTICS	EMERGENCY CARE ARRIVAL DATE	-	-	As per CDS 6.2 Type 010	-	-	-	-	Exclude all AFTER 31/01/2017
Q3	PATIENT IDENTITY – UNVERIFIED IDENTITY STRUCTURE	PERSON BIRTH DATE	-	-	As per CDS 6.2 Type 010	-	-	-	-	Exclude all BIRTH dates AFTER 31/12/2001

Related Audit Q	DATA GROUP	DATA ITEM NAME	ICD10	SNOMED	DM&D	UDDA v 3	ECDS	CDS_Code mapping used for HRG Grouping	PbR_ Category	NOTES
-	TREATMENT	PROCEDURE DATE	-	-	As per CDS 6.2 Type 010	-	-	-	-	
-	TREATMENT	PROCEDURE TIME	-	-	As per CDS 6.2 Type 010	-	-	-	-	
-	TREATMENT	Anaesthesia : local anaesthetic	-	386761002	-	-	1135110000	232	1-2	
-	TREATMENT	Anaesthesia : entonox	-	427035008	-	-	1135210000	234	1-2	
-	TREATMENT	Anaesthesia : regional block	-	27372005	-	-	1135410000	233	1-2	
-	TREATMENT	Anaesthesia : sedation	-	50697003	-	-	1135610000	235	3-4	

Flow of data searches to identify audit cases

Using codes listed above, first identify all patients attending ED between dates, then by age at time of attendance, then through treatment criteria.

Date and time of attendance

Age (exclude < 18 years)

Procedure

Additional codes that may be of use

Related audit Q	DATA GROUP	DATA ITEM NAME	ICD10	SNOMED	D&MD	UDDA version 3	ECDS	CDS_Code mapping used for HRG Grouping	PbR_Category
Q13	TREATMENT	Supplemental oxygen	-	57485005	-	-	1111110000	40	3-4
	PROCEDURE	DATE	-	-	As per CDS 6.2 Type 010	-	-	-	-
	PROCEDURE	TIME	-	-	As per CDS 6.2 Type 010	-	-	-	-

Related audit Q	DATA GROUP	DATA ITEM NAME	ICD10	SNOMED	D&MD	UDDA version 3	ECDS	CDS_Code mapping used for HRG Grouping	PbR_Category
Q16b	DIAGNOSIS	Respiratory arrest	-	87317003	-	-	1414149000	-	-
Q16c	DIAGNOSIS	Cardiogenic shock	-	89138009	-	-	1411129000	-	-
Q16d	DIAGNOSIS	Cardiac arrest	-	410429000	-	-	1411399000	-	-
Q17	DISCHARGE DESTINATION	Discharge to home	-	306689006	-	-	2018111111	-	-
		Discharge to residential home (procedure)	-	306691003	-	-	2018112111	-	-
		Discharge to nursing home (procedure)	-	306694006	-	-	2018113111	-	-
		Discharge to police custody (procedure)	-	306705005	-	-	2018114111	-	-
		Patient discharge, to legal custody (procedure)	-	50861005	-	-	2018114511	-	-
		Emergency department discharge to emergency	-	1066331000000109	-	-	2018311111	-	-

Related audit Q	DATA GROUP	DATA ITEM NAME	ICD10	SNOMED	D&MD	UDDA version 3	ECDS	CDS_Code mapping used for HRG Grouping	PbR_Category
		department short stay ward (procedure)							
		Emergency department discharge to ambulatory emergency care service (procedure)	-	1066341000000100	-	-	2018312111	-	-
		Discharge to hospital at home service (procedure)	-	1066351000000102	-	-	2018313111	-	-

Sample size
RCEM recommends auditing a different number of cases depending on the number you expect to see within the data collection period. If this is an area of concern in your ED, you can submit data for more cases for an in depth look at your ED's performance.

Basing the audit sample size on the number of cases in this way increases the reliability of your ED's audit results.

Audited cases should be consecutive during the data collection period (1 January 2017 to 31 December 2017).

Expected number of cases	Recommended audit sample
< 50	All eligible cases
50-250	50 consecutive cases
>250	100 consecutive cases

Data collection period
From 1 January 2017 to 31 December 2017.
NB: You can start the audit at any point during the data collection period, as long as you submit the data by 31 January 2018.

