Procedural Sedation for Ward and Ambulatory Areas

Purpose and Scope

Infants, children and adolescents may experience pain and/or distress during procedures. An important goal of procedural pain management is to minimise fear, anxiety and distress in relation to any procedure, including painless procedures.

The goal of procedural sedation, in ward and ambulatory areas at RCH, is to achieve anxiolysis and conscious sedation. Procedural sedation aims to provide a margin of safety that renders loss of consciousness unlikely. The purpose of this document is to provide a framework for the safe administration of sedative, anxiolytic or dissociative agents with or without analgesia to induce a state of anxiolysis and conscious sedation that allows patients to cope with unpleasant procedures while preserving cardiorespiratory function and avoiding adverse events.

Managing fear, anxiety and distress may decrease future avoidance behaviours. Recognising the evolving needs and aspirations of children and their families and the potentially detrimental effects of negative experiences, this document underscores the importance of effective management of procedural distress for promoting future resilience.

Deep sedation, referred to in section 3, is outside the scope of this document.

This procedure is related to Care Planning and Implementation

Target Audience

The *Procedural Sedation for Ward and Ambulatory Areas* procedure applies to all clinicians who are supervising, prescribing or administering sedation agents at RCH.

Procedural Sedation for Ward and Ambulatory Areas

The Royal Children's Hospital Melbourne

Table of Contents

1. RESPONSIBILITIES 4
2. DEFINITIONS 4
Term/Abbreviation 4
Explanation 4
The University of Michigan Sedation Scale – UMSS 6
3. PROCEDURE 6
3.1 Prior to sedation 7
3.1.1 Select a sedation agent 7
3.1.2 Fasting 8
Minimum fasting time 8
3.1.3 Patient assessment 8
3.1.4 Risk assessment 9
Relative contraindications for procedural sedation – seek consultation 9
3.1.5 Exclusion criteria 11
Absolute contraindication for procedural sedation 11
3.1.6 Consultation 12
Procedural sedation support services 13
3.1.7 Staffing 13
3.1.8 Sedation competency 14
3.1.9 Consent 14
3.1.10 Preparation of child and family 14
3.1.11 Patient identification 14
3.1.12 Equipment 14
3.1.13 Pre-sedation checklist 15
3.2 During Sedation 15
3.2.1 Monitoring 15
3.2.2 Excess sedation and escalation of care 16
3.2.3 Transport of a sedated patient 16
3.0.1. 3.2.4 Failure to sedate 17
3.2.5 Adverse events 17
3.3 End of Sedation 17
3.3.1 Recovery 17
3.3.2 Discharge 18

3.4 Documentation....18
3.5 Baseline observations....18
4. SEDATION AGENTS....19
5. KEY ALIGNED DOCUMENTS....19
5.1 Policies....19
5.2 Procedures....19
5.3 Guidelines....19
5.4 Standards and Legislation....19
6. REFERENCES....20
7. KEY CONTACTS....23
8. APPENDICES....23
APPENDIX A - SEDATION AGENTS....24
A.1 METHODS OF ACTION....24
A.2 CHLORAL HYDRATE....25
A.3 CLONIDINE....28
A.4 FENTANYL....32
A.5 MIDAZOLAM....35
A.6 NITROUS OXIDE....39
APPENDIX B - FAILURE TO SEDATE....43
APPENDIX C - HOW TO ORDER PROCEDURAL SEDATION....44
APPENDIX D - INTRAVENOUS MIDAZOLAM DOSING....45
Intravenous Midazolam Dose....45

1. Responsibilities

All clinicians must work within their scope of practice and maintain the registration requirements designated by their relevant registration body. All staff involved in medication management must comply with the relevant legislation and local procedures.

2. Definitions

Term/Abbreviation	Explanation
Anxiolysis	The reduction of anxiety by a sedation agent during which patients respond normally to verbal commands.
Baseline	The pre sedation level of consciousness and observations.
BLS	Basic Life Support provides rescue airway, breathing and circulation per the RCH Resuscitation CPG
Clear Fluids	Clear fluids are those which when held to light, are transparent e.g. water, diluted cordial, tea/coffee without milk, clear juice without pulp, glucose based drinks, RCH supplied icy poles.
Competent clinician	The designated staff member who has medication endorsement from their professional governing body may administer sedation agents for procedures, in accordance with the Medication Management policy.
Conscious sedation	The drug induced depression of consciousness during which patients may sleep but are able to respond to verbal commands or light tactile stimulation.
Line of sight	The sedated patient has visual clinical observation 'line of sight' for the sedation period.
Non-pharmacological techniques	The use of distraction or cognitive behavioural therapies within a developmental context that provides preparation and engages the child to adopt positive coping strategies, reducing anxiety and pain experienced.

Proceduralist	The designated staff member who will perform the procedure. The proceduralist is responsible for preparing equipment and obtaining informed consent for the procedure. Where possible, the proceduralist provides written information, which includes the nature and risks of the procedure. The proceduralist is separate from the sedationist and may be assisted by an additional staff member.
Procedural pain	Short-lived pain associated with medical investigations and treatments.
Procedural Sedation	The safe administration of sedative or dissociative agents +/- analgesia to induce a state of consciousness that allows patients to tolerate/cope with potentially unpleasant procedures while preserving cardiorespiratory function
Procedure plan	The plan developed by staff, with input from families, to guide the approach to supporting a medical investigation or treatment.
Sedationist	The designated staff member who is responsible for the sedated patient and delivery of the sedation agent. The sedationist will be competent to administer the sedation agent and must complete the relevant risk assessment and sedation record documentation within the electronic medical record (EMR). The sedationist is separate from the proceduralist, monitoring the patient's level of consciousness and cardiorespiratory status. The sedationist detects and appropriately manages any complications arising from the procedural sedation. The sedationist should communicate with the family to obtain informed consent for administering sedation.
Sedation period	Commences with the administration of sedative drugs and ends when the patient has recovered to baseline level of consciousness and observations are within normal limits for the patient.

'Sip til sedate'	Practice that allows children to safely sip on clear fluids when they are thirsty, up until the time they receive sedation for their procedure. Children should not be forced to sip. **Children who are nil by mouth for medical or surgical reasons should not be offered any fluids.**
UMSS	The University of Michigan Sedation Scale (UMSS) See table below.

