Trust Policy

Plymouth Hospitals NHS
NHS Trust

Policy for Safe Sedation during Healthcare Procedures in Adults

Date	Version
15th December 2011	2

Purpose

To provide a Trust-wide policy, based on current evidence and best practice, for safe sedation of adult patients during healthcare procedures.

Who should read this document?

All medical, nursing and other support staff involved directly or participating in the use of Conscious Sedation of adults, within or on behalf of Plymouth Hospitals NHS Trust.

Key messages

- All healthcare practitioners involved directly or participating in sedation techniques must have the necessary knowledge, skills and competencies required.
- All healthcare practitioners must comply with this policy when they are involved directly or participating in sedation techniques.

Accountabilities

Production	Dr Francis Luscombe, Associate Medical Director for Quality & Consultant in Pain Management
Review and approval	Clinical Governance Steering Group
Ratification	Dr. Alex Mayor, Medical Director
Dissemination	Peter Gray, Pharmacist
Compliance	Dr Francis Luscombe, Associate Medical Director for Quality & Consultant in Pain Management

Links to other policies and procedures

PHNT Medicines Management Policy
PHNT Policy for Consent to Examination or Treatment

Version History

	Version 1	Published January 2009
	Version2	December 2011. • Re-titled **Policy** for Safe Sedation during Healthcare Procedures in Adults to reflect that these are not merely guidelines. • Re-wording to emphasise that Deep Sedation requires the same level of training and skill as general anaesthesia. • Other re-wording to indicate the patient must have consented to sedation, patient “check list” to include ASA grading, staff involved in directly supervising sedation **must** have the necessary skills, training and knowledge, and **must** undergo specific documented instruction on the use of medical equipment. • Rather than specifying a fixed initial dose of IV midazolam, the initial dose of midazolam should be guided by the same patient and procedure related criteria as for fentanyl.

Last Approval	Due for Review
15th December 2011	November 2013

PHNT is committed to creating a fully inclusive and accessible service.

Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff.

We will treat people with dignity and respect, actively promote equality and diversity, and eliminate all forms of discrimination regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/ maternity.

An electronic version of this document is available on the Trust Documents Network Share Folder (G:\TrustDocuments). Larger text, Braille and Audio versions can be made available upon request.

1 Introduction

- Sedation techniques may make unpleasant healthcare procedures more acceptable to Patients.
- Sedation techniques also have the potential to cause life - threatening complications.
- Safe-Practice guidelines, when implemented, can reduce morbidity and mortality
- Sedation is an intervention in its own right, which requires organisation, resources and time to be safely performed.
- In response to nationally reported patient safety incidents involving use of midazolam injection for conscious sedation, the National Patient Safety Agency (NPSA) released a Rapid Response Report 9th December 2008 (NPSA/2008/RRR011) restricting the use of "High Strength" midazolam injection within the NHS and other healthcare sectors. The same report also stipulated that healthcare institutions must have an organizational policy that covers sedation.

2 Purpose, including legal or regulatory background

- The purpose of this Trust-wide policy is to ensure that sedation of adults undergoing healthcare procedures within or on behalf of the Trust, is performed in a safe manner and in accordance with current evidence and best practice.
- This policy will also ensure that the Trust is compliant with the requirements of NPSA Rapid Response Report 2008/RRR011 (Reducing risk of overdose with midazolam injection in adults)

3 Definitions

Conscious sedation

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, but during which verbal contact with the patient is maintained throughout. The drugs and techniques used to provide conscious sedation should carry a margin of safety wide enough to render loss of consciousness unlikely.

Deep Sedation

No matter how "deep sedation" is defined, it is always the case that the patient does not respond to verbal or simple physical stimuli, and may not maintain a clear airway. In terms of the procedures that can be performed this state may not equate to general anaesthesia, but there is a consensus that its supervision requires the same level of training and skill as general anaesthesia[1].

Adults

For the purposes of this document, adults are defined as being 16 years of age and above.

