



CONSCIOUS SEDATION IN ADULTS PROCEDURE

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Documents to read alongside this Procedure	Consent to Examination or Treatment Policy
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1. INTRODUCTION AND BACKGROUND

- 1.1 In December 2008 the National Patient Safety Agency (NPSA) alerted healthcare organisations to risks of overdose with midazolam in adult patients by issuing a Rapid Response Alert. The NPSA, in a review of the patient safety incidents reported to the National Reporting and Learning System, found that between November 2004 and November 2008 498 incidents of adult patients being given the wrong dose of midazolam injection when used for conscious sedation were reported. This included the death of three patients. 48 incidents resulted in moderate harm to patients and the other 447 were low or no harm to the patients involved.

The Rapid Response Alert *Reducing risk of overdose with midazolam injection in adults* (1) placed a requirement on all organisations within the NHS to ensure that sedation is covered by organisational policy.

- 1.2 In 2001 the U.K. Academy of Medical Royal Colleges and their Faculties published *Implementing and ensuring safe sedation practice for healthcare procedures in adults*. (2) This document acknowledged that existing guidelines provide advice which should prevent such complications; however the document went on to make further recommendations to ensure that risks are reduced when using sedation techniques. This U.K. Academy of Medical Royal Colleges document has been used to inform the UHB procedure.
- 1.3 There is a wide variation in critical incidents between specialities using sedation. This implies poor education of sedation practice in the UK.

2. POLICY STATEMENT

- 2.1 Cardiff and Vale University Local Health Board (UHB) is committed to achieving excellence in providing safe, effective, efficient and compassionate care. In order to achieve this it is necessary to ensure that effective arrangements are in place to reduce the risks relating to sedation practices.

3. AIMS AND OBJECTIVES

- 3.1 The aim of this procedure is to ensure that robust practices for conscious sedation are implemented, promoting safe care and best possible clinical outcomes for patients.

4. CONSCIOUS SEDATION

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

UHB staff applying conscious sedation to a patient must be registered trained professionals who are responsible for maintaining competency to practice this skill. The prescriber is responsible for the choice of drug and ensuring the prescribing is appropriate. All members of the team applying conscious sedation must be aware of the drug being used, its indications, contraindications and usual dose range. Airway protection is paramount.

Conscious sedation is not light general anaesthesia. Inducement of deeper level of sedation than that defined above must only be undertaken by a trained professional, usually an anaesthetist or intensivist, who has the skills and training to manage this level of central nervous system depression safely.

5. GENERAL PRINCIPLES

- 5.1 Sympathetic patient management is the foundation of all clinical care. Explanation at each and every stage of any procedure is essential, particularly where sudden manoeuvres may disturb the patient acutely.
- 5.2 Anxiety, discomfort and pain may still occur. These modalities are inter-related, and each may increase the others. Drug treatment must be targeted specifically to each symptom to improve patient tolerance and to increase the technical success of the procedure.
- 5.3 Anxiety can often be alleviated by careful explanation, a sympathetic attitude and expert clinical management. Drug sedation must **not** be used for operator convenience, but as a supplement to behavioural management.
- 5.4 The nature and site of potentially painful components of the procedure must be identified in advance so that local anaesthetic or systemic analgesic drugs can be administered to **prevent** that pain whenever possible.
- 5.5 If pain is variable or unpredictable the patient should be made aware of this, and the operator should have in place a safe strategy for dealing with any pain that occurs during the course of the procedure.

- 5.6 In many situations, good analgesia and expert management suffice. The need for additional sedation should be related to the individual patient's psychological and medical status because both affect the response to, and the need for, sedation.
- 5.7 When conscious sedation is employed, the agents and doses chosen must be adjusted to the patient's requirements and ensure that verbal contact is possible at all times.
If verbal responsiveness is lost the patient is oversedated and requires IMMEDIATE assessment and action to support airway breathing and circulation
Manage with an ABC approach according to ILS guidelines and consider use of reversal agents. Call for help. (3)
- 5.8 Interactions between drugs of different types (especially opioids and sedatives) are often synergistic so that both the degree of effect and its rate of onset are increased significantly. Drug combinations must be used with particular care.
- 5.9 A practitioner prescribing or administering a drug should have knowledge of the pharmacokinetics and pharmacodynamics of that drug and therefore be aware of important side effects, drug interactions and other potential complications.
See Appendix 1 in the BNF which lists drug interactions.(4)
- 5.10 Clinical and instrumental monitoring, to a degree relevant to the patient's medical status and the sedation method, should be used. In addition, one member of the team must have a defined responsibility for patient observation and record keeping.

