AARC Clinical Practice Guideline: Management of Pediatric Patients With Tracheostomy in the Acute Care Setting

Teresa A Volsko, Sara W Parker, Kathleen Deakins, Brian K Walsh, Katherine L Fedor, Taher Valika, Emily Ginier, and Shawna L Strickland

Children requiring a tracheostomy to maintain airway patency or to facilitate long-term mechanical ventilatory support require comprehensive care and committed, trained, direct caregivers to manage their complex needs safely. These guidelines were developed from a comprehensive review of the literature to provide guidance for the selection of the type of tracheostomy tube (cuffed vs uncuffed), use of communication devices, implementation of daily care bundles, timing of first tracheostomy change, type of humidification used (active vs passive), timing of oral feedings, care coordination, and routine cleaning. Cuffed tracheostomy tubes should only be used for positive-pressure ventilation or to prevent aspiration. Manufacturer guidelines should be followed for cuff management and tracheostomy tube hygiene. Daily care bundles, skin care, and the use of moisture-wicking materials reduce device-associated complications. Tracheostomy tubes may be safely changed at postoperative day 3, and they should be changed with some regularity (at a minimum of every 1–2 weeks) as well as on an as-needed basis, such as when an obstruction within the lumen occurs. Care coordination can reduce length of hospital and ICU stay. Published evidence is insufficient to support recommendations for a specific device to humidify the inspired gas, the use of a communication device, or timing for the initiation of feedings. *Key words: pediatrics; tracheostomy; tracheostomy care; intracuff pressure; pressure injury; care coordination.* [Respir Care 2021;66(1):144–155. © 2021 Daedalus Enterprises]

Introduction

A tracheostomy is a tracheal tube that is surgically placed in the neck to provide a channel for air exchange and secretion clearance between the lungs and the external environment.[1] A tracheostomy tube is most frequently used in critically ill or medically complex infants and children to alleviate upper-airway obstruction, facilitate airway clearance, and provide long-term mechanical ventilatory support.[2]

There is, however, significant morbidity and mortality associated with tracheostomy use in this vulnerable population. Compared to adults who receive a tracheostomy, children have higher reported complication rates.[3] These complications occur as a consequence of the surgical procedure or as a result of long-term use. The most frequently reported complications include irritation or abrasion at the stoma site, infection, granuloma formation within the airway or at the stoma, obstruction of the cannula lumen, inadvertent decannulation, pneumothorax, subcutaneous emphysema, accidental reinsertion into a false track, and tracheocutaneous fistula following elective decannulation.[4,5] Mortality rates cited in the literature vary. Those associated with the surgical procedure ranged from 0–5.9%, but reports for overall mortality rates were higher at 2.2–59%.[6] Most deaths in infants and children were associated with the underlying disease process.[7] Morbidity and mortality rates were highest among those < 2 y old, as well as those who had one or more underlying congenital anomaly (eg, congenital heart defect, neuromuscular impairment) or acquired conditions (eg, chronic lung disease).[7]

There are several clinical considerations that impact outcomes of infants and children requiring a tracheostomy. Most are medically complex and have underlying medical conditions that require a variety of equipment such as a feeding pump, portable mechanical ventilator, and mobilization device used in the home or alternate care setting. Assessment of tracheostomy tube size, as well as airway patency and function, are required as the child grows to assure individualized goals for clinical use in each infant or child are met. Therefore, care coordination, training, and clinical and psychosocial support for the family and child are critical elements to the care of a tracheostomized infant or child. Communicating the plan of care, including educational requirements, skill assessment, preparation of the home environment for a safe transition from the acute care setting, the frequency of follow-up visits with subspecialists, and coordination of home care services such as home nursing and physical and rehabilitation services are associated with improved outcomes.[8,9]

A paucity of published evidence exists to support the use of standardized protocols and bundles of care to improve outcomes for this vulnerable population. Published studies are often retrospective, performed at a single institution, have small sample sizes, and involve institution-specific protocols.[10-12] The lack of randomized controlled trials and standardized protocols makes it difficult to compare outcomes and base recommendations on research with rigor.

There are a few published guidelines with respect to the care of infants and children requiring a tracheostomy. The Bronchopulmonary Dysplasia Collaborative reported there was insufficient evidence to support the optimal timing of tracheostomy for infants with severe bronchopulmonary dysplasia.[13] The collaborative did find utility in the use of tracheostomy for sustained mechanical ventilatory support to relieve distress and to provide the respiratory stability necessary to enhance neurocognitive, behavioral, and developmental outcomes.[13] In 2017, the Brazilian Academy of Pediatric Otorhinolaryngology and Brazilian Society of Pediatrics published clinical consensus and national recommendations to standardize the care of children requiring tracheostomy. These guidelines were based on low levels of evidence and addressed indications for tracheostomy, criteria for selecting a cannula type (single- vs double-lumen), surgical technique recommendations, daily care bundle elements, and general guidelines and decannulation.[14]

The American Academy of Otolaryngology–Head and Neck Surgery Foundation convened a consensus panel to

Ms Volsko is affiliated with the Nursing Administration, Akron Children's Hospital, Akron, OH. Ms Parker is affiliated with the School of Health Professions, University of Missouri, Columbia, MO. Ms Deakins is affiliated with Respiratory Care, UH Rainbow Babies & Children's Hospital, Cleveland, OH. Dr Walsh is affiliated with the Department of Allied Health Professions, Liberty University, Lynchburg, VA. Ms Fedor is affiliated with Respiratory Therapy, Cleveland Clinic Children's, Cleveland, OH. Dr Valika is affiliated with the Division of Pediatric Otolaryngology, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL and with the Feinberg School of Medicine, Northwestern University, Chicago, IL. Ms Ginier is affiliated with the Taubman Health Sciences Library, University of Michigan, Ann Arbor, MI. Dr Strickland is affiliated with the American Association for Respiratory Care, Irving, TX.

Correspondence: Teresa A Volsko MHHS RRT FAARC, Nursing Administration, Akron Children's Hospital, One Perkins Square, Akron, Ohio, 44308. E-mail: tvolsko@akronchildrens.org.

review the literature, synthesize information, and clarify controversial or ambiguous aspects of the care and management of children and adults requiring a tracheostomy. A literature search identified clinical practice guidelines, systematic reviews, and meta-analyses related to tracheostomy care in pediatric and adult patients through April 2011. This panel used a modified Delphi technique to obtain consensus on 43 recommendations for care, which included the type of material used to construct tracheostomy tubes (plastic vs metal), routine use of humidification, cannula type (single- vs double-lumen), care required with a speaking valve, postoperative care bundle elements, and training requirements for caregivers in the home prior to discharge.[15]

This clinical practice guideline addresses gaps in the currently available consensus guidelines. Unlike previously published guidelines, this document links essential components of care to clinical and process outcomes. The purpose of this guideline is to provide guidance for the selection of the type of tracheostomy tube used (cuffed vs uncuffed), use of communication devices, implementation of daily care bundles, timing of first tracheostomy change, type of humidification used (active vs passive), timing of oral feedings, care coordination and routine cleaning to reduce complications, facilitating developmental milestones, minimizing the length of stay (LOS) in intensive care, and reducing hospital readmissions in hospitalized infants and children requiring a tracheostomy.

