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# Clinical Practice Guideline: Tonsillectomy in Children

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## Abstract

**Objective.** Tonsillectomy is one of the most common surgical procedures in the United States, with more than 530 000 procedures performed annually in children younger than 15 years. Tonsillectomy is defined as a surgical procedure performed with or without adenoidectomy that completely removes the tonsil including its capsule by dissecting the peritonsillar space between the tonsil capsule and the muscular wall. Depending on the context in which it is used, it may indicate tonsillectomy with adenoidectomy, especially in relation to sleep-disordered breathing. This guideline provides evidence-based recommendations on the preoperative, intraoperative, and postoperative care and management of children 1 to 18 years old under consideration for tonsillectomy. In addition, this guideline is intended for all clinicians in any setting who interact with children 1 to 18 years of age who may be candidates for tonsillectomy.

**Purpose.** The primary purpose of this guideline is to provide clinicians with evidence-based guidance in identifying children who are the best candidates for tonsillectomy. Secondary objectives are to optimize the perioperative management of children undergoing tonsillectomy, emphasize the need for evaluation and intervention in special populations, improve counseling and education of families of children who are considering tonsillectomy for their child, highlight the management options for patients with modifying factors, and reduce inappropriate or unnecessary variations in care.

**Results.** The panel made a *strong recommendation* that clinicians should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy. The panel made a *strong recommendation against* clinicians routinely administering or prescribing perioperative antibiotics to children undergoing tonsillectomy. The panel made *recommendations* for

(1) watchful waiting for recurrent throat infection if there have been fewer than 7 episodes in the past year or fewer than 5 episodes per year in the past 2 years or fewer than 3 episodes per year in the past 3 years; (2) assessing the child with recurrent throat infection who does not meet criteria in statement 2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to multiple antibiotic allergy/intolerance, periodic fever, aphthous stomatitis, pharyngitis and adenitis, or history of peritonsillar abscess; (3) asking caregivers of children with sleep-disordered breathing and tonsil hypertrophy about comorbid conditions that might improve after tonsillectomy, including growth retardation, poor school performance, enuresis, and behavioral problems; (4) counseling caregivers about tonsillectomy as a means to improve health in children with abnormal polysomnography who also have tonsil hypertrophy and sleep-disordered breathing; (5) counseling caregivers that sleep-disordered breathing may persist or recur after tonsillectomy and may require further management; (6) advocating for pain management after tonsillectomy and educating caregivers about the importance of managing and reassessing pain; and (7) clinicians who perform tonsillectomy should determine their rate of primary and secondary post-tonsillectomy hemorrhage at least annually. The panel offered *options* to recommend tonsillectomy for recurrent throat infection with a frequency of at least 7 episodes in the past year or at least 5 episodes per year for 2 years or at least 3 episodes per year for 3 years with documentation in the medical record for each episode of sore throat and 1 or more of the following: temperature >38.3°C, cervical adenopathy, tonsillar exudate, or positive test for group A  $\beta$ -hemolytic streptococcus.

## Keywords

tonsillectomy, adenotonsillectomy, tonsillitis, sleep disordered breathing, pediatric guideline

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**T**onsillectomy is one of the most common surgical procedures in the United States, with more than 530 000 procedures performed annually in children younger than 15 years.<sup>1</sup> Indications for surgery include recurrent throat infections and sleep-disordered breathing (SDB),<sup>2</sup> both of which can substantially affect child health status and quality of life (QoL). Although there are benefits of tonsillectomy, complications of surgery may include throat pain, postoperative nausea and vomiting, delayed feeding, voice changes, hemorrhage, and rarely death. The frequency of tonsillectomy, associated morbidity, and availability of hundreds of randomized clinical trials assessing interventions create a pressing need for evidence-based guidance to aid clinicians.

This document is intended for all clinicians who diagnose or manage patients aged 1 to 18 years for whom tonsillectomy is being considered for indications of recurrent throat infection and/or SDB as defined as follows:

- *Tonsillectomy* is defined as a surgical procedure performed with or without adenoidectomy that completely removes the tonsil, including its capsule, by dissecting the peritonsillar space between the tonsil capsule and the muscular wall. Depending on the context in which it is used, it may indicate tonsillectomy with adenoidectomy, especially in relation to SDB.
- *Throat infection* is defined as sore throat caused by viral or bacterial infection of the pharynx, palatine tonsils, or both, which may or may not be culture positive for group A streptococcus. This includes the terms *strep throat* and *acute tonsillitis*, *pharyngitis*, *adenotonsillitis*, or *tonsillopharyngitis*.
- *Sleep-disordered breathing* is characterized by abnormalities of respiratory pattern or the adequacy of ventilation during sleep, which include snoring, mouth breathing, and pauses in breathing. SDB encompasses a spectrum of obstructive disorders that increases in severity from primary snoring to obstructive sleep apnea (OSA). Daytime symptoms associated with SDB may include excessive sleepiness, inattention, poor concentration, and hyperactivity.
- *Caregiver* is used throughout the document to refer to parents, guardians, or other adults providing care to patients undergoing tonsillectomy.

The importance of tonsillectomy as an intervention relates to its documented benefit on child QoL. For example, when compared with healthy children, children with recurrent throat infections have more bodily pain and poorer general health and physical functioning.<sup>3</sup> Tonsillectomy may improve QoL by reducing throat infections, health care provider visits, and the need for antibiotic therapy.<sup>4</sup> Similarly, SDB is associated with cognitive and behavioral impairment in children that usually improves after tonsillectomy<sup>5-8</sup> along with QoL,<sup>6,9-12</sup> sleep disturbance,<sup>5,10,13,14</sup> and vocal quality.<sup>15,16</sup>

Wide variations in tonsillectomy rates have been reported across the world, including Japan,<sup>17</sup> Canada,<sup>18</sup> the United Kingdom,<sup>19</sup> and the United States.<sup>20</sup> Such variations are usually ascribed to heterogeneity in clinical practice and training rather than to differences in clinical need.<sup>21</sup> The current lack of consensus in the United States on surgical indications and perioperative management further supports the need for an evidence-based clinical practice guideline to highlight best practices.

## Guideline Scope and Purpose

This guideline is intended for all clinicians in any setting who interact with children aged 1 to 18 years who may be candidates for tonsillectomy. The guideline does not apply to tonsillotomy, intracapsular surgery, or other partial removal techniques of the tonsil because of the relatively sparse high-quality published evidence on these techniques and limited long-term follow-up. Similarly, the guideline does not apply to populations of children excluded from most tonsillectomy research studies, including those with diabetes mellitus, cardiopulmonary disease, craniofacial disorders, congenital anomalies of the head and neck region, sickle cell disease, and other coagulopathies or immunodeficiency disorders.

The primary purpose of this guideline is to provide clinicians with evidence-based guidance in identifying children who are the best candidates for tonsillectomy. Secondary objectives are to optimize the perioperative management of children undergoing tonsillectomy, emphasize the need for evaluation and intervention in special populations, improve counseling and education of families of children who are considering tonsillectomy for their child, highlight the management options for patients with modifying factors, and reduce inappropriate or unnecessary variations in care. Lastly, we sought to identify gaps in knowledge that would guide future research. This guideline predominantly addresses indications for tonsillectomy based on

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obstructive and infectious causes. Other indications for surgery, including orthodontic concerns, tonsilliths, halitosis, and chronic tonsillitis, are not extensively discussed. The evidence in these areas is limited and generally of lesser quality, and a role for shared decision making is present.

This guideline is intended to focus on quality improvement opportunities judged most important by the working group. It is not intended to be a comprehensive, general guide for managing patients undergoing tonsillectomy. In this context, the purpose is to define useful actions for clinicians, regardless of discipline, to improve the quality of care. Conversely, the statements in this guideline are not intended to limit or restrict care provided by clinicians based on the assessment of individual patients.

Although there is evidence to guide management of certain aspects of tonsillectomy, there is no evidence-based clinical practice guideline relevant to all specialties managing such patients in the United States. A guideline is warranted because of documented practice variations in the care of patients who undergo tonsillectomy and the morbidity and mortality associated with this surgical intervention.

## Health Care Burden

### *Incidence of Tonsillectomy*

Tonsillectomy is the second most common ambulatory surgical procedure performed on children in the United States.<sup>1</sup> In 2006, there were 530 000 tonsillectomies performed in children younger than 15 years, constituting 16% of all ambulatory surgery in this age group. The only procedure with greater frequency was myringotomy with insertion of tube, for which 667 000 procedures were reported the same year.

Between 1915 and the 1960s, tonsillectomy was the most frequently performed surgical procedure in the United States. Data in 1993 from the National Hospital Discharge Survey, however, noted a decrease of more than 50% in inpatient tonsillectomy rates from 1977 to 1989.<sup>22</sup> Similar reports from 1978 to 1986 showed that the rate of tonsillectomy for treatment of throat infections declined; however, the frequency of SDB as the primary indication for the procedure increased.<sup>2</sup> A recent study reported that the overall incidence rates of tonsillectomy have significantly increased in the past 35 years, with SDB being the primary indication for surgery.<sup>23</sup>

### *Indications for Surgery*

The 2 most common indications for tonsillectomy are recurrent throat infections and SDB. Throat infections are a common reason to see a primary care physician and often result in antibiotic treatment.<sup>24</sup> The cost of outpatient visits and the medications prescribed for sore throats including antibiotics are substantial. Indirect costs associated with throat infections and SDB are substantial due to missed school and loss of time from work for caregivers.

Treatment of SDB is associated with an increase in health care utilization and cost. Children with SDB, compared with controls, have a significantly higher rate of antibiotic use, 40% more hospital visits, and an overall elevation of 215% in

health care usage mostly from increased respiratory tract infections.<sup>25</sup> Children with tonsillar disease, including children with throat infections and SDB, also showed significantly lower scores on several QoL subscales including general health, physical functioning, behavior, bodily pain, and caregiver impact when compared with healthy children.<sup>3</sup>

SDB represents a spectrum of disorders ranging in severity from primary snoring to OSA. The prevalence of OSA in the pediatric population is 1% to 4%<sup>26</sup>; as many as 10% of children have primary snoring.<sup>27</sup> Up to 30% to 40% of children with clinically diagnosed SDB exhibit behavioral problems that include enuresis,<sup>28</sup> hyperactivity, aggression, anxiety, depression, and somatization.<sup>29</sup> OSA is also associated with poor school performance and a decrease in QoL.<sup>8</sup> The QoL of children with OSA is similar to children with chronic conditions such as asthma and juvenile rheumatoid arthritis.<sup>30</sup>

Controversy persists about the actual benefits of tonsillectomy as compared with observation and medical treatment of throat infections. Although tonsillectomy for recurrent throat infections in severely affected children has been shown in a randomized controlled trial to reduce the frequency and severity of infections in the 2 years following surgery,<sup>31</sup> the same cannot be shown for less severe cases or for a period greater than 2 years after surgery.<sup>20,31</sup> Observational studies, however, show improved disease-specific and global QoL after tonsillectomy for recurrent or chronic sore throat, as measured by validated instruments.<sup>4</sup> These children suffered fewer infections after surgery, resulting in fewer antibiotics and physician visits.

A growing body of evidence indicates that tonsillectomy is an effective treatment for SDB,<sup>32</sup> based on the idea that tonsillar hypertrophy is a principal cause. A meta-analysis of case series<sup>33</sup> and a recent study<sup>34</sup> showed that tonsillectomy was effective at improving or resolving SDB in most children. There is also evidence that behavioral parameters, school performance, and QoL improve after resolution of this sleep disorder.<sup>8</sup>

### *Harms and Adverse Events of Tonsillectomy*

Tonsillectomy is a surgical procedure with an associated morbidity that includes possible hospitalization, risks of anesthesia, prolonged throat pain, and financial costs. A common complication of tonsillectomy is bleeding during or after the surgery. In published reports, the rate of primary hemorrhage (within 24 hours of surgery) has ranged from 0.2% to 2.2% and the rate of secondary hemorrhage (more than 24 hours after surgery) from 0.1% to 3%.<sup>35</sup> Hemorrhage after tonsillectomy may result in readmission for observation or in further surgery to control bleeding.

Other complications of tonsillectomy are diverse and have been well described.<sup>36</sup> Operative complications include trauma to the teeth, larynx, pharyngeal wall, or soft palate; difficult intubation; laryngospasm; laryngeal edema; aspiration; respiratory compromise; endotracheal tube ignition; and cardiac arrest. Injury to nearby structures has been reported, including lip burn, eye injury, and fracture of the mandibular condyle. Postoperative complications include nausea, vomiting, pain, dehydration, referred otalgia, postobstructive pulmonary

edema, velopharyngeal insufficiency, and nasopharyngeal stenosis. Complications are more common in patients with craniofacial disorders, Down syndrome, cerebral palsy, major heart disease, or bleeding diatheses and in children younger than 3 years with polysomnography (PSG)–proven OSA.<sup>37–41</sup>

After tonsillectomy, about 1.3% of patients experience delayed discharge during the initial hospital stay, and up to 3.9% have secondary complications requiring readmission.<sup>42</sup> The primary reasons for readmission or prolonged initial stay included pain, vomiting, fever, and tonsillar hemorrhage. In addition to these common causes of morbidity, many unusual and rare complications of tonsillectomy have also been described.<sup>43</sup> Among these are reports of vascular injury, subcutaneous emphysema, jugular vein thrombosis, atlantoaxial subluxation (Grisel syndrome), taste disorders (hypogeusia, ageusia, dysgeusia, and phantogeusia), and persistent neck pain (Eagle syndrome).