The University of Michigan Sedation Scale – UMSS

UMSS	Response
0	Awake and alert
1	Minimally sedated: may appear tired/sleepy, responds to verbal conversation +/- sound
2	Moderately sedated: somnolent/sleeping, easily roused with tactile stimulation or verbal command
3	Deep sedation: deep sleep, rousable only with deep or physical stimulation
4	Unrousable

3. Procedure

This procedure outlines the requirement for procedural sedation in the ward and ambulatory areas at The Royal Children's Hospital.

The aim of this procedure is to inform and provide a structured and standardised approach in the delivery of procedural sedation in ward and ambulatory areas. This document outlines safe practice and addresses the relationship between risk assessment, preparation, and prevention of adverse events.

- Defines patient groups for whom minimal or moderate sedation presents risk or is not permitted.
- Identifies the equipment, staffing and documentation requirements.
- Specifies the safe delivery of clonidine, chloral hydrate, midazolam, nitrous oxide and intranasal fentanyl.
- Addresses procedural sedation in ward and ambulatory areas.

- **Deep sedation** which is undertaken in the following designated areas: theatre, ED, PICU, NICU and the burns treatment room by a critical care specialist or an anaesthetist **is not addressed in this document.**
    - Optimise non-pharmacological techniques such as language of consent or reframing of consent and procedural process, optimisation of the setting to mitigate need for deep sedation. This may permit a lighter plane of sedation to achieve a successful procedure.

3.1 Prior to sedation

A procedure plan should be established prior to commencing sedation, to ensure that the patient, procedure, staff, location and equipment are appropriate.

The procedure plan must be:

- Supported by the treating team
- In an appropriate clinical environment
- Appropriate to the duration and intensity of the stimulus of the procedure
- Appropriate to the patient's risk and clinical assessment
- Understood and agreed by the guardian +/- patient as appropriate

The Procedure/Sedation Hub tool can be utilised to support this planning.

Use of non-pharmacological supports should also be optimised to may also reduce the need for sedation and support sedation utilisation.

3.1.1 Select a sedation agent

Sedation is a continuum ranging from minimal sedation, through moderate sedation to deep levels of sedation, which may progress to general anaesthesia. As sedation is a continuum, it is not always possible to predict how an individual will respond.

When selecting appropriate sedation agent(s), consider the following:

- Desired clinical effect (e.g. anxiolysis, analgesia, amnesia)
- Onset time
- Duration of effect vs procedure time
- Possible side effects (e.g. respiratory depression, bradycardia, hypotension)

- Contraindications
- Dose requirement
- Access required (E.g. IV access)

Multi-agent sedation may be appropriate provided all of the listed risk assessments and considerations have been addressed. Caution should be taken with regard to the risk of summation and synergy with multiple agents as this increases the risk of complications.

See Appendix C for how to order sedation agents in EPIC

3.1.2 Fasting

Minimum fasting time	
2 Hours	Solids / formula / breast milk
'Sip til sedate'	Clear fluids

Fasting for procedural sedation (UMSS 1 - 2) aims to decrease the incidence of nausea and vomiting. At these levels of sedation, patients maintain airway protective reflexes to reduce risk of aspiration.

A liberal 'sip-till-sedate' practice is employed. 'Sip-till-sedate' allows children to safely sip on clear fluids when they are thirsty, up until the time they receive sedation for their procedure. Children should not be forced to sip.

Exceptions to Sip-till-Sedate

- Children who are nil by mouth for medical or surgical reasons should not be offered any fluids.
- Consider a longer fasting time for children with risk factors for delayed gastric emptying
- Consider a longer fasting time in the setting of co-administration of opioids or medications which may have a sedative effect.
- Children with a higher risk of hypoglycaemia (diabetes mellitus, certain metabolic disorders) may have special requirements; consult treating team or anaesthetist.
- Sedation with single agent clonidine does not require fasting

3.1.3 Patient assessment

The following assessments should be completed prior to any sedation event:

- Base line observations
- Sedation score
- Checking scheduled / delivered meds
- Allergies

- Fasting status
- Previous sedation experiences
- Weight
- Cardiorespiratory assessment

3.1.4 Risk assessment

Risk assessment is undertaken to identify the significance of conditions, disease groups or agents that may result in an adverse event, such as loss of airway, hypotension, drug interaction, prolonged sedation or agitation.

Relative contraindications for procedural sedation – seek consultation

Contraindication	Risk	Note
Abnormal conscious state / risk of raised ICP	Risk of excess sedation and increasing ICP	E.g. Head injury, meningitis, space occupying lesion
Age	Risk of airway obstruction / apnoea	See individual sedation agents Appendix A
Airway or respiratory conditions	Risk of hypoventilation / obstruction / laryngospasm / aspiration	Head, neck or chest pathology (e.g. burns, tumour, trauma, infection or surgery) Reactive airways (e.g. respiratory tract infection, poorly controlled asthma, prematurity) Apnoea (e.g. Obstructive Sleep Apnoea) Significant snoring and drooling Significant work of breathing, tachypnoea or bradypnoea Musculoskeletal and neurological disorders (e.g. weak, restrictive, aspiration, chronic lung disease)
Co-morbidity	Risk for dosing calculation	Seek consultation to assess if co-morbidities will impact procedural sedation plan. E.g. Adrenal insufficiency, hypothyroidism, hyperthyroidism, diabetes

		insipidus, endocrinopathies, mitochondrial disease, inborn errors of metabolism
Concurrent opioids or sedative agents	Risk of excess sedation	Additional opioid or sedation agents may have a synergistic effect producing excess sedation. Sedation may be an effect of medications such as anticonvulsants and antihistamines
Deteriorating child (physiological limits meet Rapid Review criteria as per ViCTOR)		Clinical review indicated but not completed Modified observation parameters on ViCTOR E.g. Acute systemic infection (sepsis)
Liver or renal disease / dysfunction	Risk of excess sedation	See individual sedation agents Appendix A
Prior adverse event (AE) or allergic reaction to a sedation or anaesthetic agent	Risk of adverse event	Determine the reaction and the severity
Significant fasting concern		Patient condition or treatment complicated by fasting E.g. hypoglycaemia
Significant or severe cardiovascular disease	Risk of inadequate reserve / decompensation	Poor myocardial function e.g. dilated cardiomyopathy Significant pulmonary hypertension Marked hypovolemia. Marked cyanosis or significant limitation of physical activity
Significant risk of delayed gastric emptying or vomiting or excess secretion	Risk of aspiration	E.g. Bowel obstruction, gastro-oesophageal reflux, GLP-1 receptor agonist (Ozempic)

