

# Clinical Practice Guideline: Tonsillectomy in Children (Update)—Executive Summary

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## Abstract

**Objective.** This update of a 2011 guideline developed by the American Academy of Otolaryngology–Head and Neck Surgery Foundation provides evidence-based recommendations on the pre-, intra-, and postoperative care and management of children 1 to 18 years of age under consideration for tonsillectomy. 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. Tonsillectomy is one of the most common surgical procedures in the United States, with 289,000 ambulatory procedures performed annually in children <15 years of age, based on the most recent published data. This guideline is intended for all clinicians in any setting who interact with children who may be candidates for tonsillectomy.

**Purpose.** The purpose of this multidisciplinary guideline is to identify quality improvement opportunities in managing children under consideration for tonsillectomy and to create explicit and actionable recommendations to implement these opportunities in clinical practice. Specifically, the goals are to educate clinicians, patients, and/or caregivers regarding the indications for tonsillectomy and the natural history of recurrent throat infections. Additional goals include the following: optimizing the perioperative management of children undergoing tonsillectomy, emphasizing the need for evaluation and intervention in special populations, improving the counseling and education of families who are considering tonsillectomy for their children, highlighting the management options for patients with modifying factors, and reducing inappropriate or unnecessary variations in care. Children aged 1 to 18 years under consideration for tonsillectomy are the target patient for the guideline.

For this guideline update, the American Academy of Otolaryngology–Head and Neck Surgery Foundation selected a panel representing the fields of nursing, anesthesiology, consumers, family medicine, infectious disease, otolaryngology–head and neck surgery, pediatrics, and sleep medicine.

**Key Action Statements.** The guideline update group made *strong recommendations* for the following key action statements (KASs): (1) Clinicians should recommend watchful waiting for recurrent throat infection if there have been <7 episodes in the past year, <5 episodes per year in the past 2 years, or <3 episodes per year in the past 3 years. (2) Clinicians should administer a single intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy. (3) Clinicians should recommend ibuprofen, acetaminophen, or both for pain control after tonsillectomy.

The guideline update group made *recommendations* for the following KASs: (1) Clinicians should assess the child with recurrent throat infection who does not meet criteria in KAS 2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to multiple antibiotic allergies/intolerance, PFAPA (periodic fever, aphthous stomatitis, pharyngitis, and adenitis), or history of >1 peritonsillar abscess. (2) Clinicians should ask caregivers of children with obstructive sleep-disordered breathing and tonsillar hypertrophy about comorbid conditions that may improve after tonsillectomy, including growth retardation, poor school performance, enuresis, asthma, and behavioral problems. (3) Before performing tonsillectomy, the clinician should refer children with obstructive sleep-disordered breathing for polysomnography if they are <2 years of age or if they exhibit any of the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses. (4) The clinician should advocate for polysomnography prior to

tonsillectomy for obstructive sleep-disordered breathing in children without any of the comorbidities listed in KAS 5 for whom the need for tonsillectomy is uncertain or when there is discordance between the physical examination and the reported severity of obstructive sleep-disordered breathing. (5) Clinicians should recommend tonsillectomy for children with obstructive sleep apnea documented by overnight polysomnography. (6) Clinicians should counsel patients and caregivers and explain that obstructive sleep-disordered breathing may persist or recur after tonsillectomy and may require further management. (7) The clinician should counsel patients and caregivers regarding the importance of managing posttonsillectomy pain as part of the perioperative education process and should reinforce this counseling at the time of surgery with reminders about the need to anticipate, reassess, and adequately treat pain after surgery. (8) Clinicians should arrange for overnight, inpatient monitoring of children after tonsillectomy if they are <3 years old or have severe obstructive sleep apnea (apnea-hypopnea index  $\geq 10$  obstructive events/hour, oxygen saturation nadir <80%, or both). (9) Clinicians should follow up with patients and/or caregivers after tonsillectomy and document in the medical record the presence or absence of bleeding within 24 hours of surgery (primary bleeding) and bleeding occurring later than 24 hours after surgery (secondary bleeding). (10) Clinicians should determine their rate of primary and secondary posttonsillectomy bleeding at least annually.

The guideline update group made a *strong recommendation against* 2 actions: (1) Clinicians should not administer or prescribe perioperative antibiotics to children undergoing tonsillectomy. (2) Clinicians must not administer or prescribe codeine, or any medication containing codeine, after tonsillectomy in children younger than 12 years.

The policy level for the recommendation about documenting recurrent throat infection was an *option*: (1) Clinicians may recommend tonsillectomy for recurrent throat infection with a frequency of at least 7 episodes in the past year, 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  $\geq 1$  of the following: temperature  $>38.3^{\circ}\text{C}$  ( $101^{\circ}\text{F}$ ), cervical adenopathy, tonsillar exudate, or positive test for group A beta-hemolytic streptococcus.

