

**Hospital Clinical Guidelines
EVIDENCE TABLE**

GUIDELINE TOPIC: Procedural Sedation Guideline

Please record all references used in developing the clinical guideline. This form must be filled out electronically and emailed to Jody.Smith@rch.org.au
NB: If you need assistance with completing this table, please contact Jody Smith on x 6956.

Reference (include title, author, journal title, year of publication, volume and issue, pages)	Method	Evidence level (I-V)	Summary of recommendation from this reference (point form)
Pitetti R, Davis PJ, Redlinger R, White J, Wiener E, Calhoun KH. Effect on hospital-wide sedation practices after implementation of the 2001 JCAHO procedural sedation and analgesia guidelines. <i>Arch Paediatr Adolesc Med</i> 2006;160(2):211-6	Prospective descriptive study	V	<ul style="list-style-type: none"> ▪ Implementation of Healthcare organization guidelines for the provision of procedural sedation agents appeared to lead to a decrease in the incidence of adverse events during the study. ▪ Implementation of uniform standards of monitoring and care for the provisions of PSA may lead to safer conditions for paediatric undergoing PSA.
McDowall RH, Scher CS, Barst SM. Total intravenous anesthesia for children undergoing brief diagnostic or therapeutic procedures. <i>J Clin Anesth.</i> 1995;7:273-280.	Retrospective study	V	<ul style="list-style-type: none"> ▪ The aim of the study was to compare the quality of anaesthesia with propofol, ketamine, or etomidate in children undergoing brief diagnostic or therapeutic procedures. ▪ The study demonstrated anaesthetics including propofol, ketamine, or etomidate safe and efficacious for children undergoing brief procedures.

Agrawal D, Manzi SF, Gupta R, et al Pre Procedural fasting state and adverse events in children undergoing procedural sedation and analgesia in a pediatric emergency department . Ann Emerg Med. 2003;42:636-646.	Case series	IV	<ul style="list-style-type: none"> ▪ Case review conducted in France whereby pre procedural review of fasting states and adverse events. ▪ Conclusions of this study no significant differences in pre procedural fasting state and adverse events.
Cote J, Notterman D, Karl H, Wienburg J, McCloskey. Adverse Sedation Events in Pediatrics: A Critical Incidents Analysis of Contributing Factors. Pediatrics 2000; 105:805-814.	Critical incidence analysis	V	<ul style="list-style-type: none"> ▪ The aim of the analysis by multiple American paediatric facilities was to identify factors that contribute to adverse sedation events in children undergoing procedures. ▪ The study identified several features related to adverse events and poor outcome. These varied across centres and included such things as inadequate pre sedation, medication errors, and inadequate recovery procedures. ▪ Uniform, specialty-independent guidelines for monitoring children during and after sedation are essential. ▪ It is recommended health care providers who sedate children, regardless of practice venue, should have advanced airway assessment and management training and be skilled in the resuscitation of infants and children.
Priestley S, Babl F, Kriesser D, Law A, Miller J, Spicer M, Tully M. Evaluation and the impact of a paediatric procedural sedation credentialing programme on quality care. Emergency Medicine Australia 2006; 18;(5-6), 498-504.	Chart review	IV	<ul style="list-style-type: none"> ▪ The aim of the study is to describe changes in documentation, risk assessment, observation and clinical care post implementation of paediatric procedural sedation (PPS) credentialing program for medical and nursing. Two Australian emergency department's one urban mixed Ed and specialist paediatric ED. ▪ Outcome: Implementation of PPS credentialing program resulted in significant improvement to risk assessments, monitoring. Indicating improvements in quality and safety of PPS.

Paediatric and Child Health Division, The Royal Australasian College of Physicians. Management of procedure-related pain in children and adolescents. Journal of Paediatric child health. Blackwell Publishing 2006; 42.	Guidelines	I-IV	<ul style="list-style-type: none"> ▪ Document is review of literature and expert opinion for health professionals for the management of procedural pain and distress for paediatric patients. Guidelines were graded following criteria based on the NHMRC levels of evidence.
Frampton A, Browne GJ, Lam LT, Cooper MG, Lane LG. Nurse administered relative analgesia using high concentration nitrous oxide to facilitate minor procedures in children in an emergency department. Emergency Medical Journal 2003 Sep; 20:410-3,	Case series	IV	<ul style="list-style-type: none"> ▪ Aim of the study is to describe the experience of using nitrous oxide administration by nursing staff in children having minor procedures in the Emergency department. To demonstrate its safety in children greater than 12 months of age. ▪ Conclusion: nurse led nitrous oxide administration for procedures in children one year of age may safely be administered in concentrations of up to 70%. Appropriate training of nursing staff was required.
Krauss B, Green S M, Procedural sedation and analgesia in children. Lancet 2006; 367: 768-80	Review	V	<ul style="list-style-type: none"> ▪ Review of principles underlying safe and effective procedural sedation and analgesia outside the operating theatres. Included in review risk assessments, clinical decision making to determine appropriate agent, and sedation duration. ▪ Outline international differences in practices and guidelines. ▪ Sites future of procedural sedation focus on training, safety and establishment of a registry for adverse events. ▪
Heistein L, Ramaciotti C, Scott W, Coursey M, Sheeran P, Lemler M. Chloral Hydrate Sedation for Pediatric Echocardiography: Physiological Responses, Adverse Events, and Risk Factors. Pediatrics March 2006; 117(3) ppe 434-441	Retrospective analysis.	IV	<ul style="list-style-type: none"> ▪ Analysis of patient sedated for echocardiography using chloral hydrate and the absence and presence of minor to major adverse events.