6. PRE ASSESSMENT

- 6.1 In advance of the procedure the patient, preferably assisted by attendant staff, must complete a 'check-list' to identify any risk factors. The level of detail, and the need for further clinical examination or investigations, will depend on the procedure and the patient's general condition.
- 6.2 Of particular importance to take note of are starvation status, potential airway problems, details of co-morbidities, weight and body mass index, drugs and allergy history.
- 6.3 Sedation should not be carried out in the patient with a potential full stomach. All patients should be starved as for general anaesthesia ie 6 hours for solids, milky and fizzy drinks and 2 hours for clear fluids. The dental hospital has its own fasting guidelines which they adhere to supported by a report of an expert group on sedation for dentistry and this policy.

- 6.4 Baseline observations of Blood pressure, Heart rate (pulse), Pulse Oximetry and Respiration Rate must be recorded prior to the procedure.
- 6.5 In the case of outpatients or day-cases, written instructions on activities before and after the procedure must be provided for the patient at an early stage. This should include details of potential complications, aftercare and adequate information regarding emergency contact.
Need to establish that there is a responsible adult escort to accompany the patient home to a suitable place of care and assume responsibility of post sedation care for the rest of the day.
It is the responsibility of the department undertaking the procedure to ensure that point 6.5 is adhered to.

7. DRUG ADMINISTRATION

Sedative drugs can be administered by the oral, intravenous, inhalational and intranasal routes. The intravenous and inhalational routes have the advantage of a rapid onset and are therefore easier to titrate. When the intravenous route is used, secure venous access is mandatory until the patient has fully recovered and specific antagonist drugs must be to hand. Combinations of drugs, especially sedatives and opioids, should be employed with particular caution particularly in the elderly population. The opioid should be given first and allowed time to become maximally effective before any sedative is added.

Drug ampoules can often contain different concentrations. The most common intravenous sedative agent used by non anaesthetists is midazolam. Following NPSA/2008/RRR011 guidance we have removed high concentration midazolam (10mg/2ml and 10mg/5ml) from most clinical areas. Conscious sedation should only be undertaken using the weaker 1mg/ml concentration. However it is imperative to always closely read an ampoule to check correct drug and concentration to avoid fatal drug errors.

All syringes should be clearly labelled with name of drug and concentration.

NPSA recommend that intravenous medication requires a two registered person independent check. NMC Standards for Medicines Management state that a Nurse/Midwife administering intravenous medicines must have a second registered person independent check (wherever possible)

If using midazolam it must be checked that flumazenil is readily available in case of *inadvertent* overdose.

Flumazenil is presented in a 5ml ampoule 100mcg/ml and initial dose is 200mcg over 15 seconds followed by further 100mcg doses at 60 second intervals. The usual dose range is 300-600mcg with a maximum total dose of 1mg. **Of importance is the much shorter**

elimination half life of flumazenil than midazolam which can result in re-sedation much later.

Please read appendix 1 of NPSA/2008/RRR011” Details on use of midazolam (dosing) and flumazenil.” (1)

8. MONITORING

It is not acceptable or safe to have a single operator also responsible for sedation and monitoring.

A registered suitably trained and competent member of the team must be allocated the responsibility for the task of monitoring the patient throughout the procedure. It is important to monitor the level of sedation ensuring verbal contact can be maintained whilst observing frequency and depth of respiration and patient colour. A **pulse oximeter** must be attached to ALL patients and remain attached until the patient is fully recovered. ECG may not be necessary in young healthy patients, but are essential in ASA 3 patients, it is the responsibility of the clinician in charge of the procedure to determine the need for ECG. Any emergency patient who is acutely unwell must have an ECG recorded.