This clinical practice guideline was developed from a systematic review that centered on the following questions relevant to the management of pediatric patients hospitalized with the need for a surgical airway:

1. Does the use of a cuffed tracheostomy tube compared to an uncuffed tube reduce device-associated complications, facilitate developmental milestones, and minimize ICU and hospital readmission?

2. Does the use of a communication device compared to non-use reduce associated device-associated complications, facilitate developmental milestones, and minimize ICU and hospital readmission?

3. Does the implementation of a daily care bundle versus nonstandardized care reduce device-associated complications, facilitate developmental milestones, minimize ICU and hospital readmissions, and reduce barriers to hospital discharge?

4. Does early timing of the first tracheostomy tube change compared to late reduce device-associated complications and reduce ICU LOS?

5. Does active versus passive humidification affect device-associated complications?

6. Does cleaning versus disinfecting a tracheostomy tube reduce device-associated complications and cost of care?

7. Does routine cleaning and tracheostomy tube change reduce device-associated complications and cost of care?

8. Does care coordination prior to transition from acute care to alternate sites versus no coordination of care reduce LOS and minimize ICU and hospital readmission?

9. In the absence of prohibitive diagnoses/factors/criteria, does early versus late initiation of oral feeding facilitate developmental milestones and reduce hospital LOS?

Committee Composition

A committee was selected by American Association for Respiratory Care (AARC) leadership based on their known experience related to the topic, interest in participating in the project, and commitment to the process details. The committee first met face-to-face, where they were introduced to the process of developing clinical practice guidelines. At that time, the committee selected a chair and wrote a first draft of questions in a format that directly related to the patient, intervention, comparator, and outcome (PICO). Subsequent meetings occurred by conference call and included AARC staff as needed. The committee members received no remuneration for their participation in the process, though their expenses for the face-to-face meeting were reimbursed by the AARC.

Search Strategy

A literature search was conducted using the PubMed, CINAHL by EBSCOhost, and Scopus.com databases for studies on tracheostomy care and techniques in pediatric patients. The search strategies used a combination of relevant controlled vocabulary (ie, Medical Subject Headings and CINAHL Headings) and keyword variations that related to tracheostomy care and techniques, pediatrics, and outcomes. The searches were limited to English-language studies about human populations. The searches were also designed to filter out citations indexed as commentaries, editorials, interviews, news, or reviews. No date restrictions were applied to the searches, although citations published prior to 1987 were excluded before title and abstract screening. Refer to the online supplement for the complete search strategy executed in each database on January 17, 2018 (see the supplementary materials at http://www.rcjournal.com). Duplicate citations were identified and removed using EndNote X7 citation management software (Clarivate Analytics, Philadelphia, Pennsylvania).

Study Selection

Two reviewers independently assessed study eligibility in the Covidence systematic review software (Melbourne, Australia). Inclusion criteria used to assess eligibility were: (1) tracheostomy care; (2) pediatric population, including neonates, infants, and children; and (3) hospitalization, including long-term care and subacute care. The exclusion

criteria used were: (1) not tracheostomy care; (2) adult population; (3) home care; (4) not empirical research, including theory or opinion articles; and (5) published prior to 1987.

Development of Recommendations

Using a standardized multi-round rating process, which is a modification of the RAND/UCLA Appropriateness Methodology, the committee reviewed the evidence gleaned from the literature along with the collective experience of the panel to derive recommendations for each of the PICO questions.[16] The literature was collapsed into evidence tables according to each PICO question (Table 1). Individual panel members were assigned the task of writing a systematic review of the topic, drafting one or more recommendations, and suggesting the level of evidence used to support each recommendation as follows: (A) convincing scientific evidence-based on randomized controlled trials of sufficient rigor; (B) weaker scientific evidence-based on lower levels of evidence such as cohort studies, retrospective studies, case-control studies, and cross-sectional studies; (C) based on the collective experience of the committee.

Committee members reviewed the first drafts of evidence tables, systematic reviews, recommendations, and evidence levels. Committee members individually rated each recommendation for those supported by evidence levels A and B using a Likert scale of 1–9, with 1 meaning expected harms greatly outweigh the expected benefits and 9 meaning expected benefits greatly outweigh the expected harms. The scores were returned to the committee chair. Because the first ratings were done with no interaction among committee members, a conference call was convened, during which time the individual committee rankings were discussed. Particular attention was given to the discussion and justification of any outlier scores. Recommendations and evidence levels were revised with committee member input. After discussing each PICO question, committee members re-rated each recommendation. The final median and range of committee members' scores are reported (Table 2). Strong agreement required all committee members to rank the recommendation as 7 or higher. Weak agreement meant that one or more member rated the recommendation below 7, but the median vote was at least 7. For recommendations with weak agreement, the percentage of those who rated 7 or above was calculated and reported after each weak recommendation. Figure 1 illustrates the process that the panel used to rate the appropriateness and quality of the literature selected through the search process.

Drafts were distributed among committee members in several iterations. When all committee members were satisfied, the document was submitted for publication. The clinical practice guidelines were subjected to peer review before final publication.

Assessment and Recommendations

The search strategies retrieved 3,079 articles (Fig. 2). After removal of duplicates, 2,103 articles remained for screening. Another 238 articles were excluded based on publication date, and 1,482 were excluded at the title and abstract level. Of the remaining 391 articles, 376 were excluded after full review of the text against the inclusion and exclusion criteria, and 7 were excluded during extraction.

Cuffed Versus Uncuffed Tracheostomy Tube Use

Tracheostomy tubes used in children may contain a cuff, which results in a seal within the airway and allows for adequate ventilatory support or aspiration prevention. A cuffless tracheostomy tube should be considered in pediatric patients who do not require positive-pressure ventilation. Manufacturer guidelines provide instructions for cuff management, although these can be inadequate for patient care. Several types of tracheostomy tube cuffs are available in the market, including low-pressure cuffs, air-filled cuffs, water-filled cuffs, and foam cuffs. Choosing an appropriate cuffed tube is patient- and diagnosis-dependent. Improper cuff care can result in mild (eg, mucosal erosion) to severe (eg, tracheal necrosis) tracheal injury. To reduce the propensity for harm, it is imperative that caregivers use proper cuff care.