4 Patient Selection

- Cultural and individual patient factors, as well as the clinical skill of the individual doctor or dentist, play a part in the need for sedation.

- Encourage use of other techniques to minimize the need for sedation (e.g. pain control, increased patient understanding, reassurance).

- Each specialty has to evaluate those factors that influence effectiveness and patient satisfaction, but the benefits must outweigh the risks in every case.

Contraindications for Sedation

There are no absolute contraindications to sedation properly administered in the right setting by an appropriately trained individual, to a consented patient.

5 Patient Assessment

In advance of the procedure the patient, preferably assisted by attendant staff, should complete a 'check-list' to identify any risk factors:

- Significant past medical history
- ASA grading (See Appendix 1)
- Significant abnormalities in major organ systems
- Previous adverse experiences with sedation, analgesia or anaesthesia
- Medications
- Allergies
- Times of last food and drink

The level of detail, and the need for further clinical examination or investigations, will depend on the procedure and the patient's general condition. Suggested pre-procedure examination may include:

- Blood pressure
- Pulse rate
- Weight (kg)
- Temperature
- Auscultation of heart sounds and lung fields
- Brief airway assessment

In the case of outpatients or day-cases, written instructions on activities before and after the procedure are provided for the patient at an early stage.

6 Patient Preparation

- Patients should be informed about procedure, including details of risks, benefits, alternatives and limitations. For elective procedures this information should, ideally, take the form of both spoken and written information and should be delivered prior to the procedure date. Consent should be gained and recorded as per Trust policy.

In urgent cases, or other situations in which gastric emptying is impaired, the potential for pulmonary aspiration must be considered in determining

  - the level of sedation
  - whether the procedure should be delayed
  - whether the respiratory tract should be protected by intubation

7 Monitoring

Minimum level of continuous monitoring

- Score the sedation level:
  - Awake
  - Drowsy – responds to verbal stimulation
  - Drowsy – responds to physical stimulation
  - Unresponsive

  Response to verbal stimulation is usually lost before gross airway, cardiovascular or respiratory decompensation takes place. Effective monitoring will be difficult for patients with learning difficulties or for uncooperative patients.

- Observation of airway patency and respiratory function. Use of capnography is recommended.
- Oxygen saturation monitoring with audible tone
    - must have pulse oximeter in place, and respond promptly to information from monitoring oxygen saturation.

Consider additional monitoring

- Continuous ECG, in particular for patients with a history of cardiovascular disease, or if arrythmias are expected as part of the procedure.
- Intermittent blood pressure monitoring (every 5 minutes)
- Auscultation

Recording of monitoring

- Before sedation begins
- At regular intervals throughout the period of sedation and early recovery
- Before discharge

Recording may be automatic but audible alarms must be set for each patient.

8 Personnel

- Named consultant for each patient
- Individual directly supervising procedure:
    - Doctor or other registered healthcare professional trained in sedation
- Individual with responsibility for monitoring patient and recording throughout:
    - Should not be involved in other ancillary tasks, even if of short duration
- Immediate availability of individual(s) with up-to-date training in basic and immediate life support.
- Onsite critical care / anaesthesia cover

9 Training

Individuals involved in directly supervising sedation must have received instruction and training in sedation. They must take steps to ensure up-to-date knowledge and skills, including; basic pharmacology of agents, effects on respiratory / cardiovascular / neurological functions, dose intervals for safe titration, use of antagonists, and complications of sedation (recognition and initial treatment). All new personnel must undergo specific and documented instruction on the use of medical equipment in their areas as part of their induction. Each directorate is responsible for design and delivery of sedation training within their own work environment. This should be documented in a directorate training needs assessment.