## Differences from Prior Guideline.

- Incorporating new evidence profiles to include the role of patient preferences, confidence in the evidence, differences of opinion, quality improvement opportunities, and any exclusion to which the action statement does not apply.
- There were 1 new clinical practice guideline, 26 new systematic reviews, and 13 new randomized controlled trials included in the current guideline update.
- Inclusion of 2 consumer advocates on the guideline update group.
- Changes to 5 KASs from the original guideline: KAS 1 (Watchful waiting for recurrent throat infection), KAS 3 (Tonsillectomy for recurrent infection with modifying factors), KAS 4 (Tonsillectomy for obstructive sleep-disordered breathing), KAS 9 (Perioperative pain counseling), and KAS 10 (Perioperative antibiotics).
- Seven new KASs: KAS 5 (Indications for polysomnography), KAS 6 (Additional recommendations for polysomnography), KAS 7 (Tonsillectomy for obstructive sleep apnea), KAS 12 (Inpatient monitoring for children after tonsillectomy), KAS 13 (Postoperative ibuprofen and acetaminophen), KAS 14 (Postoperative codeine), and KAS 15a (Outcome assessment for bleeding).
- Addition of an algorithm outlining KASs.
- Enhanced emphasis on patient and/or caregiver education and shared decision making.

## Keywords

tonsillectomy, adenotonsillectomy, child, tonsillitis, sleep disordered breathing, obstructive sleep apnea, polysomnography

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**T**onsillectomy is one of the most common surgical procedures in the United States, with 289,000 ambulatory procedures performed annually in children

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<15 years of age based on the most recent published data.<sup>1</sup> Indications for surgery include recurrent throat infections and obstructive sleep-disordered breathing (oSDB),<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, dehydration, delayed feeding, speech disorders (eg, velopharyngeal incompetence), bleeding, and, rarely, death.<sup>3,4</sup> The frequency of tonsillectomy, the associated morbidity, and the availability of new randomized clinical trials create a need for an updated evidence-based guidance to aid clinicians. The following definitions were used during this guideline update:

- **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.
- **Throat infection** is defined as a 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 term *strep throat*, *acute tonsillitis*, *pharyngitis*, *adenotonsillitis*, or *tonsillopharyngitis*.
- **Obstructive sleep-disordered breathing (oSDB)** is a clinical diagnosis characterized by obstructive abnormalities of the respiratory pattern or the adequacy of oxygenation/ventilation during sleep, which include snoring, mouth breathing, and pauses in breathing. oSDB encompasses a spectrum of obstructive disorders that increases in severity from primary snoring to obstructive sleep apnea (OSA). Daytime symptoms associated with oSDB may include inattention, poor concentration, hyperactivity, or excessive sleepiness. The term oSDB is used to distinguish oSDB from SDB that includes central apnea and/or abnormalities of ventilation (eg, hypopnea-associated hypoventilation).
- **Obstructive sleep apnea (OSA)** is diagnosed when oSDB is accompanied by abnormal polysomnography with an obstructive apnea-hypopnea index  $\geq 1$ . It is a disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnea) that disrupts normal ventilation during sleep and normal sleep patterns.<sup>5</sup>
- The term **caregiver** is used throughout the document to refer to parents, guardians, or other adults providing care to children under consideration for or undergoing tonsillectomy.

There have been changes in practice since the 2011 guideline (Table I) that include or were influenced by a reduction in the use of routine postoperative antibiotics,<sup>6</sup> as well as an Food and Drug Administration black box warning on the use of codeine in children posttonsillectomy.<sup>7</sup> Additionally, there have

been published guidelines on the diagnosis and treatment of OSA by the American Academy of Pediatrics,<sup>8</sup> the American Academy of Sleep Medicine,<sup>9</sup> and the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF).<sup>10</sup> The frequency of performing tonsillectomy in children—with the many issues in the diagnosis and perioperative management of children undergoing tonsillectomy, including significant practice variations in management—supports the need for an updated evidence-based clinical practice guideline to replace the previous guideline.

## Guideline Scope and Purpose

The purpose of this multidisciplinary updated guideline is to identify quality improvement opportunities in managing children undergoing tonsillectomy and to create clear and actionable recommendations to implement these opportunities in clinical practice. The target patient population for the guideline is any child aged 1 to 18 years that may be a candidate for tonsillectomy. The guideline does not apply to populations of children excluded from most tonsillectomy research studies, including those with neuromuscular disease, diabetes mellitus, chronic cardiopulmonary disease, congenital anomalies of the head and neck region, coagulopathies, or immunodeficiency.

This guideline predominantly addresses indications for tonsillectomy based on obstructive and infectious causes. The evidence that supports tonsillectomy for orthodontic concerns, dysphagia, dysphonia, secondary enuresis, tonsilliths, halitosis, and chronic tonsillitis is limited and generally of lesser quality, and a role for shared decision making is present. Equally, tonsillectomy is strongly indicated for posttransplant lymphoproliferative disorders or malignancy, but these indications are outside the scope of this document.

Although the development group recognizes that partial intracapsular tonsillectomy (also known as *tonsillotomy* or *intracapsular tonsillectomy*) is frequently performed, we decided not to include it in this guideline, because the evidence base is found predominantly for children undergoing complete tonsillectomy. Therefore, the group decided not to compare tonsillectomy and partial tonsillectomy outcomes; a separate commentary is being prepared to address this topic.<sup>11</sup>

This updated guideline is intended to focus on evidence-based 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 and to improve 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.

