NHS Musgrove Park Hospital	Trust Policy
Title: Sedation Policy for Adult Patients	
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Ratified by: Policy Review Group	**Active date**: 1st June 2010
Ratification date: 1st July 2010	**Review date**: 1st June 2013
Applies to: All staff participating in any form of patient sedation.	**Exclusions:** Gaseous inhalation (Entonox®)
Purpose: To ensure that all staff involved in sedating patients do so safely and to the guidance of ratified local sedation guidelines.	

Key Points

- All practices within the Trust must comply with this Policy.
- Guidelines, protocols and procedures in specialist areas must be written and approved in compliance with this Policy.
- The introduction sets out definitions and exclusions.
- The policy section sets out the requirements.
- Training of staff, role responsibility and professional accountability are covered.
- Clinical assessment of the patient and fasting of the patient is included.
- Drugs used for sedation, including the safe use of midazolam (and flumazenil) in accordance with the National Patient Safety Agency alert (RRR11) is an important inclusion within the Policy.
- Other aspects include: patient clinical monitoring, record keeping, facilities including recovery, reporting adverse outcomes are covered.
- General guidance on safety procedures and additional considerations when undertaking moderate sedation are included.
- The effectiveness of this policy will be monitored by the Drug and Therapeutics Committee.

1 Introduction

1.1 This policy includes drug induced sedation by all routes of administration **excluding** gaseous inhalation (Entonox®) It is not limited by the former definition of "conscious sedation" and covers the situation where such sedation is a predictable property of a given drug even though it may be administered for another purpose (eg analgesia or as an antiepileptic). This includes:

- **Minimal sedation (anxiolysis)**: 'a state during which patients respond normally to verbal command or can be woken up to full consciousness by minimal stimuli. Although cognitive function and co-ordination may be impaired, ventilatory and cardiovascular functions are unaffected.

- **Moderate sedation (or Conscious sedation):** depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation (reflex withdrawal from a painful stimulus is *not* considered a purposeful response). No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

- **Sedation used to supplement local anaesthesia**

1.2 This policy does **NOT** cover sedation that Trust policy requires to be administered by trained anaesthetists and the use of Entonox®. Any anaesthetic service policy or trust wide policy e.g. Entonox® takes priority in these circumstances.

This includes **propofol** and **ketamine** and where it is intended for the patient to have:

- **Deep sedation/analgesia**: depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function is impaired. Patients require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- **Anaesthesia**: consists of general anaesthesia and spinal or major regional anaesthesia. It does *not* include local anaesthesia.

2 Policy.

2.1 Minimal sedation practice will be covered by generic guidelines or standard operating procedures (SOP).

2.2 Specific, ratified clinical guidelines or clinical policies will be available via the Trust intranet to cover situations where an Injectable or gaseous agent is used to deliberately induce moderate sedation (conscious sedation). These will exist in clinical areas such as but not exclusively Cardiology, Endoscopy, Haematology and A&E.

2.3 Such guidelines or SOPs will specify the drugs allowed to be used in particular clinical circumstances, their order of choice, dose ranges and routes of administration.

2.4 Where appropriate the guideline or SOP will unambiguously state any mandatory requirements.

2.5 Situations where a sole practitioner or service utilise a form of moderate sedation, or where moderate sedation is administered as part of a another procedure or investigation will be included and is covered by this policy.

3 Training

3.1 All clinical staff prescribing or administering sedation must be trained to a level consistent with patient safety. In the case of those trained to administer any form of moderate sedation/analgesia the Trust requires formal evidence of such training in the form of a 'sign off' by an educational supervisor, recognised trainer or clinical director/lead clinician. Such a sign off requires that the supervisor and person signed off has read this policy and the relevant local Trust sedation guideline or SOP relevant to their area of practice.

3.2 Specific training requirements relevant to the local area of practice will be contained in the local guidance or SOP.