Data submission period
Data can be submitted online at the link below between 1 August 2017 to 31 January 2018. You can find the link to log into the data entry site at www.rcem.ac.uk/audits

Data Sources
ED patient records (paper, electronic or both).

STANDARDS

STANDARD	GRADE
1. Patients undergoing procedural sedation in the ED should have documented evidence of pre-procedural assessment, including: a. ASA grading[4] b. Prediction of difficulty in airway management[4] c. Pre-procedural fasting status[4]	F
2. There should be documented evidence of the patient's informed consent unless lack of mental capacity has been recorded[4].	D
3. Procedural sedation should be undertaken in a resuscitation room or one with dedicated resuscitation facilities.	F
4. Procedural sedation requires the presence of all of the below: a. a doctor as sedationist[4] b. a second doctor, ENP or ANP as procedurist[4] c. a nurse	F
5. Monitoring during procedural sedation must be documented to have included all of the below: a. Non-invasive blood pressure[4] b. Pulse oximetry[4] c. Capnography[4] d. ECG	F F F F
6. Appropriate oxygen therapy should be given from the start of sedative administration until the patient's condition is returned to baseline[4].	D
7. For invasive procedures, a Local Safety Standard for Invasive Procedures checklist (LocSSIP) or NatSSIP compliant checklist is used[6, 7].	D
8. Following procedural sedation, patients should only be discharged after documented formal assessment of suitability, including all of the below: a. Return to baseline level of consciousness[4] b. Vital signs within normal limits for the patient[4] c. Absence of respiratory compromise[4] d. Absence of significant pain and discomfort[4] e. Written advice on discharge for all patients	F F F F D

Grade definition

F - Fundamental: need to be applied by all those who work and serve in the healthcare system. Behaviour at all levels and service provision need to be in accordance with at least these fundamental standards. No provider should provide any service that does not comply with these fundamental standards, in relation to which there should be zero tolerance of breaches.

D - Developmental: set requirements over and above the fundamental standards.

A - Aspirational: setting longer term goals.

Standards definitions

Standard	Term	Definition
Standard 1	ASA	American Society of Anaesthesiologists Physical Status Classification[8]. See answer definition for further detail.
Standard 2	Evidence of consent	A form with a ticked box for verbal consent is adequate, or documentation of verbal consent in the ED record. Written consent by the patient is not obligatory.
Standard 4	ENP ANP	Emergency Nurse Practitioner Advanced Nurse Practitioner
Standard 5	ECG Capnography	Electrocardiogram Sedation is a continuum. It is not always possible to predict the level of sedation in advance, therefore in this audit capnography is a standard for all sedation levels.

AUDIT QUESTIONS

Casemix

Q1	Reference (do not enter identifiable data)	
Q2	Date of arrival *(dd/mm/yyyy)* and time of arrival or triage, whichever is earlier *(use 24 hour clock e.g. 11.23pm = 23:23)*	dd/mm/yyyy HH:MM
Q3	Age of patient on attendance	• 16-40 • 41-64 • 65 and above
Q4	Level of sedation intended	• Minimal • Conscious – Moderate • Deep • Dissociative • Not recorded
Q5	Deepest level of sedation achieved	• Minimal • Conscious – Moderate • Deep • Dissociative • Not recorded

Pre-procedure

Q6a	Were the following elements of pre-procedural assessment recorded in the ED notes? *(tick all that apply)*	• ASA grade • Prediction of difficulty in airway management • Pre-procedural fasting status
Q7	Was there documented evidence of the patient's informed consent for the sedation?	• Yes - consent given • No - lack of mental capacity noted • No - unable to assess mental capacity • No information

Procedure

Q8	Was the sedation carried out in a resuscitation room or one with dedicated resuscitation facilities?	• Yes • No • Not recorded
Q9	Which of the following staff were present during the procedure? (tick all that apply)	• Doctor • Second doctor, ENP or ANP procedurist • Nurse • Other
Q10	What was the speciality of the sedating practitioner?	• EM practitioner • Anaesthetist • Other • Not recorded