Significant weight concern	Risk for dosing calculation Risk of airway obstruction	Failure to thrive, cachectic Obesity
Pregnancy	Risk of harm to foetus	Specific to nitrous oxide: Consider possibility of pregnancy in young people of childbearing age If pregnant stratify risk and minimise harm

3.1.5 Exclusion criteria

Absolute contraindication for procedural sedation

All Agents		
Contraindication	**Risk**	**Note**
Deteriorating child (physiological limits meet MET criteria as per ViCTOR)	Cardiorespiratory compromise	Follow RCH MET procedure
Nitrous Oxide		
Contraindication	**Risk**	**Note**
Age <2 years of age	Risk of airway obstruction	
Gas filled space	Risk of expansion of gas filled space	E.g. Pneumothorax, lung cyst, obstructive pulmonary disease, bowel obstruction, recent craniotomy with pneumocephalus resulting in trapped gas, significant middle ear disease or surgery resulting in trapped gas, decompression sickness
Respiratory illness or infection	Risk of airway obstruction	E.g. Pneumonia or respiratory tract infection with excessive secretions and poor respiratory reserve E.g. Severe asthma (wheeze present)

Severe pulmonary hypertension associated with limited exercise tolerance	Risk of hypoxia, Cardiorespiratory compromise	
Oral Sedation		
Contraindication	**Risk**	**Note**
Liver Failure / Hepatic Encephalopathy	Risk of excess sedation	Chloral hydrate must not be administered for these patients.
IV Sedation – Midazolam (Koala Ward & Critical Care only)		
Contraindication	**Risk**	**Note**
Age <6 months (corrected age)	Risk of airway obstruction / apnoea	E.g. Ex premature infant, neonate or any infant with a significant co-morbidity
Note: Use of IV sedation in ward and ambulatory areas is limited only to IV midazolam in Koala ward by competent staff. Use of IV midazolam in any other ward or ambulatory area must be approved by the RCH Medication Safety Committee, in consultation with the Anaesthesia and Pain Management Department.		

3.1.6 Consultation

A child with a risk factor may still undergo procedural sedation provided they are assessed as having adequate reserve to tolerate that sedation.

This may require consultation with the bed card team or appropriate treating medical team to confirm whether the patient has adequate reserve.

Procedural sedation support services

Service	Comfort Kids Program	Anaesthesia and Pain Management
Staff	CNC's (Department of Anaesthesia & Pain Management)	In charge anaesthetist
Contact	55776 or 57075 Ascom 52771	Ascom 52000
Hours	M-F Business Hours	Available 24/7
Consultation	Procedural sedation	Referral to GA After hours procedural sedation advice

3.1.7 Staffing

The minimum staff requirement for all procedures under sedation is two staff members; the proceduralist and the sedationist. The sedationist role is separate to the proceduralist. Medical staff are to be present if requested and available in the clinical area. All staff present must identify their roles to the team, parent and child/adolescent.

The sedationist will be responsible for the following:

- Baseline and ongoing vital signs
- Airway patency and adequacy of ventilation
- Level of sedation for the duration of procedure and until patient has returned to baseline sedation score

The sedationist will:

- Be up to date with BLS competency and be responsible for maintaining airway patency and adequate ventilation
- Be competent to safely administer the sedation agent
- Be required to have a working knowledge of the following: dose range, action, interactions, adverse effects and reversal agent
- Determine when the child is ready for the procedure to commence

3.1.8 Sedation competency

Administration of inhaled nitrous oxide and intravenous midazolam requires the clinician to be determined competent via the relevant RCH competency framework.

3.1.9 Consent

Consent should be obtained for both the procedure and the sedation agent(s). Consent must be obtained prior to the procedure as per the RCH Consent – Informed procedure

• A staff member who can explain to the patient/ parent/ carer the indications for use and possible risks involved, must obtain informed consent for the procedural sedation agent.

• It is recommended that the child or adolescent/parent/carer be provided with a fact sheet for the selected sedation agent. Kids Heath Info: Sedation for Procedures

• Informed consent is documented on the Procedure Sedation Hub

3.1.10 Preparation of child and family

Follow the below procedure when preparing the child and family for procedures

Procedure Management Guideline

3.1.11 Patient identification

Prior to the procedural sedation, patient identification, as per the Patient Identification procedure must be conducted and documented on the Procedure/ Sedation Hub.

3.1.12 Equipment

Procedural sedation must only occur in a designated clinical area that has the equipment listed below. This equipment must be identified as appropriate for the child or adolescent and must be functioning prior to the procedure.

Equipment
Oxygen outlet
Face mask and tubing
Suction unit, Yankauer & Y-suction catheters
Pulse oximetry
Blood pressure monitoring equipment
A room and appropriate bed/trolley

Resuscitation equipment
Resuscitation trolley located in the clinical area
Identify location of emergency alarm
Identify location of reversal agent
Identify appropriate size airway
Identify appropriate size air cushion mask
Identify appropriate size self-inflating bag

3.1.13 Pre-sedation checklist

This can be found within the procedure sedation hub in EPIC. The minimum requirements for documentation of a sedation procedure include:

- Previous allergy or adverse events
- Risk of excess sedation
- Risk of airway compromise
- Risk of cardiovascular compromise
- Fasting timeframe
- Equipment checks
- Baseline observations
- Informed consent

3.2 During Sedation

During a procedural sedation event, it is the responsibility of the 'sedationist' to ensure the safety of the patient, by monitoring observations and sedation levels.

3.2.1 Monitoring

The patient must remain in the line of sight of the sedationist from the time of administration to the end of the procedural sedation event, this is defined as the sedation period.

