University Hospitals of Leicester NHS
NHS Trust

# Sedation UHL Policy

| | |
|---|---|
| **Approved by:** | **Policy and Guideline Committee** |
| **Date Approved:** | **8 March 2005** |
| **Trust re f:** | **B10/2005** |
| **Most recent review:** | **20 September 2019 (replaces June 2016 version)** |
| **ne x t review d ate:** | **April 2025 6 month extension Approved at CPGC 10/10/24** |
| **Policy Lead:** | **Dr R Leighton, Consultant Anaesthetist** |

**CONTENTS**

## 1. Introduction

**1.1. Sedation is a drug-induced depression of consciousness, a continuum culminating in general anaesthesia. (Academy of Medical Colleges, 2013)**

**1.2.** In the United Kingdom **Conscious sedation** has been defined as**:**

- A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out.
- During the period of sedation verbal contact with the patient is maintained throughout.
- The drugs and techniques used should carry a margin of safety wide enough to render loss of consciousness unlikely.
- The endpoint is clearly defined and wide margins of safety stipulated.
- The airway is normally unaffected and spontaneous ventilation adequate.
- **If verbal responsiveness is lost the patient requires a level of care identical to that needed for general anaesthesia.**

**1.3.** This policy draws together recommendations and guidelines made within several documents which are detailed at the end of the document in Appendix 3. The Trust is required to comply with these documents and must be able to demonstrate this compliance.

**1.4.** UHL maintains a sedation committee with overall responsibility for sedation for procedures within UHL. Each CMG is invited to nominate a representative for this committee.

**1.5.** This is an overarching policy. Individual Clinical Management Groups (CMGs) are responsible for developing their own procedure guidelines to support practice in line with this policy. CMGs should identify a Lead Clinician who can take forward the development of such guidelines.

## 2. Scope

This policy applies to adult patients only and to all Health Care Practitioners working for the University Hospitals of Leicester who are involved in the conscious sedation of adult patients and who have received appropriate training to undertake this role.

## 3. Roles and Responsibilities

3.1 Medical Director Responsibilities

- Executive lead for this Policy

3.2 CMG Clinical Director Responsibilities

- To nominate a representative for the UHL sedation committee
- To identify a lead clinician for sedation
- To develop local guidelines (where appropriate) in line with this policy
- To ensure that this policy is implemented in the clinical environment
- To ensure that all staff involved in sedation have received appropriate training
- To ensure audit activity meets the requirements of section 7 of this policy

3.3 Responsibilities of health care professionals involved in the sedation of adult patients or the care of those patients

- To work within their own professional competence
- To acquire and maintain the relevant knowledge skills through continued learning.
- To comply with the governance and audit requirements.

## 4 Education and Training

- Safety will only be optimised if practitioners use defined methods of sedation for which they have received formal training.
- All staff caring for patients who received sedation as detailed within this policy must undergo training and be deemed competent. They should also be supported by their line manager to undertake any extended roles. (Details of training guidelines can be found in Appendix 2)
- Trainee doctors must be adequately instructed in IV sedation techniques and closely supervised by an experienced professional until competent.
- Where the clinician takes responsibility for both sedating the patient and carrying out the procedure they must be trained and deemed competent to do so. During such procedures a **second** appropriately trained individual other than the operator **must** monitor the patient's status and should have this as their primary role during the procedure. They should not also be assisting the operator for the procedure.

## 5. Policy Statement

**These standards have been drawn directly from the documents listed in Appendix 3.**

**In the absence of any department/directorate specific guidelines and procedures these standards must be followed.**

### 5.1 Environment and equipment

- Safety and monitoring should be part of a quality assurance program in areas where conscious sedation is carried out.

- Resuscitation equipment and sedation reversing/antagonist drugs (eg flumazenil and naloxone) must be available in the procedure room and recovery area.

- Drugs and equipment necessary for the maintenance of airway, breathing and circulation must be present in the areas where conscious sedation is carried out and resuscitation equipment and drugs should be checked prior to commencing each list.

- Records of management outcome and adverse events must be taken as part of the patient plan and kept and used for audit of departmental practice. Incidents should be reported using the Trust adverse incident reporting forms and systems.