<p>Hospital for Sick Children, Toronto, Canada. Procedural Sedation Record and Care of the Child Receiving Procedural Sedation policy. 2002 December.</p>	<p>Record of sedation and policy</p>	<p>V</p>	<ul style="list-style-type: none"> ▪ Review of sedation guidelines at urban paediatric centre ▪ Review of Procedural sedation record.
<p>The Children Hospital at Westmead. Procedural Sedation for Common diagnostic and Therapeutic Interventions.</p>	<p>Practice Guidelines.</p>	<p>V</p>	<ul style="list-style-type: none"> ▪ Review of sedation guidelines at urban paediatric centre
<p>Lucile Packard Children's Hospital, Stanford University Medical Centre. Sedation Policy and Procedures. 2001.</p>	<p>Sedation policy</p>	<p>V</p>	<ul style="list-style-type: none"> ▪ Policy and guidelines for procedural sedation including drug administration and recommended sedation agents for use in paediatrics.
<p>Recommended minimum fasting times for Procedural Sedation are consistent with current clinical practice in Australian paediatric centres and College of Physician Guidelines.</p>	<p>Review of fasting practices for procedural sedation in Australian paediatric centres.</p>	<p>V</p>	<ul style="list-style-type: none"> ▪ Changes to the fasting guidelines were the results of feedback from the clinical staff at RCH and discussion with CPMS services in Sydney, Darwin and Perth. ▪ Resulted in minimal fasting guidelines for nitrous oxide to be changed to two hours. ▪ Document MR 56S Record of Sedation for Procedures 2007.

<p>Priestley S, Babl F, Kriesser D, Miller J. Sedation of children in Emergency Department of Sunshine and Royal Children Hospital, Education for Guideline for Nurses and Doctors. 2004 Oct.</p>	<p>Clinical Practice Guideline.</p>	<p>V</p>	<ul style="list-style-type: none"> • The emergency paediatric guidelines presented were developed by RCH clinicians primarily for use within the inpatient wards and emergency department of the Royal Children's Hospital, Melbourne. • These Clinical Practice Guidelines were produced by staff of The Departments of General & Emergency Medicine, often with input from sub specialist surgical and medical departments. Where possible we have achieved consensus between practicing clinicians.
<p>Royal Children Hospital Paediatric Pharmacopeia 13th edition, Royal Children's Hospital. (2003)</p>	<p>Pharmacopoeia</p>	<p>V</p>	<ul style="list-style-type: none"> • The drugs and preparations listed are generally those used within the Royal Children's Hospital. • Notes after most monographs supply readers with important or specific information for paediatrics. These notes are not comprehensive; general drug information should be consulted (eg. in the MIMS) in conjunction with the information in the <i>Paediatric Pharmacopoeia</i>. Further information on specialised drugs is available on request from a Drug Information Centre

Level of Evidence
Clinical Guidelines
Royal Children's Hospital

The Hierarchy of Evidence

The Hierarchy of evidence is based on the National Health and Medical Research Council (2000) and Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

- I** Evidence obtained from a systematic review of all relevant randomised control trials.
- II** Evidence obtained from at least one properly designed randomised control trial.
- III-1** Evidence obtained from well-designed pseudo-randomised controlled trials (alternative allocation or some other method).
- III-2** Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies, or interrupted time series with a control group.
- III-3** Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
- IV** Evidence obtained from case-series, either post-test or pre-test and post test.
- V** Expert opinion without critical appraisal, or based on physiology, bench research, or historically based clinical principles.

Clinical guidelines are based on reviews of the best available evidence. **Level 1 evidence represents the gold standard for intervention studies**; however it is not available for all areas of practice and for some guidelines it may be appropriate to utilise results from studies with lower levels of evidence. Some clinical guidelines may also be informed by experts in the field, locally (RCH) and internationally (Journal articles) (expert opinion) etc. This NHMRC Hierarchy can be used to grade evidence. Please record details on the evidence table and return to Clinical Quality and Safety (CQS) with guideline draft. The Evidence table can be filled out electronically or printed and used as a hard copy.

Please contact Jody Smith Clinical Guideline and Path Coordinator on ext 6956 if you have any concerns or require assistance.