The pressure in the cuff is typically less than, but closely reflects, the pressure exerted against the tracheal wall.[25] If a cuffed tracheostomy tube is needed, it is important to ensure that the least amount of air or distilled water is used in the cuff to secure a seal and to avoid excessive pressure (ie, > 30 cm H_2O) against the tracheal wall.[26] Although there remains a paucity of clinical data, an intracuff pressure of 20–30 cm H_2O sufficiently creates a seal, which reduces risk for microaspiration.[27,28] Complications associated with excessive cuff pressure mirror those reported in the literature for cuffed endotracheal tubes, such as tracheal necrosis, tracheal rupture, and tracheomegaly.[29,30] Pressure exerted by the cuff on the tracheal wall depends on the child's anatomical features and is also affected by positional changes. Therefore, assessing cuff pressure with changes in patient position or when alterations in tidal volume delivery are detected and adjusting the amount of substance used to secure a seal may avoid cuff-related injuries.[28] Although there were methods to evaluate cuff seal against the tracheal wall (eg, minimum occluding volume, minimum leak technique) only a pressure-monitoring device provides an objective measure of intracuff pressure. Pressure-monitoring devices incorporating a manometer and a mechanism to inflate or deflate the cuff can be used to measure pressure only when the cuff is filled with air.

Manufacturer guidelines specify whether the cuff should contain air or water. Saline has been reported to erode the cuff and result in early breakage.[31] When sterile water is

Table 1.   Summary of Evidence for Each PICO Question Included in the Systematic Review

PICO Question	Study	Intervention	Device-Associated Complications
1. In pediatric patients hospitalized with the need for a surgical airway, does the use of a cuffed tracheostomy tube compared to an uncuffed tube reduce device-associated complications, facilitate developmental milestones, and minimize ICU and hospital readmission?	No published evidence identified.		
2. In pediatric patients hospitalized with the need for a surgical airway, does the use of a communication device compared to non-use reduce associated device-associated complications, facilitate developmental milestones, and minimize ICU and hospital readmission?	Ongkasuwan et al[17]		Presence of speaking valve did not reduce laryngeal aspiration or penetration ($P = .5$)
3. In pediatric patients hospitalized with the need for a surgical airway, does the implementation of a daily care bundle vs nonstandardized care reduce device-associated complications, facilitate developmental milestones, minimize ICU and hospital readmissions, and reduce barriers to hospital discharge?	Kuo et al[18]	Care bundle with protective dressing vs nonstandardized care without protective dressing	Decreased incidence of wound breakdown ($P = .02$)
	Lippert et al[19]	Care bundle vs no care bundle	Reduction in skin breakdown ($P = .005$)
	Boesch et al[20]	Post-bundle implementation analysis vs historical control	Reduction in pressure ulcers ($P = .007$)
	McEvoy et al[21]	Post-care coordination enrollment and pre-intervention assessment	Decreased pressure injury ($P = .006$); decreased stage 3 and 4 wounds ($P = .001$)
4. In pediatric patients hospitalized with the need for a surgical airway, does early timing of the first tracheostomy tube change compared to late reduce device-associated complications and reduce ICU length of stay?	Lippert et al[19]	Late tracheostomy change (day 6.21) vs early tracheostomy change (day 3.17)	Fewer issues with skin breakdown ($P = .005$); day of change significantly impacted likelihood of skin breakdown (odds ratio 2.04, $P = .003$)
	Van Buren et al[22]	Early tracheostomy change ($<$ day 3) vs late ($>$ day 5)	NR*
5. In pediatric patients hospitalized with the need for a surgical airway, does active vs passive humidification affect device-associated complications?	No published evidence identified.		
6. In pediatric patients hospitalized with the need for a surgical airway, does cleaning vs disinfecting a tracheostomy tube reduce device-associated complications and cost of care?	No published evidence identified.		
7. In pediatric patients hospitalized with the need for a surgical airway, does routine cleaning and tracheostomy tube change reduce device-associated complications and cost of care?	Boesch et al[20]	Tracheostomy care bundle	Reduction in pressure ulcers ($P = .007$)
	Kuo et al[18]	Protective dressing vs no protective dressing	Decreased incidence of wound breakdown ($P = .02$)
8. In pediatric patients hospitalized with the need for a surgical airway, does care coordination prior to transition from acute care to alternate sites vs no coordination of care reduce length of stay and minimize ICU and hospital readmission?	Peña-Lopez et al[23]	Pre/post evaluation of implementation of a care bundle	Reduction in ventilator-associated pneumonia ($P = .03$); reduction in ventilator days ($P < .001$)†
	Baker et al[24]	Pre/post evaluation of implementation of a care bundle	NR‡

(Continued)

Table 1. Continued

PICO Question	Study	Intervention	Device-Associated Complications
9. In pediatric patients hospitalized with the need for a surgical airway, in the absence of prohibitive diagnoses/factors/criteria, does early vs late initiation of oral feeding facilitate developmental milestones and reduce hospital length of stay?	No published evidence identified.		

* Shorter ICU length of stay with early change vs late change (14 vs 40 d).
† Not reported.
‡ Shorter ICU length of stay with care coordination vs no care coordination (94 vs 137 d). Shorter hospital length of stay with care coordination vs no care coordination (143 vs 249 d).
PICO = patient, intervention, comparator, and outcome
NR = not reported

used, the volume needed to create a seal depends on the age of the child, anatomical features of the trachea, and the size of the tracheostomy tube. Typically, an adequate seal can be obtained with 2–3 mL sterile water. Placing a larger tracheostomy tube may be warranted if more distilled water is needed in a fluid-filled cuff or if a pressure > 30 cm H_2O is required for an air-filled cuff to create an adequate seal. No evidence exists to support a specific cuff type, such as a low-pressure cuff or a foam cuff, to reduce tracheal injuries. However, low-pressure or foam-cuffed tracheostomy tubes are used in situations where there is likely already tracheal injury present and an alternative solution is required to allow for appropriate ventilation.[31]

We found no published evidence to define optimum cuff care. However, an uncuffed tracheostomy tube should be used when there is no need for mechanical ventilatory support. Although the presence of a cuff may increase the risk of tracheal complications, there is insufficient evidence showing an increase in complications with cuffed tubes. Despite common practice, there is also insufficient evidence to support checking cuff pressures every shift or deflating the cuff several times a day. In addition, there was insufficient evidence to indicate the use of foam or low-pressure cuffs to reduce tracheal-related complications.