## Health Care Burden Incidence of Tonsillectomy

Tonsillectomy is the second-most common ambulatory surgical procedure performed on children in the United

**Table 1.** Changes to the Key Action Statements from the Original Guideline.

Original Guideline (2011)	Updated Guideline (2018)	Changes Made to Reflect Recent Literature
<p><b>STATEMENT 1. WATCHFUL WAITING FOR RECURRENT THROAT INFECTION:</b> 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. <u>Recommendation</u></p>	<p><b>STATEMENT 1. Watchful waiting for recurrent throat infection:</b> Clinicians should recommend watchful waiting for recurrent throat infection if there have been &lt;7 episodes in the past year, &lt;5 episodes per year in the past 2 years, or &lt;3 episodes per year in the past 3 years. <u>Strong recommendation</u></p>	Change to “Strong recommendation”
<p><b>STATEMENT 3. TONSILLECTOMY FOR RECURRENT INFECTION WITH MODIFYING FACTORS:</b> 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. <u>Recommendation</u></p>	<p><b>STATEMENT 3. Tonsillectomy for recurrent infection with modifying factors:</b> Clinicians should assess the child with recurrent throat infection who does not meet criteria in Key Action Statement 2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to multiple antibiotic allergies/intolerance, PFAPA (periodic fever, aphthous stomatitis, pharyngitis, and adenitis), or history of &gt;1 peritonsillar abscess. <u>Recommendation</u></p>	Change to “>1 peritonsillar abscess”
<p><b>STATEMENT 4. TONSILLECTOMY FOR SLEEP DISORDERED BREATHING:</b> 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. <u>Recommendation</u></p>	<p><b>STATEMENT 4. Tonsillectomy for obstructive sleep-disordered breathing:</b> Clinicians should ask caregivers of children with obstructive sleep-disordered breathing (oSDB) and tonsillar hypertrophy about comorbid conditions that may improve after tonsillectomy, including growth retardation, poor school performance, enuresis, asthma, and behavioral problems. <u>Recommendation</u></p>	Changed to obstructive sleep-disordered breathing throughout the document. “Asthma” added to the list of comorbid conditions
<p><b>STATEMENT 8. PERIOPERATIVE ANTIBIOTICS:</b> Clinicians should not routinely administer or prescribe perioperative antibiotics to children undergoing tonsillectomy. <u>Strong recommendation against</u></p>	<p><b>STATEMENT 10. Perioperative antibiotics:</b> Clinicians should <u>not</u> administer or prescribe perioperative antibiotics to children undergoing tonsillectomy. <u>Strong recommendation against</u></p>	The word “routinely” was removed
<p><b>STATEMENT 9. POSTOPERATIVE PAIN CONTROL:</b> The clinician should advocate for pain management after tonsillectomy and educate caregivers about the importance of managing and reassessing pain. <u>Recommendation</u></p>	<p><b>STATEMENT 9. Perioperative pain counseling:</b> The clinician should counsel patients and caregivers regarding the importance of managing posttonsillectomy pain as part of the perioperative education process and should reinforce this counseling at the time of surgery with reminders about the need to anticipate, reassess, and adequately treat pain after surgery. <u>Recommendation</u></p>	Updated statement emphasizes patient and/or caregiver counseling and education in the perioperative period

States.<sup>12</sup> In the most recent report, 289,000 ambulatory tonsillectomy procedures were performed in 2010 in children <15 years of age.<sup>1</sup> The only procedure with greater frequency was myringotomy with insertion of tubes, for which 699,000 procedures were reported the same year.<sup>1</sup>

Data in 1993 from the National Hospital Discharge Survey noted a decrease of >50% in inpatient tonsillectomy rates from 1977 to 1989.<sup>13</sup> Similar reports from 1978 to

1986 showed that the rate of tonsillectomy for treatment of throat infections declined; however, the frequency of oSDB as the primary indication for the procedure increased, especially in children <3 years of age.<sup>2,14</sup> A previous study reported that the overall incidence rates of tonsillectomy have significantly increased in the past 35 years, with oSDB being the primary indication for surgery in up to 67% of children.<sup>14-16</sup>

## Indications for Surgery

The 2 most common indications for tonsillectomy are recurrent throat infections and oSDB. Throat infections are a common reason to see a primary care provider and often result in antibiotic treatment.<sup>17</sup> The cost of outpatient visits and the medications prescribed for sore throats, including antibiotics, are substantial. Indirect costs associated with throat infections and oSDB are significant due to missed school and loss of time from work for caregivers.<sup>17,18</sup>

Treatment of oSDB is associated with an increase in health care utilization and cost. Children with oSDB, as 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>18</sup> Failure to thrive is reported in 27% to 62% of pediatric OSA cases.<sup>19</sup> Children with tonsillar disease, including those with throat infections and oSDB, also show significantly lower scores on several QoL subscales, including general health, physical functioning, behavior, bodily pain, and caregiver impact, when compared with healthy children.<sup>20</sup>

oSDB represents a spectrum of disorders ranging in severity from primary snoring to hypoventilation and OSA. The prevalence of OSA in children is 1.2% to 5.7%,<sup>21-23</sup> while as many as 10% of children have primary snoring.<sup>24</sup> Up to 40% of children with oSDB exhibit behavioral problems, including enuresis,<sup>25</sup> hyperactivity, aggression, anxiety, depression, and somatization.<sup>26</sup> OSA is also associated with poor school performance and a decrease in QoL.<sup>27</sup> The QoL of children with OSA is comparable to that of children with other chronic conditions, such as asthma and juvenile rheumatoid arthritis.<sup>28</sup>

