Joint Trust Guideline for the Safe use of Conscious Sedation in Adult Patients

Document Control:

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Version	Date	Author	Reason/Change
V3.0	2019	Helen Goddard	Original
V4.0	2022	D. Stolady	Updates to national guidance, addition of non IV sedation

Previous Titles for this Document:

Previous Title/Amalgamated Titles	Date Revised
Joint Trust Guideline for the Safe use of IV Conscious Sedation in Adult Patients	Not applicable

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:
All departments involved in conscious sedation across the Acute Hospital Collaborative. This was achieved through either each trusts sedation committee/group or individual departments (e.g. JPUH ED as appropriate).

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g., changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a clinical guideline applicable to the Acute Hospital Collaborative.

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1. Quick reference

- All departments using conscious sedation should have a named lead clinician responsible for the use of sedation, a registrar of sedation practitioners and a local departmental protocol for safe sedation.
- All staff involved in the administration of IV drugs for conscious sedation and patient care should have up to date resus training and have training in conscious sedation.
- All patients should have a comprehensive pre procedural assessment of their medical history and medication. Consent for conscious sedation should be taken. Vital signs should be recorded. Records should be made including pre procedural information and vital signs, sedation level and drugs and dose given during the procedure use of antagonists and adverse events. The use of a sedation proforma is recommended to achieve this.
- Procedures should only take place in areas prepared for sedation, e.g., endoscopy, emergency department, radiology and theatres. All areas should be equipped with oxygen, resuscitation equipment and full monitoring.
- Capnography is mandatory for any sedation intended to be of moderate depth or deeper.
- A trained staff member should be responsible for monitoring and recording the observations of the patient during the procedure. This should be the sole duty of this staff member. For prolonged, complex procedures or frail patients with significant comorbidities, a separate dedicated sedationist must be used.
- Antagonists should be available, and practitioners must be trained in their administration (Appendix 2)
- Patients should be monitored in a recovery area with a fully trained nurse until discharge criteria are met. (Appendix 4)
- Patients must be accompanied by a competent adult for the next 24 hours if discharged home. They should be given comprehensive post sedation instructions.

2. Introduction

2.1 Rationale & Objective

These guidelines are designed to guide the safe use of conscious sedation reduce discomfort and anxiety of a procedure not requiring a general anaesthetic (including sedation in theatres, but not using an anaesthetist). These guidelines do not cover sedation in the intensive care unit.

Sedation is used to make uncomfortable and painful procedure more acceptable to patients but has the potential to cause life threatening complications. The National Patient Safety Agency (NPSA) rapid response alert[1] highlighted the use of midazolam for conscious sedation has been responsible for 3 deaths and the 2004 National Confidential Enquiry into patient Outcome and Death (NCEPOD) report[2] showed elderly patients are particularly vulnerable.

2.2 Definition of Conscious Sedation

A technique in which the use of drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drug and techniques used to provide conscious sedation should carry a margin of safety wide enough to render loss of consciousness unlikely.

2.3 Classification of Depth of Sedation

- Minimal - Anxiolysis. normal response to verbal stimulation.
- Moderate – “conscious sedation” Purposeful response to verbal and tactile stimulation.
- Deep – purposeful response to repeated painful stimulation only.
- General Anaesthesia – No response to painful stimulation.

Deeper levels of sedation, where verbal contact is lost, have the potential to cardiovascular and or respiratory depression as well as loss of airway reflexes. This may result in significant morbidity and mortality.[9]

3. Broad Recommendations and Guidelines

3.1 Staff Training

All departments using IV conscious sedation should have a named lead clinician responsible for the use of IV sedation and a departmental protocol including the points covered in this general guideline specific to their department and the procedures it is being used for.

The doctors supervising conscious (moderate) sedation should be up to date with current ALS or ILS protocols and regularly attend mandatory resuscitation training. All staff members involved in the administration of IV drugs for conscious sedation, including operator and observer, should have recent and current resuscitation training. (BLS for minimal sedation, ILS for moderate sedation and ALS for deep sedation)

Sedationists should also have training in the administration and actions of the drugs being used and be able to recognise and deal with the complications of administration. Training can be either completion of a course on conscious sedation, sedation modules built into training programmes (e.g., RCOA IAC, RCEM sedation module) and/or a suitable period of training with an experienced sedationist until considered competent (see below).

3.2 Drugs Preferred for sedation

There are a wide range of sedation drugs available. It is recognised that the sedation requirements will vary across the trusts and the individual departments depending on the nature of the exact procedure, individual patient and practitioner choice. The best sedative agent may vary significantly. A summary is provided in appendix 2. Dose reductions must be considered in frail or elderly patients.