10 Equipment

- Immediate access to equipment and drugs for advanced life support as found on a resuscitation trolley. The equipment should undergo regular restocking and checks by a named responsible person. A record should be kept of these checks.
- Suction
- Naloxone and Flumazenil injections must be available.
- Oxygen supply
- Means of administering oxygen including nasal cannulae, face masks, non-rebreathing masks.
- Patient Trolley that allows immediate head down tilt
- Stethoscope

11 Conduct of Safe Sedation

Agents

- Clinical areas should standardise their choice of analgesics and sedatives.
- Fentanyl and Midazolam* offer advantages over other agents in most settings
- Supplementary Entonox may be useful for short, intensely painful procedures.
- Anaesthetic agents (e.g. Propofol, Thiopentone, Ketamine) should only be used where personnel and equipment are immediately available for the safe conduct of anaesthesia, and their use is outside the remit of this document.

*In accordance the NPSA/2008/RRR011 report, the use of "High Strength" midazolam injection (10mg in 2ml and 10mg in 5ml ampoules) may only now be used in Intensive Care (Penrose, Pencarrow, Children's HDU, Torrington, Neonatal ICU), the Emergency Department, Plym Theatre and in palliative care. **All other areas using midazolam injection will only be allowed to stock and use 1mg/ml midazolam injection (5mg in 5ml or 2mg in 2ml ampoules).**

Intravenous access

- Intravenous access should be maintained until patient is ready for discharge from recovery.
- If intravenous access is lost before this, an Intravenous cannula should be re-sited.

Personnel trained in intravenous access should be immediately available during this time.

Oxygen administration

- Consider use of oxygen from onset of sedation in patients with cardiovascular or respiratory disease.
- Oxygen should be administered in other patients if oxygen saturation $\leq$ 94%.
- It may be appropriate to continue oxygen for several hours post-procedure.

Dosing and titration

The following technique is recommended:

- Administer an initial dose of fentanyl guided by:
    - Age
    - Weight
    - Other medications
    - Medical history and co-existing disease
    - Planned procedure
- Wait 2-3 minutes
- Administer an initial dose of midazolam guided by the same criteria as for fentanyl above.
- Assess the level of sedation after 2-5 minutes and repeat as necessary (minimum of 2 minutes between subsequent doses).
- During the procedure, additional doses may be given (fentanyl if in pain, midazolam if under-sedated).

Note that agitated patients may be in pain, or hypoxic, or occasionally under-sedated. They require careful assessment.

12 Reversal

- Naloxone and Flumazenil should always be immediately available when intravenous opioids and benzodiazepines are administered.
- Patients who have been over sedated or narcotised should receive standard 'Airway / Breathing / Circulation' support, including oxygen, before and after administration of reversal.

Naloxone Hydrochloride (Narcan®): *by intravenous injection*, 100–200 micrograms (1.5–3 micrograms/kg); if response inadequate, increments of 100 micrograms every 2 minutes; further doses *by intramuscular injection* after 1–2 hours if required

Flumazenil (Anexate®): *by intravenous injection*, 200 micrograms over 15 seconds, then 100 micrograms at 60-second intervals if required; usual dose range, 300–600 micrograms; max. total dose 1 mg. *By intravenous infusion*, if drowsiness recurs after injection, 100–400 micrograms/hour, adjusted according to level of arousal

See BNF for full information. Resedation may occur as antagonists have shorter half-lives than many opioids/benzodiazepines. Patients therefore require observation over several hours. If conscious levels fail to improve sufficiently after administration of appropriate antagonist, other causes of decreased consciousness must be excluded.

The reason for having to administer naloxone or flumazenil should be recorded on the appropriate page in the ward/department Controlled Drugs Record Book, in accordance with the PHNT Medicines Management Policy.

13 Recovery

The patient's level of sedation may initially deepen during the recovery period. Levels of monitoring, staffing and equipment should be maintained during the initial recovery period, until the patient is no longer at risk of cardio-respiratory depression. Facilities to recover patients should be located geographically close to the treatment area to reduce the risks on transfer, and to allow rapid intervention should other staff be required.