Controversy persists regarding the actual benefits of tonsillectomy as compared with observation and medical treatment of throat infections. A comparative effectiveness review from the Agency for Healthcare Research and Quality reported that in children with recurrent throat infections undergoing tonsillectomy, the number of throat infections (moderate strength of evidence) and associated health care utilization and work/school absences (low strength of evidence) improved in the first postsurgical year. These benefits did not persist, and long-term results were lacking.<sup>29</sup>

Although tonsillectomy for recurrent throat infections in severely affected children was shown, in a randomized controlled trial,<sup>30</sup> to reduce the frequency and severity of infections in the 2 years following surgery, the same results did not apply to less severe cases or for >2 years after surgery.<sup>30,31</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>32</sup> These children suffered fewer infections after surgery, resulting in fewer antibiotics and physician visits. There is also generalized satisfaction with tonsillectomy in up to 92% of patients and their caregivers.<sup>33-35</sup>

Evidence supporting tonsillectomy as an effective treatment for oSDB<sup>36</sup> is based on tonsillar hypertrophy being the

principal cause of crowding of the oropharynx. A meta-analysis of case series<sup>37</sup> and another study<sup>38</sup> showed that tonsillectomy was effective at improving or resolving oSDB in the majority of children. The Childhood Adenotonsillectomy Trial (CHAT) study showed that, when compared with a strategy of watchful waiting, surgical treatment for OSA in school-age children did not significantly improve attention or executive function as measured by neuropsychological testing. Tonsillectomy did reduce symptoms and improve secondary outcomes of behavior, QoL, and polysomnographic findings versus 7 months of observation.<sup>39</sup> The Agency for Healthcare Research and Quality review also demonstrated that tonsillectomy can lead to short-term improvement in sleep outcomes as compared with no surgery in children with oSDB (moderate strength of evidence).<sup>29</sup> There is also evidence that behavioral parameters, school performance, and QoL improve after resolution of oSDB.<sup>27</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 bleeding (within 24 hours of surgery) has ranged from 0.2% to 2.2% and the rate of secondary bleeding (>24 hours after surgery), from 0.1% to 3%.<sup>3</sup> Bleeding after tonsillectomy may result in readmission for observation or further surgery to control bleeding.

Other complications of tonsillectomy are diverse and have been well described.<sup>4</sup> Operative complications include trauma to the teeth, larynx, pharyngeal wall (constrictor muscle or underlying arterial structures), or soft palate, as well as difficult intubation, laryngospasm, laryngeal edema, aspiration, respiratory compromise, endotracheal tube ignition, and cardiac arrest. Injury to nearby structures have been reported, including carotid artery injury, tongue swelling, altered taste, lip burn, eye injury, and fracture of the mandibular condyle. Postoperative complications include nausea, vomiting, pain and dehydration, referred otalgia, postobstructive pulmonary edema, velopharyngeal insufficiency, and nasopharyngeal stenosis. Complications are more common in children with craniofacial disorders, Down syndrome, cerebral palsy, neuromuscular diseases, major heart disease, or bleeding diatheses and children <3 years of age.<sup>40-44</sup>

After tonsillectomy, about 1.3% of patients experience delayed discharge of 4 to 24 hours during the initial hospital stay, and up to 3.9% have secondary complications requiring readmission.<sup>45</sup> The primary reasons for readmission or prolonged initial stay include pain, vomiting, fever, and tonsillar bleeding.

Current US reported mortality rates for tonsillectomy are 1 per 2360 and 1 per 18,000 in inpatient and ambulatory settings,<sup>46,47</sup> respectively, while the province of Ontario, Canada, reported a combined inpatient-outpatient setting

mortality rate of 1 per 56,000 for the years 2002 to 2013. A prospective audit reported only 1 postoperative death after 33,921 procedures in England and Northern Ireland.<sup>45</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>3,48</sup> Similarly, airway compromise is the major cause of death or major injury in malpractice claims after tonsillectomy.<sup>49</sup>

### Structure and Function of the Tonsils

The palatine tonsils are lymphoepithelial organs located at the junction of the oral cavity and 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 immunologic activity of the tonsils is found between the ages of 3 and 10 years.<sup>50</sup> As a result, the tonsils are most prominent during this period of childhood and subsequently demonstrate age-dependent involution.<sup>51</sup>

The epithelium of the tonsils is cryptic and reticulated and contains a system of specialized channels lined by “M” cells.<sup>52</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>52</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 (SIgA), 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>53</sup> This component is necessary for binding of IgA monomers to one another 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 recurrent tonsillitis, the controlled process of antigen transport and presentation is altered due to shedding of the M cells from the tonsil epithelium.<sup>52</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 immunologic 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 diseased tonsils. However, some studies demonstrate minor alterations of Ig concentrations in the serum and adjacent tissues following tonsillectomy.<sup>54-57</sup> Nevertheless, there are no studies to date that demonstrate a significant clinical impact of tonsillectomy on the immune system.<sup>58</sup>

## Methods

### General Methods

In the development of this update of the evidence-based clinical practice guideline, the methods outlined in the third edition of the AAO-HNSF’s guideline development manual were followed explicitly.<sup>59</sup>

A draft of the original “Tonsillectomy in Children” guideline<sup>60</sup> was sent to a panel of expert reviewers from the fields of nursing, infectious disease, consumers, family medicine, anesthesiology, sleep medicine, pediatrics, and otolaryngology–head and neck surgery. Several group members had significant prior experience in developing clinical practice guidelines. The reviewers concluded that the original guideline action statements remained valid but should be updated with major modifications. Suggestions were also made for new key action statements.