The collective knowledge and experience of the committee indicates that cuffed tracheostomy tubes should only be used if requiring positive-pressure ventilation or preventing aspiration (Evidence level C), and manufacturer guidelines should be closely followed for cuff management (Evidence level C).

Communication Devices

Communication devices, such as speaking valves, restore phonation by allowing gas to enter through the tracheostomy tube during inspiration and redirecting exhaled gas around the exterior of the tracheostomy tube and through the larynx. Communication devices that restore phonation require a leak around the tube and must be used with either a cuffless tracheostomy tube or with the tracheostomy tube cuff deflated. Minimal leakage around the tracheostomy tube or suprastomal airway obstruction may restrict a child's ability to exhale easily and may compromise device tolerance.

The literature is sparse regarding the impact that a communication device has on reducing device-associated complications, facilitating developmental milestones, and minimizing ICU and hospital readmission. In a prospective study of infants and young children with a tracheostomy, Ongkasuwan and colleagues[17] evaluated the effect of a communication device on swallowing ability in 12 children < 2 y old requiring a tracheostomy for upper-airway obstruction, respiratory insufficiency, or a neurologic condition. A communication device did not significantly reduce laryngeal penetration or aspiration of liquids or purees during oral feeding ($P = .5$). This study did not address the impact of a communication device on device-associated complications, developmental milestones, or ICU and hospital readmissions.

Because of the paucity of evidence in the literature, there are no suggestions for the use or non-use of a speaking valve to reduce device-associated complications, facilitate developmental milestones, and ICU and hospital readmissions.

Use of a Daily Care Bundle

The elements of direct care provided to the infant or child with a tracheostomy vary depending on geographic region and organizational policy. Many facilities use a daily care bundle to standardize tracheostomy care. Bundled components of daily care may include assessing tracheostomy cuff pressures (if inflated), facilitating speech and language milestones, providing humidifiction, ensuring patency of the inner cannula or tracheostomy tube,

Table 2.   Summary of Recommendations for Each PICO Question

PICO Question	Summary of Recommendations
1. In pediatric patients hospitalized with the need for a surgical airway, does the use of a cuffed tracheostomy tube compared to an uncuffed tube reduce device-associated complications, facilitate developmental milestones, and minimize ICU and hospital readmission?	• Cuffed tracheostomy tubes should only be used if requiring positive-pressure ventilation or preventing aspiration (Evidence level C). • Manufacturer guidelines should be followed for cuff management (Evidence level C).
2. In pediatric patients hospitalized with the need for a surgical airway, does the use of a communication device compared to non-use reduce associated device-associated complications, facilitate developmental milestones, and minimize ICU and hospital readmission?	• There are no suggestions for the use or non-use of a speaking valve to reduce device-associated complications, facilitate developmental milestones, and minimize ICU and hospital readmissions.
3. In pediatric patients hospitalized with the need for a surgical airway does the implementation of a daily care bundle vs nonstandardized care reduce device-associated complications, facilitate developmental milestones, minimize ICU and hospital readmissions, and reduce barriers to hospital discharge?	• A daily care bundle is supported to reduce device-associated complications (Evidence level B; appropriateness score median 8, range 8–9).
4. In pediatric patients hospitalized with the need for a surgical airway, does early timing of the first tube tracheostomy change compared to late reduce device-associated complications and reduce ICU stay?	• Low-level evidence supports changing a tracheostomy tube at postoperative day 3 in pediatric patients without a risk of increased complications (Evidence level B; appropriateness score median 8; range 5–9).
5. In pediatric patients hospitalized with the need for a surgical airway, does active vs passive humidification affect device-associated complications?	• There are no suggestions for the type of humidification used for hospitalized pediatric patients to reduce device-associated complications, facilitate developmental milestones, and minimize ICU and hospital readmission.
6. In pediatric patients hospitalized with the need for a surgical airway, does cleaning vs disinfecting a tracheostomy tube reduce device-associated complications and cost of care?	• Expert experience of the committee supports regular tracheostomy tube hygiene according to manufacturer's recommendations to prevent mucus plugging resulting in airway obstruction and infection (Evidence level C).
7. In pediatric patients hospitalized with the need for a surgical airway, does routine cleaning and tracheostomy tube change reduce device-associated complications and cost of care?	• A moisture-wicking material placed under the tracheostomy tube is recommended to help keep the skin dry (Evidence level B; appropriateness score median 8; range 8–9). • Skin of the neck should be cleansed, and moisture-wicking material should be changed daily (Evidence level B; appropriateness score median 8; range 8–9). • Tracheostomy tubes should be changed as needed secondary to obstruction, and with some regularity at a minimum of 1–2 weeks (Evidence level B; appropriateness score median 7; range 6–9).
8. In pediatric patients hospitalized with the need for a surgical airway, does care coordination prior to transition from acute care to alternate sites vs no coordination of care reduce stay and minimize ICU and hospital readmission?	• Low-level evidence supports care coordination to reduce hospital and ICU stay (Evidence level B; appropriateness score median 8; range 8–9).
9. In pediatric patients hospitalized with the need for a surgical airway, in the absence of prohibitive diagnoses/factors/criteria, does early vs late initiation of oral feeding facilitate developmental milestones and reduce hospital stay?	• There are no suggestions for the timing of oral feeding in hospitalized infants and children requiring a tracheostomy tube.

PICO = patient, intervention, comparator, and outcome

conducting equipment safety checks, changing tracheostomy dressings, and documenting the respiratory care plan. There is scant published evidence regarding the impact of daily care bundles versus nonstandardized, individualized tracheostomy care on device-associated complications, developmental milestones, ICU and hospital readmissions, and hospital discharge. The literature mostly focused on preventing device-associated complications.

In a single institutional retrospective case review, Kuo and colleagues[18] evaluated the impact of a skin barrier on tracheostomy-related pressure-related injuries. Care in this retrospective study was not standardized in the control group (no skin barrier) or in the group where a skin barrier was used. A
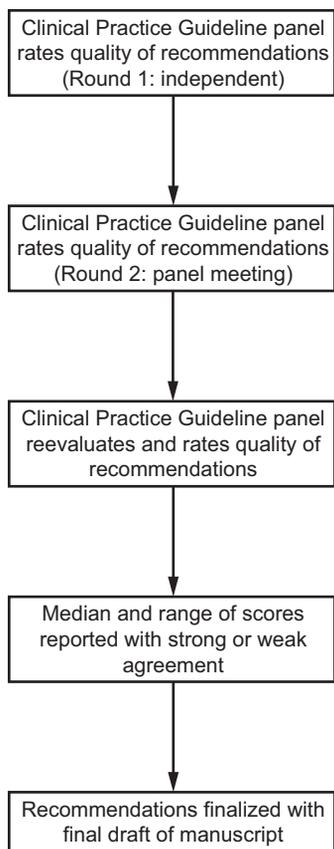
Fig. 1. Literature appraisal process.

