



Western Health
and Social Care Trust

POLICY FOR PROCEDURAL SEDATION: CHILDREN AND YOUNG PEOPLE

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1.0 Introduction

The use of oral or inhaled sedation for some procedures may be desirable to ensure the success of treatment and to alleviate suffering which might otherwise result.

Sedation may be defined as a continuum ranging from minimal sedation (whereby the patient is calm and remains able to communicate) to deep levels equivalent to anaesthesia. The response to sedative drugs is not always predictable, so staff need to be prepared during a procedure to manage a patient who becomes more sedated than intended. Excessively sedated patients may lose their protective airway reflexes and be at risk of adverse effects including hypoventilation, apnoea, airway obstruction, aspiration and cardiovascular impairment.

This policy is intended for use in patients who are generally healthy or have only mild systemic disease requiring interventions in a non-theatre environment (see Appendix I for general contraindications).

The key principles to consider are:

- Best practice from pre-sedation assessment until fitness for discharge;
- Different sedation options should be used for painless and painful procedures (see Appendices 2 and 8);
- Minimum standards of monitoring are required when sedating a child or young person;
- Record keeping must conform to the standard set out in the appendices below (see Appendix 6 for record of procedural sedation).

2.0 Scope

This policy will apply to all medical, dental, nursing and play staff caring for otherwise healthy children and young people aged over one year and up to their sixteenth birthday. The scope of the policy is Trust wide.

The policy does not cover:

- Use of intravenous sedation except for use of intravenous (IV) Ketamine and Propofol in Emergency Departments (Appendix 9 & 10);
- Community Dentistry who follow Dental Clinical Guidance in relation to sedation;
- Sedation in Neonates.

3.0 Policy Statement

The purpose of the policy is to:

- Standardise and simplify the practice of sedation for children and young people throughout the Trust;
- Support practitioners by recommending best practice with widely-used sedation techniques;
- Comply with national guidance, specifically NICE CG112, 2010.

4.0 Roles & Responsibilities

- Individual medical, dental, nursing and play practitioners must ensure that their practice is compliant with this policy.
- The Children's Perioperative Group will review any incidents which are reported in relation to sedation of children and young people.
- The Trust will review this policy if new standards are developed, under the auspices of the Children's Perioperative Group.
- The Trust will support staff training needs that may be identified by Ward Managers and Clinical Leads to comply with the policy.

5.0 Personnel and Environment

- Sedation should be prescribed, administered and monitored using a team approach in an appropriate environment and documented in a standardised way (Appendix 5).
- A minimum of two practitioners are required. One should be a qualified dental or medical practitioner (ST3 grade or higher) and the other must be a qualified nurse.
- Doctors must have attained provider status Advanced Paediatric Life Support (APLS) and should have clinical experience in sedation. The latter is assumed for Consultant Paediatricians. Trainees should document experience of sedation as part of their training e.g. Direct Observation of Procedural Skills (DOPS) or Mini-Clinical Evaluation Exercise (MiniCEX) etc.
- Doctors prescribing sedation must have experience in safe sedation and must be able to recognize the target level of sedation required. They must remain present for the duration of the procedure until the patient has recovered consciousness.
- Nurses must possess up to date basic life support credentials e.g. Paediatric Immediate Life Support (PILS) including skills in basic airway management, bag-valve-mask ventilation and administration of Cardiopulmonary Resuscitation (CPR).
- The environment chosen must have immediate access to full resuscitation equipment and must be accessible for senior anaesthetic and paediatric support if required.
- All equipment and medications must be checked prior to use and a clear method of summoning senior help must be in place. Patients must receive oxygen as appropriate and pulse oximetry must be used as a minimum level of monitoring.

6.0 Consent

Written consent must be obtained prior to administration of procedural sedation and this must be documented on the standard consent form (see Appendix 4).

This is to ensure that the purpose of any procedure together with common side effects and serious uncommon side effects have been adequately explored with the patient and/or parents/carers.

Practitioners obtaining consent should seek to realistically convey the purpose of the procedure and a clear rationale for using sedation. Carers and parents must be involved in the decision-making process and accommodated if they wish to be present during the procedure.