Mortality rates for tonsillectomy have been estimated at between 1 in 16 000 to 1 in 35 000, based on data from the 1970s.<sup>44</sup> There are no current estimates of tonsillectomy mortality, but a prospective audit reported only 1 postoperative death after 33 921 procedures in England and Northern Ireland.<sup>42</sup> About one-third of deaths are attributable to bleeding, while the remainder are related to aspiration, cardiopulmonary failure, electrolyte imbalance, or anesthetic complications.<sup>35,45</sup> Similarly, airway compromise is the major cause of death or major injury in malpractice claims after tonsillectomy.<sup>46</sup>

### Structure and Function of the Tonsils

The palatine tonsils are lymphoepithelial organs located at the junction of the oral cavity and the oropharynx. They are strategically positioned to serve as secondary lymphoid organs, initiating immune responses against antigens entering the body through the mouth or nose. The greatest immunological activity of the tonsils is found between the ages of 3 and 10 years.<sup>47</sup> As a result, the tonsils are most prominent during this period of childhood and subsequently demonstrate age-dependent involution.<sup>48</sup>

The epithelium of the tonsils is cryptic and reticulated and contains a system of specialized channels lined by “M” cells.<sup>49</sup> These cells take up antigens into vesicles and transport them to the extrafollicular region or the lymphoid follicles. In the extrafollicular region, interdigitating dendritic cells and macrophages process the antigens and present them to helper T lymphocytes. These lymphocytes stimulate proliferation of follicular B lymphocytes and their development into either antibody-expressing B memory cells capable of migration to the nasopharynx and other sites or plasma cells that produce antibodies and release them into the lumen of the crypt.<sup>49</sup>

While all 5 immunoglobulin (Ig) isotypes are produced in the palatine tonsils, IgA is arguably the most important product of the tonsillar immune system. In its dimeric form, IgA may attach to the transmembrane secretory component to form secretory IgA, a critical component of the mucosal immune system of the upper airway. Although the secretory component is produced only in the extratonsillar epithelium, the tonsils do produce immunocytes bearing the J (joining)

chain carbohydrate.<sup>50</sup> This component is necessary for binding of IgA monomers to each other and to the secretory component and is an important product of B-cell activity in the follicles of the tonsil.

### Effects of Tonsillitis and Tonsillectomy on Immunity

With chronic or recurrent tonsillitis, the controlled process of antigen transport and presentation is altered due to shedding of the M cells from the tonsil epithelium.<sup>49</sup> The direct influx of antigens disproportionately expands the population of mature B-cell clones and, as a result, fewer early memory B cells go on to become J-chain–positive IgA immunocytes. In addition, the tonsillar lymphocytes can become so overwhelmed with persistent antigenic stimulation that they may be unable to respond to other antigens. Once this immunological impairment occurs, the tonsil is no longer able to function adequately in local protection, nor can it appropriately reinforce the secretory immune system of the upper respiratory tract. There would therefore appear to be a therapeutic advantage to removing recurrently or chronically diseased tonsils. On the other hand, some studies demonstrate minor alterations of Ig concentrations in the serum and adjacent tissues following tonsillectomy.<sup>51–54</sup> Nevertheless, there are no studies to date that demonstrate a significant clinical impact of tonsillectomy on the immune system.<sup>51–53</sup>

### Methods and Literature Search

The guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm.<sup>55</sup> The guideline panel was chosen to represent fields of sleep medicine, advanced practice nursing, anesthesiology, infectious disease, family medicine, otolaryngology–head and neck surgery, pediatrics, and consumers. Several group members had prior experience in developing clinical practice guidelines.

The systematic literature search was divided into 2 stages and aimed to identify clinical practice guidelines, systematic reviews, or meta-analyses (stage I) and randomized controlled trials (stage II) using key biomedical literature databases (**Table 1**). The search was based on the string tonsillectom\*, adenotonsillectom\*, tonsillotom\*, posttonsillectom\*, (tonsil\* OR adenotonsil\*) AND (surg\* OR operat\* OR remov\* OR preop\* OR periop\* OR postop\*). Results were screened to remove duplicates and citations that were not pertinent.

1. Published and unpublished consensus- and evidence-based clinical practice guidelines less than 10 years old in English met inclusion criteria. The final data set included 17 guidelines, and of those, 2 guidelines<sup>56,57</sup> met quality criteria of having been produced under the auspices of a medical association or organization and having an explicit, a priori, method for ranking evidence and linking evidence to recommendations.
2. Systematic reviews less than 15 years and meta-analyses with a systematic review in English met

**Table 1.** Databases Housing Guidelines, Systematic Reviews, and Randomized Controlled Trials

Guidelines	Systematic Reviews	Randomized Controlled Trials
National Guidelines Clearinghouse	NHS Evidence ENT & Audiology (UK)	Cochrane ENT Disorders Group Trials Register
CMA Infobase (Canada)	Cochrane Library (Cochrane Database of Systematic Reviews, DARE, HTA Database, NHS EED)	CENTRAL (Cochrane Library)
NHS Evidence ENT & Audiology (UK)		HTA Database (Cochrane Library)
National Library of Guidelines (UK)		PubMed
NICE (UK)	TRIP Database	EMBASE
SIGN (Scotland)	PubMed	CINAHL
New Zealand Guidelines Group	EMBASE	AMED
Australian National Health and Medical Research Council	CINAHL	BIOSIS Previews
TRIP Database	AMED	CAB Abstracts
PubMed	BIOSIS Previews	ISI Web of Science
GIN	CAB Abstracts	clinicaltrials.gov
	ISI Web of Science	mRCT
	AHRQ	ICTRP
	HSTAT	TRIP Database

inclusion criteria. The search filter used to identify systematic reviews in PubMed was devised based on the search strategy used by the National Health Service Evidence–Cancer.<sup>58</sup> Reviews that met a rating of adequate required a clear objective, explicit search strategy, and valid data extraction. The final data set included 36 systematic reviews (including 9 Cochrane systematic reviews).

3. Randomized controlled trials published in English with no age restrictions were identified using an adaptation of the Cochrane Highly Sensitive Search Strategy.<sup>59</sup> Published or unpublished completed trials with a definite or possible randomized controlled design met inclusion criteria. The final data set yielded 705 studies that were grouped into the following broad topics: analgesia (193), technique (125), anesthesia (67), nausea/vomiting (62), hemostasis (45), recovery (35), steroids (26), surgical indications (24), antibiotics (16), outcomes assessment (15), surgical complications (2), perioperative care (2), and other (93).

Results of the literature searches were distributed to guideline panel members at the first meeting, including electronic listings with abstracts (if available) of the searches for guidelines, randomized controlled trials, and systematic reviews. This material was supplemented, as needed, with targeted systematic searches to address specific needs identified in developing the guideline through April 11, 2010.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 9 months devoted to guideline development ending in 2010, the group met twice with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.<sup>60</sup>

The Guideline Implementability Appraisal and Extractor tool<sup>61</sup> was used to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and

to predict potential obstacles to implementation. Guideline panel members received summary appraisals in May 2010 and modified an advanced draft of the guideline. The final draft guideline was distributed to a multidisciplinary group of 44 external reviewers, representing the target audience, for feedback and comment. Responses were compiled, reviewed by a subgroup of the panel, and incorporated into the guideline. The document was then submitted to the journal's peer-review process before publication. A scheduled review process will occur at 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

### Classification of Evidence-Based Statements

Guidelines are intended to reduce inappropriate variations in clinical care, to produce optimal health outcomes for patients, and to minimize harm. The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements<sup>62</sup> are listed in **Tables 2 and 3**.

Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a "strong recommendation" than might be expected with a "recommendation." "Options" offer the most opportunity for practice variability.<sup>63</sup> Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.<sup>62</sup>

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline

**Table 2.** Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B). <sup>a</sup> In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C). <sup>a</sup> In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (Grade D) <sup>a</sup> or that well-done studies (Grade A, B, or C) <sup>a</sup> show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No recommendation	No recommendation means there is both a lack of pertinent evidence (Grade D) <sup>a</sup> and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

<sup>a</sup>See Table 3 for definition of evidence grades.

**Table 3.** Evidence Quality for Grades of Evidence

Grade	Evidence Quality
A	Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline's target population
B	Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
C	Observational studies (case control and cohort design)
D	Case reports, reasoning from first principles (bench research or animal studies)
X	Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit over harm

panel sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the committee was to maintain transparency and be explicit about how values were applied and to document the process.

### Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American

Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) Foundation. Potential conflicts of interest for all panel members were compiled and distributed before the first conference call. After review and discussion of these disclosures,<sup>64</sup> the panel concluded that individuals with potential conflicts could remain on the panel if they: (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Lastly, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.<sup>65</sup>

### Guideline Key Action Statements

Each evidence-based statement is organized in a similar fashion: **an evidence-based statement in bold**, followed by a *strength of the recommendation in italic*. Several paragraphs subsequently discuss the evidence base supporting the statement, concluding with an "evidence profile" of aggregate evidence quality, benefit-harm assessment, and statement of costs. Lastly, there is an explicit statement of the value judgments, the role of patient preferences, clarification of any intentional vagueness by the panel, and a repeat statement of the strength of the recommendation. An

overview of evidence-based statements in the guideline and their interrelationship is shown in **Table 4**.

The role of patient preference in making decisions deserves further clarification. For some statements, the evidence base may demonstrate clear benefit, which would minimize the role of patient preference. If the evidence is weak or benefits are unclear, however, not all informed patients might opt to follow the suggestion. In these cases, the practice of shared decision making, where the management decision is made by a collaborative effort between the clinician and the informed patient, becomes more useful. Factors related to patient preference include (but are not limited to) absolute benefits (number needed to treat), adverse effects (number needed to harm), cost of drugs or procedures, and frequency and duration of treatment.

**STATEMENT 1. WATCHFUL WAITING FOR RECURRENT THROAT INFECTION: Clinicians should recommend watchful waiting for recurrent throat infection if there have been fewer than 7 episodes in the past year or fewer than 5 episodes per year in the past 2 years or fewer than 3 episodes per year in the past 3 years.** *Recommendation based on randomized controlled trials with limitations and observational studies with a preponderance of benefit over harm.*

### Supporting Text

The purpose of this statement is to avoid unnecessary intervention in children with recurrent throat infection who have a favorable natural history and are likely to improve on their own without surgery. Watchful waiting does not imply inaction; rather, patients should be closely monitored and episodes of pharyngotonsillitis accurately documented.

Throat infections are treated most often by the primary care provider, but other clinicians may be involved (eg, health care providers at emergency departments or urgent care centers). The primary care provider should collate documentation of all

such visits. In addition, the primary care provider should educate the caregiver on acquiring and maintaining an at-home record of the child's throat infection and health history. The clinical characteristics of each episode should include the symptoms, physical findings, and culture results if performed, as well as days of school absence and any QoL issues. Only with this information can the clinician assess the significance of the impact of recurrent pharyngotonsillitis for the patient and caregiver.

The importance of documentation cannot be overemphasized. In one study of patients observed for 1 year, only 17% of patients meeting the "Paradise criteria" (**Table 5**) actually had adequate documentation and confirmation of their clinical course.<sup>66</sup> This may have been due to information that was overstated by caretakers or to a tendency for recurrences to diminish over time.

*History less than 12 months.* There are currently no randomized controlled trials investigating the efficacy of tonsillectomy for patients experiencing recurrent tonsillitis over a period of less than 12 months. Although the 3 best randomized controlled trials assessing the efficacy of tonsillectomy differed in study entry requirements (ie, the frequency and severity of recurrent pharyngotonsillitis), they all required a minimum number of sore throats in the preceding 12 months.<sup>20,31,66</sup> For example, in the study by Paradise et al,<sup>31</sup> 62 (33%) of the 187 children that satisfied the Paradise criteria had 7 or more throat infections in the preceding 12 months. It is possible that all the reported infections occurred in a shorter period than 12 months, but these data were not reported. Furthermore, one of these studies<sup>66</sup> explicitly observed children with recurrent throat infections and found high rates of spontaneous resolution over 12 months. Because of this tendency to improve with time, at least a 12-month period of observation is recommended prior to consideration of tonsillectomy as an intervention.