### Literature Search

An information specialist conducted 2 literature searches from January 2017 through February 2017 using a validated filter strategy to identify clinical practice guidelines, systematic reviews, and randomized controlled trials. The search terms used were as follows: (“Tonsillitis”[MeSH] OR “Palatine Tonsil”[MeSH] OR tonsil OR adenotonsil) AND (“Surgical Procedures, Operative”[Mesh] OR surg\*[tiab] OR excis\*[tiab] OR extract\*[tiab] OR remov\*[tiab])) OR (tonsillectom\* OR tonsillectomy\* OR adenotonsillectom\* OR adenotonsilectom\* OR tonsillotom\* OR tonsilotom\*) OR (tonsillectom\* OR tonsilectom\* OR adenotonsillectom\* OR adenotonsilectom\* OR tonsillotom\* OR tonsilotom\*) OR (“Tonsillectomy”[Mesh]) OR “Palatine Tonsil/surgery”[Mesh]. These search terms were used to capture all evidence on the population, incorporating all relevant treatments and outcomes.

The English-language searches were performed in multiple databases, including BIOSIS Previews, CAB Abstracts, AMED, EMBASE, PubMed Search, and CINAHL.

The initial English-language search identified 11 clinical practice guidelines, 71 systematic reviews, and 814 randomized controlled trials published in 2010 or later. Clinical practice guidelines were included if they met quality criteria of (1) an explicit scope and purpose, (2) multidisciplinary stakeholder involvement, (3) systematic literature review, (4) explicit system for ranking evidence, and (5) explicit system for linking evidence to recommendations. The final data set retained 4 guidelines that met inclusion criteria. Systematic reviews were emphasized and included if they met quality criteria of (1) clear objective and methodology,

(2) explicit search strategy, and (3) valid data extraction methods. Randomized controlled trials were included if they met the following quality criteria: (1) trials involved study randomization; (2) trials were described as double blind; or (3) trials denoted a clear description of withdrawals and dropouts of study participants. After removal of duplicates, irrelevant references, and non-English-language articles, 4 clinical practice guidelines, 30 systematic reviews, and 101 randomized controlled trials were retained prior to the update of the guideline. Additional evidence was identified, as needed, with targeted searches to support the needs of the guideline development group in updating sections of the guideline text from April 2017 through August 2017. Therefore, in total, the evidence supporting this guideline includes 1 new clinical practice guideline, 26 new systematic reviews, and 13 new randomized controlled trials. The recommendations in this clinical practice guideline are based on systematic reviews identified by a professional information specialist using an explicit search strategy. Additional background evidence included randomized controlled trials and observational studies, as needed, to supplement the systematic reviews or to fill gaps when a review was not available.

The AAO-HNSF assembled a guideline update group representing the disciplines of advanced practice nursing, consumers, family medicine, otolaryngology–head and neck surgery, pediatrics, anesthesiology, sleep medicine, and infectious disease. The group had several conference calls and 1 in-person meeting during which it defined the scope and objectives of updating the guideline, reviewed comments from the expert panel review for each key action statement, identified other quality improvement opportunities, reviewed the literature search results, and drafted the document.

The evidence profile for each statement in the earlier guideline was then converted into an expanded action statement profile for consistency with our current development standards.<sup>59</sup> Information was added to the action statement profiles regarding quality improvement opportunities, level of confidence in the evidence, differences of opinion, role of patient preferences, and any exclusion to which the action statement does not apply. New key action statements were developed with an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. Electronic decision support software (BRIDGE-Wiz; Yale Center for Medical Informatics, New Haven, Connecticut) was used to facilitate creating actionable recommendations and evidence profiles.<sup>61</sup>

The updated guideline then underwent guideline implementability appraisal to appraise adherence to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation.<sup>62</sup> The guideline update group received summary appraisals and modified an advanced draft of the guideline based on the appraisal. The final draft of the updated clinical practice guideline was revised per comments received during multidisciplinary peer review, open public comment, and journal

editorial peer review. 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 produce optimal health outcomes for patients, minimize harm, and reduce inappropriate variations in clinical care. The evidence-based approach to guideline development requires the evidence supporting that 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 are listed in **Table 2** and **Table 3**.<sup>63–65</sup>

Guidelines are not intended to supersede professional judgment but rather 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 what might be expected with a “recommendation.” “Options” offer the most opportunity for practice variability.<sup>65</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. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.<sup>65</sup> Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline panel sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the panel was to be transparent and 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 AAO-HNSF. Potential conflicts of interest for all panel members in the past 2 years were compiled and distributed before the first conference call. After review and discussion of these disclosures,<sup>66</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. Last, 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>67</sup>

### **Guideline Key Action Statements**

Each evidence-based statement is organized in a similar fashion: an evidence-based key action statement in bold,

**Table 2.** Aggregate Grades of Evidence by Question Type.<sup>a</sup>

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
A	1	Systematic review <sup>b</sup> of randomized trials	Systematic review <sup>b</sup> of randomized trials, nested case-control studies, or observational studies with dramatic effect	Systematic review <sup>b</sup> of cross-sectional studies with consistently applied reference standard and blinding	Systematic review <sup>b</sup> of inception cohort studies <sup>c</sup>
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies <sup>c</sup>
C	3-4	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a common harm; case series, case-control, or historically controlled studies	Nonconsecutive studies; case-control studies; or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study; control arm of a randomized trial; case series or case-control studies; or poor-quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles			
X		Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm			

Abbreviation: CEBM, Centre for Evidence-Based Medicine (Oxford).