14 Discharge Criteria

Each clinical area should develop discharge criteria to suit their patients, procedures and setting. Patients remain the responsibility of the supervising practitioner while in recovery.

Criteria for Discharge from Recovery

- Patients should be alert and orientated (or have returned to their pre-sedation state).
- Pulse, blood pressure and oxygen saturations should be stable and within acceptable limits when compared to pre-sedation values.
- If antagonists have been administered, sufficient time (e.g. 2 hours) must have elapsed from the last dose of sedation/analgesia, to avoid re-sedation as the reversal wears off.

Criteria for Discharge from Hospital

- Presence of a responsible adult to accompany home and supervise overnight.
- Access to a telephone on discharge.
- Patient should receive advice on, not driving, not operating machinery, not cooking and not signing any legal documents for 24 hours after sedation.
- Patients should receive relevant advice specific to their procedure, information on any necessary follow up and a point of contact.

15 Overall Responsibility for the Document

Overall responsibility for this document lies with Dr Francis Luscombe, Associate Medical Director for Quality and Consultant in Pain Management

16 Consultation and Ratification

The first edition of the Sedation Guidelines was written by Dr Chris Sweeting, Trust Lead for Safe Sedation in Adults and Consultant Anaesthetist, in consultation with all anaesthetists, a working party of interested clinicians and the Clinical Governance Steering Group. This second edition policy is based on the first edition, but has been updated by a working party comprising:

Dr Francis Luscombe, Associate Medical Director for Quality and Consultant in Pain Management

Dr Chris Sweeting, Trust Lead for Safe Sedation in adults and Consultant Anaesthetist

Surgeon Commander Anthony Kehoe, Consultant in Emergency Medicine

Dr Simon Dunlop, Consultant Gastroenterologist

Dr Lorenzo Dimpel, Consultant Anaesthetist

Andrew Prowse, Assistant Director of Pharmacy (Clinical and Governance)

Peter Gray, Pharmacist for Theatres, Anaesthetics and Pain Management

The policy has been ratified by the Clinical Governance Steering Group and the Medicines Governance Committee.

17 Dissemination and Implementation

- Following approval and ratification by the Medicines Governance Committee this second edition of the sedation policy will be rolled out across the Trust.
- Publication of this second edition will be publicised in Vital signs and in the weekly staff news brief. The new edition will be sent to all ward managers, consultants and registrars, and a copy will be made available on the Trust-wide Shared Drive called Trust Document Drive.

18 Monitoring Compliance and Effectiveness

The use of naloxone or flumazenil will be reviewed on a 3 monthly basis as part of the Controlled drugs audit programme. The audit will identify any cases of naloxone or flumazenil being administered for opioid/benzodiazepine over-dose.

Medicines-related incidents reported via the Trust Incident reporting system are collated by the Patient Safety pharmacist and reviewed by the Medicines Governance Committee (MGC) on a monthly basis. All medicine related incidents rated as either medium risk or higher have a root course analysis completed by the Patient Safety Pharmacist and this is also reviewed by the MGC. The MGC will then nominate a committee member to resolve any identified issues.

Training:

Individual training is monitored through the HR personnel and training records

19 References and Associated Documentation

1. Implementing and ensuring Safe Sedation Practice for healthcare procedures in adults. Report of an intercollegiate Working Party chaired by the Royal College of Anaesthetists. March 2002

2. Practice guidelines for sedation and analgesia by non-anaesthesiologists. An updated report by the American Society of Anaesthesiologists task force on sedation and analgesia by non- anaesthesiologists**.** *Anesthesiology* 96: 1004- 1017, 2002

3. Teague R, Bell GD, McCloy RF, Charlton JE, Campbell D, Dent NA, Gear MWL, Logan RFA. Safety and Sedation during Endoscopic Procedures. 1991 Updated 2002.

4. Safe Sedation, Analgesia and Anaesthesia within the Radiology Department. Royal College of Radiologists. September 2003.