- Where the target state of sedation **or** the complexity of procedure **or** patient co-mordbidy dictate the presence of an anaesthetist for the procedure then the standards of care and monitoring employed must be equal to those provided for general anaesthesia.

### 5.2 Staff competence

**5.2.1** Staff of all grades and descriptions involved in conscious sedation of patients must be familiar with resuscitation methods and undergo re-training as per Trust Core Training Policy (B21/2005).

**5.2.2** Specific training relevant to children is required and NICE guidance exists for practitioners intending to administer sedation to children and young people.

**5.2.3** The clinician carrying out the procedure is responsible for the health and safety of the patient throughout the procedure and is not just a technician.

## 5.3 Patient Information and Consent

**5.3.1** The risks and benefits of the procedure should be explained to the patient prior to the procedure and must be documented on a consent form as laid down in the Department of Health guidelines and in the Trust consent policy.

- Alternatives to sedation should be clearly explained.
- Patient Information leaflets should be available and offered to patients undergoing procedures involving conscious sedation

## 5.4 Pre-procedure assessment

**5.4.1** All patients must undergo a pre-procedure assessment to identify risk factors. This assessment should, wherever possible, include consultation of previous healthcare records.

**5.4.2** Many procedures are carried out on elderly patients who have significant co-morbidity and even in younger patients the presence of cardiovascular disease, respiratory disease, liver disease and morbid obesity are potentially dangerous risk factors.

**5.4.3** Emergency procedures pose additional risks directly related to the underlying problem.

**5.4.4** Patients with significant co-morbidity are likely to require smaller doses of sedative drugs which will work more slowly and take longer to recover.

**5.4.5** No one sedation technique is suitable for all patients or procedures.

## 5.5 Fasting

**5.5.1** For elective procedures patients should be fasted as per the standard 2-4-6 hour rule. Practitioners who choose to sedate unfasted patients should justify this choice in the patient's notes.

**5.5.2** For emergency procedures the decision to proceed with sedation should be based on the urgency of the procedure and the target depth of sedation.

## 5.6 Medication

**5.6.1** All staff involved should bear in mind that sedation does not negate the need for good communication with the patient at all times.

**5.6.2** Sedatives used should be within the manufacturers' guidelines and have a clear indication for best practice.

**5.6.3** Multiple drug techniques should only be considered where there is a clear clinical justification.

**5.6.4** Dosages of benzodiazepines and opiates should be titrated carefully and thus kept to a minimum to achieve the target level of sedation.

**5.6.5** Opiates should, whenever possible, be given before benzodiazepines and their peak effect observed and documented before proceeding.

**5.6.6** For most procedures it is recommended that **5mg of Midazolam should usually be the maximum dose given** and that elderly patients are given 500micrograms to 1mg initially with a sensible pause to observe effect, usually no greater than 2mg in total.

**5.6.7 Only ampoules containing 1mg in 1ml midazolam must be used** .

**5.6.8** The practice of drawing up 10mg of midazolam should be considered an adverse event and reported via Datix incident on INsite

**5.6.9** Drugs such as Propofol, Ketamine and analogous compounds should not be used without the presence of a trained Anaesthetist or Intensivist. Clinicians and departments wishing to administer such agents must only do so within the context of locally approved guidelines which have been approved by the trust sedation committee. Clinicians administering such agents within such guidelines must have undergone suitable training and be able to demonstrate ongoing competence in their use.

**5.6.10** For complicated or prolonged procedures or those requiring deep levels of sedation administration of the sedation must be the responsibility of a dedicated and appropriately trained Anaesthetist.

**5.6.11** The benzodiazepine and opioid antagonists, flumazenil and naloxone, **are usually reserved for emergency use**. Flumazenil administration following sedation should be reported on Datix.,

## 5.7 Care and monitoring during the procedure

**5.7.1** Regular communication with the patient allows monitoring of the level of sedation.

**5.7.2** A suitably trained individual competent in resuscitation and has an understanding of the technique being used must monitor and document the patient's condition during the procedure.

**5.7.3** Where the clinician takes responsibility for both sedating the patient and carrying out the procedure they must be trained and deemed competent to do so. During such procedures a second appropriately trained individual other than the operator must monitor the patient's status and should have this as their primary role during the procedure.