7.0 Governance

Administration and monitoring of sedation are not core skills for practitioners and teams must work only within the limits of their professional competencies. Senior and more experienced help must be sought if this is not the case (see wall chart in Appendix 11).

There is an organisational obligation to ensure that the environment and equipment meet the standards required for the effective delivery of resuscitation and stabilisation.

Data collection, audit and inspection will form an essential part of the continuous process of improvement (Appendix 7).

8.0 Equality Screening

It is anticipated that this policy will have a positive impact on the public as it will promote ensure best practice in the use of sedation for painful procedures.

The policy gives clear guidance on the roles and responsibilities of all staff involved. Staff are advised to contact a Consultant Paediatrician or Anaesthetist if they are concerned in relation to a patient's safety.

The policy will be communicated to staff via Trust Communication, Ward meetings and induction.

Appendix 1 - General Contraindications to Sedation

- Refusal by parent/ guardian/ child
- Abnormal airway – including large tonsils or craniofacial anomalies
- Unfasted status for level of sedation required (see Appendix 3)
- Raised intra cranial pressure or depressed conscious level
- History of sleep apnoea
- Major organ dysfunction including congenital cardiac anomalies
- Significant gastro oesophageal reflux disease
- Neuromuscular disorders.
- Bowel obstruction
- Ongoing respiratory tract infection
- Patients with trauma with cardiovascular instability
- Corrected age < 1 year because of severe prematurity

Specific contra-indications to nitrous oxide sedation

- Likelihood of intracranial air following head injury
- Pneumothorax, Pneumopericardium, Pulmonary bullae and Lobar emphysema
- Severe pulmonary hypertension
- Bowel obstruction Pneumoperitoneum
- Pregnancy

If any of the above comorbidities are identified discussion with an Anaesthetist or senior Paediatrician is mandatory.

Appendix 2 - Levels of Sedation (American Society of Anaesthesiologists 1996)

Sedation	A drug-induced state during which patients are awake and calm, and respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
Minimal Sedation	A drug-induced state during which patients are awake and calm, and respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
Moderate sedation	A drug-induced depression of consciousness during which patients are sleepy but respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation (reflex withdrawal from a painful stimulus is not a purposeful response). No interventions are required to maintain a patent airway. Spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
Conscious sedation	Drug-induced depression of consciousness, similar to moderate sedation, except that verbal contact is always maintained by the patient. The term is commonly used in dentistry
Deep sedation	A drug induced depression of consciousness during which the patient is not easily aroused but responds purposefully following repeated or painful stimulation. It may be accompanied by a complete or partial loss of protective reflexes and includes the inability to maintain a patent airway independently. Spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. In the UK, deep sedation is considered to be part of the spectrum of general anaesthesia and practitioners should consider need for anaesthetic input.

Appendix 3 - Fasting

Prior to starting sedation, confirm and record the time of last food and fluid intake in the healthcare record. Fasting is not needed for healthy children undergoing:

- Minimal sedation;
- Sedation with Entonox.

Apply the 2-4-6 fasting rule for healthy children undergoing moderate sedation:

- 2 hours for clear fluids;
- 4 hours for breast milk;
- 6 hours for solids, formula & follow-on milk.

In the emergency setting or for children who are ill (e.g. Paediatric Early Warning Score of 4 or higher, reduced level of consciousness) do not proceed with sedation without Anaesthetic and/or Consultant Paediatric/Emergency Medicine assistance.

Appendix 4 - Consent

1. Offer child/ parents/ carers verbal and written information on the proposed sedation technique, alternatives to sedation and risks and benefits.
2. Informed verbal consent for sedation should be obtained from the parents/ carer/ child and once delivered the appropriate consent form should be completed to confirm that the procedure has been discussed and verbal consent obtained.

Intended benefits of sedation

- Tolerance of an otherwise distressing or painful procedure without the potential complications and logistical difficulties of organising the same procedure under general anaesthetic.

Serious or frequently occurring risks:

- Failure of procedure due to inadequate sedation and need to progress to general anaesthesia;
- Disinhibition or paradoxical excitement;
- Vomiting whilst sedated – this rare complication can lead to aspiration pneumonia;
- Post procedure nausea, drowsiness and unsteadiness.