- Continuous pulse oximetry should be in place once the sedation agent is administered. Where a child is not able to tolerate oximetry, monitoring respiratory rate, UMSS, manual heart rate and spot checking saturations is appropriate.

- Minimum monitoring required is UMSS, HR, RR, SpO2
- If sedation score is greater than or equal to 2, or there is a significant change in patient status observe and record vital signs and record sedation score every 5 minutes
- BP as indicated for any IV sedation agents or for patients with cardiovascular risk
- The patient must be positioned to maintain an open airway
- Continuous observation of airway patency and adequate respiratory movements
- If the patient is remote from the sedationist (e.g. in the MRI suite) visual and audio contact is essential

3.2.2 Excess sedation and escalation of care

Excess sedation in patients may result in loss of protective airway reflexes and risk of adverse events including hypoventilation, apnoea, airway obstruction, aspiration and cardiovascular impairment. Procedural sedation requires that the sedationist and staff present be able to rescue patients should the level of sedation become deeper than intended (UMSS > 2).

- Additional opioid or sedation agents may have synergistic effect producing excess sedation.
- Sedation may be an effect of medications such as anxiolytics, anticonvulsants, and antihistamines.
- The patient's baseline analgesia is not required to be withheld to facilitate the procedural sedation. Prior to providing procedural sedation, assess:
    - If the UMSS baseline is 0 the patient is considered low risk for an additional agent
    - If the UMSS baseline is 1 the patient is considered moderate risk, consider consultation
    - If the UMSS baseline is 2-4 the patient must not receive an additional agent, seek consultation

In the event of excess sedation leading to respiratory depression, loss of consciousness or loss of airway patency, activate the escalation of care for the clinical area and call a MET as per the Medical Emergency Response procedure

3.2.3 Transport of a sedated patient

All sedated patients requiring transport should be accompanied by a competent clinician.

The following is required:

- Appropriate positioning for optimal airway support

- Continuous pulse oximetry

- Airway suction
- Oxygen supply
- Appropriately sized self-inflating bag
- Appropriately sized ventilating mask

3.0.1. 3.2.4 Failure to sedate

Failure to sedate occurs where the desired level of sedation to complete the procedure is not achieved. Non urgent procedures should be abandoned if patient's anxiety or distress is unable to be deescalated.

Table in Appendix B

3.2.5 Adverse events

Management of adverse events is described in section 3.2

For further information about individual sedation agents refer to Appendix A

The procedures and escalation processes described, and accompanying information are intended to prevent and mitigate the likelihood of occurrence of adverse events.

In the circumstance of adverse event occurrence, this should be reported within RCH VHIMS; subsequent processes are guided by The Quality and Safety Amendment of the Health Service Act, 1988 (VIC), and reporting if required to Safer Care Victoria.

3.3 End of Sedation

The sedation period is considered complete when:

- The patient has returned to baseline sedation score
- Vital signs are within normal limits for the patient
- The patient is easily rousable

3.3.1 Recovery

If the child does not meet the 'end of sedation' criteria, continue to monitor and reassess. Support airway and spontaneous ventilation. Allow cessation of fasting if the patient is inter-active and drugs are wearing off post procedure; if they are thirsty clear fluids may be trialled if airway patency is demonstrated (E.g. demonstrated cough).

3.3.2 Discharge

Patients may be discharged home following procedural sedation, provided they meet the below criteria:

- The patient returns to baseline level of consciousness and observations are within normal limits for the patient
- Pain is appropriately controlled
- Nausea +/- vomiting is controlled
- The patient tolerates fluids +/- diet, if interested (do not force if patient appropriately declines)
- Discharge is indicated by the medical team or criteria led discharge pathway
- The patient can sit up unaided or walk (as developmentally appropriate)
- A responsible adult is present to accompany the patient (all ages)
- Appropriate documentation of the sedation event has been completed

Post sedation care must be discussed with parents and carers including safety and injury prevention

3.4 Documentation

The following documentation is required for all sedation events:

- Medications must be prescribed on the Medication Administration Record (MAR) in EMR
- Observations / vital signs must be recorded.
- The Procedure/Sedation Hub should be completed including, record of events, patient experience, number of attempts, and recommendations for future sedation.
- See pre sedation checklist in section 3.1.13

3.5 Baseline observations

When referring to baseline observations, this includes:

- Respiratory rate
- Heart rate
- Oxygen saturations
- Blood pressure (where appropriate)
- UMSS score

4. Sedation Agents

Chloral Hydrate

Clonidine

Fentanyl

Midazolam

Nitrous Oxide

5. Key Aligned Documents

5.1 Policies

- Care Planning and Implementation

5.2 Procedures

- Procedural Pain Management

5.3 Guidelines

- Procedure Management Guideline
- Procedural Sedation
- Intranasal Fentanyl
- Communicating Procedures to children

5.4 Standards and Legislation

- ACSQHC and the Children's Healthcare Australasia. NSQHS Standards. User Guide for Acute and Community Health Service Organisations that Provide Care for Children. NSQHS Standards - Guide for Childrens Health Services

6. References

Professional Bodies

Australian and New Zealand College of Anaesthesia (http://www.anzca.edu.au/)
https://www.anzca.edu.au/getContentAsset/3faa17f6-a6e0-4719-9992-9d67acef952b/80feb437-d24d-46b8-a858-4a2a28b9b970/PG09(G)-Sedation-2023.pdf?language=en

International Association for the Study of Pain (www.iasp-pain.org)

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7. Key Contacts

Director of Anaesthesia and Pain Management Department

Clinical Nurse Consultants – Comfort Kids Program

8. Appendices

Appendix A – Sedation agents

Appendix B – Failure to sedate

Appendix C – How to order procedural sedation

Appendix D – Intravenous midazolam dosing

Appendix A - Sedation agents

A.1 Methods of Action

	Anaesthetic	Analgesic	Anxiolytic	Amnesic	Sedative
Chloral Hydrate					Y
Clonidine		Y	Y		Y
Fentanyl		Y			Y
Midazolam			Y	Y	Y
Nitrous Oxide	Y	Y	Y	Y	Y

