The Royal Wolverhampton NHS Trust

Policy Number: CP56

Title of Policy: Procedural Sedation Policy

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1.0 Policy Statement (Purpose / Objectives of the policy)

This policy has been produced as a result of the National Patient Safety Agency's Rapid Response Report "Reducing risk of overdose with midazolam injection in adults" (1). In addition, death or harm as a result of Midazolam overdose is included in the list of Never Events 2013/2014(5). The policy has been designed to encompass the use of other drugs commonly used in addition to midazolam in sedation practice.

Local Safety Standards for Invasive procedures (LocSSIPs) have been developed by Departments and Teams to compliment this guidance, outlining key steps for individual procedures which have given consideration to local conditions and circumstances.

All aspects of this document regarding potential Conflicts of Interest should refer first to the Conflicts of Interest Policy (OP109). In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.

2.0 Definitions

Sedation is a continuum as a result of the administration of drugs from full consciousness through light levels of sedation to deeper levels of sedation and eventually general anaesthesia.

Mild sedation /anxiolysis: Normal verbal response is maintained; airway ventilation and cardiovascular functions are unaffected.

Moderate sedation /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 period of sedation" (2). The airway is maintained, ventilation and cardiovascular functions are unaffected.

The drugs and techniques used to provide conscious sedation must carry a margin of safety wide enough to render loss of consciousness unlikely.

Deep sedation: Patient is purposefully responsive only to repeated or painful stimulation. The airway may not be maintained and ventilation may be inadequate.

Procedural Sedation Analgesia (PSA): Is a more recently introduced concept defined as "a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. PSA is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently" (11).

3.0 Accountabilities

The Chief Medical Director (The Director Sponsor) is accountable for compilation and review of the policy in accordance with Trust Policy OP 01, Development and Control of Trust Policies. **The Trust Management Committee** is the ratifying committee for the policy.

Deputy Chief Operating Officers, Divisional Medical Directors, and Heads of Nursing and Midwifery are accountable for ensuring this policy is made available to all relevant staff and that their attention is directed to its existence.

All staff involved in the practice of sedation are accountable for ensuring that their own practice complies with the policy, and that any incidents of non-compliance are reported through the Trust's agreed Incident Reporting System.

4.0 Policy Detail

Sedation is carried out in a number of settings and for a variety of purposes within the Trust, including but not exclusively:

- Endoscopy
- Clinical Haematology Unit and Day Case for bone marrow aspiration/trephine
- Emergency Department (New Cross)
- Cardiology Catheterisation Laboratory
- Interventional Radiology

All departments where sedation is practiced must have a dedicated local protocol which must be followed within the specific areas and the professionals involved must adhere to guidelines of their own Royal Colleges and the Academy of Royal Colleges (7.0). However, the guidance below outlines the recommendations of RRR/011(1.0) and must be referred to as the overarching policy.

When sedation is used the target level of sedation in the majority of cases must be either Mild or Moderate (conscious sedation).

It is recognised that for some procedures a deeper level of sedation may be desirable e.g. during the insertion of implantable cardiovascular electronic devices (9) and in the Emergency Department (10). See section 4.13.

4.1 Patient assessment

All patients for elective procedures must be assessed prior to the procedure. The aim of pre-assessment is to identify problems (physical, physiological or social) that need to be ameliorated or improved before the proposed procedure. Examples include; poor control of diabetes or asthma. If the conditions cannot be further improved, then the patient must be advised of the potential risks and given the opportunity to reconsider their consent, or to choose an alternative procedure that may have less attached risk.

4.2 Patient Consent

All patients should consent to sedation, and must be told of the benefits of sedation, potential adverse events, alternative approaches and the likelihood of awareness under sedation (8).

4.3 Fasting

Fasting before sedation is recommended for patients undergoing moderate or deep sedation (8).

4.4 Environment

The environment in which the sedation is to be administered must be clean and well lit. The patient must be afforded appropriate privacy and dignity with the area screened both visually and aurally well away from public areas. In most cases this would consist of a room with a closed door. The area must be of sufficient size to accommodate the patient (and sometimes a carer), medical and nursing personnel (and trainees), equipment appropriate to the procedure and equipment that may be needed for resuscitation.

4.5 Equipment

A patient trolley that can be rapidly tipped head down (tip controls must be at the head end) is a prerequisite for any procedure where loss of consciousness may occur. A suction devices powered by the hospital vacuum pipeline system must be available and must be checked before use.

Airway devices must be readily available in a range of sizes. As a minimum these must include Guedel airways, endotracheal tubes, two working laryngoscopes, facemasks, catheter mounts and filters, and a means of ventilating the patient.

Although it has become common practice to use a breathing circuit (“Waters circuit”, Mapleson – C) with a reservoir or rebreathing bag, it must be noted that these circuits are totally dependent on an oxygen supply. Therefore, a self-inflating (“Ambu” or “Laerdal”) resuscitation bag must also be immediately available.