Appendix 5 - Personnel and Equipment

	Mild Sedation	Moderate Sedation	Deep Sedation
Example procedures	Application of Plaster of Paris to fracture. Cleaning, steri-stripping, gluing laceration. Micturating cystograms. Spiral CT. Dental extractions.	Suturing under local anaesthetic. Relocation dislocated phalanx. DMSA Scan. Burn dressing change.	Fracture manipulation
Personnel required	1 Healthcare professional to perform procedure. 2 PILS trained healthcare professional to deliver sedation and monitor patient.	1 Healthcare professional to perform procedure. 2 APLS trained doctor to deliver sedation and monitor patient. 3 PILS trained nurse.	Refer to Anaesthetic Department or refer to IV Ketamine SOP for Emergency Medicine (Appendix 10)
Monitoring required	Depth of sedation including pain, coping and distress. Respiratory rate Pulse oximetry.	Depth of sedation including pain, coping and distress. Respiratory rate Pulse oximetry Heart rate	Refer to Anaesthetic Department or Ketamine SOP (Appendix 10).
Equipment required	Full paediatric resuscitation equipment must be available.	Full paediatric resuscitation equipment must be available.	Refer to Anaesthetic Department or Ketamine SOP (Appendix 10).

Essential resuscitation equipment that must be available for sedation:

- Oxygen – delivered by a reliable source to nasal prongs or mask;
- A self-inflating, appropriately sized bag valve mask arrangement;
- Head down tipping trolley and suction equipment;
- Resuscitation bags and masks;
- Oral, nasopharyngeal, laryngeal mask airways and appropriately sized endotracheal tubes;
- Pulse oximeter/ ECG machine/ NIBP monitor;
- Defibrillator with appropriate paediatric pads;
- Resuscitation drugs;
- Reversal agents –flumazenil (and naloxone if patient receiving opiates) must be immediately available.

Appendix 6 - Record of Procedural Sedation

<p><i>(Attach Sticker)</i></p> <p><i>Patient name DOB Address</i></p> <p><i>Hospital number</i></p> <p><i>H&C number</i></p>	Date: ____/____/____
	Time: ____:____ hrs
	Weight ____ kg

Procedure	
Patient Location	
Sedation administered by:	Grade:
Sedation assistant:	
Procedure performed by:	
Sedation depth required (<i>please circle</i>) MILD or MODERATE	

Pre Procedural Checks	
All contraindications ruled out? (Appendix 1)	YES or NO
Appropriate sedation technique (Appendix 2)	YES or NO
Fasting (as per appendix 3)	YES or NO
Consent (as per Appendix 4)	YES or NO
Appropriate personnel & contingencies (Appendix 5)	YES or NO
Monitoring & equipment checks (as per Appendix 5)	YES or NO
Drugs checked by two practitioners?	YES or NO
Allergies or sensitivities?	YES or NO
ANY OTHER CONCERNS?	Discuss

Medicines Administered									
Oxygen	Flow rate		Time:						
Entonox			Time:						
Midazolam	Dose:		Time:						
Chloral Hydrate	Dose:		Time:						
Others (specify)	Doses:		Times:						
OBSERVATIONS									
TIME (mins)	0	5	10	15	20	25	30	35	40
SaO2									
HR									
RR									
AVPU									
RECOVERY CRITERIA									
Normal vital signs <input type="checkbox"/> Alert/orientated <input type="checkbox"/> Nausea/vomiting/pain adequately managed <input type="checkbox"/> Discharge advice given to parent/guardian <input type="checkbox"/>									
PLEASE NOW SIGN & COMPLETE APPENDIX 7 AUDIT									