A.2 Chloral Hydrate

CHLORAL HYDRATE
Mode of Action Sedative and Hypnotic No analgesic effect
Indications for use in procedures Chloral hydrate is most successful if used for painless procedures (e.g. ECHO, CT & MRI) Chloral hydrate is more effective in < 2 years or 15kg Chloral hydrate induces sleep such that a procedure may be completed without disturbing the child. In contrast to the principles of conscious sedation—where the goal is to maintain the patient in a responsive and cooperative state—chloral hydrate is used with the intention of inducing sleep. Its primary effect is sedative-hypnotic, aiming to produce a deeper level of sedation that may limit patient responsiveness.
Contraindications UMSS >1 undertake consultation Significant liver disease/failure with Impaired liver function, chloral hydrate must not be used consultation Any adverse effect as listed below
Precautions Chloral hydrate has an unpleasant taste. Can be administered in a sweet solution to improve tolerance If opioid or sedation agent administered within 2 hours, assess UMSS and undertake consultation. Seek consultation if UMSS ≥ 2 and/ or patient receiving concurrent sedative or opioid (e.g. Clonidine or morphine). Assessing UMSS score for sedation levels below 2 may be counterproductive as stimulation required for assessment at these levels may diminish the efficacy of the sedative intervention.
Adverse effects Excessive sedation (UMSS score > 2) Respiratory depression, airway obstruction Nausea, vomiting, gastric irritation Hyperactivity can occur rarely Hangover, disorientation, delirium, ataxia, headaches, nightmares and hallucinations

Onset of action Within 20- 30 minutes Give 45-60 minutes prior to procedure		
Duration of effect 60-120 minutes Effects can last 4-8 hours		
Dose Consider reduced dose in mild hepatic or renal failure (contraindicated in significant liver disease as above).		
Standard oral dosing		
0-3 months (corrected age) Seek consultation Cardiology inpatients ONLY (for removal of wires & drains) Recommend 30mg/kg initial 20mg/kg if required in 20-30min +/- analgesia per CPMS	**3-12 months** (corrected age) 50mg/kg (single or divided dose) Recommend 30mg/kg initial 20mg/kg if required in 20-30min	**1-18 years** 50-75mg/kg (single or divided dose) Recommend 50mg/kg initial 25-50 mg/kg if required in 20-30 min Maximum dose of 100mg/kg can be used (not exceeding 2g) Risk deep sedation
Oral dosing for Medical Imaging Department & Cardiology outpatients ONLY Recommend < 4 months attempt feed & wrap if appropriate for the procedure		
Infants > 3 months (Corrected age) **> 3 months**		

Recommend 50-70mg/kg (single or divided dose) Dosing is based on assessment of patient and procedure
Competency and recommendations (Medical Imaging Department (MID) MID requires completion of a mandatory chloral hydrate competency MID recommendations for procedural assessment: • MRI 50-70mg/kg • CT 50mg/kg • Nuclear Medicine 50mg/kg
Monitoring HR, RR, SpO_2, UMMS monitored continuously Baseline blood pressure monitoring prior to administration if possible.
Practice Points If sedation proves ineffective refer to Appendix B - Failure to sedate.

A.3 Clonidine

CLONIDINE
Mode of Action Anxiolytic, analgesic and sedative
Indications for use in procedures Preoperative sedation and analgesia. Non-invasive procedures such as EEG, ultrasound and ECHO Often used in combination with other procedural sedation agents
Contraindications Hypersensitivity to clonidine, or product excipients. Severe bradycardia due to sick sinus syndrome or second/third degree AV blocks Excessive sedation (UMSS score ≥ 2)
Precautions • If opioid or sedation agent administered within 2 hours assess UMSS & undertake consultation • If the child is concurrently using transdermal clonidine undertake consultation • Patients taking Guanfacine (Intuniv) - combining these medications may cause excessive slowing of heart rate that can lead to serious or life-threatening cardiac complications • Pre-existing mild to moderate bradycardia – heart rate may decrease further with clonidine • Co-administration of enteral or intravenous clonidine with epidural clonidine – check with CPMS • Cardiovascular impairment (including hypotension or poor function) - may further decrease with clonidine • Dehydration or heart failure – in these conditions the sympathetic tone is increased. Administering clonidine blunts this important survival mechanism leading to decompensation with hypotension and reduced heart rate. If administration is necessary, start with a low dose and titrate up slowly • Raynaud's syndrome or other vasospastic peripheral vascular disease - may be exacerbated by clonidine • Renal impairment - clonidine may accumulate in renal failure and lower doses may be required • Clonidine may cause transient rise in blood glucose concentration in patients with diabetes • As per the interactions sections below, co-administration of clonidine and dexmedetomidine may potentiate the therapeutic and adverse effects of both

medications. However, both may be used concurrently in Rosella (PICU) ward when rotating from one agent to another and a cross over period where both agents are co-infusing is required (refer to PICU guideline for weaning of analgesia and sedation)

- UMSS > 1 undertake consultation
- Any adverse effect as listed below

Adverse effects

Excessive sedation (UMSS score > 2)
Airway obstruction
Hypotension
Bradycardia
Impaired coordination/balance (falls risk)
Dizziness
Dry mouth
Nausea
Constipation
Respiratory depression/apnoea (when used in combination with other sedation agents)

ORAL	**INTRAVENOUS**
Onset of action	**Onset of action**
Within 30-60 minutes Give 45-60 minutes prior to procedure	Within 5-15 minutes
Duration of effect	**Duration of effect**
60-120 minutes Effects can last 4-6 hours	Several hours (MIMS)
Dose	**Dose**
1-18 years 2-4mcg/kg per dose to maximum of 300mcg	**1-18 years** 2-4mcg/kg per dose to maximum of 300mcg
Delivery	**Delivery**
Clonidine is suitable for administration via a nasogastric tube and percutaneous endoscopic gastrostomy (PEG).	Administer as per RCH Paediatric Injectable Guideline