3.3 All local trust sedation guidelines, protocols and procedures must be written in accordance with this policy. These local procedural documents should include the responsibility for a senior staff member to monitor training and compliance with the requirements of this policy.3.4 Advice and support with training is available through the anaesthetic department

4 Role responsibility and Professional Accountability

4.1 **Sedation Practitioner**: The person responsible for carrying out the procedure after administering or supervising sedation. This is usually a doctor but may also be a Nurse Practitioner (band 6 or equivalent). The Sedation Practitioner must have the knowledge and skills required to provide safe sedation and have an Immediate Life Support or equivalent certificate.

4.2 **Sedation Assistant**: Registered nurse or experienced Health Care assistant working under the instruction of the Sedation Practitioner fulfilling a role similar to an anaesthetic nurse. S/he is responsible for patient care (monitoring, assessing level of consciousness and airway support) during the procedure. The Sedation Assistant may administer the first sedative dose and subsequent top-ups under the direct instruction and supervision of a Sedation Practitioner. S/he must hold a ***Basic*** Life Support certificate. The provision of sedation remains the responsibility of the Sedation Practitioner unless sedation is provided by another independent practitioner for example an anaesthetist or other doctor trained in providing sedation.

4.3 **Clinical Director/Clinical Lead/General Manager**: is responsible for providing an infrastructure to deliver safe sedation including providing resources to cover an after-hour service where it is required.4.4Locally designated lead for sedation: This should be a senior member of staff, who has received training and is competent in delivery of sedation. It is their responsibility to ensure staff within their responsibility are trained and competent in the administration sedation and the management of the sedated patient. They will sure that training and competency records are maintained and monitor compliance with this policy.

5. Clinical assessment of the patient

5.1 Patients must be assessed whether they are suitable to receive intravenous sedation. Significant co-morbidity should be documented. A checklist should include patient name, intended procedure, drug allergies, presence of dentures, and period of ‘starvation’.

5.2 Sedation should be avoided or used with extreme caution if the patient cannot lie flat or if the patient is breathless at rest.

5.3 Sedation should be used with extreme care if the patient has an increased risk of aspiration

5.4 Intravenous sedation is contra-indicated in the following circumstances:

- There is a known allergy or hypersensitivity to sedative drugs or opioid analgesics.
- The patient has an impaired level of consciousness.
- The patient is not appropriately starved (see below)
- The procedure is deemed too painful for conscious sedation.
- Lack of immediate access to resuscitation equipment.

5.5 When sedation is contra-indicated, consider alternatives e.g. local anaesthesia, regional anaesthesia or general anaesthesia.

5.6 Remember: The Anaesthetic Department or on-call Anaesthetist can be contacted for advice.

6. Fasting.

6.1 In accordance with the guidelines for general anaesthesia, for elective procedures, patients should be starved of solids for six hours and clear fluid (this includes coffee or tea with skimmed milk) for two hours prior to receiving intravenous sedation.

6.2 For emergency procedures the clinical urgency to perform the procedure may outweigh the risk of aspiration if a patient is not fasted. This may apply to very urgent procedures (e.g. cardioversion for life-threatening dysrhythmias, reduction of fracture or dislocation with soft tissue/neurovascular compromise or intractable pain/suffering) and urgent procedures (e.g. reduction of other fractures/dislocations, drainage of abscess cavity, pyonephrosis or upper urinary tract obstruction), rescue angioplasty and insertion of dialysis lines.

6.3 Factors that may increase the risk for aspiration must be carefully considered. If in doubt, contact the Anaesthetic Department or on-call Anaesthetist.

7. Drugs

7.1 For non-painful procedures, ideally, a single agent should be used to sedate the patient. If a combination of drugs is used there should be a clear understanding of the synergistic effects of benzodiazepines and opioids and the increased potential for causing respiratory depression. The most commonly used sedative drugs include midazolam, diazepam, fentanyl, alfentanil, pethidine, morphine and diamorphine. Where an opioid is given in combination with a sedative the opioid should be given first and allowed time to become maximally effective before any sedative is added.