Appendix 7 - Audit and Quality Assurance

Audit and Quality Assurance	
Was the intended level of sedation/ analgesia obtained	YES or NO
Was the procedure performed successfully? If "NO" Specify below.	YES or NO
Were there any adverse or critical incidents? <i>(e.g. drug errors, respiratory/ cardiovascular compromise, airway intervention, reversal agent administration)</i>	YES or NO
What was the total procedure time?	Minutes
Was the patient's recovery as planned? If "NO" specify below.	YES or NO
Were the parents and child satisfied?	YES or NO
Comments and feedback	
Signed DATE: ____/____/____	Print name & GMC no
PLEASE SEND A COPY OF THIS AUDIT TO DEPARTMENT OF PATIENT SAFETY, WHSCT HEADQUARTERS, MDEC, ALTNAGELVIN HOSPITAL	

Appendix 8 - Drug Information

A brief overview of commonly used sedative drugs is provided below. Consult current edition of BNFC for further information on contraindications, interactions, side effects etc.

Drug	Route	Dose	Advice for use
Chloral hydrate 100mg in 1 mL (PR: 250mg or 500mg suppositories)	Oral	1 – 12 years: 30-50mg/kg(max. per dose 1g) mild sedation	<ul style="list-style-type: none"> • Beware cardiac arrhythmias and respiratory depression with loss of airway reflexes at high doses. • Give 45-60 minutes prior to procedure. • To mask unpleasant taste can be mixed with water or juice. • There is NO reversal agent available.
	(or by rectum if oral route not available)	100mg/kg(max. per dose 2g) moderate sedation 12 – 16 years: 1 – 2g	
Midazolam <u>Buccal products:</u> Prefilled oral syringes: 2.5mg, 5mg, 7.5mg, 10mg Or Epistatus 10 mg in 1 mL	Buccal (preferred route)	All ages: 300-700 microgram/kg (maximum 10mg) Prefilled syringes should be used where possible	<ul style="list-style-type: none"> • Beware respiratory depression/hypotension/loss of airway reflexes at high doses. • Short acting benzodiazepine causing sedation, hypnosis, anxiolysis, anterograde amnesia. • Can lead to a distressing paradoxical excitement in children. • ORALLY give 30 - 60 minutes pre-procedure. • BUCCALLY give 15 minutes pre-procedure. • Buccal administration- give half the dose between the upper lip and gum on each side of the mouth. Try to retain in mouth for at least 5 mins before swallowing. • No easily available oral preparation. Please use buccal preparation orally. • Reversal agent is IV Flumazenil (10 microgram/kg [Max 200 mcg] over 15 seconds, repeat at 1-minute intervals up to 5 times).
	Oral	All ages: 300-700 microgram/kg (Max 10mg)	
ENTONOX Nitrous oxide (50% with oxygen).	Inhaled	Self-administration via demand valve	<ul style="list-style-type: none"> • Useful for short painful procedures and very effective in cooperative school aged children. • Delivered as Entonox – 50:50 mix with oxygen (minimal sedation).

APPENDIX 9 - KETAMINE STANDARD OPERATING PROCEDURE (SOP)

Purpose

This guideline is to assist experienced, career emergency physicians using ketamine sedation for children in Emergency Departments. This guideline covers the use of ketamine for analgesic sedation in children via either the intravenous or intramuscular route.

Indications

Ketamine can be used to induce analgesic sedation in children who will need a painful or frightening procedure during the course of their emergency care. It can be used instead of general anaesthesia for minor and moderate procedures in combination with local anaesthetic techniques. It avoids the need to physically restrain a child.

There is no evidence of improved emergence phenomena if midazolam is used as a supplement.

There is no evidence of reduced airway problems if atropine is used as a supplement with low dose ketamine.

Contraindications

- Age less than 12 months due to an increased risk of laryngospasm and airway complications. Children aged between 12 and 24 months should only receive ketamine sedation from expert staff (usually a consultant)
- Weight < 10Kgs
- Acute porphyrias
- A high risk of laryngospasm (active respiratory infection, active asthma)
- Unstable or abnormal airway. Tracheal surgery or stenosis.
- Active upper or lower respiratory tract infection
- Proposed procedure within the mouth or pharynx
- Significant cardiac disease (angina, heart failure, malignant hypertension)
- Recent significant head injury or reduced level of consciousness
- Intracranial hypertension with CSF obstruction.
- Intra-ocular pathology (glaucoma, penetrating injury)
- Previous psychotic illness
- Uncontrolled epilepsy
- Hyperthyroidism or Thyroid medication
- Prior adverse reaction to Ketamine

Preparation

1. Before ketamine is used all other options should be fully considered, including analgesia, reassurance, distraction, entonox, intranasal diamorphine, etc.
2. The doses advised for analgesic sedation are designed to leave the patient capable of protecting their airway. There is a significant risk of a failure of sedation if the procedure is

prolonged, and the clinician must recognise that the option of general anaesthesia may be preferred in these circumstances.