All equipment must be checked before each sedation procedure. A Trust resuscitation trolley with defibrillator and Pharmacy supplied emergency drug box must also be present.

4.6 Patient monitoring

The patient's vital signs must be monitored throughout the duration of sedation and also for a period of recovery. Monitoring must be by the physical senses (rational communication, colour, warmth, respiratory rate, and pulse) augmented by electronic means where appropriate. As a minimum, a pulse oximeter displaying percentage haemoglobin saturation with oxygen and heart rate must be applied to **every** patient. Further consideration must be given to monitoring blood pressure and ECG in frail patients and those with significant co-morbidities. If loss of consciousness occurs, then these monitors must be applied once the airway is secured.

4.7 Staffing

In any environment where sedation is to be employed, there must be a minimum of two trained members of staff; one as the operator and the other dedicated to monitoring the patient.

The role of the staff monitoring the patient is to maintain verbal communication with the patient, to alert the operator should consciousness be lost, and to institute supportive measures until consciousness is regained.

There must also be immediate communication with a third member of staff, who is either present or contactable immediately by a call system, to provide urgent help if required or to raise an emergency call alarm.

4.8 Training

All members of staff must have received formal training in sedation techniques and be deemed competent to practice in their clinical area by the clinical (medical) lead or senior nurse. Both members of staff must have an up to date basic life support certificate.

One of the Team must have ILS training as defined by the R.C.(UK) and have competency in the use of basic airway manoeuvres, airway adjuncts, supraglottic devices and bag and mask ventilation. Preferably one will have a current advanced life support (ALS) provider certificate. A record of this training will be maintained in the locally maintained training records/database.

An e-learning package is available on the Trust Kite site (covering background safety issues, drugs, sedation techniques and the management of the unconscious patient). Airway/bag mask ventilation training is available from clinical skills as is ILS training.

4.9 Access

Secure intravenous access must be obtained prior to the administration of sedation.

4.10 Oxygen therapy

Many of the patients undergoing invasive investigation or treatment will have significant co-morbidities. The effects of even minimal sedation are likely to suppress the patient's respiratory drive. Therefore, all patients

must be given supplementary oxygen therapy administered by an approved device.

4.11 Drugs used

The choice of drugs and the rate of administration must be tailored to the individual based upon the pre-sedation assessment and then titrated to achieve the target sedation level. **The use of fixed doses and boluses is unacceptable.**

Single drugs are easier and safer to titrate to effect than the concurrent administration of two drugs. Two drugs may be required when analgesia (opiate) is required in addition to sedation (benzodiazepine) - most sedative drugs have no analgesic properties.

Where a combination of a benzodiazepine and an opiate are administered the opiate must be administered first and the benzodiazepine only given once the peak effect of the opiate is seen. Benzodiazepines may be up to eight times more potent following prior administration of an opiate so must be titrated with care

Midazolam is the preferred benzodiazepine because of its relatively short duration of action and easily reversible effects. “Critical incidents have occurred due to unfamiliar ampoules of various concentrations of midazolam being available to operators. Only 2ml ampoules of 1mg per ml strength will be available in those areas where procedural sedation is performed. Death or harm resulting from the use of high strength concentrations of midazolam (5mg/ml or 2mg/ml) is a Never Event and must not be used for procedural sedation. (5)

Diazemuls has an active metabolite with a prolonged duration of action and is **not** recommended. Intravenous diazepam for injection is associated with a high incidence of anaphylactoid reactions and must **not** be used.

Propofol is an anaesthetic drug; it possesses a narrow therapeutic index increasing the likelihood of adverse events**.** If Propofol is used it must be administered by a dedicated and appropriately trained clinician.

Ketamine produces a state of dissociative sedation, as verbal communication is rapidly lost. If Ketamine is used it must be administered by a dedicated and appropriately trained clinician.

Inhalation of a mixture of nitrous oxide and oxygen (“Entonox”) by nasal cannulae has been extensively used in dental practice; co-administration with midazolam and/or pethidine must be administered by a dedicated and appropriately trained clinician.

There is much collective experience with the use of Pethidine as an opiate and its use in terms of sedation must be continued.

Other opioids (such as Fentanyl and Alfentanil) may be used but these are often much more potent and have a narrow therapeutic index, making overdose more likely so must be used cautiously.

Antagonist Drugs

Wherever sedation is undertaken a full range of emergency drugs including specific reversal agents must be available immediately.

The use antagonist drugs for the reversal of sedation in not without risk as these agents often have a shorter duration of action than the sedative agent and re-sedation may occur. Their routine use must be avoided

4.12 Reversal agents

Flumazenil (100 micrograms per ml, 5ml ampoule) is used to reverse the effects of benzodiazepines, administered in 100 microgram aliquots to achieve the required effect. Flumazenil has a shorter duration of action than any of the benzodiazepines; any patient given flumazenil **must** be closely observed for at least 30 minutes for signs of re-sedation, and retreated if needed.