This statement should not restrict access to tonsillectomy prior to 1 year of observation for all patients who do not meet frequency criteria for tonsillectomy (see Statement 3). Patients

**Table 4.** Summary of Evidence-Based Statements

Point of Care (Evidence-Based Statement)	Statement Strength
Surgical indications and planning	
Watchful waiting (Statement 1)	Recommendation
Recurrent throat infection with documentation (Statement 2)	Option
Tonsillectomy for recurrent infection with modifying factors (Statement 3)	Recommendation
Tonsillectomy for sleep-disordered breathing (Statement 4)	Recommendation
Tonsillectomy and polysomnography (Statement 5)	Recommendation
Outcome assessment for sleep-disordered breathing (Statement 6)	Recommendation
Perioperative care	
Steroids (Statement 7)	Strong recommendation
Antibiotics (Statement 8)	Strong recommendation against
Postoperative care	
Pain control (Statement 9)	Recommendation
Posttonsillectomy hemorrhage (Statement 10)	Recommendation

**Table 5.** Paradise Criteria for Tonsillectomy<sup>31</sup>

Criterion	Definition
Minimum frequency of sore throat episodes	7 or more episodes in the preceding year, OR 5 or more episodes in each of the preceding 2 y, OR 3 or more episodes in each of the preceding 3 y
Clinical features (sore throat plus the presence of one or more qualifies as a counting episode)	Temperature > 38.3°C, OR Cervical lymphadenopathy (tender lymph nodes or >2 cm), OR Tonsillar exudate, OR Positive culture for group A $\beta$ -hemolytic streptococcus
Treatment	Antibiotics had been administered in conventional dosage for proved or suspected streptococcal episodes
Documentation	Each episode and its qualifying features had been substantiated by contemporaneous notation in a clinical record, OR <i>If not fully documented</i> , subsequent observance by the clinician of 2 episodes of throat infection with patterns of frequency and clinical features consistent with the initial history <sup>a</sup>

<sup>a</sup>This last statement allows children who meet all other criteria for tonsillectomy except documentation to nonetheless qualify for surgery if the same pattern of reported illness is observed and documented by the clinician in 2 subsequent episodes. Because of this tendency to improve with time, a 12-month period of observation is usually recommended prior to consideration of tonsillectomy as an intervention.

with a history of recurrent severe infections requiring hospitalization, complications of infection such as peritonsillar abscess or Lemierre syndrome (thrombophlebitis of the internal jugular vein), or a family history of rheumatic heart disease or numerous repeat infections in a single household (“ping-pong spread”) may reasonably be considered for the procedure. However, caregivers should be educated on the likelihood of spontaneous improvement and the magnitude of benefit conferred by tonsillectomy for 2 years after surgery.

*History greater than 12 months.* Observation of frequent pharyngotonsillitis beyond 1 year may be indicated even in patients meeting the Paradise criteria. In several randomized controlled trials, the control group (nontonsillectomized) demonstrated a trend toward spontaneous improvement during the follow-up period, often with patients no longer meeting the original criteria for study entry. In a randomized controlled study of patients who met the Paradise criteria, children in the control group experienced only an average of 1.17 episodes of throat infection annually in the following first year, 1.03 in the second year, and 0.45 episodes in the third year.<sup>31</sup> Results were corroborated in another study that relaxed the Paradise criteria but still required more than 3 episodes of recurrent pharyngotonsillitis per year for enrollment.<sup>20</sup> As in the first study, control groups had a mean rate of throat infections of 0.43, 0.31, and 0.16 in years 1, 2, and 3. A third study with entrance criteria that were less stringent than the Paradise criteria found that the control group had an average of 0.77 throat infections during the 22-month follow-up.<sup>67</sup>

A Cochrane review on the efficacy of tonsillectomy for recurrent tonsillitis concludes that some cases may resolve without surgery.<sup>68</sup> Another systematic review of randomized controlled trials found that the rate of sore throat in the control group was on average 0.3 episodes per month.<sup>69</sup> Confirming earlier work,<sup>70</sup> the authors reported that in all studies, the control group showed a spontaneous reduction of rates of recurrent infection.<sup>69</sup>

Additional information regarding the natural history of recurrent pharyngotonsillitis is found in case series describing outcomes for patients awaiting tonsillectomy. Although most still had indications for surgery, a significant proportion did not. One study of children awaiting tonsillectomy for a history of 5 episodes over a 2-year period found that over a mean waiting period of 9 months, 27% no longer met criteria for surgery.<sup>71</sup> Another study of 623 children found that 18.6% of children placed on a waiting list for a mean of 10.8 months after meeting the Paradise criteria had no episodes of recurrent pharyngotonsillitis within the 6 months before the scheduled procedure.<sup>72</sup> A third study of 257 children selected for tonsillectomy based on a history of 4 to 6 episodes for 2 consecutive years but placed on a waiting list reached similar conclusions.<sup>73</sup> Twelve months after waiting list placement, 40% had 3 or fewer episodes of tonsillitis in the preceding 6 months, and 36 months after waiting list placement, 65% had 3 or fewer episodes of tonsillitis in the preceding 6 months. Two other studies reported that 20% to 50% of individuals no longer needed surgery.<sup>74,75</sup>

Patients and caregivers should be educated on the limited benefits of tonsillectomy when performed in less severely affected children and adolescents. Potential surgical complications should be discussed so patients and caregivers may weigh the risks and benefits. Prompt medical treatment should be implemented when indicated in cases of pharyngitis caused by Group A  $\beta$ -hemolytic streptococcus (GABHS).

### **Evidence Profile for Statement 1: Watchful Waiting for Recurrent Tonsillitis**

- Aggregate evidence quality: Grade B, randomized controlled trials with minor limitations that fail to show clinically important advantages of surgery over observation alone (as stated in Statement 1), and Grade C, observational studies showing improvement with watchful waiting

- Benefit: Avoid unnecessary surgery with potential complications of vomiting, hemorrhage, pain, infection, or anesthesia problems
- Harm: Waiting may result in delayed treatment in patients who have unusually frequent and severe recurrent throat infections
- Cost: Potential direct cost of managing future throat infections
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Panel consensus that tonsillectomy for recurrent throat infection should be limited to circumstances for which clinically important benefits are shown in randomized controlled trials; emphasis on avoiding harm related to surgery or anesthesia in a condition that may be largely self-limited
- Role of patient preferences: Limited to specific unusual circumstances such as complications of tonsillitis or comorbidities
- Intentional vagueness: None
- Exclusions: Patients with peritonsillar abscess, personal or family history of rheumatic heart disease, Lemierre syndrome, or severe infections requiring hospitalization
- Policy level: Recommendation

**STATEMENT 2. RECURRENT THROAT INFECTION WITH DOCUMENTATION: Clinicians may recommend tonsillectomy for recurrent throat infection with a frequency of at least 7 episodes in the past year or at least 5 episodes per year for 2 years or at least 3 episodes per year for 3 years with documentation in the medical record for each episode of sore throat and one or more of the following: temperature  $>38.3^{\circ}\text{C}$ , cervical adenopathy, tonsillar exudate, or positive test for GABHS.** *Option based on systematic reviews and randomized controlled trials with minor limitations, with a balance between benefit and harm.*

### Supporting Text

The purpose of this statement is to ensure that patients with recurrent throat infection who are selected for tonsillectomy have a severity of illness (**Table 5**) consistent with descriptions of disease found in well-designed clinical trials. Despite the abundance of randomized controlled trials on tonsillectomy, there are few published investigations of its efficacy or effectiveness for sore throat, and many are outdated or lacking in scientific design or validity. The preponderance of evidence suggests that in the most severely and frequently affected children, tonsillectomy results in a modest degree of improvement.

*Defining and documenting "throat infection."* Patients referred for tonsillectomy are rarely evaluated by the surgeon during an acute episode of throat infection. It is therefore incumbent upon the referring clinician to accurately describe an individual episode of throat infection and to document the frequency of these events.

The presence of sore throat was a necessary entrance criterion in all randomized controlled trials of tonsillectomy for

infection. As a result, no claim can be made that tonsillectomy is effective in those children who present with a constellation of symptoms that does not include sore throat, even when GABHS is identified. The presence of tonsillar inflammation was not a necessary criterion, and absence of tonsillar inflammation in given patients does not detract from the applicability of this statement.

When a child is evaluated for sore throat, the examining clinician should record a subjective assessment of the patient's severity of illness; physical findings including body temperature, pharyngeal and/or tonsillar erythema, tonsil size, tonsillar exudate, cervical adenopathy (presence, size, and tenderness); and the results of microbiologic testing for GABHS. In children with recurrent sore throat whose tests for GABHS are repeatedly positive, it may be desirable to rule out streptococcal carriage concurrent with viral infection as carriers are unlikely to transmit GABHS or to develop suppurative complications or nonsuppurative sequelae of the disease such as acute rheumatic fever.<sup>76,77</sup> Supportive documentation in children who meet criteria for tonsillectomy may include absence from school, spread of infection within the family, and a family history of rheumatic heart disease or glomerulonephritis. The referring clinician should furnish the consultant with a summary of the documentation to aid in the medical decision making regarding potential surgical intervention.

Many caregivers may choose not to visit a medical facility for every throat infection, and therefore documentation of events may be lacking. Studies suggest that patients whose events are less severe or well documented do not gain sufficient benefit from tonsillectomy to justify the risk and morbidity of the procedure.<sup>20</sup> In such patients, tonsillectomy should not be performed immediately; instead, clinicians should initiate an active period of observation during which documentation of additional events may be made.

*Efficacy and effectiveness of tonsillectomy for recurrent throat infection.* Most clinical trials investigating the efficacy of tonsillectomy<sup>20,31,67</sup> have a high risk of bias because of poorly defined entrance criteria, nonrandom selection of operated subjects, exclusion of severely affected patients, or reliance on caregivers for postoperative data collection. However, those studies<sup>67,68</sup> in which these factors were minimized suggest a modest but statistically significant reduction in frequency of throat infection among severely affected patients undergoing tonsillectomy, while less severely affected individuals appear less likely to benefit from the procedure.

In the most frequently cited and meticulous trial, Paradise and colleagues<sup>31</sup> included patients only if their episodes of throat infection met strict criteria outlined in **Table 5**. One of the most important criterion was that each episode and its qualifying features had been substantiated by contemporaneous notation in a clinical record. Adherence to the advice earlier in this section may facilitate that goal, but some children are likely to remain who would otherwise qualify for tonsillectomy but lack appropriate documentation. Paradise and coworkers<sup>31</sup> also recognized this possibility and therefore allowed children who met all other criteria for tonsillectomy except documentation to nonetheless qualify for surgery if

the same pattern of reported illness was prospectively documented in 2 subsequent episodes. For example, if there had been a history of 5 episodes in each of the 2 preceding years, 2 episodes would have had to be observed within 2/5 year, or within 146 days. Therefore, patients with undocumented histories of severe recurrent sore throat may still be offered surgery provided they continue to suffer severe sore throats with similar frequency after an additional period of observation and documentation. The following study results were obtained:

- Considering sore throats of any degree of severity, the tonsillectomy group experienced a mean rate reduction of 1.9 episodes per year in the first year of follow-up; although this difference was statistically significant, the sore throat associated with performance of the surgery (which would otherwise count as 1 episode) was excluded from the data. In the control group, patients also improved compared with their pre-enrollment frequency of infection, experiencing a mean of only 3.1 annual events. Group differences were no longer significant in the third year of follow-up.
- For episodes of moderate or severe throat infection, the control group experienced 1.2 episodes compared with 0.1 in the surgical group. The rate reductions diminished over the subsequent 1 years of follow-up and were not significant in the third year.
- Mean days with sore throat in the first 12 months were not statistically different between the 2 groups but included a predictable period of sore throat postoperatively. Some patients from the control group, however, opted for surgery during the follow-up period, perhaps leading to underestimation of the effect of surgery. In addition, the distribution of patients by frequency of throat infection was statistically different between the surgical and nonsurgical groups; the effect of this factor on the final results is uncertain.

In a subsequent study by the same authors,<sup>20</sup> the entrance criteria for history and/or documentation of throat infection were relaxed with less stringent criteria for the number of episodes, clinical features required, and need for concurrent documentation (ie, 4-6 episodes in the past year or 3-4 episodes per year in the past 2 years). For example, children could qualify for surgery if an episode of tonsillitis was partially documented or even not documented provided that the study team observed 1 subsequent episode of tonsillitis in the 4 months after the initial evaluation. In the 2 arms of the study (tonsillectomy and adenotonsillectomy vs control, and adenotonsillectomy vs control), patients undergoing surgery experienced rate reductions of 0.8 and 1.7 episodes/y, respectively, in the first year. For episodes of moderate or severe sore throat, control subjects in the 2 arms of the study combined experienced 0.3 episodes/y overall compared with 0.1/y in subjects undergoing surgery. Mean days with sore

throat in the first 12 months were not statistically different in either arm of the study. Although some benefits of tonsillectomy remained statistically significant over 3 years, the investigators suggested that the modest benefit conferred by tonsillectomy in children moderately affected with recurrent throat infection did not justify the inherent risks, morbidity, and cost of the surgery.

A randomized controlled trial comparing tonsillectomy with watchful waiting in children aged 2 to 8 years examined fever  $>38.0^{\circ}\text{C}$  for at least 1 day as the primary outcome measure.<sup>67</sup> Children were selected for tonsillectomy “according to current medical practice”; however, patients meeting Paradise criteria were specifically excluded, thus selecting a less severely affected population. During a mean follow-up of 22 months, children in the tonsillectomy group had 0.2 fewer episodes of fever per person-year, and from 6 to 24 months there was no difference between the groups. The surgical group also demonstrated, per person-year, mild reductions in throat infections (0.2), sore throats (0.6), days with sore throat (5.9), and upper respiratory tract infections (0.5). Absence from day care or school due to upper tract respiratory infections was comparable between the groups (difference 0.1).

Pooled data from these studies were also analyzed in a Cochrane systematic review.<sup>68</sup> Patients undergoing tonsillectomy experienced 1.4 fewer episodes of sore throat in the first year compared with the control group; however, the cost of this reduction was 1.0 episode of sore throat in the immediate postoperative period. When only episodes of moderate/severe sore throats were considered, surgery was associated with just 0.2 fewer episodes in exchange for the episode of sore throat in the immediate postoperative period. The number of sore throat days was about 4 days less in the surgical group (21 vs 17).