3. The fasting state of the child should be considered in relation to the urgency of the procedure.
4. Ketamine should be only used by clinicians experienced in its use and capable of managing any complications, particularly airway obstruction, apnoea and laryngospasm. The doctor managing the ketamine sedation and airway should be suitably trained and experienced in ketamine use, with a full range of advanced airway skills.
5. At least three staff are required: a doctor to manage the sedation and airway, a clinician to perform the procedure and an experienced nurse to monitor and support the patient, family and clinical staff. An accurate weight must be obtained. Observations should be regularly taken and recorded.
6. The child should be managed in the resuscitation area with immediate access to full resuscitation facilities. Monitoring should include ECG, blood pressure, respiration and pulse oximetry. Supplemental oxygen should be given.

Procedure

1. Discuss the proposed procedure and use of ketamine with parent or guardian and obtain written consent. The known risks are: mild agitation (20%), moderate/severe agitation (1-5%), rash (10%), vomiting (7%), transient clonic movements (5%), airway problems (1%). It is important to emphasise to the consenting adult that nystagmus, purposeless movements and some degree of dissociation are normal during ketamine sedation, so that these are expected.
2. The child should be managed in the resuscitation area with immediate access to full resuscitation facilities. Monitoring should include heart rate and SpO₂ with ECG, blood pressure and ETCO₂ available. Supplemental oxygen should be given.
3. At least three staff are required: a doctor to manage the sedation and airway, a clinician to perform the procedure and an experienced nurse to monitor and support the patient, family and clinical staff. Observations should be regularly taken and recorded.
4. The doctor managing the ketamine sedation and airway should be suitably trained and experienced in ketamine use, with a full range of advanced airway skills.
5. The fasting state of the child should be considered in relation to the urgency of the procedure, but recent food intake should not be considered as an absolute contraindication to ketamine use.
6. Where time permits, topical anaesthesia (EMLA, Amytop, etc.) should be used to reduce the pain of intravenous cannulation or intramuscular injection.
7. The dose of ketamine is 1 mg/kg by slow intravenous injection over at least one minute, or a stat dose of 2.5mg/kg IM in the lateral aspect of the thigh. The dose should be based on the child's actual weight, not age. Caution and careful checking are required in drawing up the correct dose since there are three different formulations of ketamine available (10mg/l, 50mg/ml and 100mg/ml). We would recommend a standard dilution of 100mgs of Ketamine in 10mls for all intravenous use. Concentrations for intramuscular injection should be age and size appropriate.

8. Encourage the child and parents to talk (dream) about happy topics. This helps minimise unpleasant emergence phenomena
9. Adequate sedation is usually indicated by loss of response to verbal stimuli and nystagmus: heart rate, blood pressure and respiration rate may all increase slightly.
10. Supplemental doses of 0.5mg/kg by slow IV injection or 1mg/kg IM may be given if required.
11. Local anaesthetic should be used where indicated.
12. After the procedure the child should recover in a quiet, observed and monitored area under the continuous observation of a trained member of staff. Recovery should be complete at approximately 60 minutes depending on the dose and route used.
13. The child can be safely discharged once they are able to ambulate and vocalise/converse at pre-sedation levels. An advice sheet should be given to the parent or guardian advising rest and quiet, supervised activity for the remainder of that day.
14. The medical record and local audit documentation should be completed.