Fig. 2. Flow chart.

statistically significant reduction in tracheostomy-related complications was noted when a skin barrier was used ($P = .02$).

Three studies evaluated the use of a daily care bundle versus nonstandardized care. Lippert et al[19] established a care protocol for the immediate post-tracheostomy period to reduce neck skin breakdown in children < 18 y old. The protocol included using a soft foam strap instead of twill tape and changing the drain sponge under the tracheostomy tube daily. Implementation of the standardized care bundle resulted in decreased rates of skin breakdown ($P = .005$).

McEvoy et al[21] developed a multidisciplinary postoperative protocol to reduce pressure-related tracheostomy wounds. The protocol included daily dressing changes and neck inspection. Prior to protocol implementation, 22.4% of subjects developed a pressure ulcer compared to 9.9% after protocol implementation ($P = .006$).

Boesch et al[20] developed a tracheostomy-related pressure ulcer prevention bundle for all patients with tracheostomy, regardless of the date of surgery. The bundle included skin assessments every 24 h, tracheostomy device assessments every 8-h shift, use of a moisture-free device interface, hydrophilic polyurethane foam under the tracheostomy tube, pressu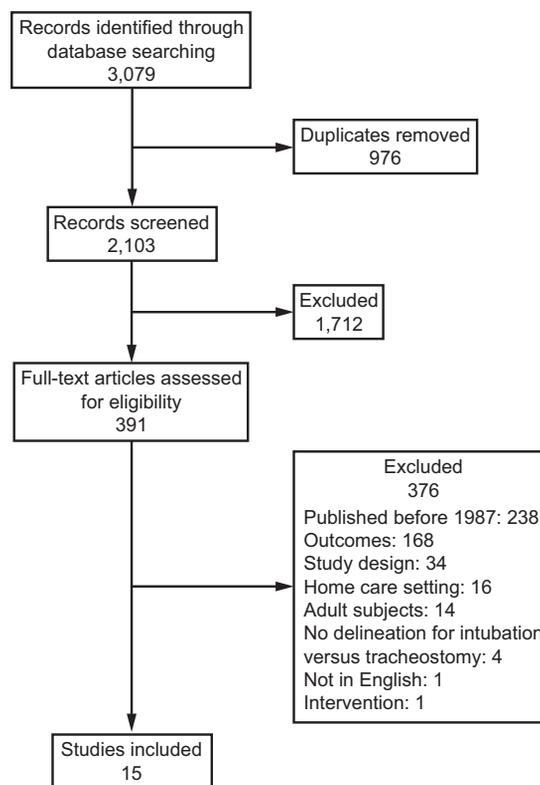re-free device interfaces, and the use of extended-length tracheostomy tubes when necessary. At the time of implementation, the mean rate of tracheostomy-related pressure ulcer development was 8.1%. After implementation, the mean rate fell to 0.3%.

Low-level evidence supports a daily care bundle to reduce device-associated complications (Evidence level B; appropriateness score median 8, range 8–9).

Timing of First Tracheostomy Change

Once a tracheostomy tube is placed, the surgeon typically determines the timing of the first tube change based on surgical expertise and preference. The first tracheostomy tube change is routinely performed at bedside but may also occur in the operating room under anesthesia if there is an increased concern for loss of the airway. The surgical team typically manages the first tracheostomy tube change to ensure that the stoma is patent and that subsequent airway care can be safely performed by the direct bedside care team.

The first tracheostomy tube change generally occurs between postoperative days 3 and 7.[22] Tube change before postoperative day 5 is defined as early, and tracheostomy tube change on or after postoperative day 5 is defined as late.[32] Advocates for early tracheostomy tube change indicate the potential for a reduction in hospital LOS, better

tracheostomy hygiene, and earlier completion of tracheostomy teaching to families.[19,22] We found no published evidence to support the role of early timing of tracheostomy tube change in reducing device-associated complications, decreased hospital LOS, or improvement in ability for family education. In a retrospective study, Carr et al[33] reported that the timing of the tracheostomy tube change had no impact on the risk of lower respiratory tract infection, creation of false passage, stoma granulation, subcutaneous emphysema, mucus plugging, or death. Unfortunately, the investigators did not directly correlate the incidence of these complications with the tracheostomy tube timing, so it is difficult to discern the appropriate recommendation.

In pediatric patients hospitalized with the need for a surgical airway, there is a lack of high-level evidence to determine if early timing of the first tracheostomy change reduces device-associated complications and ICU LOS. Lippert et al[19] reported the safety in early (ie, 3 d) tracheostomy tube change with no increase in complications. Van Buren et al[22] identified the positive impact that early tracheostomy tube change had on ICU LOS (14 d vs 40 d). No studies were found that identified the impact of early tracheostomy change on hospital LOS. This impact may be difficult to discern because there are a multitude of factors external to the direct care to the child that can affect LOS, including but not limited to resources and services that facilitate safe and timely transition from acute care to long-term or home care environments.

Low-level evidence supports changing a tracheostomy tube at postoperative day 3 in pediatric patients without a risk of increased complications (Evidence level B; appropriateness score median 8; range 5–9).

Active Versus Passive Humidification

Warming and humidifying inspired gases is an important aspect of care for infants and children requiring a tracheostomy tube. Because a tracheostomy tube bypasses the upper airway, the normal mechanisms for humidification are absent or blunted. American Thoracic Society guidelines for the care of a child with a chronic tracheostomy recommend an inspired gas temperature of 32–34°C and humidity of 36–40 mg H_2O/L.[34] Inadequate humidification (< 25 mg H_2O/L for 1 h or < 30 mg H_2O/L for 24 h) has been reported to cause mucosal malfunction.[35]

To ensure proper function of the lower respiratory tract, it is important to saturate and warm inspired gases to body temperature. Passive and active humidification devices are used to provide heat and humidification when an artificial airway bypasses the upper airway. Passive humidification refers to a heat-and-moisture exchanger (HME) attached to the proximal end of a tracheostomy tube. If mechanical ventilation is needed, the HME is placed between the tracheostomy tube and the ventilator Y-piece. HMEs extract heat and moisture from the exhaled gas and make it available for the inspiratory phase. Passive humidification is used primarily in nonventilated pediatric patients with tracheostomy, for those who are mobile and active, during transport, or for short-term use (ie, < 96 h) in larger patients.[36] HMEs should not be used in the presence of a large leak around the tube, when secretions are thick, or if the patient cannot tolerate the additional dead space.[36] HMEs place a patient at risk for airway obstruction and increased work of breathing if it becomes occluded from secretions coughed into the device.[37]