Q11	Which agents were used for sedation? (tick all that apply)	• Opioid • Benzodiazepine • Ketamine • Propofol • Other agent State name: _____ • Not recorded

Monitoring

Q12	Was there evidence of monitoring of the following during the procedure? *(tick all that apply)*	• Non-invasive blood pressure (NIBP) • Pulse oximetry • Capnography • ECG
Q13	Did the patient receive appropriate oxygen therapy during the sedation?	• Yes • No *(go to Q14)* • Not recorded *(go to Q14)*
Q13a	(Only answer if YES to Q13) please state when oxygen was given	• From the start of sedative administration • After complication • From other point • Not specified
Q13b	(Only answer if YES to Q13a) Was appropriate oxygen therapy given until the patient's condition returned to baseline?	• Yes • No
Q14	What was the procedure for which sedation was required? *(tick all that apply)*	• Joint reduction • Chest drain • DC cardioversion • Other – please state
Q15	Was the sedation to facilitate an invasive procedure?	• Yes • No *(go to Q16)* • N/A *(go to Q16)* • Not recorded *(go to Q16)*
Q15a	(Only answer if YES to Q15) If for an invasive procedure, was a LocSSIP checklist used (or other NatSSIP compliant checklist)?	• LocSSIP checklist • NatSSIP compliant checklist State name: _____ • Other State name: _____ • No • Not recorded

Adverse events

Q16	Did any of the following adverse events arise?	
Q16a	Oxygen desaturation, severe (<75% at any time) or prolonged (<90% for >60s)	• Yes • No • Not recorded
Q16b	Apnoea, prolonged (>60s)	• Yes • No • Not recorded

Q16c	Cardiovascular collapse/shock	• Yes • No • Not recorded
Q16d	Cardiac arrest/absent pulse	• Yes • No • Not recorded
Q16e	Other	• Yes State what: _____ • No
Q16f	Patient dissatisfaction with procedure (score of 5/10 or less) when assessed on leaving the resus/ procedure room	• Yes • No • Not recorded

Adverse events – further information

→ If answered *yes* to either Q16a-f please answer Q16g-j; if *not*, please skip to Q17

Q16g	Did the adverse event lead to unplanned hospitalisation or escalation of care?	• Yes • No • Not recorded
Q16h	Did any of the following outcomes arise? *(tick all that apply)*	• Death • Permanent neurological deficit • Pulmonary aspiration syndrome
Q16i	If an adverse event occurred, was this reported as follows? *(tick all that apply)*	• Reported to the department clinical lead • Discussed at the departmental clinical governance meeting • Via completion of World SIVA Adverse Sedation Event Reporting Tool[9] • Datix • Other method • Not reported/Not recorded
Q16j	If an adverse event has occurred, please provide details of the event or contact details if willing to participate in a structured interview and to supply a copy of the World SIVA form.	

Patient discharge

Q17	Was the patient discharged home from the ED?	• Yes • No • Not recorded
Q17a	(Only answer if YES to Q17) Were the following elements of formal assessment of discharge suitability documented? (tick all that apply)	• Return to baseline level of consciousness • Vital signs within normal limits for the patient • Absence of respiratory compromise • Absence of significant pain and discomfort • Written advice on discharge

Organisational audit

PLEASE ANSWER THE FOLLOWING QUESTIONS ONCE PER EMERGENCY DEPARTMENT ONLY

Q1	Is procedural sedation in children undertaken in your ED?	• No • Yes – by ED clinicians • Yes – by anaesthetic clinicians • Yes – not specified by whom
Q2	Does your department have LocSSIP checklists for relevant procedures?	• Yes • No

Notes

Question and answer definitions

Q6a
ASA - American Society of Anaesthesiologists Physical Status Classification[8]

ASA PS Classification	***Definition***
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
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes

