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Oral Sedation Guidelines for all areas outside of Theatres / PICU / ED (General)

Introduction

This guideline provides hospital staff with the **minimum standards** for use of sedation of patients all clinical areas with the exception of Theatre, PICUs and the Emergency Department (ED).

This guideline relates to the use of **oral** agents. Intravenous agents (e.g midazolam, lorazepam, diazepam, ketamine) should not be administered for procedural sedation in clinical areas covered by this guideline without consultation with Anaesthesia or senior doctors trained in their use.

The administration of intravenous lorazepam used as part of the convulsive status epilepticus protocol is not included in this guideline.

This guideline is intended for use in patients who are generally healthy or have only mild systemic disease or cardiac patients for diagnostic imaging (MRI and Echocardiography) who have been deemed suitable for sedation by a consultant cardiologist.

- Target audience. This guideline will target all clinical staff
- Patient Population: All patients undergoing sedation outside of the Theatres and PICUs
- Patient groups specifically excluded: None

Purpose of Guideline

1. Define the goals of sedation indicating the levels of sedation scores.
2. Identify the patients who are appropriate to receive minimal to moderate sedation for procedures
3. Enable staff to complete a risk assessment and outline exclusion criteria
4. Outline the staffing levels required to safely administer the sedation for procedures
5. Summarise the minimum standards for procedural sedation including patient monitoring and observations
6. Identify the medications used and provide dosing guidance
7. Define the patient transport and monitoring requirements

Goals of Sedation

If at any time you have uncertainties about the patient's suitability for sedation, or about your own capabilities to conduct the procedure safely, discuss with Pain Management Service before proceeding.

- to minimise physical discomfort or pain for procedures
- to control behaviour, particularly movement
- to minimise psychological disturbance & distress
- to maximise the potential for amnesia
- to administer sedation in a safe manner (drugs used and their administration should be less noxious than the procedure itself)

Sedation is a continuum, ranging from minimal anxiolysis to a state of deep sedation. The response to sedative drugs is not always predictable, so staff need to be prepared to deal with 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.

For all stages of the procedure (before, during and after) appropriate non-pharmacological pain management techniques are also required.

Definition of Terms

Sedation Period. The period of time commencing with the administration of sedative drugs and ending when the patient has recovered to the point where he or she meets the end of the sedation criteria (observations are within normal limits, patient returns to baseline sedation score).

Sedation Score. It is important to understand that sedation is a spectrum - one may intend to achieve a sedation score of 2 but a patient may become more deeply sedated i.e. the effects of sedation are not always predictable.

This hospital uses the **University of Michigan Sedation Score (UMSS)**, which is a five-point score, consisting of the following components:

Sedation Score (UMSS)	**Patient response**
0	**Awake and Alert**
1	**Minimal sedation ("anxiolysis")** • A drug-induced state during which patients may respond normally to verbal commands • Cognitive function and coordination may be impaired • Respiratory and cardiovascular functions are minimally affected
2	**Moderately sedated ("conscious sedation")** • A drug-induced state of depressed consciousness with preserved airway protective reflexes • Patients may be somnolent/sleeping but easily aroused with light tactile stimulation or simple verbal command **NOTE:** It is possible for patients to progress from a state of moderate sedation into a state of deep sedation/obtundation
3	**Deep sedation** • **This is the equivalent of "near anaesthesia"** • A drug-induced state of depressed consciousness from which the patient is not easily aroused • Deep sedation may be accompanied by partial or complete loss of protective airway reflexes • Patients are usually unable to respond purposefully to physical stimulation or verbal commands **IMPORTANT:** **If the aim of sedation is for 'deep sedation' it should only be administered by senior staff in ED, ICU or Dept of Anaesthesia and Pain Management.** Deep sedation's associated risks are indistinguishable from those of general anaesthesia. Patients receiving deep sedation should also have an IV line in place and be continuously monitored.
4	**Unrousable** ***If a patient is considered to have a Sedation Score of 4 please contact Medical Registrar and PICU registrar for immediate review.***

Conduct of Procedural Sedation

Indications for procedural sedation

While the procedures listed below are examples for which procedural sedation may be indicated, it is ***crucial*** *that these procedures are* ***carried out in an appropriate clinical area and with appropriately educated and trained staff present.***

Examples of suitable procedures for which procedural sedation may be indicated include:

- Lumbar puncture
- Wound dressing care
- Electrophysiological studies
- Ophthalmology studies
- Audiology studies
- Diagnostic radiology (including echocardiography)
- IV access
- Drain removal
- Skin biopsy

The procedure should not be complex, very painful or prolonged (beyond 30 minutes). It is unreasonable to expect sedation to be sufficient in these situations. Patients who are extremely anxious prior to the procedure may need special consideration. General anaesthesia may be required instead.