7.2 Use of midazolam (and flumazenil) as per ‘NPSA/2008/RRR011; Reducing risk of overdose of midazolam injection in adults. The National Patient Safety Agency (NPSA) has alerted all healthcare staff involved in the prescribing, administration or supply of injectable midazolam for use in adult conscious sedation to the risks of overdose or harm. Many UK adults are being overdosed with midazolam injection when used for conscious sedation. This is due to the variety of strengths available to practitioners, many of which represent doses higher than required by the patient e.g. midazolam as 5mg (2ml & 10ml) or 2mg/ml (5ml ampoule) exceeds the dose required for most patients. There is a risk that the entire contents of high strength ampoules are administered to a

patient when only a fraction of this dose is required. Doses often exceed that required, are not titrated to the patients individual needs, do not take into account concurrent medication (e.g. opioids) and may involve high risk groups for example, the frail or the elderly. There is frequent reliance on injectable flumazenil (antagonist or reversing agent) for reversal of sedation in patients that have been over sedated. Hence the following guidance has been issued on dosing and should appear in each local guideline or SOP:

- **Adults:** The intravenous injection of midazolam should be given slowly at a rate of approximately 1 mg in 30 seconds.
- **Adults less than 60 years of age**: The initial dose is 2 to 2.5mg given five to 10 minutes before the beginning of the procedure. Further doses of 1mg may be given as necessary. Mean total doses have been found to range from 3.5 to 7.5mg. A total dose greater than 5mg is usually not necessary.
- **Adults over 60 years of age, debilitated or chronically ill patients**: The initial dose must be reduced to 0.5-1mg and given five to 10 minutes before the beginning of the procedure. Further doses of 0.5 to 1mg may be given as necessary. Since in these patients the peak effect may be reached less rapidly, additional midazolam should be titrated very slowly and carefully. A total dose greater than 3.5mg is usually not necessary.

7.3 **Availability of midazolam strengths.**

- **Midazolam 50mg in 50ml**: only available for sedation in the ITU / HDU and in no other areas.
- **Midazolam 5mg in 5ml ampoules:** Is only to be used for sedation and is available to all areas where sedation under ratified guidelines is undertaken.
- **Midazolam 10mg in 2ml ampoules:** Is available to all areas likely to care for palliative patients requiring a subcutaneous injection or subcutaneous infusion containing among other drugs, midazolam. This strength should **NEVER** be used for any other sedation purpose.

7.4 **Flumazenil:** This is the benzodiazepine reversal agent. It has an elimination half life of only 40 to 80 minutes which is largely unaffected by age. Comparing this with midazolam's elimination half life of 1.5 to 2.5 hours in adults (and up to 4 times longer in the elderly, frail and those with renal dysfunction), care needs to be taken when reversing high doses of midazolam with flumazenil. Re-sedation can occur after the flumazenil has worn off. Therefore patients receiving flumazenil need to be monitored for up to 90 mins in a clinical environment.

8 Patient Clinical monitoring

8.1 A single person must **not** administer sedation **and** perform the procedure without another person (ideally a Sedation Assistant), dedicated specifically to the care of the sedated patient. This excludes staff with other roles related to the procedure.

8.2 Every patient should have a pulse oximeter attached until discharge from the recovery area is contemplated.

8.3 Monitoring of blood pressure, pulse and respiratory rate may not be necessary in young healthy patients, but can be essential in older patients, especially if there are any cardiovascular problems. A decrease in the respiratory rate often precedes any decrease in saturation.

8.4 Blood pressure and ECG must be monitored if sedation is used as an adjunct to regional anaesthesia.

9. Oxygen

9.1 Devices for administering oxygen via nasal cannula or facemask must be available. Oxygen should be administered if there is any concern that the oxygen saturation might decrease below the resting figure, remembering that a reading below 88-90% is potentially dangerous and requires immediate attention. Pre-oxygenation is likely to avoid desaturation and supplementary oxygen for all sedated patients has been recommended in some quarters.