There is a lack of data about nasojejunal absorption. If administration via the nasojejunal route is required, monitor for increased side effects or loss of efficacy. Tablets dissolve relatively clear and tasteless in water, so can be a good agent for patients who struggle with tolerating oral medications.	
Monitoring	**Monitoring**
HR, RR, SpO_2, UMMS monitored continuously Baseline blood pressure monitoring prior to administration if possible.	Baseline blood pressure monitoring prior to administration if possible. HR, RR, SpO_2, and UMMS score

Practice Points

- Fasting not required for clonidine administration as single agent. Consider fasting if risk factors present with single agent high dose.
- If giving clonidine in conjunction with other sedation agents, follow fasting guidelines for secondary agent.
- Consider dosage reduction in severe renal impairment; use cautiously in hepatic impairment
- Ensure adequate monitoring for adverse effects, e.g. bradycardia, hypotension, excessive sedation
- Consider adequate analgesia for painful procedures
- Tablets dissolve relatively clear and tasteless in water, so can be a good agent for patients who struggle with tolerating oral medications.
- Clonidine tablets can be halved or quartered to achieve a fractional dose. The dose can then be dispersed in water for administration, if required.
- To ensure accuracy of dosing, doses < 25 microgram should be given using the clonidine 10 mcg/mL suspension.
- See below additional considerations for advice on pre-hospital sedation.

Additional Considerations

Information for families can be found in the RCH Kids Health Information Fact sheets – Clonidine

Recommendations for safe clonidine administration for procedural sedation prior to hospital admission:

- If the patient is clonidine naïve, consider a titratable trial dose prior to procedure date.
- Consider timing of dose prior to admission or leaving house.

- Consider falls risk with sedation
- Ensure the child is secured in an appropriate car seat for age/height
- Line of sight from carer to the child while transporting is advisable
- If possible, transport with two adults

Specialist Clinics Considerations

- Clonidine may be given to support procedures in outpatients at AUM discretion.
- If the patient is clonidine naive, consider a titratable trial dose prior to procedure date.
- Consideration should be given to duration of effect given limited recovery space.

A.4 Fentanyl

FENTANYL (Intranasal)
Mode of Action Analgesic opioid
Indications for use in procedures Age > 6 months (corrected age) Minor painful procedures of short duration Limited IV access Potent & rapid onset of analgesia required Single procedural analgesic agent
Contraindications < 6months (corrected age) UMSS ≥2 Bilateral occluded nasal passage Epistaxis
Precautions If opioid or sedation agent administered within 2 hours, assess UMSS & undertake consultation.
Adverse effects Respiratory depression Hypotension Nausea and vomiting- increased risk of vomiting when combined with N_20 Chest wall rigidity (only reported with large IV doses) Pruritus
INTRANASAL
Onset of action Rapid onset of effect (2-5 minutes)
Duration of effect 30-60 minutes
Dose **Initial Dose:** 1.5 micrograms/kg

Second dose: (If UMSS <2 may administer after 10 minutes) 0.75 - 1.5 micrograms/kg

Dosing schedule per the Intranasal Fentanyl CPG with the addition of >6months (7kg) infant dosing

- Use 100micrograms/2ml strength fentanyl solution, administered intranasally
- Volumes have been rounded to the nearest 0.05mL

Weight estimate(kg)	Initial dose (1.5micrograms/kg)	Volume Initial dose (mL)	Top-up dose (0.75 - 1.5 micrograms/kg)	Volume Top up dose (mL)
7	10 mcg	0.2 mL	5mcg (limited)	0.1mL
10	15 mcg	0.3 mL	7.5 - 15 mcg	0.15 - 0.3 mL
12	18 mcg	0.35 mL	9 - 18 mcg	0.2 - 0.35 mL
14	20 mcg	0.4 mL	10 - 20 mcg	0.2 - 0.4 mL
16	24 mcg	0.5 mL	12 - 24 mcg	0.25 - 0.5 mL
18	27 mcg	0.55 mL	13.5 - 27 mcg	0.25 - 0.55 mL
20 - 24	30 mcg	0.6 mL	15 - 30 mcg	0.3 - 0.6 mL
25 - 29	37.5 mcg	0.75 mL	18.75 - 37.5 mcg	0.35 - 0.75 mL
30 - 34	45 mcg	0.9 mL	22.5 – 45 mcg	0.45 - 0.9 mL
35 - 39	52.5 mcg	1.05 mL	26.5 - 52.5 mcg	0.5 - 1.05 mL
40 - 44	60 mcg	1.2 mL	30 - 60 mcg	0.6 - 1.2 mL
45 - 49	67.5 mcg	1.35 mL	33.7- 67.5 mcg	0.65 - 1.35 mL
> 50	75 mcg	1.5 mL	37.5 - 75 mcg	0.75 - 1.5 mL

Delivery

Deliver via Mucosal Atomiser Device (MAD)

Draw up appropriate dose for weight (see above table) plus 0.1ml extra to the first dose (to account for the dead space in the device)

Attach MAD on to the end of the syringe

Sit the child at approximately 45 degrees or with head to one side

The MAD is directed at 45 degrees to spray the turbinates, rather than along the nasal floor

If directed horizontally the dose runs into pharynx & is swallowed (reducing bioavailability and efficacy)

Insert the device loosely into the nostril and press the plunger quickly

Dose are to be divided between nostrils

Note: Do NOT draw up 0.1ml extra for second dose when re-using the delivery device (MAD)

Monitoring

HR, RR, SpO_2, UMMS monitored continuously

Practice Points

Useful for short, painful procedures, less effective for sedation or prolonged procedures

Additional Considerations

Reversal Agent – Naloxone

Naloxone bolus 0.1mg/kg IM or IV, maximum 2mg

A.5 Midazolam

MIDAZOLAM			
Mode of Action Anxiolytic Sedative Amnesic Antiepileptic No analgesic effect			
Indications for use in procedures Preoperative or procedural sedation and anxiolysis			
Contraindications UMSS > 1 undertake consultation Any adverse effect as listed below			
Precautions If opioid or sedation agent administered within 2 hours assess UMSS & undertake consultation Consider dosage reduction in severe renal impairment; use cautiously in hepatic impairment consultation IV Midazolam may only be administered by a competent staff member in Koala Ward			
Adverse effects Excessive sedation (UMSS score > 2) Respiratory depression/apnoea Airway obstruction Hypotension, especially in patients with impaired cardiovascular stability Impaired coordination/balance (falls risk) Delirium/paradoxical agitation can rarely occur. More likely with younger patients or those with psychiatric comorbidity			
ORAL	**INTRANASAL**	**INTRAVENOUS**	**BUCCAL**
Onset of action	**Onset of action**	**Onset of action**	**Onset of action**
Maximum effect within 15-25 minutes Give 15 minutes before procedure	Maximum effect within 10 minutes (Absorption is rapid) Give 15-20 minutes before procedure	1-5 minutes Peak effect 3-5 minutes Give 5-10 minutes before a procedure Incremental boluses to achieve anxiolytic effect	Maximum effect within 15-25 minutes Give 15 minutes before procedure