5. Scoping our Practice. Report of the Confidential Enquiry into Patient Outcome and Death. 2004.

6. Conscious Sedation in the Provision of Dental Care. Department of Health. 2003

7. Major complications of airway management in the UK. The Royal College of Anaesthetists and The Difficult Airway Society. March 2011

Grade 1 surgery (minor)

ASA Grade 1: children < 16 years

Test	Age: < 6 months	6 to < 12 months	1 to < 5 years	5 to < 12 years	12 to < 16 years
Chest X-ray	No	No	No	No	No
ECG	No	No	No	No	No
Full blood count	No	No	No	No	No
Haemostasis	No	No	No	No	No
Renal function	No	No	No	No	No
Random glucose	No	No	No	No	No
Urine analysis*	No	No	No	No	No

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 1: adults ≥ 16 years

Test	Age (years): 16 to < 40	40 to < 60	60 to < 80	≥ 80
Chest X-ray	No	No	No	No
ECG	No			Yes
Full blood count	No	No		
Haemostasis	No	No	No	No
Renal function	No	No		
Random glucose	No	No	No	No
Urine analysis*				

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 2: adults with comorbidity from cardiovascular disease

Test	Age (years): 16 to < 40	40 to < 60	60 to < 80	≥ 80
Chest X-ray	No			
ECG	Yes	Yes	Yes	Yes
Full blood count				
Haemostasis	No	No	No	No
Renal function				
Random glucose	No	No	No	No
Urine analysis				
Blood gases	No	No	No	No
Lung function	No	No	No	No

ASA Grade 3: adults with comorbidity from cardiovascular disease

Test	Age (years): 16 to < 40	40 to < 60	60 to < 80	≥ 80
Chest X-ray				
ECG	Yes	Yes	Yes	Yes
Full blood count				
Haemostasis	No	No	No	No
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis				
Blood gases				
Lung function	No	No	No	No

ASA Grade 2: adults with comorbidity from respiratory disease

Test	Age (years): 16 to < 40	40 to < 60	60 to < 80	≥ 80
Chest X-ray	No			
ECG	No			
Full blood count				
Haemostasis	No	No	No	No
Renal function	No	No		
Random glucose	No	No	No	No
Urine analysis				
Blood gases				
Lung function	No	No	No	No

ASA Grade 3: adults with comorbidity from respiratory disease

Test	Age (years): 16 to < 40	40 to < 60	60 to < 80	≥ 80
Chest X-ray				
ECG				
Full blood count				
Haemostasis	No	No	No	No
Renal function				
Random glucose	No	No	No	No
Urine analysis				
Blood gases				
Lung function	No	No	No	No

ASA Grade 2: adults with comorbidity from renal disease

Test	Age (years): 16 to < 40	40 to < 60	60 to < 80	≥ 80
Chest X-ray*	No	No	No	
ECG†	No			
Full blood count				
Haemostasis	No	No	No	No
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis				
Blood gases	No	No	No	No
Lung function	No	No	No	No

*Chest X-ray may be considered if the patient has signs of other comorbidities often associated with renal disease, such as hypertension and coronary heart failure
†Depending on the cause of renal disease (e.g. diabetes and hypertension)

ASA Grade 3: adults with comorbidity from renal disease

Test	Age (years): 16 to < 40	40 to < 60	60 to < 80	≥ 80
Chest X-ray*	No	No		
ECG	No			
Full blood count	Yes	Yes	Yes	Yes
Haemostasis				
Renal function	Yes	Yes	Yes	Yes
Random glucose				
Urine analysis				
Blood gases				
Lung function	No	No	No	No

*Chest X-ray may be considered if the patient has signs of other comorbidities often associated with renal disease, such as hypertension and coronary heart failure

Test not recommended

Consider this test (see page 2 of the NICE guideline)

Test recommended

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease.