<sup>a</sup>Adapted from Howick and coworkers.<sup>63</sup>

<sup>b</sup>A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

<sup>c</sup>A group of individuals identified for subsequent study at an early uniform point in the course of the specified health condition or before the condition develops.

followed by the strength of the recommendation in italics. Each key action statement is followed by the action statement profile, with quality improvement opportunities, aggregate evidence quality, level of confidence in the evidence, benefit-harm assessment, and statement of costs. Additionally, there is an explicit statement of any value judgments, the role of patient preferences, clarification of any intentional vagueness by the panel, exclusions to the statement, any differences of opinion, and a repeat statement of the strength of the recommendation. Several paragraphs subsequently discuss the evidence base supporting the statement. An overview of each evidence-based statement in this guideline can be found in **Table 4**.

For the purposes of this guideline, *shared decision making* refers to the exchange of information regarding treatment risks and benefits, as well as the expression of patient preferences and values, which result in mutual responsibility in decisions regarding treatment and care.<sup>68</sup> In cases where evidence is weak or benefits are unclear, the practice of shared decision making is extremely useful, wherein the management decision is made by a collaborative effort between the clinician and an informed patient.

Factors related to patient preference include, but are not limited to, absolute benefits (numbers needed to treat), adverse effects (number needed to harm), cost of medications or procedures, and frequency and duration of treatment.

### Key Action Statements

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

### Action Statement Profile 1

- **Quality improvement opportunity:** To avoid surgery and its potential complications for children who do not meet the criteria showing benefit in randomized



**Table 3.** Guideline Definitions for Evidence-Based Statements.

Strength	Definition	Implied Obligation
Strong recommendation	A strong recommendation means that the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B). <sup>a</sup> In some clearly identified circumstances, strong recommendations may be 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 that the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits) but the quality of evidence is not as high (grade B or C). <sup>a</sup> In some clearly identified circumstances, recommendations may be based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also 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 is suspect (grade D) <sup>a</sup> or 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.

<sup>a</sup>American Academy of Pediatrics' classification scheme.<sup>64</sup>

controlled trials (National Quality Strategy Domain: Patient Safety)

- Aggregate evidence quality: Grade A, systematic reviews of randomized controlled trials that fail to show clinically important advantages of surgery over observation alone (as stated in Statement 1); Grade C, observational studies showing improvement with watchful waiting
- Level of confidence in evidence: High
- Benefits: Avoid unnecessary surgery with potential complications of vomiting, bleeding, pain, infection, or anesthesia problems
- Risks, harms, costs: Waiting may result in delayed treatment in patients who have unusually frequent and severe recurrent throat infections; 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
- Intentional vagueness: None
- Role of patient preferences: None

- Exclusions: Patients with >1 peritonsillar abscess, personal or family history of rheumatic heart disease, Lemierre's syndrome, severe infections requiring hospitalization, or numerous repeat infections in a single household ("ping-pong spread")
- Policy level: Strong recommendation
- Differences of opinions: None

**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, 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 of the following: temperature >38.3°C (101°F), cervical adenopathy, tonsillar exudate, or positive test for group A beta-hemolytic streptococcus. *Option based on systematic reviews of randomized controlled trials, with a balance between benefit and harm.*

**Action Statement Profile 2**

- Quality improvement opportunity: (1) Reinforce the need for appropriate documentation of the frequency and clinical features of throat infection episodes to ensure clinical benefits consistent with

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

Statement	Action	Strength
1. Watchful waiting for recurrent throat infection	Clinicians should recommend watchful waiting for recurrent throat infection if there have been <7 episodes in the past year, <5 episodes per year in the past 2 years, or <3 episodes per year in the past 3 years.	Strong recommendation
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, 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 $\geq 1$ of the following: temperature $>38.3^{\circ}\text{C}$ ( $101^{\circ}\text{F}$ ), cervical adenopathy, tonsillar exudate, or positive test for group A beta-hemolytic streptococcus.	Option
3. Tonsillectomy for recurrent infection with modifying factors	Clinicians should assess the child with recurrent throat infection who does not meet criteria in Key Action Statement 2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to: multiple antibiotic allergies/intolerance, PFAPA (periodic fever, aphthous stomatitis, pharyngitis, and adenitis), or history of $>1$ peritonsillar abscess.	Recommendation
4. Tonsillectomy for obstructive sleep-disordered breathing	Clinicians should ask caregivers of children with obstructive sleep-disordered breathing (oSDB) and tonsillar hypertrophy about comorbid conditions that may improve after tonsillectomy, including growth retardation, poor school performance, enuresis, asthma, and behavioral problems.	Recommendation
5. Indications for polysomnography	Before performing tonsillectomy, the clinician should refer children with obstructive sleep-disordered breathing (oSDB) for polysomnography (PSG) if they are <2 years of age or if they exhibit any of the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses.	Recommendation
6. Additional recommendations for polysomnography	The clinician should advocate for polysomnography (PSG) prior to tonsillectomy for obstructive sleep-disordered breathing (oSDB) in children <u>without</u> any of the comorbidities listed in Key Action Statement 5 for whom the need for tonsillectomy is uncertain or when there is discordance between the physical examination and the reported severity of oSDB.	Recommendation
7. Tonsillectomy for obstructive sleep apnea	Clinicians should recommend tonsillectomy for children with obstructive sleep apnea (OSA) documented by overnight polysomnography (PSG).	Recommendation
8. Education regarding persistent or recurrent obstructive sleep-disordered breathing	Clinicians should counsel patients and caregivers and explain that obstructive sleep-disordered breathing (oSDB) may persist or recur after tonsillectomy and may require further management.	Recommendation
9. Perioperative pain counseling	The clinician should counsel patients and caregivers regarding the importance of managing posttonsillectomy pain as part of the perioperative education process and should reinforce this counseling at the time of surgery with reminders about the need to anticipate, reassess, and adequately treat pain after surgery.	Recommendation
10. Perioperative antibiotics	Clinicians should <u>not</u> administer or prescribe perioperative antibiotics to children undergoing tonsillectomy.	Strong recommendation against
11. Intraoperative steroids	Clinicians should administer a single intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy	Strong recommendation
12. Inpatient monitoring for children after tonsillectomy	Clinicians should arrange for overnight, inpatient monitoring of children after tonsillectomy if they are <3 years old or have severe obstructive sleep apnea (OSA; apnea-hypopnea index [AHI] $\geq 10$ obstructive events/hour, oxygen saturation nadir $<80\%$ , or both).	Recommendation