Duration of effect	Duration of effect	Duration of effect	Duration of effect
Up to 2 hours Absorption is rapid but erratic	Up to 2 hours	Effect may last 30-60 minutes	Up to 2 hours
Dose	**Dose**	**Dose**	**Dose**
>4 month (corrected age) 0.3- 0.5mg/kg per dose to maximum of 20mg Oral administration efficacy may be variable (influenced by first-pass metabolism & duration of fasting)	**>4 month** (corrected age) 0.2- 0.4 mg/kg up to maximum 10mg (Repeat in 5–15 minutes if required)	See Appendix D	**>4 month** (corrected age) 0.3- 0.5mg/kg per dose to maximum of 10mg
Delivery	**Delivery**	**Delivery**	**Delivery**
Tastes bitter and acidic. Administer with sweet solution	Not preferred route due to nasal irritation and burning Use a Mucosal Atomization Device (MAD) to administer Draw up appropriate dose for weight (see above) plus 0.1ml extra to the first dose (to account for the dead space in the device) Attach MAD on to the end of the syringe	**Rapid administration of IV midazolam increases the risk of cardiorespiratory depression** When used for sedation/anxiolysis/amnesia for a procedure, dosage must be individualized and titrated Midazolam should always be titrated slowly dose over at least 2 minutes and allow the additional time as per the	Administer dose buccally via the space between cheek and gum Patient compliance will determine if buccal absorption occurs vs oral absorption (if swallowed) The principle is to have the drug absorbed by the buccal route-only Ideally the dose is divided (given bilaterally)

	Sit the child at approximately 45 degrees or with head to one side The MAD is directed at 45 degrees to spray the turbinates, rather than along the nasal floor If directed horizontally the dose runs into pharynx & is swallowed (reducing bioavailability and efficacy) Insert the device loosely into the nostril and press the plunger quickly Dose are to be divided between nostrils Note: Do NOT draw up 0.1ml extra for second dose when re-using the delivery device (MAD)	intervals above to fully evaluate effect Individual response will vary with age, physical status and concomitant medications	
Monitoring	**Monitoring**	**Monitoring**	**Monitoring**
HR, RR, SpO_2, and UMMS score	HR, RR, SpO_2, and UMMS score	HR, RR, SpO_2, and UMMS score monitored continuously Blood pressure monitored minimum 5 minutely	HR, RR, SpO_2, and UMMS score
Practice Points			

Midazolam injection solution (5 mg/mL ampoules) is used for oral, intranasal and IV administration
Midazolam tastes bitter and acidic. Administer in a sweet solution
Oral administration efficacy may be variable (influenced by first-pass metabolism, duration of fasting and proportion of mucosal absorption)
Enteral administration of midazolam e.g. via NGT or PEG may lead to slower time to effect due to bypassing oral mucosal absorption.
Buccal administration may be difficult for some children given bitter taste and volume of fluid – the oral route is preferred in most instances
Intranasal midazolam is used less often as it causes nasal irritation and a burning sensation
Midazolam may cause hiccups

Additional Considerations

Reversal Agent – Flumazenil

Indication: Benzodiazepine induced over-sedation
Flumazenil dose: 5mcg/kg IV every 60 seconds to maximum total of 40mcg/kg
Considerations: Re-sedation may occur. May increase the risk of seizures in predisposed patients
Location: Resuscitation trolley in ward and ambulatory areas + MET team

A.6 Nitrous Oxide

NITROUS OXIDE	
Mode of Action Sedative Anxiolytic Amnesic Analgesic	
Indications for use in procedures Minor painful procedures of short duration Procedural sedation, anxiolysis and analgesia	
Contraindications Age ≤ 2 years of age Severe pulmonary hypertension associated with limited exercise tolerance Gas filled space e.g. Pneumothorax, lung cyst, obstructive pulmonary disease, bowel obstruction, recent craniotomy with pneumocephalus resulting in trapped gas, significant middle ear disease or surgery resulting in trapped gas and decompression sickness. Respiratory illness or infection e.g. Pneumonia or respiratory tract infection with excessive secretions and poor respiratory reserve. Severe asthma (wheeze present)	
Precautions If opioid or sedation agent administered within 2 hours, assess UMSS & undertake consultation.	
Adverse effects Expansion of closed gas-filled space Respiratory depression/apnoea Loss of airway reflexes (pulmonary aspiration risk) Diffusion hypoxia (see practice points) Laryngospasm Excessive sedation (UMSS > 2) Hallucination- Scary or Nightmare Loss of consciousness	**Side effects** Dizziness Lightheaded Headache Euphoria Memory loss Mild Nausea Vomiting Auditory – amplification of noise Visual disturbance

Folate metabolism and vitamin B12 suppression	

INHALATION

Onset of action

Onset 30-60 seconds

Peak 2-5 minutes

Patient must breathe an effective concentration before commencing the procedure

Duration of effect

Offset 2-5 minutes

100% Oxygen is to be given on ceasing N_20 for 3-5 minutes to avoid diffusion hypoxia

Dose

Nitrous oxide (N_20) 10-70%. The dose is titrated to the desired effect, maintaining a UMSS ≤ 2

- N_20 must always be blended with Oxygen (30-90 %) via the designated delivery system at RCH
- The maximum percentage of N_20 which can be delivered is 70%, with a minimum O_2 30%
- Additional opioid or sedation agents may have synergistic effect producing excess sedation.