Vital signs should be recorded on the accompanying document contemporaneously throughout the procedure and during the recovery period.

9. OXYGEN THERAPY

Oxygen, and devices for administering it by the nasal and facial routes, must be immediately available. Supplemental oxygen should be administered to all patients who are acutely unwell, morbidly obese, have significant comorbidities or those over the age of 60 years. Emergency oxygen can be given without prescription. Maintenance oxygen must be prescribed. It should be administered if there is any concern that the oxygen saturation might decrease below the resting figure, remembering that a reading below 90% is dangerous and requires immediate intervention.

A self inflating bag and mask must also be immediately to hand, plus back up oxygen cylinders in the event of oxygen failure or need for emergency transfer.

10. GENERAL FACILITIES

The above requirements imply considerable human and physical resources, which must be available in both treatment and recovery areas. All patient trolleys and dental chairs should be capable of being tipped head down, suction and appropriate resuscitation equipment and drugs must be immediately available, with all staff being familiar with its use. An appropriate level of clinical and instrumental monitoring should be continued until discharge criteria are met, at which time instructions on aftercare are reinforced to the accompanying person.

AFTERCARE/ DISCHARGE

Before discharge the patients vital signs must be stable and they must be orientated to the preoperative stage. There should be minimal nausea and vomiting, pain should be controllable and no significant bleeding. There will be great variability between different departments and the procedures undertaken therefore each department must have their own specific discharge criteria.

The patient must be accompanied home by a responsible adult and provided with printed post procedure instructions and printed emergency contact number.

Again of important note any patient who has required the use of flumazenil will require an extended period of recovery due to the likely risk of re-sedation

12. RESPONSIBILITIES

11.1 The Director of Nursing, Medical Director and Director of Therapies have ultimate responsibility for ensuring effective clinical governance arrangements and the quality of patient care. This responsibility is discharged within the Divisions and Directorates via the Divisional Director, Divisional Nurse, Divisional Manager, Clinical Directors, Senior Nurses, Heads of Professions and Directorate Managers. They will ensure that where necessary Safe Conscious Sedation Procedure are developed and implemented.

11.2 The Divisional Director has overall responsibility for the practices provided within the Divisions and Directorates under their control.

11.3 It is the responsibility of all persons providing care to ensure that safe sedation techniques are used, appropriate monitoring is undertaken and emergency equipment is available.

13. RESOURCES

It is not envisaged that additional resources will be required following the introduction of this guideline as the document should be existing practice.

13. TRAINING AND DEVELOPMENT

Regular updates will be given at clinical governance sessions and junior doctor induction programmes on safe sedation practice.

All UK anaesthetists have access to an e-learning module on the Royal College of Anaesthetists website.

All staff administering intravenous sedation must have training in immediate life support.

14. FURTHER INFORMATION / REFERENCES

- (1) National Patient Safety Agency (2008) Rapid Response Alert *Reducing risk of overdose with midazolam injection in adults* www.npsa.nhs.uk/rrr
- (2) U.K. Academy of Medical Royal Colleges and their Faculties (2001) *Implementing and ensuring safe sedation practice for healthcare procedures in adults*
- (3) www.resus.org
- (4) British National Formulary bnf.org
- (5) Report of an expert group on sedation for Dentistry 2003
- (6) NCEPOD report 2004
- (7) Nursing and Midwifery Council Standards for Medicines Management.

15. AUDIT

An audit of practice will be undertaken annually to ensure the procedure is followed. A system is in place to audit the use of flumazenil which indicates oversedation with benzodiazepines. Critical incident reporting of any adverse event involving sedation is encouraged and will be reviewed to help improve future practice.

16. REVIEW

This guideline will be reviewed at least every 3 years or sooner should any developments or changes in practice inform the Trust otherwise.

17. DISTRIBUTION

This policy will be available for viewing via the UHB Intranet.

18. EQUALITY IMPACT AND ASSESSMENT

An equality impact assessment has been undertaken to assess the relevance of this policy to equality and potential impact on different groups, specifically in relation to the General Duty of the Race Relations (Amendment) Act 2000 and the Disability Discrimination Act 2005 and including other equality legislation. The assessment identified that the policy presented a low risk to the UHB.