Q15a
NatSSIPs - "are intended to provide a skeleton for the production of Local Safety Standards for Invasive Procedures (LocSSIPs) that are created by multiprofessional clinical teams and their patients, and are implemented against a background of education in human factors and working as teams. The NatSSIPs do not replace the WHO Safer Surgery Checklist. Rather, they build on it and extend it to more patients undergoing care in our hospitals. They will standardise key elements of procedural care, ensure that care is harmonised – not just within organisations delivering NHS-funded care but also between organisations – and will reinforce the importance of education to patient safety.
LocSSIPs - "Organisations should develop Local Safety Standards for Invasive Procedures (LocSSIPs) that include the key steps outlined in the NatSSIPs and to harmonise practice across the organisation such that there is a consistent approach to the care of patients undergoing invasive procedures in any location."
https://www.england.nhs.uk/wp-content/uploads/2015/09/natssips-safety-standards.pdf

Q16c
Cardiovascular collapse/shock - clinical evidence of inadequate perfusion, cardiovascular compromise raising clinical concern, need for resus, fluid, or positioning of the patient.

Q16h
Pulmonary Aspiration Syndrome – known or suspected inhalation of foreign material such as gastric contents into the respiratory tract associated with new or worsening respiratory symptom

Q17
Patients discharged from the ED clinical decision unit (CDU) or observation ward should be treated as a discharge from the ED.

EVIDENCE BASE FOR STANDARDS

STANDARD	EVIDENCE
1. Patients undergoing procedural sedation in the ED should have documented evidence of pre-procedural assessment, including: a. ASA grading[4] b. Prediction of difficulty in airway management[4] c. Pre-procedural fasting status[4]	Safe sedation practice for healthcare procedures – standards and guidance The importance of pre-operative assessment and preparation of patients, focusing on medical, social and psychological assessment and evaluation of risk, taking into consideration the limitations of the setting, cannot be overestimated. Safe Sedation of Adults in the Emergency Department 2012 p3, p9, p10 Recommendations for safe sedation in the Emergency Department - Level 1 sedation training ('conscious' sedation): • ASA grading, • Pre-procedural assessment including prediction of difficulty in airway management, • Pre-procedural fasting and risk benefit assessment
2. There should be documented evidence of the patient's informed consent unless lack of mental capacity has been recorded[4].	Safe sedation practice for healthcare procedures – standards and guidance Valid consent is an essential preliminary to sedation. Safe Sedation of Adults in the Emergency Department 2012 p3, p9, p10 Recommendations for safe sedation in the Emergency Department - Level 1 sedation training ('conscious' sedation): Consent and documentation
3. Procedural sedation should be undertaken in a resuscitation room or one with dedicated resuscitation facilities.	Safe sedation practice for healthcare procedures – standards and guidance Staffing and equipment must meet the needs of both the technique (including monitoring) and its possible complications. Appropriate recovery facilities and discharge criteria relevant to the patient's destination are necessary. Safe Sedation of Adults in the Emergency Department 2012 p8, p9 Moderate sedation/ analgesia ('conscious' sedation) using intravenous agents, typically benzodiazepines - location and facilities: Resuscitation room facilities
4. Procedural sedation requires the presence of all of the below: a. a doctor as sedationist[4]	Safe sedation practice for healthcare procedures – standards and guidance

b. a second doctor, ENP or ANP as procedurist[4] c. a nurse	Staffing and equipment must meet the needs of both the technique (including monitoring) and its possible complications. <u>Safe Sedation of Adults in the Emergency Department 2012</u> p3, p8, p10, p11 Moderate sedation/ analgesia ('conscious' sedation) using intravenous agents, typically benzodiazepines - Minimum staffing levels: One physician as sedationist *and* one Physician or ENP as operator and *one* Nurse
5. Monitoring during procedural sedation must be documented to have included all of the below: a. Non-invasive blood pressure[4] b. Pulse oximetry[4] c. Capnography[4] d. ECG	<u>Safe sedation practice for healthcare procedures – standards and guidance</u> • Existing guidance for patients undergoing anaesthesia identifies the need for pulse oximetry, ECG and automated non-invasive blood pressure monitoring. • The Association of Anaesthetists of Great Britain and Ireland recommend that continuous waveform capnography should be used to monitor adequacy of ventilation for all patients undergoing moderate or deep sedation, and should be available wherever any patients undergoing moderate or deep sedation are recovered and additionally where: ■ ventilation cannot be directly observed, e.g. MRI/CT ■ multiple drugs/anaesthetic drug techniques are used, and ■ pre-assessment highlights increased clinical risk. <u>Safe Sedation of Adults in the Emergency Department 2012</u> p3, p8, p9, p10, p11 Moderate sedation/ analgesia ('conscious' sedation) using intravenous agents, typically benzodiazepines - Monitoring: ECG, NIBP, pulse oximetry. The use of capnography is recommended.
6. Appropriate oxygen therapy should be given from the start of sedative administration until the patient's condition is returned to baseline[4].	<u>Safe sedation practice for healthcare procedures – standards and guidance</u> Oxygen, via nasal cannulae, should usually be administered from the commencement of sedation, through to readiness for discharge from recovery, particularly for patients with relevant medical conditions, where multiple drug techniques or anaesthetic drugs are used, or deeper levels of sedation administered.