An active humidification device uses a heated humidifier and circuit to condition the inspired gases by adding warmth and moisture. These devices can be used with or without ventilator support.[36] In children with a tracheostomy, proper conditioning of inspired gases reduces or prevents mucus plugging if used in combination with routine suctioning and tracheostomy care.[7] In a crossover study with a small sample of children at a single institution that compared clinical outcomes with the use of passive versus active humidification, a reduction in lower respiratory tract infections, tube obstruction, emergency tube change, and respiratory hospital admissions was realized with long-term use (ie, 10 weeks) of active humidification at night.[38] In this cohort, the use of nocturnal active humidification also reduced the need to frequently change HMEs used during the day.[38]

According to the AARC Clinical Practice Guideline,[36] active humidification is preferred over passive for mechanically ventilated patients. During rest periods or sleeping hours, active humidification has been associated with reduced tracheostomy tube-associated complications. During waking hours, either passive or active humidification is acceptable.

Warming and humidifying inspired gas is essential for patients with a tracheostomy to reduce device-associated complications. However, in pediatric patients hospitalized with a tracheostomy, there is insufficient evidence to support the exclusive use of active versus passive humidification. At this time, there are no suggestions for the type of humidification to use for hospitalized pediatric patients to reduce device-associated complications, facilitate developmental milestones, and reduce ICU and hospital readmission.

Cleaning Versus Disinfecting

As many as half of all pediatric patients clean their tracheostomy tubes at home, and these patients have been reported to have a higher hospital readmission rate compared to those who use a new tube with each change.[39] While there is no consensus on how frequently to change pediatric tracheostomy tubes, the cost of customized tubes and the number of tracheal tubes allocated to the patient for routine care contributes to the practice of cleaning or disinfecting them for re-use. The required processes for cleaning

and disinfecting begins in the hospital and continues upon discharge to a long-term care facility or the home. These requirements are challenging and involve adherence to the manufacturer's guidelines to preserve the integrity of the tracheostomy tube.

Silva et al[37] studied the 3 most commonly used pediatric tracheostomy tubes made of silicone and polyvinyl chloride and evaluated the manufacturer-recommended guidelines for cleaning and eradicating biofilm within the tracheostomy tubes. Cleaning with a detergent and sterile water was not sufficient to reduce or eliminate biofilm, and the process was less effective in the silicone tubes. Leonhard et al[40] evaluated the reprocessing methods of cuffed and uncuffed tubes and reported that manual cleaning did not entirely eradicate bacterial biofilm, whereas chemical disinfection or sterilization processes in addition to manual cleaning did reduce the bacterial colonization inside the tubes. Currently, no standardized processes exist for cleaning and disinfecting tracheostomy tubes.

When bacteria biofilm is present on a pediatric tracheostomy tube, the risk of infection due to bacterial colonization and morbidity are increased.[39] While the direct effects of biofilm formation within the tube require further investigation, complications related to repeatedly using the same tubes may result in further complications, such as the formation of granulation tissue or recurrent infections.[39]

There are no randomized controlled trials that compare methods of cleaning or disinfecting tracheostomy tubes. Nearly all instructions available for tracheostomy cleaning and disinfection available in the literature reproduced manufacturer's guidelines. Whereas hospital tube-specific cleaning methods include chemicals approved for disinfection or permit intermittent periods of sterilization, the available processes advise caregivers against repeated exposure to harsh chemicals or sterilization processes because they may result in tube cracks and cause material degradation.

The collective experience of the committee supports regular tracheostomy tube hygiene according to manufacturer's recommendations to prevent mucus plugging, which may result in airway obstruction and infection (Evidence level C).

Routine Cleaning and Tracheostomy Tube Change

Care of the stoma and surrounding tissue is essential to maintain an intact barrier between the skin and the outside environment. Adequate stoma and skin hygiene are necessary to prevent wound development. Moisture and pressure commonly contribute to device-associated complications. Boesch et al[20] reported 3 key drivers to prevent device-associated complications: (1) pressure ulcer risk and skin assessment, (2) moisture-free device interface, and (3) pressure-free device interface. In this quality improvement study, Boesch and colleagues[20] implemented a care bundle focusing on the use of an extended-style tracheostomy, featuring a flexible extension separating the flange and the 15-mm adapter, implementation of the Braden Q score to quantify pressure ulcer risk, and the use of a hydrophilic barrier under the tracheostomy tube flanges and around the stoma to wick moisture from skin. This 3-fold care bundle resulted in a reduction in wound complications from 22% prior to the bundle to 9.9% following the bundle intervention. The authors also reported that focusing on reducing moisture and pressure resulted in a significant decrease in tracheostomy-related pressure ulcers from 8.1% before to 0.3% after bundle implementation.[20]

Kuo et al[18] reported a reduction in skin breakdown when a Mepilex Ag (Mölnlycke Health Care, Norcross, Georgia) barrier was placed in the operating room and removed on postoperative day 7. Prior to utilizing the barrier, 11.8% of subjects experienced skin breakdown at the time of the first tube change (at 7 d) compared to a complete lack of breakdown with barrier use ($P = .02$).

Low-level evidence supports the use of a moisture-wicking material placed under the tracheostomy tube to help keep the skin dry (Evidence level B; appropriateness score median 8; range 8–9). In addition, the skin of the neck should be cleansed and the moisture-wicking material changed daily (Evidence level B; appropriateness score median 8; range 8–9), and tracheostomy tubes should be changed as needed secondary to obstruction and with some regularity at a minimum of every 1–2 weeks (Evidence level B; appropriateness score median 7; range 6–9).

Care Coordination

Coordination of care drives many positive patient and process outcomes. Baker et al[24] evaluated the impact of coordinating care for children requiring tracheostomy and long-term ventilatory support on LOS, mortality, emergency department visits, and unplanned readmissions. For subjects with a tracheostomy tube requiring invasive ventilatory support, a standardized discharge process decreased hospital LOS by 42% ($P = .002$) without increasing emergency department visits or unplanned readmissions.[24]

Complications associated with a tracheostomy, such as ventilator-associated respiratory infections, may prolong ICU and hospital LOS. Therefore, elements of the care targeting reduced infection rates should be incorporated into care coordination. Peña-López et al[23] reported a significant reduction in ventilator-associated pneumonia after implementing preventive care bundles. Prevention bundles consisted of elevating the head of the bed, routine oral care, use of cuffed tubes when indicated (maintaining a minimal cuff pressure), and performing circuit changes only when visibly soiled. There is insufficient evidence in the literature to determine the impact of care coordination on hospital and ICU readmission rates.