(continued)

**Table 4.** (continued)

Statement	Action	Strength
13. Postoperative ibuprofen and acetaminophen	Clinicians should recommend ibuprofen, acetaminophen, or both for pain control after tonsillectomy.	Strong recommendation
14. Postoperative codeine	Clinicians must <u>not</u> administer or prescribe codeine, or any medication containing codeine, after tonsillectomy in children younger than 12 years.	Strong recommendation against
15a. Outcome assessment for bleeding	Clinicians should follow up with patients and/or caregivers after tonsillectomy and document in the medical record the presence or absence of bleeding within 24 hours of surgery (primary bleeding) and bleeding occurring later than 24 hours after surgery (secondary bleeding).	Recommendation
15b. Posttonsillectomy bleeding rate	Clinicians should determine their rate of primary and secondary posttonsillectomy bleeding at least annually.	Recommendation

those achieved in randomized controlled trials. (2) Engage patients and families in shared decision making about tonsillectomy (National Quality Strategy Domains: Patient Safety, Effective Communication and Care Coordination)

- Aggregate evidence quality: Grade B, systematic review of randomized controlled trials with limitations in the consistency with the randomization process regarding recruitment and follow-up; some Grade C observational studies
- Level of confidence in evidence: Medium
- Benefits: Patients who proceed with the option of tonsillectomy will achieve a modest reduction in the frequency and severity of recurrent throat infection for 1 year after surgery and a modest reduction in frequency of group A streptococcal infection for 1 year after surgery
- Risks, harms, costs: Risk and morbidity of tonsillectomy, including but not limited to persistence of throat infection, pain and missed activity after surgery, bleeding, dehydration, injury, and anesthetic complications; direct cost of tonsillectomy, direct nonsurgical costs (antibiotics, clinician visit), and indirect costs (caregiver time, time missed from school) associated with recurrent infections
- 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
- Intentional vagueness: None
- Role of patient preferences: Large role for shared decision making, given favorable natural history of recurrent throat infections and modest short-term improvement associated with tonsillectomy

- Exclusions: None
- Policy level: Option
- Differences of opinions: There was near consensus among the guideline update group that tonsillectomy should be an option for children who meet the eligibility criteria in this statement, but 1 member of the group felt that tonsillectomy should not be recommended, even with appropriate documentation. Also, a minority of group members felt that the statement should list both tonsillectomy and watchful waiting as options for management, instead of just including tonsillectomy in the statement and discussing watchful waiting in the supporting text

### STATEMENT 3. TONSILLECTOMY FOR RECURRENT INFECTION WITH MODIFYING FACTORS:

Clinicians should assess the child with recurrent throat infection who does not meet criteria in Key Action Statement 2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to: multiple antibiotic allergies/intolerance, PFAPA (periodic fever, aphthous stomatitis, pharyngitis, and adenitis), or history of >1 peritonsillar abscess. *Recommendation based on randomized controlled trials and observational studies with a preponderance of benefit over harm.*

#### Action Statement Profile 3

- Quality improvement opportunity: To raise awareness about children with modifying factors who may still benefit from tonsillectomy, even though they do not meet the criteria in Statement 2 regarding documentation, frequency, or clinical features (National Quality Strategy Domains: Patient Safety, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade A, systematic review of randomized controlled trials with

limitations for PFAPA; Grade C, observational studies for all other factors

- Level of confidence in evidence: Medium
- Benefits: Identifying factors that might otherwise have been overlooked, which may influence the decision to perform tonsillectomy and ultimately improve patient outcomes
- Risks, harms, costs: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Intentional vagueness: This statement is not a recommendation for surgery but a prompt to discuss additional factors that may weigh into the decision to consider surgery
- Value judgments: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: None