**5.7.4** Oxygen should be given to all sedated patients throughout the procedure

and recovery period unless department/directorate guidelines indicate that oxygen is not appropriate. Low flow Oxygen at 2-4L via nasal cannulae or facemask is usually well tolerated and effective.

**5.7.5** All sedated patients must have 20G or larger secure venous access (not "butterfly") in situ throughout the procedure and recovery period.

**5.7.6** Continuous Pulse oximetry monitoring must be used in all sedated patients during sedation and recovery. ECG and blood pressure monitoring and capnography should be readily available.

**5.7.7** The patient must be supported appropriately through the procedure and whilst sedated. Supportive devices to be used can include beds, trolleys, pillows and specially designed tables. At no time should patients be restrained by staff members.

### 5.8 Continuing care

**5.8.1** Clinical monitoring including continuous pulse oximetry must be continued in the recovery period.

**5.8.2** The practitioner carrying out the procedure is retains responsibility for the post-procedure recovery period and should give clear instructions to the member of staff who is responsible for monitoring the patient during recovery.

**5.8.3** This information is especially important when an adverse event has occurred during the procedure or the patient has significant co-morbidity.

**5.8.4** Patients must be formally assessed as suitable for discharge from the clinical area where sedation has taken place and this should be recorded in the notes.

- Day case patients who have received sedation must be accompanied home by a responsible adult who should stay with them for at least 12 hours. Clear written instructions should be given to this person as to what to do and whom to contact in the event of problems arising.

- Patients who have been sedated with an intravenous benzodiazepine should be advised not to drive a car, operate machinery, sign legal documents or drink alcohol for 24 hours.

## 5.9 Record Keeping

The patient case notes should include a patient specific record of the procedure. This will include the pre-procedure state of the patient, drugs used during the procedure, data from monitoring during and after sedation and any adverse events encountered.

## 6. Monitoring Compliance

| Element to be monitored | Lead | Method | Frequency | Reporting arrangements |
|---|---|---|---|---|
| Compliance with CMG requirements to identify Sedation Lead, have | Sedation Committee | CMG Gap Analysis returns | Annually | Sedation Committee |
| Number of procedures undertaken using sedation and frequency of adverse events | CMG Management team | CMG Gap Analysis* | Annually | CMG Q&S Board |
| Number of staff involved in sedation that are appropriately trained | CMG Management team | CMG Gap Analysis * | Annually | CMG Q&S Board |
| Patient Safety Incidents involving: Preparation or use of 10mg Midazolam preparations | CMG Management team | Datix | Annually | CMG Q&S Board |
| Flumazenil and naloxone usage | Pharmacy | Pharmacy database | Annually | CMG Q&S Boards |
| * A Gap Analysis template is given in Appendix 1. | | | | |

# Appendix 1 - Gap Analysis of the Recommendations on Safe Sedation

| Procedure Reviewed: | | | CMG: | | | Site: |
|---|---|---|---|---|---|---|
| | **Recommendation** | **Compliance** | **Action to achieve Compliance** | **Resource** | **Time Scale** | **Lead Representative** |
| **1. Environmentand Equipment** | | | | | | |
| **1.1** | Safety and monitoring should be part of a quality assurance program. | | | | | |
| **1.2** | Resuscitationequipment and sedation reversing/antagonistdrugs must be available in the procedure room and recovery area | | | | | |
| **1.3** | Drugs and equipment necessary for the maintenance of airway, breathing and circulation should be present in the procedure room and recovery area and be checked regularly | | | | | |
| **1.4** | Records of management outcome and adverse events should be taken as part of the patient plan and kept and used for audit of departmental practice | | | | | |
| **1.5** | Incidents should be reported using the Trust adverse incident reporting forms and systems | | | | | |
| **2. Staff Competence** | | | | | | |
| **2.1** | Staff of all grades and description should be familiar with resuscitation methods and undergo re-training as per the Trust mandatory training guidelines | | | | | |
| **2.2** | The cliniciancarrying out the procedure retains responsibility for the health and safety of the patient throughout the procedure. | | | | | |