Low-level evidence supports care coordination to reduce hospital and ICU LOS (Evidence level B; appropriateness score median 8; range: 8–9).

Early Versus Late Initiation of Feeding

Promotion of early enteral nutrition in children with critical illness is associated with improved outcomes.[41] Approximately 25% of pediatric patients with a structurally abnormal altered feeding pattern go on to manifest oral aversion, texture refusal, and delay in oral feeding. The focus has been on survival to discharge, avoidance of tracheostomy, or tracheostomy decannulation rates, and issues associated with oral feeding have not been well studied. More recently, secondary outcomes such as phonation, swallowing function, dysphagia, speech, and ability to orally feed have gained attention.[42]

Successful swallowing function is complex; it requires integration of the pulmonary, gastrointestinal, neurological, and psychiatric systems, and this is difficult to study in pediatrics. Preoperative assessment of swallowing function by fiberoptic endoscopy is accurate in the prediction of postoperative feeding status in 80% of patients.[43] Temporary and occasional permanent airway insults, particularly interventions that manipulate the glottis and subglottis, hinder swallowing and may increase the risk of postoperative aspiration, leading to a conservative oral feeding approach. A systematic review of preoperative and postoperative surgical airway feeding status indicated that, after removal of an endotracheal tube or endolaryngeal stent, 85% of oral feeding subjects rapidly return to baseline diet.[44] In subjects who could not reestablish their diet by postoperative day 8 due to swallowing difficulties, their difficulties were sustained throughout the 35-d observational period. Postoperative feeding difficulties prolonged hospital courses in 5% of laryngotracheal reconstruction subjects,[43] although temporary dysphagia did not result in long-term weight loss after laryngotracheal reconstruction.[45] Successful oral feeders had an early increase in median growth percentile following laryngotracheal reconstruction compared to those who did not feed orally.

Although proper enteral or oral feeding has been associated with improved outcomes, there is a lack of published evidence to support early versus late initiation of oral feeding to facilitate developmental milestones or to reduce LOS in hospitalized infants and children who require a surgical airway. Currently, there are no suggestions for the timing of oral feeding in hospitalized infants and children requiring a tracheostomy tube.

Summary

The results of our systematic review are summarized in Table 1. The most important, and most disappointing, result of this work is the immature nature of the available evidence. The recommendations in Table 2 are based on low-level evidence, and in some cases no recommendations could be made. The recommendations provided are strongly influenced by the experience of the committee members. Despite the low level of supporting evidence, committee members were able to agree that, for the recommendations provided, the benefits were likely to outweigh the harms. Because the recommendations are based on low-level evidence, it is possible that other approaches are acceptable. Hopefully this will be viewed as hypothesis testing and will lead to research in this area.

The PICO questions were written to address important aspects of the care of children with a tracheostomy. Only after a rigorous literature search did we recognize the dearth of available evidence. The lack of available evidence suggests the potential for variability around these practices. This creates the potential for practice based on opinion rather than evidence, which may contribute to poor outcomes. Practices are likely passed from generation to generation of clinicians without ever being subjected to critical examination.

The lack of high-quality evidence provides an opportunity for researchers to collaborate on well-designed clinical trials to address these knowledge gaps and provide the evidence needed to guide improvements in clinical care. Although multicenter randomized controlled trials are preferred, this could begin with well-designed quality-assurance programs. The results of these quality-assurance projects, with institutional review board oversight, should be published and thus inform more rigorous investigations. Without such effort, care of the pediatric patient with a tracheostomy will continue to be variable, and this might lead to poor patient outcomes. Moreover, we need to identify the outcomes that are important, as well as the costs associated with best practices.

REFERENCES

1. Ozmen S, Ozmen OA, Unal OF. Pediatric tracheostomies: a 37-year experience in 282 children. Int J Pediatr Otorhinolaryngol 2009;73 (7):959-961.
2. Graf JM, Montagnino BA, Hueckel R, McPherson ML. Pediatric tracheostomies: a recent experience from one academic center. Pediatr Crit Care Med 2008;9(1):96-100.
3. Al-Samri M, Mitchell I, Drummond DS, Bjornson C. Tracheostomy in children: a population-based experience over 17 years. Pediatr Pulmonol 2010;45(5):487-493.
4. Walsh J, Rastatter J. Neonatal tracheostomy. Clin Perinatol 2018;45 (4):805-816.
5. Sidman JD, Jaguan A, Couser RJ. Tracheotomy and decannulation rates in a level 3 neonatal intensive care unit: a 12-year study. Laryngoscope 2006;116(1):136-139.
6. Dal'Astra AP, Quirino AV, Caixêta JA, Avelino MA. Tracheostomy in childhood: review of the literature on complications and mortality over the last three decades. Braz J Otorhinolaryngol 2017;83(2):207-214.

7. Watters KF. Tracheostomy in infants and children. Respir Care 2017;62(6):799-825.

8. Abode KA, Drake AF, Zdanski CJ, Retsch-Bogart GZ, Gee AB, Noah TL. A multidisciplinary children's airway center: impact on the care of patients with tracheostomy. Pediatrics 2016;137(2):e20150455.

9. Lavin J, Shah R, Greenlick H, Gaudreau P, Bedwell J. The Global Tracheostomy Collaborative: one institution's experience with a new quality improvement initiative. Int J Pediatr Otorhinolaryngol 2016;80:106-108.

10. Da Silva PS, Waisberg J, Paulo CS, Colugnati F, Martins LC. Outcome of patients requiring tracheostomy in a pediatric intensive care unit. Pediatr Int 2005;47(5):554-559.

11. DeMauro SB, D'Agostino JA, Bann C, Bernbaum J, Gerdes M, Bell EF, et al. Developmental outcomes of very preterm infants with tracheostomies. J Pediatr 2014;164(6):1303-1310.

12. McPherson ML, Shekerdemian L, Goldsworthy M, Minard CG, Nelson CS, Stein F, Graf JM. A decade of pediatric tracheostomies: Indications, outcomes, and long-term prognosis. Pediatr Pulmonol 2017;52(7):946-953.

13. Abman SH, Collaco JM, Shepherd EG, Keszler M, Cuevas-Guaman M, Welty SE, et al. Interdisciplinary care of children with severe bronchopulmonary dysplasia. J Pediatr 2017;181:12-28.

14. Avelino MAG, Maunsell R, Valera FCP, Lubianca Neto JF, Schweiger C, Miura CS, et al. First clinical consensus and national recommendations on tracheostomized children of the Brazilian Academy of Pediatric Otorhinolaryngology (ABOPe) and Brazilian Society of Pediatrics (SBP). Braz J Otorhinolaryngol 2017;83(5):498-506.