9.2 It is important to check the possibility of a significant rise in pCO2 in patients who have been sedated and who have needed prolonged supplemental oxygen to maintain their saturations above 90% if they are slow to recover and especially if underlying chronic lung disease is present or suspected.

10. Record Keeping

10.1 The Sedation Assistant is responsible for keeping a written record of observations during the procedure.

10.2 The minimum dataset should include patient details, procedure, sedative drug dose, time, top-ups, level of consciousness, oxygen saturations, and heart rate and blood pressure if necessary.

10.3 Observations should be recorded at 10 min intervals up to 30 min after the last top-up.

10.4 The record should be signed and stored in the patient's medical notes. In the absence of a directorate specific observation chart an anaesthetic chart must be used.

11. Facilities including recovery

11.1 Patients must ideally be sedated on a trolley that can tip head down although this may not be feasible in the angiosuite and interventional radiology. Suction apparatus must be present in the same room and the arrest trolley must be immediately available (in the same suite).

11.2 Patients must be recovered in a dedicated recovery area and must not be left unsupervised until they have fully recovered from sedation.

11.3 Written instructions should be given to patients including advice on refraining from driving, operating machinery, drinking alcohol and signing legal documents up to 24 hours after receiving sedation.

12. Reporting of adverse outcomes

12.1 Adverse outcomes after sedation must be documented on a clinical incident form. The Sedation Working Group will review critical incidents at regular intervals. These would include:

- Profound hypoxaemia (<85%).
- Aspiration.
- The patient is unrousable (requiring the use of either flumazenil or naloxone).
- Respiratory arrest (requiring bag and mask ventilation).
- Airway obstruction (requiring insertion of a laryngeal mask airway or endotracheal intubation).
- Cardiac arrest.

13. General guidance on sedation procedures: These considerations will be included in all ratified local sedation guidelines and SOPs.

13.1 Check resuscitation equipment

13.2 Check availability of staff

13.3 Check consent form and fasting status

13.4 Assess patient suitability for sedation

13.5 Note and record significant co-morbidity and concurrent medication

13.6 Explain proposed sedation to the patient

13.7 Attach monitoring (pulse oximeter in everyone, blood pressure and ECG when indicated)

13.8 Supplementary oxygen via nasal cannula or Hudson mask (if appropriate)

13.9 Establish intravenous access.

13.10 Titrate drug(s) to desired level of sedation.

13.11 If the sedation practitioner is also performing the procedure, patient observation

and monitoring must be handed over to a nominated sedation assistant whom may give further top-ups on instruction.

13.12 Continue to monitor and document the level of consciousness and oxygen saturations (plus pulse, BP and respiratory rate if appropriate) at 10 minute intervals.

13.13 After the procedure take the patient to a suitable recovery area and monitor until 30 minutes after the last top-up (unless flumazenil has been administered).

13.14 Discharge patient when effects of sedation have worn off.

14 Additional considerations when undertaking moderate sedation.

14.1 A pre-sedation assessment; which includes a review of the patient's past and present medical and drug history with a formal documentation of risk (eg ASA grade).

14.2 A plan for the patient's sedation, including appropriate consent and monitoring and practice consistent with relevant guideline/policies. The plan must include criteria for terminating monitoring and deeming full recovery to have occurred. Any appropriate deviation from a policy or approved guidelines needs to be documented, with reasons, in the medical record. Any clinical staff who suspect at any stage that the plan and implementation of that plan has deviated inappropriately from a policy or approved guidelines should complete a clinical incident report.

14.3 At least two appropriately qualified clinical staff present at time of induction through to termination of the procedure.

14.4 A suitably trained individual, present throughout the procedure, must have a defined responsibility for monitoring patient safety and making a written record.