| Procedure Reviewed: | | CMG: | | | | Site: |
|---|---|---|---|---|---|---|
| | **Recommendation** | **Compliance** | **Action to achieve Compliance** | **Resource** | **Time Scale** | **Lead Representative** |
| **3. Patientinformation and consent** | | | | | | |
| **3.1** | Written consent is sought as laid down in the Department of Health guidelines and in the Trust consent policy | | | | | |
| **3.2** | Patient Information leaflets should be available and offered to patients undergoing procedures involving conscious sedation | | | | | |
| **4. Pre-procedure assessment** | | | | | | |
| 4.1 | All patients should undergo a pre-procedure assessment to identify risk factors. | | | | | |
| 4.2 | Patients who are identified as having risk factors are given appropriately lower doses of sedation or referred to anaesthesia | | | | | |
| **5. Medication** | | | | | | |
| | **a)** Dosage of benzodiazepines and opiates should be kept to a minimum to achieve sedationand should be within the manufactures guidelines and have a clear indicationfor best practice. | | | | | |
| | **b)** Opioids should whenever possible be given before benzodiazepines and their effect observed and documented before proceeding | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **6. Care and monitoring during procedure** | | | | | | |
| **6.1** | A suitably trained individual competent should monitor and document the patient's condition during the procedure | | | | | |
| **6.2** | The patient should be supported appropriatelythrough the procedure and whilst sedated. | | | | | |
| **6.3** | Oxygen should be given to all sedated patients and Oxygen Saturations should not fall below 90% during the procedure. | | | | | |
| **6.4** | All sedated patients must have secure venous access throughout the procedure and recovery period | | | | | |
| **6.5** | Pulse oximerty monitoring should be used in all sedated patients. ECG, blood pressure monitoring and capnography should be readily available. | | | | | |
| **7. Continuing Care** | | | | | | |
| **7.1** | Clinicalmonitoring is continued and documented into the recovery period. | | | | | |
| **7.2** | Patients are assessed prior to discharge from the clinical area. | | | | | |
| **7.3** | Day case patients who have received sedationmust be accompanied home by a responsible adult who should stay with them for at least 12 hours. | | | | | |
| **7.4** | Clear written instructions should be given to this person as to what to do and whom to contact in the event of problems arising | | | | | |
| **7.5** | Patients who have been sedated with an intravenous benzodiazepine should be advised not to drive a car, operate machinery, sign legal documents or drink alcohol for 24 hours. | | | | | |

## Appendix 2 – Training Guidelines

**Basic requirements:**

All staff involved in the sedation of patients should be:

- Competent in Basic Life Support
- Familiar with the procedure being performed under sedation
- Competent to monitor the patient's vital signs, safety, comfort and well-being pre, during and post procedure

Staff administering sedation must also be

- Competent to administer IV sedation drugs
- Be familiar with the relevant trust and CMG policies
- Have undergone training in sedation practice

## Appendix 3 – Supporting Reference Documents

Safe Sedation Practice for Healthcare Procedures: Standards and Guidance, Academy of Medical Colleges (Oct 2013)

Guidelines for the Provision of Sedation Services 2016 from Guidelines for the provision of anaesthetic services, Royal College of Anaesthetists (2016)

Safe Sedation of Adults in the Emergency Department (Nov 2012)

NPSA Rapid Response Report NPSA/2008/RRR011: Reducing risk of overdose with midazolam injection in adults (2008)

British Society of Gastroenterology (2003) Guidelines in Gastroenterology September. 2003

National Confidential Enquiry into Patient Outcome and Deaths (NCEPOD) advice on recommended doses of sedative drugs 2006

NPSA Rapid Response Report: Reducing risk of overdose with midazolam injection in adults. (2008)

NPSA NHS/PSA/Re/2015/009 Support to minimise the risk of distress and death from inappropriate doses of naloxone (2015)

## Appendix 4 – Changelog

Section 4.2
rewording of sentence.

Section 6.6 paragraph 9
Addition of “Clinicians and departments wishing to administer such agents must only do so within the context of locally approved guidelines which have been approved by the trust sedation committee. Clinicians administering such agents within such guidelines must have undergone suitable training and be able to demonstrate ongoing competence in their use.”

Gap Analysis Tool

Clarification of requirements in response to feedback.