Another systematic review<sup>69</sup> reported an odds ratio of 0.57 favoring tonsillectomy, suggesting a 43% overall reduction in sore throat events. The number needed to treat with tonsillectomy to prevent 1 sore throat per month for the first year after surgery was 11. A final systematic review that included 13 randomized controlled trials and nonrandomized controlled studies on the efficacy of tonsillectomy in children<sup>70</sup> reported pooled estimated risk differences favoring tonsillectomy over observation of 1.2 fewer episodes of sore throat, 2.8 fewer days of school absence, and 0.5 fewer episodes of upper respiratory infection per person-year. Both of the reviews just described also found that, in all of the trials studied, the control group showed a significant spontaneous reduction in the rate of recurrent infection.<sup>69,70</sup> Furthermore, in most case series describing outcomes for patients on tonsillectomy wait lists, indications for surgery were no longer present in a sizeable proportion of patients with mean follow-up periods of up to 3 years.<sup>71-75,78</sup>

Despite the modest advantages conferred by tonsillectomy for sore throat, studies of QoL all suggest a significant improvement in patients undergoing the procedure. Only 2 of these studies enrolled children exclusively,<sup>4,79</sup> and both reported increased scores in nearly all subscales. However, both also had numerous methodological flaws such as inclusion of patients with chronic tonsillitis without definition

based on signs and symptoms, absence of a control group, low response rates with potential selection bias, poor follow-up, and caregiver collection of data. Additional QoL studies that avoid these problems would be useful for clinical decision making.

**Balance of benefit versus harm for tonsillectomy in severe recurrent throat infection.** Families of patients who meet the appropriate criteria for tonsillectomy as described above should be advised of the modest anticipated benefits of tonsillectomy weighed against the natural history of resolution and the risk of surgical morbidity and complications. The harm and adverse events of tonsillectomy are not trivial and have been fully described earlier in this guideline under the section titled “Health Care Burden.” In considering the potential harms, in aggregate, the guideline panel agreed there was not a clear preponderance of benefit over harm for tonsillectomy, even for children meeting the strict criteria in the first study by Paradise et al.<sup>31</sup> Instead, there was felt to be a balance that still allows tonsillectomy as an appropriate management option for these children but does not imply that all qualifying children should have surgery.

The role of tonsillectomy as an option in managing children with recurrent throat infection means there is a substantial role for shared decision making with the child’s caregiver and primary care clinician. Moreover, decisions may be influenced by modifying factors, described in the next section, that may favor surgical intervention over observation. Whenever there is doubt or hesitation about the appropriateness of surgery, even if the criteria in **Table 5** are fulfilled, a consultation with an otolaryngologist and a period of watchful waiting to confirm persistence of a problem should be considered.

Limitations of the available randomized controlled trials must also be considered when assessing the benefits versus harms of surgery. In their first study, Paradise and colleagues<sup>31</sup> randomized 91 children to surgery versus observation, but they screened thousands of study candidates to arrive at this sample. Only a small percentage of the initial cohort met the strict entry criteria (**Table 5**), and only about half of eligible children had parents who agreed to randomization. This was less of a problem in the second study by these investigators,<sup>20</sup> in which most eligible children were enrolled. In both studies, however, only about half (46%–62%) of enrolled children completed all 3 years of follow-up. The panel did not consider these limitations sufficient to invalidate the studies, the same conclusion reached in a Cochrane review,<sup>68</sup> but did downgrade the aggregate evidence level from A (randomized trials) to B (randomized trials with limitations) to reflect this situation.

### **Evidence Profile for Statement 2: Recurrent Infection With Documentation**

- Aggregate evidence quality: Grade B, well-designed randomized controlled trials with minor limitations; some Grade C observational studies
- Benefit: Modest reduction in the frequency and severity of recurrent throat infection for up to 2 years

after surgery; modest reduction in frequency of group A streptococcal infection for up to 2 years after surgery; improved disease-specific QoL

- Harm: Risk and morbidity of tonsillectomy in patients appropriately selected for the procedure, including, but not limited to, persistence of throat infection, pain, and missed activity after surgery, hemorrhage, dehydration, injury, and anesthetic complications
- Cost: Direct cost of tonsillectomy; direct nonsurgical costs (antibiotics, clinician visit) and indirect costs (caregiver time, time missed from school) associated with recurrent infection
- Benefits-harm assessment: Balance between benefit and harm
- Value judgments: Importance of balancing the modest, short-term benefits of tonsillectomy in carefully selected children with recurrent throat infection against the favorable natural history seen in control groups and the potential for harm or adverse events, which, although infrequent, may be severe or life-threatening
- Role of patient preferences: Large role for shared decision making in severely affected patients, given favorable natural history of recurrent throat infections and modest improvement associated with surgery; limited role in patients who do not meet strict indications for surgery
- Intentional vagueness: None
- Exclusions: None
- Policy level: Option

**STATEMENT 3. TONSILLECTOMY FOR RECURRENT INFECTION WITH MODIFYING FACTORS: Clinicians should assess the child with recurrent throat infection who does not meet criteria in Statement 2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to multiple antibiotic allergy/intolerance, PFAPA (periodic fever, aphthous stomatitis, pharyngitis, and adenitis), or history of peritonsillar abscess. *Recommendation based on randomized controlled trials and observational studies with a preponderance of benefit over harm.***

### **Supporting Text**

Modifying factors, which can lead to significant morbidity, may be especially important in situations for which, in general, the benefits and risks of surgery are closely matched but compelling individual features (such as excessive morbidity) may nonetheless warrant tonsillectomy. Modifying factors are defined within 3 categories: (1) exceptions to recognized criteria based on individual features of illness such as multiple antibiotic allergies, (2) specific clinical syndromes such as PFAPA or recurrent tonsillitis associated with peritonsillar abscess, and (3) poorly validated clinical indications (eg, halitosis, febrile seizures, and malocclusion).

With regard to category 1, tonsillectomy is efficacious in reducing the number and severity of subsequent infections for at least 2 years when children fulfill stringent criteria for recurrent sore throat (**Table 5**).<sup>31</sup> For children with a lesser degree of illness, however, the pattern of illness may influence a recommendation for tonsillectomy. For example, when sore throat episodes are very severe or tolerated poorly by the child, or if the child has extensive drug allergies making antimicrobial therapy selection difficult, or if illness-related absences interfere with school performance, then surgery with its attendant reduction of episodes of illness may be recommended.

With regard to the second category of specific clinical syndromes, PFAPA and recurrent peritonsillar abscess may be indications for tonsillectomy. PFAPA is now a well-recognized syndrome occurring primarily in children younger than 5 years of age. The illness (which does not usually last more than 5 days) recurs (at least 3 documented episodes) at regular intervals of 3 to 6 weeks and is characterized by the sudden onset of fever, pharyngitis plus tender cervical lymphadenopathy, or aphthous ulcers.<sup>80</sup> While the use of steroids usually leads to prompt termination of an episode, the interval between episodes shortens.<sup>80</sup> Other potential therapies such as cimetidine may be helpful. Two small, randomized controlled trials demonstrated that tonsillectomy was effective for treating PFAPA syndrome, but children in the control groups also showed improvement.<sup>81,82</sup> Tonsillectomy may be considered based on the frequency of illness, severity of infection, and the child's response to medical management.

The role of tonsillectomy in managing peritonsillar abscess remains controversial, but the threshold for surgery is lowered when a child with recurrent throat infection develops, or has a past history of, peritonsillar abscess.<sup>83</sup> When peritonsillar abscess is treated with needle aspiration or incision and drainage, the need for subsequent tonsillectomy is about 10% to 20%.<sup>84,85</sup> This rate may not merit routine tonsillectomy unless a patient also has a history of frequent prior throat infections, especially when a culture is positive for GABHS. Some authors advocate "quinsy" tonsillectomy when the abscess is present, especially if general anesthesia is required for drainage (eg, uncooperative child) and there is a prior history of tonsil disease.<sup>85</sup>

Tonsillectomy has been recommended for treating pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS), but evidence is anecdotal and the entity is poorly understood.<sup>86</sup> The role of tonsillectomy in managing PANDAS is uncertain and unproved.

The last category contains a series of poorly validated indications for tonsillectomy that have not been tested in any controlled trials or case series, including chronic tonsillitis, febrile seizures, muffled ("hot potato") speech, halitosis, malocclusion of teeth, tonsillar hypertrophy, cryptic tonsils, or chronic pharyngeal carriage of GABHS. There is a substantial role for shared decision making with caregivers when considering tonsillectomy for 1 or more of these conditions, with individualized decisions that take into account severity of illness and QoL. Any potential benefits of tonsillectomy for these conditions must be balanced against the attendant risks of surgery.

### **Evidence Profile for Statement 3: Tonsillectomy for Recurrent Infection With Modifying Factors**

- Aggregate evidence quality: Grade B, randomized controlled trials with limitations, for PFAPA; Grade C, observational studies for all other factors
- Benefit: Identifying factors that might otherwise have been overlooked, which may influence the decision to perform tonsillectomy and ultimately improve patient outcomes
- Harm: None
- Cost: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Role of patient preferences: Should be included
- Intentional vagueness: None
- Exclusions: None
- Policy level: Recommendation

**STATEMENT 4. TONSILLECTOMY FOR SLEEP-DISORDERED BREATHING: Clinicians should ask caregivers of children with sleep-disordered breathing and tonsil hypertrophy about comorbid conditions that might improve after tonsillectomy, including growth retardation, poor school performance, enuresis, and behavioral problems.** *Recommendation based on observational before-and-after studies with a preponderance of benefit over harm.*

### **Supporting Text**

The purpose of this statement is to: (1) help clinicians and caregivers make informed decisions about tonsillectomy in children with clinically diagnosed SDB and (2) highlight the importance of eliciting a history about modifying factors that affect the decision to proceed with surgery. Although PSG is the gold standard for diagnosing SDB in children, it is unnecessary (or not necessary) to perform in every case and does not establish the effects of the sleep disorder on the child's well-being. The initial approach to a child with suspected SDB should include an assessment of these factors (behavioral problems, poor school performance, decreased QoL, failure to thrive, and enuresis) by history and physical examination. Failure to identify such factors may lead to suboptimal care with an inability to address the underlying problem.

SDB is characterized by recurrent partial or complete upper airway obstruction during sleep, resulting in disruption of normal ventilation and sleep patterns.<sup>87</sup> The diagnosis of SDB in children may be based on history, physical examination, audio/video taping, pulse oximetry, or limited or full-night PSG. History and physical examination are the most common initial methods for diagnosis. The presence or absence of snoring neither includes nor excludes SDB, as not all children who snore have SDB, and caregivers may not observe intermittent snoring that occurs during the night.<sup>88</sup> Although caregivers often describe their children as having excessive daytime sleepiness, this seems to be less of a problem in children than adults. Children with SDB display sleepiness scores that are

**Table 6.** Gradation of Tonsillar Enlargement<sup>90</sup>

Grade	Definition	Description
0	Not visible	Tonsils do not reach tonsillar pillars
1+	Less than 25%	Tonsils fill less than 25% of the transverse oropharyngeal space measured between the anterior tonsillar pillars
2+	25% to 49%	Tonsils fill less than 50% of the transverse oropharyngeal space
3+	50%-74%	Tonsils fill less than 75% of the transverse oropharyngeal space
4+	75% or more	Tonsils fill 75% or more than the transverse oropharyngeal space

within the normal range for adults. However, they are higher than controls, and primary snorers exhibit similar scores to those of children with OSA.<sup>89</sup>

Tonsillar and adenoid hypertrophy is recognized as the most common cause of SDB in children. Tonsil size is readily identified using a tonsil grading scale (**Table 6**),<sup>90</sup> with tonsillar hypertrophy defined as grades 3+ or 4+. Tonsillar size alone does not correlate with the severity of SDB,<sup>91</sup> although the combined volume of the tonsils and adenoids more closely correlate with SDB severity.<sup>92,93</sup> It is likely that the severity of SDB is related to a combination of tonsillar and adenoid hypertrophy, craniofacial anatomy, and neuromuscular tone. For example, tonsils that are only 1+ or 2+ in size may nonetheless contribute to airway obstruction in healthy children and especially those with hypotonia or craniofacial anomalies.<sup>94</sup>

SDB is known to increase the risk for externalizing (eg, aggression, hyperactivity) and internalizing behaviors (eg, depression) in some children, leading to symptoms of attention-deficit hyperactivity disorder.<sup>8,95,96</sup> Problems with memory and attention, often associated with SDB, may lead to poor school performance.<sup>97</sup> Studies have found that the QoL in children with SDB is worse than that of controls. For example, in one study, the QoL of children with SDB was similar to, or worse than, that of children with chronic diseases such as asthma or juvenile rheumatoid arthritis.<sup>98</sup> It is therefore important to view SDB as a condition that can dramatically affect the well-being of the child, family, and the primary caregiver.

Several studies have shown that up to 50% of children with SDB have enuresis.<sup>99-103</sup> Since enuresis can be embarrassing for the child and family, its presence may not be mentioned during routine evaluations. The primary care physician and the caregiver may also not be aware of an association between SDB and enuresis. SDB can also lead to failure to thrive and should be considered in children evaluated for growth failure.<sup>104</sup> It remains unknown whether growth failure is a result of hormonal changes caused by SDB or simply excessive energy expenditures to overcome the airway obstruction. Consequently, a child with mild SDB may have significant behavioral problems, poor school performance, reduced QoL, enuresis, and growth failure that may equally contribute to the decision to proceed with tonsillectomy.