Risk Assessment

A risk assessment to determine suitability for procedural sedation must be carried out **on all patients**. Patients who may require sedation for a procedure including diagnostic imaging (eg CT, MRI or isotope scanning, echocardiography), must have a risk assessment carried out by the medical team **prior to booking the patient for the procedure.**

Patients who had a risk assessment carried out at the time of booking a procedure must have a repeat risk assessment on the day of the procedure because the patient's clinical status may have changed since the time of booking. This may be done by medical or by nursing staff.
Any relative risk identified below, must be discussed by a member of the medical team in charge of the patient's care (at least registrar level) with the Anaesthetic consultant on call.

Contraindications to Sedation

- **Airway abnormality** *e.g. craniofacial anomalies,*
- **Increased risk of delayed gastric emptying or vomiting (which may increase risk of aspiration)** *e.g. bowel obstruction, gastro-oesophageal reflux* **except** *mild reflux or resolved reflux in an otherwise healthy child*
- **Significant respiratory disease** e.*g. upper airway obstruction including obstructive sleep apnoea, stridor, airway infection, apnoea, exacerbation of asthma, pneumonia, on supplemental oxygen,*
- **Significant cardiovascular impairment** *e.g. pulmonary hypertension, cardiomyopathy, hypovolemia, oxygen saturation less than what is normal for the patient's condition.* Cardiac patients deemed suitable for sedation with choral hydrate by consultant cardiologist may have choral hydrate.
- **Abnormal conscious state/risk of raised ICP/impaired bulbar reflexes** *e.g. head injured, meningitis, space occupying lesion*
- **Significant neuromuscular disease/kyphoscoliosis**
- **Acute systemic infection** *e.g. sepsis*
- **Prior allergic reaction**
- **Prior failed sedation**

- **Age less than or equal to 6 months except:**
  - Infants of weight 3kg and over and age greater than 40 weeks gestation may be sedated with chloral hydrate for Radiological imaging and Echocardiocraphy.
  - Infants of age greater than 2 months may be sedated with oral midazolam for removal of chest drains, removal of pacing wires on infant cardiology ward

Relative Contraindications to sedation / Cautions

Primary team (at least registrar level) should discuss with Anaesthetic Consultant

- **Prior adverse event during sedation** (eg oversedation)
- **Hepatic or renal impairment**
- **Babies for MRI for Hypoxic ischemic encephalopathy** (**HIE**) **should be discussed with Anaesthesia**
- **Neonates for MRI/CT/Isotope scanning where duration of scan is expected to be prolonged**
- **Patient for painless procedures (eg diagnostic imaging) who are receiving opioids** (e.g codeine, morphine) **or other sedative agents** e.g. Phenobarbital. Consider omitting or delaying the dose of opioid or sedative agent.

General Patient Assessment

The treating medical team who request the patient to have the procedure with sedation should perform a patient assessment.

The following should be included in the assessment:

1. prior illnesses and conditions (refer to risk assessment and exclusion criteria)
2. drug history
3. drug allergies (recorded on Medication Chart)
4. relevant pathology results
5. last food/fluid intake
6. previous sedation experiences and drugs used
7. accurate weight (recorded on Medication Chart)

Fasting

For ward patients (exceptions are Burns Unit and Emergency Dept) and outpatients fasting times are:

Oral agents: 6 hours solids and formula feed, 4 hours breastfeed, 2 hours clear fluids

Preparation of the child and parent

- Adequate preparation and education of the patient and family should be provided - provide age appropriate information about the procedure and any sensations to expect.
- Sedation Parent information Leaflet must be discussed with patient/parents by nursing staff or medical staff
- Non-pharmacological techniques should be planned and employed during procedures to complement and sometimes prevent the need for drug sedation.
- Parents should be encouraged to be present during the procedure to allay anxiety and they should be taught to coach their child effectively in the use of coping methods

Intravenous cannulation

IV access required in:

- All cardiac patients receiving chloral hydrate
- All patients under 1year old receiving chloral hydrate
- All patients who will have intravenous contrast medium
- All patients receiving more than one agent (e.g. midazolam and morphine for removal of chest drains)

IV cannulation should be considered in patients with complex medical histories receiving choral hydrate or midazolam.

Consent

Informed and written consent for BOTH sedation and the procedure are to be obtained by medical staff.

Staffing

A **minimum of two appropriately educated and trained** staff should be present for procedures for which a child is sedated.
One staff member is responsible for performing the procedure.
The **other staff member** must be responsible for administration of the sedative drug and continuously responsible for observation for the duration of the "Sedation Period". The appropriate training for this staff member will vary according to the sedative agent given.
For **oral agents*:*** 2 staff required, one being a competent RN or medical staff member

Medications

- Patients should not have received sedative drugs prior to arrival at hospital.
- All sedative agents should be recorded on Medication Prescribing and Administration Chart (Kardex)
- If appropriate, local anaesthetic cream (e.g. *Ametop*) may be used to help limit the amount of sedation and analgesia required.
- Adequate analgesia should also be provided.
- Generally, the agents used for ward-based sedation will be one of the oral agents, chloral hydrate or midazolam.