4.13 Record Keeping

A contemporaneous record of the procedure must be kept in the patient's medical records. This must include details of the staff involved, the procedure performed, drugs given (including oxygen), monitoring applied, and readings from the monitors. Clear written instructions must be available for recovery personnel. Any incidents arising during the course of the procedure or the patient's recovery must be recorded as per the agreed Trust Policy.

4.14 Recovery

The recovery area must be equipped to the same level as a modern-day surgery unit. Monitoring and oxygen therapy from the procedure room must be continued through to the recovery area and maintained until it is considered safe to do without. Staff must be trained in Basic life support techniques.

4.15 Discharge

Locally agreed criteria for discharge must be agreed and available, and every patient must meet these criteria or be admitted to the hospital until these criteria are satisfied. Patients must be given clear, written instructions for their own post procedure care, and whom and how to contact in case of complications.

4.16 Deep Sedation

Where deeper levels of sedation are thought necessary, this must be for short periods only and performed by an experienced operator (this individual must be able to rescue a patient who becomes inadvertently over sedated or enters a state of general anaesthesia).

The operator must be supported by at least two trained members of staff, one to monitor the patient and one to assist the operator. If this is not possible, general anaesthesia administered by or in the presence of an anaesthetist must be planned.

During the use of deep sedation, the use of capnography is mandatory (10.0).

5.0 Governance

There must be a zero incidence of over sedation; the use of flumazenil and naloxone must be audited in every area where sedation is administered.

6.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the implementation of this policy require additional revenue resources	No
3	Does the implementation of this policy require additional manpower	No
4	Does the implementation of this policy release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff.	No
	Other comments	

7.0 Equality Impact Assessment

This policy has been assessed as per Appendix 5, OP01, and no adverse effects on equality or diversity have been identified.

8.0 Maintenance

The policy will be reviewed every three years or sooner if guidance changes or if other factors prompt an earlier review.

The Director Sponsor is responsible for review and for ensuring approval and ratification via the Policy Reader Group.

9.0 Communication and Training

The policy will be placed on the Trust's Intranet Policies page under the "Clinical Practices" section and in Medical and Surgical guidelines.

The Divisional Healthcare Governance Managers will facilitate distribution of the policy to all relevant staff within the clinical divisions.

Appropriate information about conscious sedation techniques will be delivered during local induction to relevant staff. If training needs are identified an appropriate training package will be agreed and competency assessed as per local protocol.

10.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Committee
Audit of compliance with procedural safety checklist	Clinical Director	Reporting compliance with safe monitoring and administration of drugs through use of safety checklist in individual areas.	Monthly review of safety checklists	Directorate Governance Meetings
The use of naloxone and flumazenil must be audited	Pharmacy Lead	Monitoring of stock levels and Datix in case of over sedation. Any operator noted to be administering reversal agents on a regular basis must be appraised of their abilities and further training offered if identified as necessary.	As per stock levels checked	Directorate Governance Meetings. In the event of over sedation this may be classed as a Never Event and root cause analysis take place
Death or Serious Harm resulting from sedation		Datix	All incidents will be discussed at Departmental Meetings and any lessons learned or actions planned as a result duly noted and shared.	

10.0 References

1.0 Reducing risk of overdose with midazolam injection in adults. National Patient Safety Agency Rapid Response Report; December 2008 (NPSA/2008/RRR011) www.nrls.npsa.nhs.uk/alerts/?entryid45=59896&q=0%c2%acmidazolam%c2%ac

2.0 Skelly AM. Analgesia and sedation; in Watkinson A, Adam A (Eds.) *Interventional Radiology* Oxford: Radcliffe Medical Press, 1996: pp3 – 11

3.0 National patient safety first campaign. http://www.patientsafetyfirst.nhs.uk/Content.aspx?path=/interventions/High- risk medication.

4.0 Report of the UK Academy of medical Royal Colleges and their Faculties *Implementing and ensuring Safe Sedation Practice for Healthcare procedures in Adults.2004.*

5.0 *The Never Events List for 2018. NHS improvement Jan 2018. NHS England.*

6.0 Guidance for the use of Propofol sedation for adult patients undergoing ERCP and other complex upper GI endoscopic procedure. RCoA and BSG, London 2011.

7.0 Safe sedation Practice for Healthcare Procedures. Standards and Guidance, Academy of Medical Royal Colleges. October 2013.