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

Dissemination Plan | Appendix 2

Core Information	
Document Title	Policy for Safe Sedation during Healthcare Procedures in Adults
Date Finalised	December 2011
Dissemination Lead	Peter Gray, Pharmacist
Previous Documents	
Previous document in use?	Yes
Action to retrieve old copies.	Only available electronically.

Dissemination Plan

Recipient(s)	When	How	Responsibility	Progress update
All ward managers	December 2011	Vital signs and Trust-wide e-mail	Dr. Francis Luscombe	
All consultants	December 2011	Vital signs and Trust	Dr. Francis Luscombe	
All registrars	December 2011	Vital signs and Trust	Dr. Francis Luscombe	

Review and Approval Checklist | Appendix 3

Review		
Title	Is the title clear and unambiguous?	Y
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Y
	Does the style & format comply?	Y
Rationale	Are reasons for development of the document stated?	Y
Development Process	Is the method described in brief?	Y
	Are people involved in the development identified?	Y
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Y
	Is there evidence of consultation with stakeholders and users?	Y
Content	Is the objective of the document clear?	Y
	Is the target population clear and unambiguous?	Y
	Are the intended outcomes described?	Y
	Are the statements clear and unambiguous?	Y
Evidence Base	Is the type of evidence to support the document identified explicitly?	Y
	Are key references cited and in full?	Y
	Are supporting documents referenced?	Y
Approval	Does the document identify which committee/group will review it?	Y
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	NA
	Does the document identify which Executive Director will ratify it?	Y
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Y
	Does the plan include the necessary training/support to ensure compliance?	Y
Document Control	Does the document identify where it will be held?	Y
	Have archiving arrangements for superseded documents been addressed?	Y
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y
	Is there a plan to review or audit compliance with the document?	Y
Review Date	Is the review date identified?	Y
	Is the frequency of review identified? If so is it acceptable?	Y
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Y

Equalities and Human Rights Impact Assessment | Appendix 4

Core Information	
Manager	Andrew Prowse
Directorate	Pharmacy
Date	25.11.2011
Title	Policy for Safe Sedation during Healthcare Procedures in Adults
What are the aims, objectives & projected outcomes?	The purpose of this Trust-wide policy is to ensure that sedation of adults undergoing healthcare procedures within or on behalf of the Trust, is performed in a safe manner and in accordance with current evidence and best practice. This policy will also ensure that the Trust is compliant with the requirements of NPSA Rapid Response Report 2008/RRR011 (Reducing risk of overdose with midazolam injection in adults)
Scope of the assessment	
See names and contributors on page one of the policy	
Collecting data	
Race	There is no evidence to suggest that there is a disproportionate impact on race regarding this policy
Religion	There is no evidence to suggest that there is a disproportionate impact on religion or belief and non-belief regarding this policy
Disability	There is no evidence to suggest that there is a disproportionate impact on disability regarding this policy
Sex	There is no evidence to suggest that there is a disproportionate impact on gender regarding this policy
Gender Identity	There is no evidence to suggest that there is a disproportionate impact on gender identity regarding this policy
Sexual Orientation	There is no evidence to suggest that there is a disproportionate impact on sexual orientation regarding this policy
Age	There is no evidence to suggest that there is a disproportionate impact on age regarding this policy
Socio-Economic	There is no evidence to suggest that there is a disproportionate impact on socio-enonomic issues regarding this policy
Human Rights	There is no evidence to suggest that there is a disproportionate impact on human rights regarding this policy
What are the overall trends/patterns in the above data?	Overall patterns and trend are not identified.
Specific issues and data gaps that may need to be addressed through consultation or further research	There are no specific equality & human rights issues and data gaps that need to be addressed through consultation and/or further research

Involving and consulting stakeholders	
Internal involvement and consultation	Clinical Governance Steering Group
External involvement and consultation	There has been no external consultation or involvement
Impact Assessment	
Overall assessment and analysis of the evidence	This policy has no impact on equality

Action Plan

Action	Owner	Risks	Completion Date	Progress update