Preparation of Venue and Equipment

The Venue

- Should ideally be a hospital procedure room with appropriate lighting (adequate lighting for the procedure and patient observation) and minimal noise.
- Facilities for observation should be available and used until the child has recovered from sedation to a point where it is safe to be discharged from that area.
- The child should have an appropriate size bed or trolley.
- Sedated patients should not be left to wait in corridors or waiting rooms and ideally not transported within the hospital.

The Equipment

- Prepare **procedure equipment** before patient enters the room.
- Ensure **emergency equipment** is present and functioning
- Head down tilting bed/trolley
- Suction device (Rigid Yankauer device - present and functioning)
- Appropriate size bag and mask
- O_2 available and means to deliver it
- Resuscitation trolley
- Pulse oximetry
- Ensure a **distraction box** is available with age appropriate toys/distraction agents.

'Time Out' or 'Positive Identification'

The TWO staff members involved in the procedure (the proceduralist and the person administering the sedation) will confirm the following corresponds with the Consent Form:

- The patient's identity checked via identity band or positive identification

- The procedure to be performed and sedation agent to be given.
- Mark procedure side if applicable.

Observations and Monitoring

Prior to the sedation

- Document baseline vital signs on observation chart immediately prior to commencing sedation.

During sedation period

- Oral medications administered by appropriately educated and trained staff member.
- For oral agents, the patient must remain in-line of sight to the nurse throughout the Sedation Period.
- Document sedation score **on observation chart every 5 minutes for sedation level 2 and above.**
- Monitor continuous oxygen saturation and heart rate monitoring with appropriate alarm limits set;
- If sedation score 2 and above, record SpO_2, HR, RR every 5minutes for 30 minutes, then every 10minutes for 30 minutes, then every 15 minutes until Sedation Score 1 is reached.
- Place the child in the “recovery position” when the procedure has been completed.

End of Sedation Criteria

Line of sight nursing, observation and recording sedation score (+/- vital signs) can **cease** once when the patient meets the following criteria:

- Observations are within normal limits
- Patient returns to baseline sedation score (including co-ordination and gait) or mental status.

If the patient is returning from the treatment room to the general ward, ensure that the allocated staff member has a handover about the sedation and procedure performed.

Transport

- If patients in the "Sedation Period" need to be transported, always use a trolley or a bed with suction and oxygen, bag and mask apparatus available and continuous pulse oximetry.
- They should be accompanied by a competent staff member who must be continuously responsible for observation of the patient’s heart rate, airway patency, adequacy of ventilation, and level of sedation, and be able to initiate resuscitation procedures and know how to call for additional help.
- **It is unsafe to transport sedated patients unaccompanied by an appropriately trained and educated staff member, and in any transport device other than a hospital trolley.**
- Patients under deep sedation should not usually be transported during the sedation period unless clinically necessary.
- **Deep sedation (UMSS Level 3) should not occur on the wards.**

Documentation

- Complete Hospital Sedation Record
- Document procedure, response to sedation
- Record observations

Additional Criteria for Discharge

For Outpatients

Discharge home may be considered (provided other medical factors permit) when the patient meets **End of Sedation Criteria** as well as the following criteria:

- Satisfactory travel arrangements and supervision for patient confirmed. One adult driving and one competent person supervising the child.
- Post sedation handout should be discussed with parents. Safety and injury prevention highlighted.

Sedation Agents

Chloral Hydrate

General information:	Chloral hydrate is a sedative hypnotic agent. It has no analgesic properties. It is useful as a sedative agent for painless diagnostic studies in children under 4 years of age and body weight <20kg. CNS depressant effect of chloral hydrate results mainly from its active metabolite, trichloroethanol. It is administered orally. It has a bitter taste and causes gastric irritation.
Indications:	Useful for diagnostic imaging, ophthalmic examination.
Cautions:	Avoid in severe liver, or renal impairment. Use with caution in patients with cardiac impairment. Cardiac patients deemed suitable for sedation with choral hydrate by consultant cardiologist may have choral hydrate.
Adverse effects:	• Gastric irritation, nausea, vomiting, abdominal distension, • Prolonged sedation, coma, • Paradoxical agitation in 1-2% of patients, • Respiratory depression, especially in young term and preterm infants, • Tachyarrhythmia with excessive dosing.
Pharmacokinetics:	Onset of action: 30- 60minutes Duration of effect: 1-2 hours but can last up to 8hours Half life of trichloroethanol (active metabolite): 28 hours in term neonates, 10 hours in older children.
Dosing for diagnostic imaging (CT, MRI, Isotope scan, ECHO):	**NON- CARDIOLOGY PATIENTS:** • **CT scanning:** Chloral hydrate to be administered in the MRI/CT or Isotope scanning suite. **Neonates:** 12.5 - 50mg/kg PO stat 45-60 minutes before the procedure. No repeat dose. **Age over one month and body weight ≤ 20kg:** 30–50 mg/kg (max. 1 g stat) 45–60 minutes before procedure; a second dose of 20 -30mg/kg may be administered if required **after adequate time has been allowed for first dose to take effect**. Maximum total dose 80mg/kg. • **MRI, Isotope scanning:** **Neonates:** 12.5 - 50mg/kg PO stat 45-60 minutes before the procedure. No repeat dose. **Age over one month and body weight ≤ 20kg:** 50 – 80mg/kg to start 45–60 minutes before procedure; a second dose of 20mg/kg may be administered if required **after adequate time has been**