15. Mitchell RB, Hussey HM, Setzen G, Jacobs IN, Nussenbaum B, Dawson C, et al. Clinical consensus statement: tracheostomy care. Otolaryngol Head Neck Surg 2013;148(1):6-20.

16. Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR, Lazaro P, et al. The RAND/UCLA appropriateness method user's manual. Santa Monica, CA: RAND; 2001.

17. Ongkasuwan J, Turk CL, Rappazzo CA, Lavergne KA, Smith EO, Friedman EM. The effect of a speaking valve on laryngeal aspiration and penetration in children with tracheotomies. Laryngoscope 2014;124(6):1469-1474.

18. Kuo CY, Wootten CT, Tylor DA, Werkhaven JA, Huffman KF, Goudy SL. Prevention of pressure ulcers after pediatric tracheotomy using a Mepilex Ag dressing. Laryngoscope 2013;123(12):3201-3205.

19. Lippert D, Hoffman MR, Dang P, McMurray JS, Heatley D, Kille T. Care of pediatric tracheostomy in the immediate postoperative period and timing of first tube change. Int J Pediatr Otorhinolaryngol 2014;78(12):2281-2285.

20. Boesch RP, Myers C, Garrett T, Nie A, Thomas N, Chima A, et al. Prevention of tracheostomy-related pressure ulcers in children. Pediatrics 2012;129(3):e792-e797.

21. McEvoy PT, Seim NB, Aljasser A, Elmaraghy CA, Ruth B, Justice L, et al. Prevention of post-operative pediatric tracheotomy wounds: a multidisciplinary team approach. Int J Pediatr Otorhinolaryngol 2017;97:235-239.

22. Van Buren NC, Narasimhan ER, Curtis JL, Muntz HR, Meier JD. Pediatric tracheostomy: timing of the first tube change. Ann Otol Rhinol Laryngol 2015;124(5):374-377.

23. Peña-López Y, Pujol M, Campins M, González-Antelo A, Rodrigo JA, Balcells J, Rello J. Implementing a care bundle approach reduces ventilator-associated pneumonia and delays ventilator-associated tracheobronchitis in children: differences according to endotracheal or tracheostomy devices. Int J Infect Dis 2016;52:43-48.

24. Baker CD, Martin S, Thrasher J, Moore HM, Baker J, Abman S, Gien J. A standardized discharge process decreases length of stay for ventilator dependent children. Pediatrics 2016;137(4):e20150637.

25. Leigh JM, Maynard JP. Pressure on the tracheal mucosa from cuffed tubes. Br Med J 1979;1(6172):1173-1174.

26. Bhardwaj N. Pediatric cuffed endotracheal tubes. J Anaesthesiol Clin Pharmacol 2013;29(1):13-18.

27. Wettstein RW, Gardner DD, Wiatrek S, Ramirez KE, Restrepo RD. Endotracheal cuff pressures in the PICU: incidence of underinflation and overinflation. Can J Respir Ther 2020;56:1-4.

28. Krishna SG, Hakim M, Sebastian R, Dellinger HL, Tumin D, Tobias JD. Cuffed endotracheal tubes in children: the effect of the size of the cuffed endotracheal tube on intracuff pressure. Paediatr Anaesth 2017;27(5):494-500.

29. Silva MJ, Aparício J, Mota T, Spratley J, Ribeiro A. Ischemic subglottic damage following a short-time intubation. Eur J Emerg Med 2008;15(6):351-353.

30. Cooper JD. Tracheal injuries complicating prolonged intubation and tracheostomy. Thorac Surg Clin 2018;28(2):139-144.

31. Weiss M, Dullenkopf A. Cuffed tracheal tubes in children: past, present and future. Expert Rev Med Devices 2007;4(1):73-82.

32. Deutsch ES. Early tracheostomy tube change in children. Arch Otolaryngol Head Neck Surg 1998;124(11):1237-1238.

33. Carr MM, Poje CR, Kingston L, Kielma D, Heard C. Complications in pediatric tracheostomies. Laryngoscope 2001;111(11 Pt 1):1925-1928.

34. Sherman JM, Davis S, Albamonte-Petrick S, Chatburn RL, Fitton C, Green C, et al. Care of the child with chronic tracheostomy; official statement of the American Thoracic Society was adopted by the ATS Board of Directors, July 1999. Am J Respir Crit Care Med 2000;161 (1):297-308.

35. Williams R, Rankin N, Smith T, Galler D, Seakins P. Relationship between humidity and temperature of inspired gas and the function of the airway mucosa. Crit Care Med 1996;24(11):1920-1929.

36. Restrepo RD, Walsh BK, American Association for Respiratory Care. Humidification during invasive and noninvasive mechanical ventilation: 2012. Respir Care 2012;57(5):782-788.

37. Silva RC, Ojano-Dirain CP, Antonelli PJ. Effectiveness of pediatric tracheostomy tube cleaning. Arch Otolaryngol Head Neck Surg 2012;138(3):251-256.

38. McNamara DG, Asher MI, Rubin BK, Stewart A, Byrnes CA. Heated humidification improves clinical outcomes compared to a heat and moisture exchanger in children with tracheostomies. Respir Care 2014;59(1):46-53.

39. Fiske E. Effective strategies to prepare infants and families for home tracheostomy care. Adv Neonatal Care 2004;4(1):42-53.

40. Leonhard M, Assadian O, Zumtobel M, Schneider-Stickler B. Microbiological evaluation of different reprocessing methods for cuffed and un-cuffed tracheostomy tubes in home-care and hospital setting. GMS Hyg Infect Control 2016;11:Doc02.

41. Haney A, Burritt E, Babbitt CJ. The impact of early enteral nutrition on pediatric acute respiratory failure. Clin Nutr ESPEN 2018;26:42-46.

42. Kelchner LN, Miller CK. Current research in voice and swallowing outcomes following pediatric airway reconstruction. Curr Opin Otolaryngol Head Neck Surg 2008;16(3):221-225.

43. Willging JP. Benefit of feeding assessment before pediatric airway reconstruction. Laryngoscope 2000;110(5 Pt 1):825-834.

44. Smith LP, Otto SE, Wagner KA, Chewaproug L, Jacobs IN, Zur KB. Management of oral feeding in children undergoing airway reconstruction. Laryngoscope 2009;119(5):967-973.

45. Andreoli SM, Nguyen SA, White DR. Feeding status after pediatric laryngotracheal reconstruction. Otolaryngol Head Neck Surg 2010;143(2):210-213.