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 randomized control trials.

**II** Evidence obtained from at least one properly designed randomized control trial.

**III-1** Evidence obtained from well-designed pseudo-randomized 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 randomized, 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 utilize 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.*

**Hospital Clinical Guidelines**
**EVIDENCE TABLE**

**GUIDELINE TOPIC: Tracheostomy Management**

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** | **Summary of recommendation from this reference (point form)** |
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| Doherty C. et al. Multidisciplinary guidelines for the management of paediatric tracheostomy emergencies. Anaesthesia 2018; 73:https://doi.org/10.1111/anae.14378 | **Expert opinion** | **IV - V** | • Outlines clear, practical guidelines for managing emergency management.<br>• Outlines causes and management of paediatric tracheostomy emergencies.<br>• Bed signs for emergency management to alert staff.<br>• Importance of standardized, structural educational programmes for parents and carers. |
| Chorney SR, et al. Paediatric Tracheostomy Outcomes after development of a multidisciplinary airway team: A quality improvement initiative. OTO Open 2021; Vol 5 (3) pp1-9. | **QI initiative** | **IV** | • Establishment of MDT clinic demonstrated reduced length of stay and improved outcomes. |
| Luu K. et al. Dysphagia in Paediatric Patients with Tracheostomy. Annals of Otology, Rhinology & Laryngology 2021; 00(0) | **Retrospective study** | **III -3** | • Tracheostomy can functionally and anatomically affect swallowing in paediatric patients.<br>• Timely, objective measurements of swallowing post-operatively to identify those at risk of aspiration. |
| Verma R. et al. Decannulation following tracheostomy in children: A systematic review of decannulation protocols. Pediatric Pulmonology 2021; 1-18 | **Systematic review** | **III - 2** | • Highlights the need for standardized evidence-based paediatric tracheostomy care guidelines to improve Decannulation outcomes.<br>• The role of PSG prior to Decannulation is not clear. |

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| Lindquist SJ, Morrison SE, and Iseli CE. Pediatric tracheostomy decannulation: post implementation of tracheostomy team and decannulation protocol. Australian Journal of otolaryngology. 2020; 3:24 http://dx.doi.org/10.21037/ajo.2020.03.07 | **Retrospective review** | **IV** | • Demonstrated significant improvement in Decannulation outcomes following the introduction of Tracheostomy MDT and Decannulation protocols at the RCH. |
| Fuller C, Wineland AM, and Gresham TR. Update on Pediatric Tracheostomy: Indications, Technique, Education, and Decannulation. Current Otorhinolaryngology Reports 2021; 9:188-199. | **Literature Review** | **IV** | Standardized tracheostomy management to improve outcomes Identified further research in Decannulation protocols/procedures warranted. |
| Boyce, JM.; Pitlet, D. Healthcare Infection Control Practices Advisory Committee. Society for Healthcare Epidemiology of America. Association for Professionals in Infection Control. Infectious Diseases Society of America. Hand Hygiene Task Force. Guideline for hand hygiene in health-care settings: recommendations of the healthcare infection control practices advisory committee and the HICPAC/SHEA/ APIC/ IDSA hand hygiene task force.<br><br>Infection Control and Hospital Epidemiology, 2002; 23 (12 Suppl), S3-40. | Review of data regarding handwashing and hand antisepsis in health-care settings. | I | • Wash hands with either a non-antimicrobial soap and water or an antimicrobial soap and water if hands are visibly dirty or contaminated.<br><br>• If hands are not visibly dirty, decontaminate hands with either alcohol- based hand rub or an antimicrobial soap in water before having direct contact with patients or inserting invasive device.<br><br>• Decontaminate hands after contact with a patient's skin, body fluid, excretions, mucous membranes or wound dressings. |