	allowed for first dose to take effect. Maximum total dose 100mg/kg not to exceed 2g. **CARDIOLOGY PATIENTS:** • **Echocardiography:** **Neonates:** 12.5 - 50mg/kg PO stat 45-60 minutes before the procedure. No repeat dose. **Age over one month and body weight ≤ 20kg:** 50mg/kg to start 45–60 minutes before procedure; a second dose of 20 - 30mg/kg may be administered if required **after adequate time has been allowed for first dose to take effect**. Maximum total dose 80mg/kg not to exceed 2g. • **Cardiac MRI:** **Neonates:** 12.5 - 50mg/kg PO stat 45-60 minutes before the procedure. No repeat dose. Consider GA if procedure is expected to be of prolonged duration. **Age over one month and body weight ≤ 20kg:** 50mg/kg to start 45–60 minutes before procedure; a second dose of 20 - 30mg/kg may be administered if required **after adequate time has been allowed for first dose to take effect**. Maximum total dose 80mg/kg not to exceed 2g.
Dosing for procedures EXCEPT diagnostic imaging:	**Other clinical areas (Wards, Audiology, Ophthalmology):** **Neonates:** Swaddling and sucrose 24% should be used. Neonates should not generally receive chloral hydrate in clinical areas outside Radiology. **Age over one month and body weight less than 20kg:** 30–50 mg/kg (max. 1 g) 45–60 minutes before procedure. No repeat dose.
Reversal agent:	No specific reversal agent for chloral hydrate

Midazolam

This guideline refers to the use of orally administered midazolam for procedural sedation. It does not apply to the administration of midazolam as premedication prior to a procedure in the operating theatre.

General information:	Midazolam is a benzodiazepine used in children as a sedative hypnotic agent for management of procedural anxiety and to produce amnesia. **It has no analgesic effects**. Midazolam can be administered orally. It may also be administered buccally, nasally, rectally and parenterally (these routes not applicable to this guideline). Absorption varies with route of administration. Orally administered midazolam is partly metabolised by the liver before reaching systemic circulation (first pass effect).
Indications:	Useful for procedures such as lumbar puncture, wound care, removal of chest drains
Adverse effects:	Cardiorespiratory depression (hypotension, bradycardia and respiratory depression) Paradoxical excitement (10-15%) Emergence delirium

Dose:	**Oral:** 0.5mg/kg (max 15mg) given 20 – 30minutes before procedure
Pharmacokinetics:	**Oral Midazolam:** Bioavailility: 40 – 50% of oral dose reaches systemic circulation Onset of action: Within 10-20 minutes Duration of effect: 1 – 2 hours Half life: 2.2 – 6.8 hours
Drug interactions:	Co-administration of systemic opioids potentiates sedative effect of midazolam and can cause a worsening of respiratory depression. Sedative effect of midazolam also potentiated by antiretrovirals (protease inhibitors, efavirenz), itraconazole, posaconazole, voriconazole, clarithromycin, erythromycin. Consider reducing the dose of midazolam when used in combination with medicines that potentiate its effects
Reversal Agent:	• Flumazenil, a benzodiazepine antagonist can reverse overdose symptoms of midazolam • Flumazenil is administered intravenously. It has a short duration of action and might require several doses or an infusion. • Dose of flumazanil: 10 microgram/kg bolus (maximum dose 200 micrograms) repeat if the desired effect is not achieved in 1 minute, repeat with half the initial dose at 1 minute intervals until recovering or maximum of 5 doses. Then if drowsiness recurs administer 2-10 micrograms/kg/hr by continuous IV infusion. • Flumazenil should **not** be used in patients with seizure disorders or those who receive benzodiazepines on a chronic basis because of the risk of precipitating seizures or withdrawal symptoms, respectively.

Companion Documents

Link to References