Several studies have shown improvement or resolution of these modifying factors following tonsillectomy for SDB in children. Behavioral and neurocognitive problems have been shown to improve significantly after tonsillectomy for SDB by both objective<sup>95,96</sup> and subjective testing.<sup>105</sup> This improvement in behavior has been shown to continue for at least 2 years after tonsillectomy.<sup>8</sup> School performance has also been shown to improve significantly in children with SDB following tonsillectomy as compared with those who do not undergo surgical intervention.<sup>97</sup> There is also a dramatic improvement in QoL in children after tonsillectomy for SDB,<sup>10,11,98</sup> and this improvement is maintained for up to 2 years after surgery.<sup>98</sup>

Enuresis has been shown to resolve or improve in most children with SDB after tonsillectomy. One study showed that 61% of children were free of enuresis and 23% had a decrease in enuresis after surgical therapy for SDB.<sup>28</sup> Other studies that have followed children beyond 1 year have reported similar results, with the resolution rate increasing proportionally as the time following surgery increases.<sup>102,103</sup> A systematic review and meta-analysis of studies that evaluated height and weight changes after tonsillectomy for SDB<sup>104</sup> reported that height, weight, and growth biomarkers increased significantly after tonsillectomy, concluding that SDB, secondary to tonsil and adenoid hypertrophy, should be considered when screening, treating, and referring children with growth failure.

These modifying factors, however, do not affect every child with SDB to the same degree. For example, only 30% to 40% of children with SDB proven by PSG score in the abnormal range for hyperactivity,<sup>105</sup> and an unknown, but very small percentage, have growth failure. Equally, the severity of SDB does not correlate closely with the severity of behavioral or QoL scores.<sup>105,106</sup> Similar reports show a significant difference in prevalence of enuresis in children with an apnea-hypopnea index (AHI) >1 compared with children with an AHI <1.<sup>100</sup> However, there was no significant difference in the prevalence of enuresis in children with an AHI 1 of 5, 5 to 15, or >15.

Behavioral problems, decreased school performance, decreased QoL, enuresis, and growth failure may have a wide range of causes that includes but is not limited to SDB. Therefore, the clinician should be aware of the association between SDB and these modifying factors, recognizing that the sleep disorder may contribute to but not be the sole cause of the problem. Nevertheless, the clinician evaluating a child primarily for one of these modifying factors should elicit an adequate sleep history.

Tonsillar asymmetry can be seen in children and may have an effect on the decision to proceed with tonsillectomy. Tonsillar asymmetry can lead to concern as it may suggest the presence of a tumor, specifically lymphoma, in the larger tonsil. Careful assessment of the patient with tonsillar asymmetry is necessary to determine if a lymphoma is present. This would include a history, physical examination, and appropriate lab testing. However, in isolation, the presence of tonsillar asymmetry alone is not an indication for tonsillectomy.<sup>107-109</sup>

To date, most outcomes data on the efficacy of tonsillectomy and adenoidectomy for SDB in children have been based

on observational studies<sup>110,111</sup> and systematic reviews of observational studies.<sup>32,33</sup> Few studies have randomized children to an intervention and control group. These studies have shown an association between tonsillectomy and improved outcomes in children with SDB. Furthermore, most studies have reported on a single outcome measure such as behavior or QoL. In the future, prospective randomized controlled studies using multidimensional outcome measures are needed to determine if tonsillectomy with adenoidectomy, versus non-surgical intervention, causes significant improvement in outcomes, and if so, the magnitude of these improvements.

#### **Evidence Profile for Statement 4: Tonsillectomy for Sleep-Disordered Breathing**

- Aggregate evidence quality: Grade C, before-and-after observational studies
- Benefit: To improve decision making in children with SDB by identifying comorbid conditions associated with SDB, which might otherwise have been overlooked, and may improve after tonsillectomy
- Harm: None
- Cost: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception that potentially important comorbid conditions may be overlooked or not included in routine assessment of children with SDB, even though they may improve after intervention; consensus that substantial evidence from before-and-after studies supports inquiring about these conditions, despite an absence of randomized controlled trials supporting a recommendation for or against tonsillectomy
- Role of patient preferences: Large role for caregiver education and shared decision making
- Intentional vagueness: None
- Exclusions: None
- Policy level: Recommendation

**STATEMENT 5. TONSILLECTOMY AND POLYSOMNOGRAPHY: Clinicians should counsel caregivers about tonsillectomy as a means to improve health in children with abnormal polysomnography who also have tonsil hypertrophy and sleep-disordered breathing.** *Recommendation based on observational before-and-after studies with a preponderance of benefit over harm.*

#### **Supporting Text**

The purpose of this statement is to guide the clinician in making decisions about tonsillectomy in a child with hypertrophy of the tonsils who has already had PSG and the test is interpreted as “abnormal” by the sleep laboratory. This section will not discuss indications for PSG, nor will the definition of what is “normal” versus “abnormal” be considered since there is limited consensus and this topic is beyond the scope of this guideline. Although the guideline panel recognizes that children do not routinely need PSG before tonsillectomy, for

some children who present for surgical consideration, a PSG has already been obtained, and the clinician therefore needs to incorporate the result into decision making.

Overnight PSG is recognized as the most reliable and objective test to assess the presence and severity of OSA.<sup>112</sup> Consensus-based guidelines for performing PSG in children were established by the American Thoracic Society, and normative data in children have been reported in numerous studies.<sup>13,113,114</sup> Whereas standardized criteria for interpreting PSG in children are lacking, a consensus has emerged that the adult OSA criteria are not applicable to children. Most sleep specialists consider PSG in a child to be abnormal if there are pulse oximetry levels less than 92% or an AHI >1 (greater than 1 apneic or hypopneic event in 2 or more consecutive breaths per hour) or both.<sup>115</sup> Furthermore, an AHI >5 is considered by many to warrant tonsillectomy.<sup>116</sup> There is no evidence-based cutoff value, however, to indicate the need for tonsillectomy in children, and some children with AHI <5 may still be symptomatic and require intervention.<sup>117,118</sup>

Clinicians with expertise in pediatric respiratory and sleep disorders are needed to accurately interpret PSGs in children. Sleep centers may use different scoring criteria in defining OSA in children reflecting the lack of consensus of the definition.<sup>119</sup> Care should be taken when comparing sleep studies from different sleep laboratories as controversy exists surrounding which respiratory events in children are significant enough to be recorded. Some authors have advocated the use of respiratory disturbance index (RDI) instead of AHI to score and report abnormal airflow that could lead to clinical symptoms in children.<sup>117,118</sup> The scoring and reporting of RDI helps to identify abnormal breathing events that are less dramatic than apnea and hypopnea but are significant enough to cause arousal and sleep fragmentation. Any decision to recommend tonsillectomy should not be based solely on PSG findings but should be based on clinical history, examination, and the likelihood that adenotonsillectomy will improve the sleep-related breathing issues.

The measure of oxygenation by pulse oximetry is standard for PSG. Hypoxemia and repetitive oxygen desaturation can be frequent in children with SDB. Children may have significant oxygen desaturation (<85%) yet have a low apnea index or AHI.<sup>120</sup> There is also evidence that even mild oxygen desaturation can negatively affect academic performance.<sup>27</sup> Therefore, the interpretation of oxygen desaturation levels is as important as the AHI in assessing the severity of OSA. Oxygen saturation <85% is clearly abnormal, and treatment should be recommended. However, mild desaturation (<92%) may still be clinically relevant in the presence of high suspicion of SDB based on clinical examination and history.

While there are no randomized controlled trials comparing tonsillectomy to other interventions for children with SDB, favorable short-term outcomes have been reported extensively in nonrandomized studies. Tonsillectomy for the indication of SDB significantly improves QoL based on validated questionnaires measuring sleep disturbance, physical symptoms, emotional symptoms, hyperactivity, and daytime functioning.<sup>9-12,95</sup> Similarly, pulmonary hypertension has normalized

after tonsillectomy based on echocardiography assessment<sup>121</sup>; school performance has improved<sup>26,97</sup>; health care utilization has been reduced<sup>122</sup>; and sleep parameters have improved as demonstrated by PSG.<sup>32,33</sup> Despite the documented improvement, PSG is often not normalized, and many children either continue to have residual symptoms of SDB and remain symptomatic or have recurrence of symptoms.<sup>32,33,110,123-126</sup> Risk factors for persistent or recurrent OSA include severe preoperative OSA, obesity, children with craniofacial and neuromuscular anomalies, positive family history of OSA, and African American ethnicity.<sup>32,110,123-126</sup>

Tonsillectomy is typically performed in an outpatient setting. Children with complicated medical histories including cardiac complications of OSA, neuromuscular disorders, prematurity, obesity, failure to thrive, craniofacial anomalies, or recent respiratory infection should be treated in an inpatient setting.<sup>112</sup> Obesity increases the postoperative risk of respiratory complications in SDB with an overall odds ratio of 7.13; therefore, overnight hospitalization may be recommended.<sup>127</sup> SDB severity is a risk factor for postoperative respiratory complications<sup>128-131</sup> and is therefore an indication for postoperative admission for children.<sup>116,128</sup> The level of desaturation correlates with the number of obstructive events, thereby reflecting a higher AHI.<sup>128,132</sup> Although there is no general consensus in defining the level of severity of SDB in children based on AHI, the American Society of Anesthesiologists guideline defines severe OSA as AHI >10.<sup>133</sup> Young children with SDB also have been shown to have higher risk of postoperative airway complications,<sup>134-136</sup> and hospitalization is generally recommended for children less than 3 years of age.<sup>112,116</sup>

### Evidence Profile for Statement 5: Tonsillectomy and Polysomnography

- Aggregate evidence quality: Grade C, observational, before-and-after studies and meta-analysis of observational studies showing substantial reduction in the prevalence of SDB and abnormal PSG after tonsillectomy
- Benefit: Improved caregiver awareness of how tonsillectomy may benefit their child when PSG is abnormal, including improved sleep, better nighttime and daytime functioning, improved functional health status, and prevention or improvement of comorbid conditions, including growth retardation, poor school performance, enuresis, and behavioral problems
- Harm: Potential anxiety to caregivers from counseling
- Cost: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Panel consensus that objectively documented SDB with PSG may warrant intervention, even if not associated with comorbid conditions; recognition that abnormal PSG results encompass a broad range of values, with lack of evidence to support definitions of severity that correlate with surgical outcomes; concern that not treating children with

abnormal PSG may lead to future morbidity or impaired health status

- Role of patient preferences: Moderate; different caregivers may seek different levels of information and detail
- Intentional vagueness: The panel uses the term *abnormal PSG* recognizing there is no consensus among clinicians, institutions, or disciplines regarding the exact criteria that define an abnormal study. The panel agreed that indications for PSG are an important area for clarification, but it was deemed beyond the guideline scope and excluded from discussion
- Exclusions: None for counseling
- Policy level: Recommendation

**STATEMENT 6. OUTCOME ASSESSMENT FOR SLEEP-DISORDERED BREATHING: Clinicians should counsel caregivers and explain that SDB may persist or recur after tonsillectomy and may require further management.** *Recommendation based on observational studies, case-control and cohort design, with a preponderance of benefit over harm.*

### Supporting Text

The purpose of this statement is to emphasize that SDB may persist after tonsillectomy, despite perceptions by caregivers and clinicians that surgery is curative. As a result, clinicians should counsel, or educate, caregivers of patients who may require further management (**Table 7**). Counseling may be accomplished by either (1) discussing briefly the reasons why SDB may persist or recur after tonsillectomy and require further management or (2) providing an informational brochure or summary handout. The method of counseling should be documented in the medical record.

Children with SDB may have other underlying medical conditions, such as obesity, which contribute to their symptoms and persist after tonsillectomy. PSG is considered the gold standard for evaluating patients with suspected SDB and is also the most reliable outcome measure for treatment evaluation. PSG may be difficult to obtain because of limited availability and restrictions in coverage by insurers or third-party payers.

Observational studies show that tonsillectomy has a variable effect on resolving SDB as measured by PSG; however, less than 10% of children undergo preoperative PSG, and an even smaller percentage undergo postoperative studies.<sup>8</sup> A recent meta-analysis<sup>32</sup> reported an improvement in SDB in most children but a resolution in only 60% to 70% of subjects. The percentage of children in whom SDB has resolved is also dependent on the proportion of children, in the study population, who are overweight or obese. In a meta-analysis of 4 studies, resolution of SDB in obese children after tonsillectomy occurred in 10% to 25% of patients.<sup>137</sup> This is in contrast to a reported resolution of SDB in 70% to 80% of normal weight children.<sup>111</sup>

**Table 7.** Tonsillectomy and Sleep-Disordered Breathing (SDB) Caregiver Counseling Summary

1. Hypertrophic tonsils may contribute to SDB in children.
2. SDB often is multifactorial.
3. Obesity plays a key role in SDB in some children.
4. PSG is considered the best test for diagnosing and measuring outcomes in children, but it is not necessary in all cases and access may be limited by availability of sleep laboratories and willingness of insurers and third-party payers to cover the cost of testing.
5. Tonsillectomy is effective for control of SDB in 60%-70% of children with significant tonsillar hypertrophy.
6. Tonsillectomy produces resolution of SDB in only 10%-25% of obese children.
7. Caregivers need to be counseled that tonsillectomy is not curative in all cases of SDB in children, especially in children with obesity.