	Safe Sedation of Adults in the Emergency Department 2012 p7, p8, p9, p10 Oxygen should be given to sedated patients, who may experience a fall in oxygen saturation from the baseline level measured on room air. Oxygen should be given from the start of sedative administration until the patient is ready for discharge from the recovery area.
7. For invasive procedures, a Local Safety Standard for Invasive Procedures checklist (LocSSIP) or NatSSIP compliant checklist is used[6,7].	NHS England National Safety Standards for Invasive Procedures Organisations should develop Local Safety Standards for Invasive Procedures (LocSSIPs) that include the key steps outlined in the NatSSIPs and to harmonise practice across the organisation such that there is a consistent approach to the care of patients undergoing invasive procedures in any location.
8. Following procedural sedation, patients should only be discharged after documented formal assessment of suitability, including all of the below: a. Return to baseline level of consciousness[4] b. Vital signs within normal limits for the patient[4] c. Absence of respiratory compromise[4] d. Absence of significant pain and discomfort[4] e. Written advice on discharge for all patients	Safe sedation practice for healthcare procedures – standards and guidance Patients should be formally assessed for suitability for discharge from the clinical area where sedation has taken place. Discharge criteria are as follows: ■ The patient has returned to their baseline level of consciousness. ■ Vital signs are within normal limits for that patient. ■ Respiratory status is not compromised. ■ Pain and discomfort have been addressed. ■ If there is a requirement to discharge the patient prior to meeting these criteria they should be transferred to an appropriate clinical environment with continuation of peri-procedure monitoring standards. ■ Patients meeting discharge criteria following sedation who go on to be discharged home should be discharged into the care of a suitable third party. ■ Verbal and written instructions should be given. Safe Sedation of Adults in the Emergency Department 2012 p3, p10, p11 Patients should be formally assessed for discharge suitability from the clinical area where sedation has taken place. Discharge criteria are as follows: • The patient has returned to their baseline level of consciousness.

	• Vital signs are within normal limits for that patient. • Respiratory status is not compromised. • Pain and discomfort have been addressed.

REFERENCES

[1] NCEPOD. Scoping our practice 2004

[2] NPSA. Rapid Response Report: Reducing risk of overdose with midazolam injection in adults December 2008

[3] NICE. Clinical Guidelines (CG112): Sedation in children and young people 2010; RCEM Summary of NICE CG112 June 2012

[4] AoMRC. Safe sedation practice for healthcare procedures – standards and guidance 2013

[5] RCoA and RCEM. Safe sedation of adults in the emergency department 2012

[6] NHS England. National Safety Standards for Invasive Procedures https://www.england.nhs.uk/wp-content/uploads/2015/09/natssips-safety-standards.pdf

[7] RCEM. Invasive procedure checklist for EDs 2016

[8] ASA. Physical Status Classification System 2014

[9] Mason, K. P, Green S. M, Piacevoli Q and the International Sedation Task Force. Adverse event reporting tool to standardise the reporting and tracking of adverse events during procedural sedation: a consensus document from the World SIVA International Sedation Task Force. British Journal of Anaesthesia 2012;108 (1): 13–20

RCoA. Guidelines for the provision of anaesthesia: Chapter 20 – Sedation Services 2014

Knape, J.T.A et al. Guidelines for sedation and/or analgesia by non-anaesthesiology doctors. European Journal of Anaesthesiology 2007, 24:563-567