8.0 Safe sedation Practice for Health Care procedures. An Update. Academy of Royal colleges. Feb 2021.

9.0 Furniss, Snyed. Safe sedation in modern cardiology practice. Heart 2015,101 p1526-1530.

10.0 Safe Sedation of Adults in the Emergency Department. Report and Recommendations by the RCoA and CEM. November 2012.

11.0 Goodwin SA, Caro DA, Wolf SJ. (2005) Procedural sedation and analgesia in the emergency department. *Annals of Emergency Medicine* 45: 177–96

Part A - Document Control

To be completed when submitted to the appropriate committee for consideration/approval

<table>
<tr><td>Policy number and Policy version:

CP56 version 4.0</td><td>Policy Title

Procedural Sedation Policy</td><td colspan="2">Status:

Final</td><td>Author:
Dr. A R Claxton

Chief Officer Sponsor:

Chief Medical Officer</td></tr>
<tr><td rowspan="5">Version Amendment History</td><td>Version</td><td>Date</td><td>Author</td><td>Reason</td></tr>
<tr><td>1.0</td><td>Jan. 2011</td><td>Dr A Claxton</td><td>Introduction</td></tr>
<tr><td>2.0</td><td>June 2014</td><td>Dr A Claxton</td><td>3 Yearly review</td></tr>
<tr><td>3.0</td><td>May 2018</td><td>Dr A Claxton</td><td>3 Yearly review</td></tr>
<tr><td>4.0</td><td>May 2021</td><td>Dr A Claxton</td><td>3 yearly review</td></tr>
<tr><td colspan="5">Intended Recipients: All Clinical staff in the Trust involved in the provision of procedural sedation Procedural Sedation is practiced.</td></tr>
<tr><td colspan="5">Consultation Group / Role Titles and Date: Clinical leads for Endoscopy, Emergency medicine, invasive radiology and Haematology.</td></tr>
<tr><td colspan="2">Name and date of Trust level group where reviewed</td><td colspan="3">Trust Policy Group – August 2021</td></tr>
<tr><td colspan="2">Name and date of final approval committee</td><td colspan="3">Trust Management Committee – September 2021</td></tr>
<tr><td colspan="2">Date of Policy issue</td><td colspan="3">October 2021</td></tr>
<tr><td colspan="2">Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)</td><td colspan="3">August 2024 (Every 3 years)</td></tr>
<tr><td colspan="5">Training and Dissemination: Distributed to heads of departments which deliver procedural sedation and published on the hospital intranet site.</td></tr>
<tr><td colspan="5">Publishing Requirements: Can this document be published on the Trust's public page:

Yes</td></tr>
<tr><td colspan="5">To be read in conjunction with:</td></tr>
<tr><td colspan="5">Initial Equality Impact Assessment (all policies): Completed Yes Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Administrator8904</td></tr>
<tr><td colspan="2">Monitoring arrangements and Committee</td><td colspan="3"></td></tr>
</table>

1. **Document summary/key issues covered.** The practice of Procedural Sedation is subject to risks associated with overdose. This policy outlines the safe practice of Procedural Sedation, mitigation of these risks and the avoidance of deeper levels of sedation. In the event of death or harm as a result of the use of Midazolam, actions must be taken to escalate this to the Medical Director or Chief Nursing Officer.
2. Death or harm as a result of Midazolam overdose is included in the list of Never Events 2018.
3. The practice of safe use of Procedural sedation takes place in the following clinical areas:
    a. Heart & Lung Centre: Cardiac Catheterisation Laboratory
    b. Emergency Department (New Cross)
    c. Endoscopy
    d. Interventional Radiology
    e. Bone marrow aspiration and trephine in Clinical Haematology Ward (CHU) and CHU Day Case

The audit of drugs used to reverse the effects of Midazolam which will alert the pharmacist to actual harm or near misses.

Key words for intranet searching purposes	Procedural sedation
High Risk Policy?	**No**

Part B **Ratification Assurance Statement**

Name of document: CP56, Procedural Sedation Policy

Name of author: Dr Andrew Claxton Job Title: Consultant Anaesthetist

I, the above named author confirm that

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.

- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.

- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines (OP01).

- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.

- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.

- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.

- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:

Date:

Name of Person Ratifying this document (Chief Officer or Nominee):
Job Title:
Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version	**Policy Title** **CP56, Procedural Sedation Policy**	
Reviewing Group	Trust Policy Group	**Date reviewed: July 2021**
Implementation lead: Print name and contact details		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Publicize the update policy highlight the changes from to existing policy 2. Publish new version on intranet	Distribution to heads of relevant department for dissemination to staff	Dr A Claxton on approval of policy group
Training; 1. See Policy 2. Update existing e-learning package and ensure it is available of the Kite site/my academy site.		Update by Dr Claxton
Development of Forms, leaflets etc; Consider		
Strategy / Policy / Procedure communication; Consider Financial cost implementation Consider Business case development	N/A	
Other specific Policy issues / actions as required **e.g. Risks of failure to implement, gaps or barriers to implementation**		