When children have tonsillectomy for specific comorbid conditions related to SDB (eg, growth retardation, poor school performance, enuresis, or behavioral problems), the SDB is often considered cured when the caregiver reports symptom resolution after surgery. In this situation, a postoperative PSG would generally be unnecessary, unless the symptoms later relapsed. Postoperative caregiver report of continuing symptoms is a good indicator of persistent SDB<sup>34</sup> and indicates the need for further evaluation, including PSG. Conversely, the severity of SDB preoperatively correlates poorly with severity of behavioral<sup>14</sup> or QoL<sup>10</sup> parameters, and resolution of SDB also does not correlate well with improvements in behavior.<sup>14</sup> Significant improvements in behavior and QoL have been reported regardless of the preoperative severity of SDB.<sup>34,106</sup>

#### Evidence Profile for Statement 6: Outcome Assessment for Sleep-Disordered Breathing

- Aggregate evidence quality: Grade C, before-and-after observational studies and systematic reviews
- Benefit: Identify children who require further management of SDB; improve outcomes
- Harm: None
- Cost: Time spent in counseling
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception of inadequate counseling by physicians and underappreciation that SDB may persist or recur despite tonsillectomy
- Role of patient preferences: Limited
- Intentional vagueness: None
- Exclusions: None
- Policy level: Recommendation

**STATEMENT 7. INTRAOPERATIVE STEROIDS:** Clinicians should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy. *Strong recommendation based on randomized controlled trials and systematic reviews of randomized controlled trials with a preponderance of benefit over harm.*

#### Supporting Text

One of the most important morbidities associated with pediatric tonsillectomy is postoperative nausea and vomiting (PONV). PONV occurs independent of dissection technique<sup>138</sup> and in more than 70% of children who do not receive prophylactic antiemetics.<sup>139-141</sup> Because of its very nature to cause discomfort and pain, PONV is acutely distressing to the patient. PONV often necessitates overnight hospital admission to provide intravenous hydration and analgesic administration and is associated with decreased patient satisfaction and increased use of resources.<sup>142-144</sup>

For several decades, evidence has accumulated that the administration of a single intraoperative dose of dexamethasone in children undergoing tonsillectomy results in decreased PONV.<sup>145-154</sup> A systematic review from the Cochrane Collaboration showed that children receiving dexamethasone were less likely to vomit in the first 24 hours than children receiving placebo (relative risk, 0.54; 95% CI, 0.42-0.69) and more likely to advance to a soft or solid diet on posttonsillectomy day 1 (relative risk, 1.69; 95% CI, 1.02-2.79).<sup>153</sup> On average, about 4 children would need to receive intravenous dexamethasone to result in 1 fewer patient experiencing posttonsillectomy emesis (number needed to treat = 4).<sup>153,154</sup>

The mechanism of efficacy of dexamethasone is unknown but may be related to its anti-inflammatory properties that reduce pain and swelling.<sup>155-157</sup> Most published studies used a dexamethasone dose of 0.5 mg/kg<sup>150</sup>; however, lower doses may be equally effective.<sup>158,159</sup> In one systematic review of randomized controlled trials, for example, doses ranged from 0.15 to 1.00 mg/kg, with a maximum dose range of 8 to 25 mg.<sup>153</sup>

Additional comorbidities after tonsillectomy include pain, poor oral intake, and changes in voice character. In addition to having a beneficial effect on PONV, dexamethasone also decreases throat pain after tonsillectomy and time to resumption of oral intake,<sup>160-162</sup> which may be of particular benefit when electrosurgery is used to remove the tonsils.

There is little evidence that administration of a single dose of dexamethasone in nondiabetic patients results in harmful effects. No adverse events were reported in any of the trials included in the Cochrane review, nor were any reports found in the literature of complications from using a single intravenous dose of corticosteroid during pediatric tonsillectomy.<sup>153</sup> One trial published after this review found increased postoperative hemorrhage in children who were randomized to receive 0.5 mg/kg of dexamethasone.<sup>150</sup> However, this was a secondary outcome that was not adjusted for other risk factors and lost significance when primary hemorrhage cases, which are largely related to surgical technique, were excluded from the analysis.<sup>163</sup> Increased hemorrhage with dexamethasone has not occurred in any other published trials, and the significance of this single report has been challenged.<sup>163</sup>

#### Evidence Profile for Statement 7: Intraoperative Steroids

- Aggregate evidence quality: Grade A, randomized controlled trials and multiple systematic reviews, for preventing PONV; Grade A, randomized controlled

- trials and 1 systematic review, for decreased pain and shorter times to oral intake
- Benefit: Decreased incidence of PONV up to 24 hours posttonsillectomy, decreased times to first oral intake, and decreased pain as measured by lower pain scores and longer latency times to analgesic administration
  - Harm: No adverse events in all randomized controlled trials except one, which reported increased hemorrhage as a secondary outcome unadjusted for other risk factors
  - Cost: Direct cost of medication and indirect costs of drug administration
  - Benefits-harm assessment: Preponderance of benefit over harm
  - Value judgments: Decreased PONV and postoperative pain likely to result in increased patient satisfaction and decreased incidence of overnight hospital admission, associated with lower total health care costs compared with direct and indirect costs of drug administration
  - Role of patient preferences: None
  - Intentional vagueness: None
  - Exclusions: Patients with endocrine disorders who are already receiving exogenous steroids or in whom steroid administration may interfere with normal glucose-insulin regulation (eg, diabetics)
  - Policy level: Strong recommendation

**STATEMENT 8. PERIOPERATIVE ANTIBIOTICS: Clinicians should not routinely administer or prescribe perioperative antibiotics to children undergoing tonsillectomy.** *Strong recommendation against administering or prescribing based on randomized controlled trials and systematic reviews with a preponderance of benefit over harm.*

### Supporting Text

The purpose of this statement is to address the issue of how antimicrobial therapy affects recovery after tonsillectomy and whether routine use is justified. Early randomized controlled trials of antibiotic therapy have largely shaped the delivery of care by otolaryngologists, suggesting improved recovery after tonsillectomy when antibiotics were prescribed.<sup>164,165</sup> Up to 79% of polled otolaryngologists in the United States use antibiotics in patients undergoing tonsillectomy to reduce postoperative morbidity, presumably through a reduction in bacteremia or through the anti-inflammatory properties of some antibiotics.<sup>166</sup>

The accumulated body of evidence, however, brings into question these early suggestions of benefit, because of methodological limitations in older trials and because of newer trials, which in aggregate do not support any benefit for routine antimicrobial therapy in the perioperative period. In an outpatient setting, the term *perioperative* is considered to mean the 24 hours prior to and following the surgical procedure. Patients excluded from these studies were those requiring preoperative

prophylactic antibiotics because of heart murmurs, implants, or other recognized reasons. Other exclusions included unilateral tonsillectomy, tonsillar biopsy, known tonsillar carcinoma, or tonsillectomy in conjunction with palatal surgery.

A Cochrane review of 10 randomized controlled trials found “no evidence to support a consistent, clinically important impact of antibiotics in reducing the main morbid outcomes after tonsillectomy.”<sup>167</sup> In the pooled analyses, antibiotics had no impact on rates of secondary hemorrhage (of any severity; 7 trials) or on significant secondary hemorrhage (requiring readmission, blood transfusion, or return to the operating room; 3 trials). An additional pooled analysis (2 trials) showed reduced incidence of fever greater than 99.9°F with antibiotics, but 2 other trials (not suitable for pooled analysis) showed no benefit.

The impact of antibiotics on pain, diet, and activity was not suitable for meta-analysis in the Cochrane review, but individual trials primarily showed no benefits. Antibiotics had no impact on pain in 5 of 7 trials, no impact (or an uncertain impact) on analgesic use in 5 of 6 trials, no impact on time to normal activity in 4 of 6 trials, and no impact on time to normal diet in 4 of 7 trials. When benefits were observed, they were generally small (1- to 2-day differences in return to normal diet) and were potentially explainable by bias in study design or outcome assessment. The authors of the Cochrane review concluded that antibiotics should be used “with caution” after tonsillectomy, a sentiment reflected in subsequent reviews and commentaries.<sup>168-170</sup>

Conclusions of no beneficial effects for antibiotics in the Cochrane review do not appear to be related to insufficient evidence or flaws in study design. The evidence base of 10 randomized controlled trials between 1986 and 2008 with 1035 participants is sufficient to draw conclusions, with the 3 trials published in 2000 or later showing no benefits for any outcomes. Although the trials had significant design flaws (90% inadequate allocation concealment, 80% not suitable for intent-to-treat analysis, 50% inadequate double blinding), these limitations would produce bias favoring antibiotics, which was not observed in the overall results. The trials were also heterogeneous, but this was unlikely to affect conclusions because results from individual trials broadly conformed to one another and to meta-analysis, when performed.

Any real or theoretical benefit of antibiotics on recovery after tonsillectomy must be balanced against the known risks, harms, and adverse events of therapy.<sup>171</sup> Aside from the direct costs of acquiring the drug, adverse events include rash, allergy, and gastrointestinal upset or diarrhea. Adverse events from antibiotics account for about 20% of all drug-related emergency department visits in the United States, most of which are attributable to allergic reactions.<sup>171</sup> Allergy to  $\beta$ -lactam antibiotics is cited as 2% per course, and anaphylaxis is estimated to occur in 0.01% to 0.05% of all penicillin courses.<sup>167</sup>

Antimicrobial use is also a well-known promoter of bacterial resistance, which is of particular concern in young children, who often require antimicrobials for otitis media, bacterial

sinusitis, and other infections. Last, an important consideration not discussed in the literature is the burden of trying to get the patient to swallow another liquid he or she struggles to take postoperative fluids. This creates an additional load on caregivers in the early postoperative period and may explain the high overall dropout rate observed in many studies of antibiotics and tonsillectomy.

The routine use of antibiotics after tonsillectomy in the face of increasing bacterial resistance, risk of allergic reactions, or other side effects should be weighed against the possible reduction in postoperative fever, which is the only outcome for which a significant benefit has been observed. The possibility of bias in explaining the sole significant outcome must also be considered. The absence of good evidence for the effectiveness of antibiotics to provide clinically relevant benefit confirms that there is insufficient evidence to support their routine use as a method to reduce morbidity after pediatric tonsillectomy.

### Evidence Profile for Statement 8:

#### Perioperative Antibiotics

- Aggregate evidence quality: Grade A, randomized controlled trials and systematic reviews, showing no benefit in using perioperative antibiotics to reduce posttonsillectomy morbidity
- Benefit: Avoidance of adverse events related to antimicrobial therapy, including rash, allergy, gastrointestinal upset, and induced bacterial resistance
- Harm: None
- Cost: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Although the panel recognizes that antimicrobial therapy is often used in perioperative management, this practice is suboptimal given the lack of demonstrable benefits in randomized controlled trials plus the well-documented potential adverse events and cost of therapy
- Role of patient preferences: None
- Intentional vagueness: The panel advises against routine antimicrobial therapy, recognizing that there may be individual circumstances in which use of antimicrobials for a given patient is deemed appropriate by the clinician
- Exclusions: Patients with cardiac conditions requiring perioperative antibiotics for prophylaxis against bacterial endocarditis or implants; patients undergoing tonsillectomy with concurrent peritonsillar abscess
- Policy level: Strong recommendation against

**STATEMENT 9. POSTOPERATIVE PAIN CONTROL:** **The clinician should advocate for pain management after tonsillectomy and educate caregivers about the importance of managing and reassessing pain.** *Recommendation based on randomized controlled trials with limitations and observational studies with a preponderance of benefit over harm.*

### Supporting Text

The purpose of this statement is to prevent pain and decrease morbidity following tonsillectomy, based on a perception by the panel that pain control may be underemphasized or inadequately discussed with the child's caregiver (**Table 8**). The main cause of morbidity after tonsillectomy is oropharyngeal pain, which may result in decreased oral intake, dysphagia, dehydration, and weight loss. As discussed previously, a single dose of intravenous dexamethasone reduces PONV and pain after tonsillectomy, but perioperative antibiotics are ineffective and not recommended. This section deals with additional measures for postoperative pain control, seeking to educate and empower caregivers and patients in the process.

Clinicians should advocate for pain management by establishing strategies to control pain after tonsillectomy. The panel avoided a recommendation to prescribe specific drugs, since pain can often be managed with over-the-counter analgesics and hydration. Educating caregivers about the need to manage and reassess pain is also part of the action statement, because caregivers have the most frequent contact with the child and are often best suited to monitor the child frequently after surgery. Clinicians are encouraged to advocate and educate prior to surgery and to reinforce the education prior to discharge on the day of tonsillectomy. Documentation should appear in the medical record describing how this was accomplished (eg, verbal discussion, written handout, educational brochure).

*Education and perioperative strategies.* Preoperative education programs targeting the caregivers are well established, but a focus on the child's understanding of the procedure is relatively new. Recent advances in the understanding of children's preprocedure education studies has identified

**Table 8.** Posttonsillectomy Pain Management Education for Caregivers

1. Throat pain is greatest the first few days following surgery and may last up to 2 wk.
2. Encourage your child to communicate with you if he or she experiences significant throat pain, since pain may not always be expressed and therefore not recognized promptly.
3. Discuss strategies for pain control with your health care provider before and after surgery; realize that antibiotics after surgery do not reduce pain and should not be given routinely for this purpose.
4. Make sure your child drinks plenty of fluids after surgery. Staying well hydrated is associated with less pain.
5. Ibuprofen can be used safely for pain control after surgery.
6. Pain medicine should be given as directed by your health care provider. Especially for the first few days following surgery, it should be given often.
7. Many clinicians recommend not waiting until your child complains of pain. Instead, the pain medication should be given on a regular schedule.
8. Expect your child to complain more about pain in the mornings—this is normal.
9. Rectal administration may be given if your child refuses to take pain medication orally. Call your health care provider if you are unable to adequately control your child's pain.

preoperative pain education as valuable for children prior to tonsillectomy.<sup>172,173</sup> Although concerns have been expressed about the possibility of pain education increasing children's anticipatory anxiety and adversely influencing their postoperative pain experience,<sup>174</sup> recent experience has suggested such concerns may be unfounded.<sup>175</sup> The preoperative introduction and teaching of a numeric pain intensity scale is useful for children to communicate their pain experience; however, it does not decrease anxiety or pain intensity, improve the quality of sleep or pain, or increase oral intake.<sup>175</sup>

Intraoperatively, local anesthesia injections in the tonsillar fossae have been used to reduce morbidity. A Cochrane review assessed the effects of preoperative and postoperative local anesthesia for pain reduction following tonsillectomy.<sup>176</sup> Randomized controlled trials of adults and children that were included in the review found no evidence that the use of perioperative local anesthetic in patients undergoing tonsillectomy improves postoperative pain control. The results suggest that local anesthetics should not be used as they have not been proven to be effective for postoperative pain control.