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APPENDIX 10 - PROPOFOL STANDARD OPERATING PROCEDURE (SOP)

Purpose

This guideline is to assist experienced Emergency Physicians using PROPOFOL sedation for children in Emergency Departments. **Propofol is only given in the direct presence of an Emergency Consultant with experience in its use and, who has the prerequisite critical care skills to manage its potential adverse effects.**

Indications

PROPOFOL can be used to induce sedation in children who will need an emergent joint or fracture reduction during the course of their emergency care. It should only be given to children who are 13 years or older and, who are of normal body habitus.

Contraindications

- Age less than 13 years.
- Haemodynamically unstable/ hypovolaemia/ shock due to the risk of profound bradycardia and hypotension.
- Low or High BMI.
- If the procedure has the potential to be prolonged- the physician should consider the appropriateness of procedural sedation and whether general anaesthetic would be more appropriate.
- A high risk of laryngospasm or desaturation (active upper or lower respiratory infection, active asthma).
- Unstable or abnormal airway e.g. mandibular fracture, tracheal surgery or stenosis.
- Proposed procedure within the mouth or pharynx.
- Significant cardiac disease (Congenital heart defect or prior corrective cardiac surgery, heart failure, hypertension).
- Known renal or hepatic impairment.
- Reduced level of consciousness.
- Prior adverse reaction to General Anaesthetic.

Preparation

1. Before propofol is used, all other options should be fully considered, including analgesia, reassurance, distraction, entonox, intranasal diamorphine.
2. The doses advised for analgesic sedation are designed to leave the patient capable of protecting their airway. The clinician must recognise that the option of general anaesthesia is preferred if the procedure is likely to be prolonged.
3. The fasting state of the child should be considered in relation to the urgency of the procedure.
4. Propofol should be only used in the direct presence of Emergency Medicine Consultants who are suitably trained and experienced in its use and, who are competent in the full range of advanced airway skills.
5. Emergency drugs such as ephedrine, phenylephrine and adrenaline should be drawn up, labelled with the drug name and concentration per ml, and ready for use at the bedside.
6. At least three staff are required: a doctor to manage the sedation and airway, a clinician to perform the procedure and an experienced nurse to monitor and support the patient, family and clinical staff. Observations should be regularly taken and recorded as per the departmental paediatric sedation proforma.
7. After the procedure the child should recover in a quiet, observed and monitored area under the continuous observation of a trained member of staff. Recovery should normally be complete in 10 minutes, depending on the dose used.
8. Discuss the proposed procedure, use of propofol, the risks and benefits with parent or guardian. Obtain written consent.

Procedure

1. The child should be managed in the resuscitation area with immediate access to full resuscitation facilities. Supplemental oxygen should be given. Monitoring should include ECG, blood pressure, respiration and pulse oximetry and ETCO₂. A properly fitted, size appropriate mask with Mapleson circuit, should be to hand.
2. At least three staff are required: a doctor to manage the sedation and airway, a clinician to perform the procedure and an experienced nurse to monitor and support the patient, family and clinical staff. Observations should be regularly taken and recorded as per the paediatric procedural sedation proforma.
3. The doctor managing the propofol sedation and airway should be suitably trained and experienced in propofol use, with a full range of advanced airway skills. Emergency rescue medications described above must be ready at the bedside.

4. The fasting state of the child should be considered in relation to the urgency of the procedure.
5. Where time permits, topical anaesthesia (EMLA, Amytop, etc.) should be used to reduce the pain of intravenous cannulation.
6. The dose of propofol is 1mg/kg given slowly at a rate of 20mg over 10secs (2mls of 1% propofol solution) until sedation is achieved.
7. Adequate sedation is usually indicated by loss of response to verbal stimuli and relaxed muscle tone. Supplemental doses of 0.5mg/kg, at a rate of 20mg over 10secs, can be given cautiously up at a maximum of 3 mg/kg.
8. After the procedure the child should recover in a quiet, observed and monitored area under the continuous observation of a trained member of staff. Recovery should be complete at approximately 10 minutes depending on the dose used.
9. The child can be safely discharged after once they are able to ambulate and vocalise/converse at pre-sedation levels. An advice sheet should be given to the parent or guardian advising rest and quiet, supervised activity for the remainder of that day.
10. The medical record and local audit documentation should be completed.

Appendix 11 - Template Wallchart for Display in Clinical Areas (Excepting ED)