14.5 Secure venous access (where consent is not obtained for this, a patient specific risk assessment is mandatory).

14.6 Where an opioid is given in combination with a sedative the opioid should be given first and allowed time to become maximally effective before any sedative is added.

14.7 Equipment that must be present and functioning:

- Blood pressure and ECG monitoring equipment (may not be necessary in young healthy patients but must be available and used where appropriate such as those with cardiovascular problems)
- Pulse oximeter
- Source of supplemental oxygen and apparatus for delivery
- Suction apparatus with appropriate suction catheters
- Cardiac arrest trolley immediately available

- Patient bed/trolleys should be capable of being tipped head down (if procedure excludes this a specific risk assessment is necessary)

14.8 If moderate sedation is to be used and an antagonist exists for that sedative, sufficient antagonist to reverse any accidental overdose situation is to be verified as immediately available in that clinical area ('antidote box').

14.9 If verbal responsiveness is lost the patient requires a level of care identical to that needed for general anaesthesia. Accordingly, such care must be deliverable.

14.10 Adherence to a clinical policy where it specifies:

- The minimal experience and number of clinical staff to be present
- A specific formulation of a drug for an indication
- The maximum amount of a sedative to be pre-prepared (eg drawn up) before a procedure based on age or weight or other patient variable.

14.11 A clinical incident report should be completed where patient harm has occurred as a result of sedation or it transpires that this policy has been transgressed.

14.12 **Equality Impact Assessment:** By the nature of the policy (to put the patient at the centre of the process) it is designed to be accessible and suited to all. The principles of the process specifically require that staff consider at an early stage whether the client has any special needs. The policy recognises the rights of staff within the process.

15 Monitoring

15.1 All guidelines, protocols and procedures written in accordance with this policy should include a designated senior staff member as lead who will monitor training and compliance with the requirements of this policy.

15.2 A designated person of the Anaesthetics Department (Dr Mitesh Khakar – Consultant Anaesthetist) will assist with training and monitoring compliance with this Policy within the Trust.

15.3 The DTC will ensure that the implementation plan is monitored and ensure action is taken to remedy any non-compliance with the plan. This policy will be monitored by the Drugs & Therapeutic Committee annually. In order to monitor the policy, a nominated anaesthetist will carry out a sample review of the notes of (30) patients who have received sedation. And request to see copies of training/competency records

- The review of patient records will use an assessment tool containing criteria required by the policy (see appendix A)
- The number of training/competency requested as evidence will be proportionate to the size of the speciality and the number of clinical staff

administering sedation with that specialty.

The results from the review will be presented to the Drugs & Therapeutic CommitteeResults from the review will be circulated to the Clinical Director for each Directorate that provides sedation and each of the Divisional Governance leads.

The results report will include:

- The overall compliance with the policy according to sample results
- The actions needed to be taken by the Clinical Directors to address any deficiencies identified.
- The actions required by the Divisional Governance leads in the progress monitoring of action plans and dissemination of learning and improvements.

A Divisional representative will present completed action plans for sign off to the Drugs & Therapeutic Committee. They will also report any exceptions to this committee. The committee chair will escalate concerns to the Trust Medical Director

16 References

NPSA Rapid Response Alert NPSA/2008/RRR011 Reducing risk of overdose with midazolam injection in adults, December 2008.

British Society of Gastroenterology: Safety and sedation during endoscopic procedures, Sept 2003

Implementing and ensuring safe sedation practice for healthcare procedures in adults, November 2001. *UK Academy of Medical Royal Colleges and their Faculties*

NCEPOD recommendations – Elderly patients vulnerable because of excessive doses of sedatives. 2006.

Standards for conscious sedation in dentistry - alternative techniques.

A report from the standing committee on sedation for dentistry. 2007.

Safe sedation in children undergoing diagnostic and therapeutic procedures. SIGN 58 2004.