Despite the efforts of surgeons intraoperatively to decrease postoperative pain, the first few days following tonsillectomy are problematic. Oral intake improves over time but is highly variable between children.<sup>172,177</sup> Investigations into the oral fluid intake at home following tonsillectomy in the United States is limited but strongly suggests hydration is inadequate for most children following tonsillectomy.<sup>177-180</sup> This is important because inadequate hydration has been reported to be associated with increased reports of pain following tonsillectomy.<sup>181</sup> Most reported studies do not control or report the fluid intake of their subjects. Food intake is similarly reduced and often results in weight loss. It has not been the focus of extensive research, but dietary restrictions following surgery do not appear to be important.<sup>182,183</sup>

A significant contributing factor to poorly controlled postoperative pain may be noncompliant caregivers. American data<sup>177,184-186</sup> have mirrored the European experience regarding the inadequacy of caregiver compliance with the administration of analgesics following tonsillectomy.<sup>184,187-189</sup> Fortier and colleagues<sup>185</sup> recently showed that up to 24% of children received either no pain medication or a single dose on the first postoperative day, despite caregivers indicating that their children were in severe pain. By day 3 following surgery, despite 67% of the children experiencing severe pain, 41% received no pain medication or a single dose throughout the day. Other reported prospective, controlled experimental evidence has not found that compliance is a problem, although that was not the focus of the study.<sup>190</sup>

Topical agents have been used in an effort to reduce postoperative pain. A variety of oral rinses, mouthwashes, and sprays have been used. A recent Cochrane review analyzed 6 trials including nearly 400 children<sup>191</sup>; however, the risk of bias was high in most studies, the reporting quality poor, and the data inadequate to permit comprehensive and reliable conclusions to be made.

**Oral analgesics after tonsillectomy.** Although widely used, acetaminophen with codeine does not provide superior control of pain compared with acetaminophen only following tonsillectomy

either at rest or with swallowing.<sup>192,193</sup> The level of useful pain relief was similar to that reported in adults with moderate to severe postoperative pain.<sup>194</sup> Some of codeine's lack of efficacy may be due to the substantial genetic variation that exists in the activity of the cytochrome P450 enzyme CYP2D6, which is responsible for the metabolism of codeine into its active metabolite morphine. The presence of this polymorphism may render codeine ineffective,<sup>195,196</sup> and ultrarapid metabolism of codeine may put some children at risk with the use of codeine.<sup>197</sup> Postoperative nausea, vomiting, and constipation from acetaminophen with codeine use has led some to use just acetaminophen; however, acetaminophen alone may not provide adequate analgesia.<sup>198</sup> Rectal administration of medication was better tolerated than oral administration of acetaminophen and codeine.<sup>199</sup>

The use of nonsteroidal anti-inflammatory drugs (NSAIDs) after tonsillectomy has been controversial because of adverse effects on platelet function that may prolong bleeding time and other parameters.<sup>200,201</sup> A review from the Cochrane Collaboration<sup>202</sup> with nearly 1000 children from 13 randomized controlled trials found that NSAIDs did not significantly alter postoperative bleeding compared with placebo or other analgesics (odds ratio, 1.46; 95% CI, 0.49-4.40). In a subgroup analysis of 7 trials involving 567 children, the odds ratio for bleeding requiring reoperation was 0.91 (CI, 0.22-3.71) when ketorolac was excluded, suggesting no significant impact. These data suggest that NSAIDs, ketorolac excluded, can be safely used for the postoperative treatment of pain following tonsillectomy. Posttonsillectomy hemorrhage rates with ketorolac range from 4.4% to 18%, and therefore ketorolac use should be avoided.<sup>203,204</sup>

Administration of pain medication according to a fixed schedule is widely embraced but has not been proven to be superior to dosing the medication as needed (PRN).<sup>205</sup> Four randomized clinical trials evaluating the effectiveness of around-the-clock dosing of analgesics in children following tonsillectomy have been completed.<sup>190,192,206,207</sup> Pain regimens using acetaminophen,<sup>206</sup> acetaminophen and codeine,<sup>192</sup> and rofecoxib and hydrocodone<sup>207</sup> are equivalent, and despite the medications, children still experienced moderate levels of pain. The most recent study compared acetaminophen with hydrocodone PRN dosing around the clock. Time-dependent dosing was more effective than PRN dosing, and again, moderate pain in the study subjects was demonstrated.<sup>190</sup>

Discomfort after tonsillectomy is greater in the mornings than the evenings, independent of the dosing schedule, even when around-the-clock dosing was employed.<sup>172,190</sup> A variety of explanations has been offered for the increase in morning discomfort: decreased nocturnal caregiver analgesic administration or home environment distractions during the day,<sup>187,208</sup> muscle spasm, increased edema secondary to positioning, and poor sleep quality.<sup>190</sup> An equally likely plausible explanation is that the children become relatively dehydrated overnight.<sup>177,181</sup>

Sleep disturbances may occur,<sup>172,209-211</sup> and awakenings during the night may reflect inadequate control of postoperative pain and lessen as pain decreases.<sup>172</sup> Individual child factors have also been implicated as predictors of sleep disturbances and other maladaptive postoperative behavioral changes.<sup>212</sup>

In summary, regardless of the dosing regimen used, postoperative analgesic management is best determined by basing the starting dose on the child's weight and adequately monitoring pain levels. No ideal postoperative medication has been identified for postoperative pain following tonsillectomy, nor has the frequency of administration of pain medication been detailed. Despite its wide appeal, scheduled administration of medication for pain lacks conclusive proof of superiority, except for acetaminophen and hydrocodone administration following tonsillectomy. The use of acetaminophen with codeine may be ineffective since genetic polymorphism may render the codeine ineffective.<sup>195,196</sup> Caregivers should be educated on the perioperative events associated with tonsillectomy (**Table 4**), but specifically, education on the assessment of pain is important and may improve caregiver compliance with medication administration. Failure to control the pain should prompt the caregiver to call his or her clinician to seek additional treatment or assessment.

### **Evidence Profile for Statement 9: Postoperative Pain Control**

- Aggregate evidence quality: Grade B, randomized controlled trials comparing analgesics after tonsillectomy, and Grade C, observational studies suggesting inadequate pain control and hydration after tonsillectomy
- Benefit: Pain relief, improved and faster recovery; avoidance of complications from dehydration, inadequate food intake
- Harm: Adverse effects of specific analgesic preparations
- Cost: Time spent by clinician advocating; direct cost of medications used
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception by the panel that pain control is often underemphasized and inadequately discussed after tonsillectomy; importance of engaging the caregiver and providing education about pain management and reassessment
- Role of patient preferences: Limited regarding advocacy; substantial role in choice of analgesic and method of reassessment
- Intentional vagueness: None
- Exclusions: None
- Policy level: Recommendation

**STATEMENT 10. POSTTONSILLECTOMY HEMORRHAGE: Clinicians who perform tonsillectomy should determine their rate of primary and secondary posttonsillectomy hemorrhage at least annually.** *Recommendation based on observational studies with a preponderance of benefit over harm.*

### **Supporting Text**

The purpose of this statement is to encourage self-assessment by clinicians who perform tonsillectomy to determine how their

personal rate of hemorrhage compares with expected rates based on audit data and published reports. This allows communication of surgical risk during the informed consent discussion with caregivers and may identify circumstances in which a surgeon needs to reassess his or her technique and process of care for quality improvement opportunities. The panel felt that this approach was preferable to specific recommendations regarding choice of surgical technique because prospective trials are lacking to justify strong guidance in this regard.

Hemorrhage after tonsillectomy may be categorized as primary or secondary. Primary hemorrhage is defined as bleeding that occurs within the first 24 hours after the procedure and is generally attributed to surgical technique and the reopening of a blood vessel(s). Rates of primary hemorrhage range from 0.2% to 2.2% of patients. Secondary hemorrhage occurs more than 24 hours following the procedure, often between 5 and 10 days, and is usually caused by sloughing of the primary eschar as the tonsil bed heals by secondary intention. Rates of secondary hemorrhage range from 0.1% to 3%.<sup>35</sup>

Determination of posttonsillectomy hemorrhage should be performed by the operating surgeon or other clinician involved in the patient's postoperative care for all patients undergoing tonsillectomy. Clinicians should inquire about bleeding following surgery (primary and secondary) and whether further treatment was necessary. This can be accomplished at the time of a postoperative visit with the treating clinician (not necessarily the surgeon) or by telephone.<sup>213,214</sup>

Volume of bleeding may be difficult to accurately quantify. Minimal bleeding is frequently managed at home with observation alone. However, more than minimal bleeding that requires reevaluation of the patient in a clinical setting, and bleeding (of any volume) requiring intervention (cauterization, hospitalization, transfusion, or surgery) must be documented. Additional information such as emergency department and/or hospital admission, requirement for further treatment, and surgery to control bleeding must be conveyed to the operating surgeon in the event that he or she was not the clinician rendering that postoperative care. Good communication and continuity of care is necessary to facilitate quality improvement.

**Impact of surgical technique on bleeding.** The traditional cold (metal instruments) dissection technique for tonsillectomy involves removal of the tonsil by dissecting the peritonsillar space, with continuous hemostasis obtained through ligation of blood vessels during tonsil removal. This is still considered the standard with which to compare the effectiveness and safety of other newer techniques. Electrosurgical dissection (diathermy) remains a common tonsillectomy technique and is also used for hemostasis during cold tonsillectomy. Many of the newer "hot" techniques (radiofrequency, coblation, and harmonic scalpel) have been introduced to reduce postoperative morbidity and risk of hemorrhage. The heat produced by these techniques produces hemostasis during tonsil dissection.<sup>42,215</sup>

The National Prospective Tonsillectomy Audit (NPTA), performed in the United Kingdom in 2005, investigated the occurrence of postoperative hemorrhage in 33 921 patients undergoing tonsillectomy in England and Northern Ireland over a

14-month period from 2003 to 2004.<sup>42</sup> Primary posttonsillectomy hemorrhage rates were 0.6%, and secondary hemorrhage rates were 3%. Hot surgical techniques for both dissection and hemostasis (diathermy or coblation) increased the risk of secondary hemorrhage by 3-fold when compared with cold steel tonsillectomy without the use of any hot technique. The risk of secondary hemorrhage for operations using cold steel for dissection and bipolar diathermy for hemostasis was approximately 1.5 times higher than for cold steel operations using only ties/packs for hemostasis. The use of coblation was associated with an elevated risk of return to the operating room for bleeding.

A Cochrane review from 2001 investigated randomized controlled trials comparing morbidity associated with tonsillectomy performed using dissection versus diathermy.<sup>216</sup> Only 2 of the 22 studies met the necessary inclusion criteria. There was no difference in the rate of secondary bleeding overall, although the power of both studies to detect small differences was insufficient. There were insufficient data to show that one method of tonsillectomy was superior.