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| Ridling D, Martin LD and Bratton S. Endotracheal Suctioning With or Without Instillation of Isotonic Sodium Chloride Solution in Critically Ill Children. American Journal of Critical Care 2003; Vol 12, no 3 pp: 212-219. | Randomized Control Trial | II<br><br>No power analysis, small sample size, with many confounding factors | • Instillation of isotonic sodium chloride solution during endotracheal tube suctioning may not be beneficial and actually may be harmful, and routine instillation of bolus of isotonic sodium chloride solution during suction is not recommended. |
| American Thoracic Society<br><br>Care of the child with a chronic tracheostomy. American Journal of Respiratory Critical Care Medicine, 2000; vol 161. pp 297- 308. www.atsjournals.org | Guideline, consensus agreement, expert opinion | V | • Routine instillation of isotonic sodium chloride is not recommended.<br><br>• The premeasured technique is recommended for all routine suctioning.<br><br>• With adequate and continuous suction pressure, the length of time required to perform the premeasured technique should be on the order of a few seconds at most.<br><br>• The technique should also include twirling and rotating the catheter between figure and thumb.<br><br>• Suctioning should be done on the basis of clinical assessment. In children with no evidence of secretion, suctioning patient twice a day to check for tube patency is recommended.<br><br>• Clean technique is recommended for home care. |

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| Hussey SG, Ryan, CA and Murphy BP. Comparison of three manual ventilation devices using an intubated mannequin. Arch Dis. Child. Fetal Neonatal Ed. 2007; 89; 490-93. | Comparative study | • The anaesthetic bag with manometer and neopuff™ device facilitate accurate and reproducible manual ventilation by health care professionals. |
| Choate K and Snadford M. Tracheostomy: Clinical Practice and the formation of policy and guidelines. Australian Nursing Journal 2003; 10, 8 p: CU1. | Guideline, consensus agreement, expert opinion | • Phone survey was conducted of 14 major hospitals within Australia to benchmark the level of observation of patients in general wards with a tracheostomy. Common practice is to locate patients with a tracheostomy close to areas where they can be observed easily or heard by nursing staff, usually near the nurse's desk area.<br>• The working party recommended the level and frequency of observation be decided on the basis of individual clinical assessment of the patients. |
| Scoble M, Copnell B, Taylor A, Kinney S and Shann F. Effect of reusing suction catheters on the occurrence of pneumonia in children. Heart and Lung 2001; Vol 30, 3 p: 225-233. | RCT | • The study investigated the practice of reusing suction catheters in paediatric intensive care patients for up to 24 hours.<br>• It was found that practice had no effect on either the rate of pneumonia or the time taken to develop infection.<br>• It was concluded the practice of reusing suction catheters for up to 24 hours was both safe and cost effective. |
| Blackwood, and Bronagh. Normal saline instillation with endotracheal suctioning: primum non nocere (first do no harm). Journal of Advanced Nursing 1999; 29 (4), 928-934 | Meta-analysis and systematic review of the literature | • The existing evidence does not support NSI as being beneficial in removing secretions |

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| Halm M and Krisko-Hagel K. Instilling Normal Saline with Suctioning: Beneficial Technique or Potentially Harmful Sacred Cow? American Journal of Critical Care 2008; 17: 469-472. | Clinical Evidence Review | • Support against the routine use of normal saline with suctioning<br>• Hydration, adequate humidification, use of mucolytic agents and mobilization best interventions for managing thick, tenacious secretions<br>• Normal saline may be indicated in situations to elicit a cough |
| Wang CH, et al. Normal saline instillation before suctioning: A meta-analysis of randomized controlled trials. Australian Critical Care, 2017 Sep: 30(5): 260-265. | Meta-analysis of randomized controlled trials<br>5 RCT included | • NS instillation before suctioning does not benefit patients undergoing endotracheal intubation or tracheostomy.<br>• Included 5 RCT studies – adult patients only >18 years of age |
| Paratz, J & Stockton, K. Efficacy and safety of normal saline instillation: A systematic review. Physiotherapy 95, 2009; 241-250. | Systematic review: Included<br>5 RCT studies<br>8 randomized cross-over studies<br>1 bench top study<br>1 observational | • Decrease in oxygenation following NSI – limited clinical significance<br>• Positive effect of NSI with increase in sputum yield<br>• 4 studies – neonatal (3) and paediatric (1) patients |

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| Schultz J, Mitchell M, Cooke M, and Schibler A. Efficacy and safety of normal saline instillation and paediatric endotracheal suction: An integrative review. Australian Critical Care 2018; 31 (2018) 3-9. | 3 studies<br>2 RCT | • Efficacy of NSI is inconsistent<br>• NSI was associated with a transient decrease in oxygen saturation, bronchospasm<br>• In children with obstructive mucous, NSI may have a positive effect.<br>• Inclusion criteria - paediatric patients 0 -18 years, ETT insitu, defined ETS solution intervention |