Rather than being prescriptive with the type of sedative used, this guideline emphasizes

- That the practitioner administering the sedative must be familiar with the drugs pharmacokinetic and pharmacodynamic properties ensuring safe usage.
- The practitioner delivering the sedation should be aware of the contraindications to its use and be able to treat the complications and side effects of their chosen sedative.
- The practitioner should be able to provide evidence of this competence (e.g., Sedation Module (RCEM)/Initial assessment of competence (RCOA) or similar, a logbook of practice or similar.
- Practice should be audited as part of the departments audit programme.

Until the above are met the practitioner should be supervised by more experienced seditionist during the procedure.

3.3 Pre-procedural Assessment

All patients should have an assessment covering previous medical history, drug history, allergies, smoking and alcohol history, previous anaesthetic history including complications. The presence of heart disease, cerebrovascular disease, insulin dependent diabetes, lung disease, liver failure, anaemia, shock and morbid obesity are risk factors for complications of sedation. The possible effect of any concurrent medication should be assessed as to its possible effects on the sedation process.[4] Baseline vital signs including heart rate, blood pressure, oxygen saturation, weight. Consent for sedation and procedure should be taken. American Society of Anaesthesiologists (ASA) grade should be noted (see Appendix 1).

Consent for conscious sedation and the procedure should be taken at this time and information should be given on oral intake and post procedural requirements.

3.4 Equipment

Equipment should be available in both procedural areas and recovery areas. This should include full monitoring equipment including:

- ECG.
- Blood pressure.
- Oxygen saturation monitoring.
- Resuscitation equipment including defibrillator and resuscitation drugs; oxygen and oxygen delivery systems; suction; a tipping trolley; intravenous access devices and fluids.
- The use of continuous capnography is recommended wherever sedation is planned, and mandatory if moderate or deeper levels of sedation are intended. (Deep sedation is considered by the RCoA to equate to anaeasthesia and therefore requires a seditionist with anaesthetic competences (e.g., RCOA IAC or equivalent) presence if planned).

3.5 Management of Sedation

For elective cases a period of starvation of 6 hours for food and with clear fluids limited to 50mls per hour is recommended to reduce the risk of aspiration should over-sedation occur.

For emergency cases a risk benefit analysis should be made to weigh the risk of potential aspiration if over sedation occurs, against the risks of either delaying the procedure until appropriate starvation times have occurred or undertaking full general anaesthetic with a secured airway.

Use of single agents is preferable where possible due the synergistic effect of combining most sedatives, particularly opiates and benzodiazepines, leading to inadvertent over sedation and cardiorespiratory compromise. If a combination of drugs is considered necessary the opioids should, whenever possible, be given before and their effect observed before proceeding[4] to give any sedative. Each IV drug should be flushed with sterile 0.9% sodium chloride after each administration. Verbal contact should be always kept with the patient during light to moderate sedation (Dissociative sedation with Ketamine may be considered an exception to this).

Reversal agents should always be available, and staff should know how and when to administer the drugs and recognise the complications. (Appendix 2).
The use of oxygen via face mask or nasal prongs is recommended during sedation to reduce the risk of hypoxia.[5]

A suitably trained member of staff should be responsible for monitoring the patient throughout procedure. They should also regularly record the level of sedation and vital observations and sedatives given.

The cannula should be flushed at the end of the procedure with 0.9% NaCl to ensure no sedative remains in the cannula.

3.6 Recovery and Post Procedure Monitoring

The patients should be recovered in a dedicated recovery area, equipped with resuscitation equipment, full monitoring and oxygen. There should be always a fully trained member of staff in attendance and monitoring should be continued until the

level of consciousness and other vital signs have returned to pre-procedural baseline levels. The patients should be discharged into the care of a competent adult and should not drive, operate machinery or sign legal documents for the next 24 hours. Patients should be given written instructions about common aftereffects of their procedure and sedation. A contact number should be provided in case of any problems.

3.7 Clinical Audit Standards

Audit should be an integral part of the written record of sedation. Drug dosage, use of antagonists and adverse events should be audited regularly as part of the local department audit process

4. References

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9. General Provision of Anaesthetic Practice (GPAS 2021). https://www.rcoa.ac.uk/gpas/chapter-7
10. Practice for Healthcare Procedures: Standards and Guidance. *AoMRC*, London 2013 (www.rcoa.ac.uk/node/15182).
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5. Audit of the process

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Standard set as per guideline	Departmental audits	Individual departments where sedation is used	Sedation Committees or equivalent at each trust	Annual

The audit results are to be discussed at relevant governance meetings to review the results and recommendations for further action. Then sent to the individual trust sedation committees or equivalents who will ensure that the actions and recommendations are suitable and sufficient.