Delivery

Nitrous oxide is delivered via the Porter MXR Nitrous Oxide delivery system

Check nitrous oxide equipment and fail-safe mechanisms prior

Gas scavenging must be set up and on

Maximum 45 minutes per procedural sedation episode. Prolonged or repeated exposure increases the incidence of adverse effects.

Monitoring

HR, RR, SpO_2, and UMMS score monitored continuously

Practice Points

- Nitrous oxide may only be administered by a competent staff member
- Vomiting occurs in 6-10% receiving 50% N_20. This increases up to 25% with co-administration of an opioid. Vomiting may also increase with higher concentration and longer administration time. If patient has a history of nausea & vomiting, consider anti-emetic prior & slower titration of N_20
- If the patient is extremely anxious (despite non-pharmacological techniques and preparation), consider commencing N_20 at 50%, increase at a greater rate. Once the patient is calm, titrate up or down as appropriate, and maintain UMSS ≤ 2

- Preparation for mask use is helpful to reduce anxiety related to administration and may increase tolerance of firm mask application
- 50-70% patients achieve mild to moderate sedation with N_20 as a single agent. A few patients may reach moderate to deep sedation at 70%. Close monitoring of UMSS is essential throughout
- 10% of children may be poorly sedated & for 10% analgesia is not effective or may have psychological resistance. See Appendix B – Failure to sedate
- Diffusion Hypoxia may occur when the $N_20/0_2$ mix is suddenly stopped. When nitrous oxide is discontinued, nitrous oxide diffuses out of the blood into the alveoli in large volumes. If the patient is allowed to breathe air at this time, the combination of nitrous oxide and nitrogen in the alveoli reduces the alveolar PO_2. This causes diffusion hypoxia and is avoided by administering 100% oxygen for 3-5 minutes post procedure (this may be through a Hudson mask if more tolerable)
- If the patient's mask is off for more than 30 seconds, monitor oximetry and apply 100% oxygen if saturations decrease or respiratory function is impaired.
- Use of Midazolam / Opioids with N_20 - If the patient is extremely anxious (despite non-pharmacological techniques and preparation), consider a rapid titration approach or midazolam prior
- If the patient is considered to require additional analgesia, consider timing the procedure with the patient's baseline analgesia or consider intranasal fentanyl

Additional Considerations

Occupational Health and Safety

To minimise occupational exposure to nitrous oxide, the following controls must be implemented:

- Nitrous oxide must be administered in a well-ventilated clinical environment using a compliant and fully operational scavenging system.
- Prior to each use, staff must verify that the delivery system, breathing circuit, connections and scavenging equipment are intact, free from leaks and functioning correctly.
- Equipment should undergo regular inspection, servicing and preventative maintenance to ensure effective gas capture and safe operation.
- Nitrous oxide cylinders and gas supplies must be turned off immediately after use.
- Any equipment faults, leaks or concerns regarding exposure should be reported promptly through established incident reporting processes.

- While short-term occupational exposure of nitrous oxide is not known to cause adverse health effects. Staff should minimise exposure wherever reasonably practicable and avoid unnecessary, prolonged or repeated exposure.

Pregnancy

- Staff who are pregnant are encouraged to minimise occupational exposure to nitrous oxide wherever reasonably practicable.
- Current evidence suggests that brief, incidental exposure in a well-controlled environment presents a very low risk; however, precautionary measures should be maintained, and unnecessary exposure should be avoided.
- Staff who are planning pregnancy, pregnant or breastfeeding should complete the Pregnancy Risk Assessment with their line manager to identify any workplace hazards, discuss concerns and determine whether additional control measures or reasonable adjustments are required.

Environmental Considerations

Nitrous Oxide is a known greenhouse gas. Medical use of nitrous oxide is responsible for a significant amount of greenhouse gas emissions per year. Aim to reduce nitrous oxide waste wherever possible.

Appendix B - Failure to sedate

If sedation fails, consider non-pharmacological and pharmacological factors that may influence sedation.

See Procedure Management Clinical Practice Guideline for further information

Preparation

- Ensure developmentally appropriate procedural preparation and expectations
- Overstimulating environment
    - Environmental noise
    - Bright lighting
    - Too many people

Medication

- Timing
    - Review timing between administration and procedure
- Dosing
    - Review dose for weight
    - If divided doses were used, consider larger single dose (E.g. 0.3mg followed by 0.2mg top up dose of oral midazolam – opt for 0.5mg dose in future)
- Agent
    - When a single agent fails, multi-agent sedation may be required

Procedure

- Pain
    - Inadequate analgesia (consider opioids in conjunction with sedation)
- Duration
    - Duration of procedure exceeds sedation period

Appendix C - How to order procedural sedation

To order procedural sedation using Epic EMR:

Preferred:

- Search the Orders and Order Sets for 'IP Procedural Sedation'.
- Select order set 'IP Procedural Sedation'
- Nursing observations and communication will be automatically selected.
- From the medications list, select the appropriate procedural sedation.
- Select any additional orders such as CLT referral.
- Sign order set.

Alternatively:

- Search the Orders and Order Sets for the individual drug names.
- Use caution with this approach as alternative doses for use in critical care areas may also be available.

Appendix D - Intravenous midazolam dosing

Intravenous Midazolam Dose

> 6 months < 12 months (corrected age)	**≥ 12 months or ≤ 50kg**	**> 50kg**
0.1mg/kg of midazolam dilute to 10mLs of 0.9% normal saline	0.1mg/kg of midazolam dilute to 10mLs of 0.9% normal saline	5mg of midazolam dilute to 10mLs of 0.9% normal saline
Bolus: Give 1mL and repeat bolus at intervals of no less than 5 minutes to achieve or maintain anxiolysis	Bolus: Give 1–2mLs and repeat bolus at intervals of no less than 3 minutes to achieve or maintain anxiolysis	Bolus: Give 1–2mLs and repeat bolus at intervals of no less than 3 minutes to achieve or maintain anxiolysis
Do not exceed total dose of 0.15mg/kg in 15mLs of 0.9% normal saline	Do not exceed total dose of 0.15mg/kg in 15mLs of 0.9% normal saline	Do not exceed total dose of 7.5mg in 15mLs of 0.9% normal saline