A systematic review of electrosurgery for tonsillectomy indicated that the risk of postoperative hemorrhage is higher following hot techniques compared with cold dissection.<sup>217</sup> In the meta-analysis models, bipolar diathermy dissection and hemostasis were associated with statistically significant lower odds of primary hemorrhage, including primary hemorrhage requiring return to the operating room compared with cold steel dissection with ties/packs hemostasis. Coblation was associated with a statistically significant increase in secondary hemorrhage requiring return to the operating room. Monopolar and bipolar diathermy dissection and hemostasis, coblation, and cold steel dissection with monopolar or bipolar diathermy hemostasis were all associated with statistically significant higher odds of secondary hemorrhage. In addition, a randomized controlled trial<sup>218</sup> and large prospective cohort studies demonstrated a higher risk of postoperative hemorrhage after hot tonsillectomy compared with cold dissection.<sup>219-221</sup> In a systematic review of hot (monopolar electrosurgery) versus cold knife tonsillectomy, only 6 of 815 prospective trials met the necessary inclusion criteria and revealed that postoperative hemorrhage rates were not significantly different when comparing the 2 methods.<sup>222</sup>

In a systematic Cochrane review of coblation versus other surgical techniques for tonsillectomy, 19 randomized controlled trials were evaluated.<sup>223</sup> Nine trials met inclusion criteria, and there was no significant difference between coblation and other tonsillectomy techniques with respect to postoperative bleeding. A case series of 1997 pediatric patients undergoing coblation adenotonsillectomy from January 2000 to June 2004 demonstrated that coblation tonsillectomy had similar rates of primary and secondary hemorrhage when compared with electrocautery tonsillectomy.<sup>224</sup>

Regarding harmonic scalpel tonsillectomy compared with conventional methods for tonsillectomy, Neumann et al concluded in a systematic review that the current evidence regarding the use of harmonic scalpel and postoperative hemorrhage is of low quality and does not support any difference in postoperative hemorrhage rates.<sup>225</sup>

*Impact of medications on posttonsillectomy bleeding.* A Cochrane review of NSAIDs and perioperative bleeding in pediatric tonsillectomy included 13 randomized controlled trials involving 955 children and examined bleeding requiring surgical intervention, in addition to 7 trials involving 471 children that examined bleeding not requiring surgical intervention.<sup>202</sup> NSAIDs did not significantly increase bleeding following tonsillectomy in either review. A meta-analysis demonstrated an increased risk of posttonsillectomy hemorrhage with the use of aspirin after tonsillectomy but not for nonaspirin NSAIDs such as diclofenac and ibuprofen.<sup>226</sup> Another systematic review concluded that although there was some evidence for an increased likelihood of reoperation for bleeding in patients given NSAIDs postoperatively, the evidence for postoperative bleeding was equivocal.<sup>227</sup>

A Cochrane review demonstrated that perioperative antibiotics were not associated with a reduction in significant secondary hemorrhage rates or total secondary hemorrhage rates.<sup>167</sup> Both a systematic review<sup>170</sup> and a meta-analysis<sup>228</sup> also did not demonstrate a significant difference in postoperative bleeding between the antibiotic-treated groups and untreated groups. In a review of 11 studies that met inclusion criteria for an Evidence Report from the Center for Clinical Effectiveness in Clayton, Australia, antibiotic and steroid therapy had no effect on either primary or secondary hemorrhage.<sup>229</sup>

*Other factors influencing posttonsillectomy bleeding.* The UK NPTA audit demonstrated that there was a higher risk of postoperative bleeding with increasing patient age, male gender, and those with a history of recurrent acute tonsillitis (3.7%) and previous peritonsillar abscess. The rate was highest in quinsy patients (5.4%) compared with patients with pharyngeal obstruction and OSA (1.4%).<sup>42</sup>

### **Evidence Profile for Statement 10: Posttonsillectomy Hemorrhage**

- Aggregate evidence quality: Grade C, observational studies and large-scale audit, showing variability in postoperative hemorrhage rates and some association with surgical technique; Grade C, observational studies, showing hemorrhage as a consistent sequelae of tonsillectomy with heterogeneity among studies
- Benefit: Improve preoperative counseling for tonsillectomy; encourage quality improvement efforts
- Harm: None
- Cost: Administrative burden
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perceived heterogeneity among clinicians regarding knowledge of their own hemorrhage rates after tonsillectomy; potential for clinicians to reassess their process of care and improve quality
- Role of patient preferences: Limited
- Intentional vagueness: Specifics of how to determine the hemorrhage rate are left to the clinician
- Exclusions: None
- Policy level: Recommendation

## Comparison of Tonsillectomy Guidelines

Three major multidisciplinary guidelines on tonsillectomy have been produced in the past 3 years by 3 different countries (Scotland, Italy, and the United States). Similarities and differences between these guidelines are presented in **Table 9**. Some differences may reflect national experience, process differences, or different interpretations of the evolving the medical literature.

## Implementation Considerations

The complete guideline is published as a supplement to *Otolaryngology—Head and Neck Surgery*, which will facilitate reference and distribution. A full-text version of the guideline will also be accessible free of charge for a limited time at [www.entnet.org](http://www.entnet.org). The guideline will be presented to AAO-HNS members as a mini-seminar at the AAO-HNS annual meeting and OTO EXPO. Existing brochures and publications by the AAO-HNS will be updated to reflect the guideline recommendations.

The panel identified several potential areas of the guideline in which obstacles to implementation might occur based on current practice patterns. Clinicians may be unfamiliar with the Paradise criteria for tonsillectomy (**Table 5**), having relied on less stringent personal or organizational criteria to identify surgical candidates. Moreover, the importance of concurrent documentation to support the medical history is not always appreciated. Overcoming these beliefs will require teaching materials plus integration of this knowledge into existing continuing medical education venues for clinicians who assess tonsillectomy candidacy. Educational material will also be needed for caregivers of children with recurrent throat infection to explain the rationale for watchful waiting instead of earlier surgical intervention.

Antibiotics are commonly used in the routine, perioperative care of children having tonsillectomy, despite convincing evidence of no beneficial impact on recovery (except for possibly reduced fever). Changing this behavior will require a paradigm shift, which is likely to be met with resistance based on long-established practices and anecdotal perceptions as to why antibiotics may be beneficial. Similarly, NSAIDs are used infrequently for pain control based on unfounded concerns about increased postoperative hemorrhage, which are not supported by systematic reviews of randomized trials. Conversely, codeine is often used after tonsillectomy despite no benefit over acetaminophen in randomized controlled trials plus a known adverse event profile that includes nausea and vomiting. Educational materials and brochures will be needed to reduce perioperative antibiotics, promote NSAIDs for pain control, and avoid codeine as a routine addition to acetaminophen.

Several of the guideline recommendations deal with advocacy, education, or counseling. The panel opted for this approach, instead of recommending specific drugs or interventions, because in many cases high-quality, consistent evidence was lacking. Relevant statements in the guideline deal with managing the child with an abnormal

PSG, anticipating possible persistence of SDB and abnormal PSG after tonsillectomy, and involving the caregiver in postoperative pain management. Appropriate education materials and brochures will be needed to efficiently implement these strategies at the point of care.

The guideline statement on posttonsillectomy hemorrhage requests that clinicians who perform tonsillectomy determine their rate of primary and secondary posttonsillectomy hemorrhage at least annually. Existing information systems at some hospitals or surgicenters may allow this to be readily accomplished, but for others, there will be an administrative burden in acquiring these data. This barrier to implementation suggests the need for a tool or data form to assist clinicians in gathering the relevant data.

## Research Needs

While there is a body of literature from which the guidelines were drawn, significant gaps remain in knowledge about preoperative, intraoperative, and postoperative care in children who undergo tonsillectomy. As determined by the guideline panel's review of the literature, assessment of current clinical practices, and determination of evidence gaps, research needs were determined as follows:

1. Investigate the treatment of recurrent throat infections by tonsillectomy versus antibiotics/watchful waiting (less than and greater than 12 months) using a multicenter, randomized controlled trial design and including the following endpoints: QoL, health care utilization, missed school days, parental satisfaction, and recurrence of throat infections.
2. Conduct prospective cohort studies on indications for PSG in children with SDB and other comorbidities.
3. Measure QoL/school performance (not just missed school days) following tonsillectomy in mild SDB patients and those with recurrent infections whose history does not meet Paradise criteria.
4. Determine if the 12-month watchful-waiting period causes unnecessary morbidity based on QoL/school performance measures.
5. Determine the optimal follow-up schedule for SDB following tonsillectomy.
6. Determine when postoperative polysomnogram is indicated after tonsillectomy for SDB.
7. Determine when preoperative polysomnogram is indicated.
8. Determine the percentage of patients who have full resolution/partial resolution/no resolution of SDB in the short-term and long-term postoperative period.
9. Assess how future weight gain/obesity would play a role in failure to respond following tonsillectomy for SDB.

**Table 9.** Comparison of Scottish, Italian, and American Guidelines

Parameter	Scottish Guideline	Italian Guideline	AAO-HNS Guideline
Audience	Multidisciplinary	Multidisciplinary	Multidisciplinary
Target population	Children (4-16 y) and adults	Children and adults	Children (1-18 y)
Scope	Management of sore throat and indications for tonsillectomy	Appropriateness and safety of tonsillectomy	Management of children who are candidates for tonsillectomy
Methods	Based on a priori protocol; systematic literature review; SIGN scale of evidence quality	Systematic literature review; PNLG scale of evidence quality	Based on a priori protocol; systematic literature review; AAP scale of evidence quality
Recommendations			
Recurrent infection	Tonsillectomy should be considered for recurrent, disabling sore throat due to acute tonsillitis when the episodes are well documented and adequately treated that meet the Paradise criteria ( <b>Table 5</b> ) for frequency of illness	Tonsillectomy is indicated in patients with at least 1 y of recurrent tonsillitis (5 or more episodes per year) that is disabling and impairs normal activities, but only after an additional 6 mo of watchful waiting to assess the pattern of symptoms using a clinical diary	Tonsillectomy is an option for children with recurrent throat infection that meets the Paradise criteria ( <b>Table 5</b> ) for frequency, severity, treatment, and documentation of illness
Pain control	Recommendation for adequate dose of acetaminophen for pain relief in children	Recommendation to administer acetaminophen before and after surgery	Recommendation to advocate (ie, provide information, prescribe, etc) for pain relief and educate caregivers about the importance of managing and reassessing pain
Antibiotics	No statement regarding perioperative antibiotics	Recommendation for short-term perioperative antibiotics <sup>a</sup>	Recommendation against perioperative antibiotics
Steroids	Recommendation for a single intraoperative dose of dexamethasone	Recommendation for a single intraoperative dose of dexamethasone	Recommendation for a single intraoperative dose of dexamethasone
Sleep-disordered breathing	NA	Recommendation for diagnostic testing in children with suspected sleep respiratory disorders	Recommendation to counsel caregivers about tonsillectomy as a means to improve health in children with sleep-disordered breathing (and comorbid conditions)
Polysomnography	NA	Recommendation for polysomnography when pulse oximetry results are not conclusive in agreement with Brouillette criteria	Recommendation to counsel caregivers about tonsillectomy as a means to improve health in children with abnormal polysomnography
Surgical technique	NA	Recommendation for "cold" technique	NA
Hemorrhage	NA	NA	Recommendation that the surgeon document primary and secondary hemorrhage posttonsillectomy at least annually
Adjunctive therapy	Recommendation against <i>Echinacea purpurea</i> for treatment of sore throat Recommendation for acupuncture in patients at risk for PONV where antiemetic drug use is not suitable	NA	NA

Abbreviations: AAP, American Academy of Pediatrics; NA, not applicable; PNLG, Italian National Program Guidelines; PONV, postoperative nausea and vomiting; SIGN, Scottish Intercollegiate Guidelines Network.

<sup>a</sup>Statement made prior to most recent Cochrane review (reference 163).

10. Assess the immunological role of the tonsils and, specifically, at what point the benefits of tonsillectomy exceed the harm using a biomarker approach.
11. Determine the cost-effectiveness (direct and indirect) of different tonsillectomy techniques.
12. Evaluate and compare oral postoperative pain medications.
13. Conduct studies that incorporate hydration as an outcome measure.
14. Determine the optimal regimen for treating PONV in children who have received dexamethasone.

15. Investigate microbiologic and immunologic changes associated with tonsillectomy to provide a reasonable pathophysiologic explanation for perceived improvement with surgical intervention through a change in oropharyngeal and/or nasopharyngeal biofilms or flora.
16. Assess for areas of improvement in the postoperative coordination between the primary care clinician and specialist.
17. Evaluate the impact and use of the guideline by determining how the guideline translates to performance measurement and performance improvement.
18. Evaluate shared decision making in tonsillectomy, specifically how to present risks and benefits in a quantitative or qualitative way to nonmedical individuals.

### Disclosures

**Raouf S. Amin**, grant: Proctor and Gamble; **Eric Wall**, consultant: Anthem/Wellpoint (low-back pain pilot guideline), Senior Medical Director: Qualis Health.

### Disclaimer

This clinical practice guideline is not intended as a sole source of guidance in managing children who are candidates for tonsillectomy. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to managing this problem.

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TEXAS CHILDREN'S HEALTH PLAN Addendum to  
Clinical Practice Guideline: Tonsillectomy in Children

Purpose of addendum: On review of the national Clinical Practice Guideline: Tonsillectomy in Children from the American Academy of Otolaryngology Head and Neck Surgery, local otolaryngology experts do not agree with several areas of the guidelines. Texas Children's Health Plan acknowledges that competent experts may look at the same information and come to different conclusions.

Addendum to the Clinical Practice Guideline: Tonsillectomy in Children is as follows:

- 1) TEXAS CHILDREN'S HEALTH PLAN acknowledges that there is substantial diversity of opinion regarding the use of perioperative antibiotics to children undergoing tonsillectomy. TEXAS CHILDREN'S HEALTH PLAN does not recommend either for or against the use of perioperative antibiotics for children undergoing tonsillectomy.
- 2) TEXAS CHILDREN'S HEALTH PLAN acknowledges that documentation of recurrent throat infections may be challenging to obtain as complete records may not be available to the surgeon and decisions will need to be based on medical history as available.
- 3) TEXAS CHILDREN'S HEALTH PLAN acknowledges that there remains substantial concern about the safety of ibuprofen for pain control after tonsillectomy surgery due to the adverse effects of ibuprofen on platelet functioning. Furthermore, the studies reported by the clinical practice guideline failing to document evidence of harm of ibuprofen were not able to provide sufficiently precise estimates of the effect of ibuprofen on post operative bleeding risk (odds ratio, 1.46; 95% CI, 0.49-4.40) to confidently conclude that no clinically important harm exists.
- 4) TEXAS CHILDREN'S HEALTH PLAN acknowledges that modifying factors, such as history of peritonsillar abscess, PFAPA syndrome, halitosis, or history of antibiotic allergy may influence decision about adenotonsillectomy outside of the strict guideline criteria.

Respectfully submitted,

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