6. Appendices

6.1 ASA grade

ASA Grade	Description
1	Normal healthy individual
2	Mild systemic disease that does not limit activity
3	Severe systemic disease that limits activity but is not incapacitating
4	Incapacitating systemic disease which is constantly life threatening
5	Moribund, not expected to survive 24 hours with or without surgery

6.2 Pharmacological Agents for sedation.

Adapted from RCEM Pharmacological Agents for Procedural Sedation and Analgesia in the emergency department 2013

Agent	Role	Route	Initial dose Elderly/Frail	Repeat dose Elderly/Frail	Initial Dose Adult	Repeat dose Adult	Initial onset time (min)*	Peak effect time (min)*
Propofol	Sedation / Amnesia	IV	10-20 mg Give slowly	10-20 mg Give slowly	0.5mg 1mg/kg	0.5mg/kg every 3- 5mins	0.5-1	1-2
Midazolam	Sedation / Amnesia	IV over 1-2min	0.5mg	0.5mg	1-2mg	1-2mg after 2-5min	1-2	3-4
Ketamine IV	Sedation /Amnesia / Analgesia	IV over 1 min	10 - 30 mg		1mg/kg	0.25 -0.5mg/kg Every 5-10 mins	0.5-1	1-2
Ketamine IM	Sedation / Amnesia / Analgesia	IM			4-5mg/kg	2-2.5mg/kg every 5 - 10mins	0.5-1	1-2
Ketamine	Analgesia only	IV			0.3mg/kg		0.5-1	1-2
Fentanyl	Sedation / Analgesia	IV			Up to 0.5µg/kg	Up to 0.5µg/kg every 2 mins	1-2	3-5

Fentanyl	Sedation / Analgesia	IV			Up to 0.5 to 1µg/kg	0.5 - 1.0µg/kg every 2 mins	1-2	3-5
Entonox	Sedation / Analgesia	Inhaled	50%N_2O/O_2		50%N_2O/O_2		1-2	1-2

6.3 Antagonists and treatment of oversedation

Sedative Drug	Antagonist	Dose	Onset	Side effects	Cautions
Midazolam	Flumazenil	O.2mg IV boluses up to max 1mg Infusion may be required.	1-2 minutes, peak 6-10 minutes. Lasts 15-140min	Nausea, vomiting, and flushing; agitation, anxiety, and fear; transient increase in blood pressure and heart rate; *very rarely* convulsions (Particularly in those with epilepsy), hypersensitivity reactions including anaphylaxis.	Short acting, Benzodiazepine dependence (seizures), prolonged treatment of convulsions (seizures), head injury, elderly, children, hepatic impairment, pregnancy, breast feeding.
Opioid	Naloxone	0.1mg-0.2mg IV boluses. Repeat doses at 2-3min. 0.4-2mg can be used if required up to max 10mg. Infusion may be required.	2 minutes. Lasts 20 minutes	Hypotension, hypertension, Ventricular tachycardia or fibrillation, cardiac arrest, hyperventilation dyspnoea, pulmonary hypertension, agitation.	Cardiovascular disease or cardiotoxic drugs, physical dependence on opioids acute withdrawal, short acting, pregnancy.

6.4 Criteria for discharge

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

6.5 Procedural Sedation Observation Chart

Sedation Procedure Observations Chart

Sedation score
0. Fully Alert
1. Drowsy but responsive and orientated
2. Dozing but easily roused
3. Asleep but aroused by pain
4. Moves/groans only to pain
5. Unresponsive

Patient Identifier Label

Procedure date																
Time																
Medication and dose																
Oxygen L/min																
Oxygen delivery method																
O2 saturations																
Capnography (4.5-6.5)																
Respiratory rate																
Sedation Score																
Pain score (0-10)																
BP AND PULSE	**220**															
	200															
	180															
	160															
	140															
	120															
	100															
	80															
	60															
	40															
	20															

7. Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Surgical	**Department**	Anaesthetic
Name of person completing form	Daniel Stolady	**Date**	29/12/2022

Equality Area	**Potential Negative Impact**	**Impact Positive Impact**	**Which groups are affected**	**Full Impact Assessment Required YES/NO**
Race	Nil	Nil	N/A	No
Pregnancy & Maternity	Nil	Nil	N/A	No
Disability	Nil	Nil	N/A	No
Religion & beliefs	Nil	Nil	N/A	No
Sex	Nil	Nil	N/A	No
Gender reassignment	Nil	Nil	N/A	No
Sexual Orientation	Nil	Nil	N/A	No
Age	Nil	Nil	N/A	No
Marriage & Civil Partnership	Nil	Nil	N/A	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?		N/A		

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.