#### STATEMENT 4. TONSILLECTOMY FOR OBSTRUCTIVE SLEEP-DISORDERED BREATHING:

Clinicians should ask caregivers of children with obstructive sleep-disordered breathing (oSDB) and tonsillar hypertrophy about comorbid conditions that may improve after tonsillectomy, including growth retardation, poor school performance, enuresis, asthma, and behavioral problems. *Recommendation based on randomized controlled trials, systematic reviews, and observational before-and-after studies with a preponderance of benefit over harm.*

##### Action Statement Profile 4

- Quality improvement opportunity: To raise awareness about conditions that may be overlooked when assessing children for tonsillectomy but should be included in the decision-making process because they could increase the likelihood that children might benefit from surgery (National Quality Strategy Domains: Patient Safety, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade B, randomized controlled trials, systematic reviews, and before-and-after observational studies
- Level of confidence in evidence: Medium
- Benefits: To improve decision making in children with oSDB by identifying comorbid conditions associated with oSDB, which might otherwise have been overlooked and may improve after tonsillectomy
- Risks, harms, costs: 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

oSDB, even though they may improve after intervention; consensus that substantial evidence supports inquiring about these conditions

- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: None

#### STATEMENT 5. INDICATIONS FOR POLYSOMNOGRAPHY:

Before performing tonsillectomy, the clinician should refer children with obstructive sleep-disordered breathing (oSDB) for polysomnography (PSG) if they are <2 years of age or if they exhibit any of the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses. *Recommendation based on observational studies with a preponderance of benefit over harm.*

##### Action Statement Profile 5

- Quality improvement opportunity: Increase use of PSG in children with risk factors placing them at high risk for severe obstructive sleep apnea (OSA) or for surgical complications related to their underlying conditions and OSA (National Quality Strategy Domains: Patient Safety, Person and Family Centered Care, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade B, observational studies with consistently applied reference standard; Grade A for the 1 systematic review of observational studies on obesity
- Level of confidence in evidence: High
- Benefits: PSG confirms indications and appropriateness of tonsillectomy, helps plan perioperative management, provides a baseline for postoperative PSG, and defines severity of OSA
- Risks, harms, and costs: Delay in treatment; procedural cost; indirect cost of missed work
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Knowledge gained through PSG can assist in diagnosing and quantifying OSA in high-risk children to stratify risk and determine the likelihood of persistent OSA after tonsillectomy
- Intentional vagueness: The panel decided to use the broad categories of neuromuscular disorders and craniofacial anomalies, rather than a comprehensive list of diseases and syndromes, to emphasize the need for individualized assessment
- Role of patient preferences: High for obesity; moderate for Down syndrome
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: None

**STATEMENT 6. ADDITIONAL RECOMMENDATIONS FOR POLYSOMNOGRAPHY:** The clinician should advocate for polysomnography (PSG) prior to tonsillectomy for obstructive sleep-disordered breathing (oSDB) in children without any of the comorbidities listed in Key Action Statement 5 for whom the need for tonsillectomy is uncertain or when there is discordance between the physical examination and the reported severity of oSDB. *Recommendation based on observational and case-control studies with a preponderance of benefit over harm.*

#### Action Statement Profile 6

- Quality improvement opportunity: Promote appropriate use of PSG for children with oSDB without the high-risk factors noted in Key Action Statement 5 but for whom there is uncertainty about the need for tonsillectomy that could be reduced through more objective data obtained from PSG (National Quality Strategy Domains: Patient Safety, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade B, a randomized controlled trial, observational and case-control studies
- Level of confidence in evidence: Medium; the role of PSG in evaluating children with oSDB is well documented, but the specific role in the children specified here is less certain
- Benefits: Selection of appropriate candidates for tonsillectomy and avoidance of surgery for those where it is not indicated
- Risks, harms, costs: Delay in treatment; procedural cost; indirect cost of missed work
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Based on expert consensus, there are circumstances in which PSG will improve diagnostic certainty and help inform surgical decisions
- Intentional vagueness: The panel decided to “advocate for” PSG rather than to “recommend” PSG in these circumstances to avoid setting a legal standard for care and to recognize the role for individualized decisions based on needs of the child and caregiver(s). Furthermore, the word “uncertain” is used in the statement to encompass a variety of circumstances regarding the need for tonsillectomy that include, but are not limited to, disagreement among clinicians or caregivers, questions about the severity of oSDB or validity of the oSDB diagnosis, or any other situation where the additional information provided by PSG would facilitate shared decisions
- Role of patient preferences: None for advocating; high for deciding whether or not to proceed with PSG
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: None

**STATEMENT 7. TONSILLECTOMY FOR OBSTRUCTIVE SLEEP APNEA:** Clinicians should recommend tonsillectomy for children with obstructive sleep apnea (OSA) documented by overnight polysomnography (PSG). *Recommendation based on randomized controlled trial and observational before-and-after studies with a preponderance of benefit over harm.*

#### Action Statement Profile 7

- Quality improvement opportunity: Promote appropriate use of tonsillectomy for children with documented OSA; reduce morbidity from OSA in children by encouraging timely and effective intervention (National Quality Strategy Domains: Patient Safety, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade B, randomized controlled trial, observational before-and-after studies, and meta-analysis of observational studies showing substantial reduction in the prevalence of sleep-disordered breathing and abnormal PSG after tonsillectomy
- Level of confidence in evidence: Medium
- Benefits: Improved caregiver awareness of how tonsillectomy may benefit children when they have OSA; prevention or improvement of comorbid conditions
- Risks, harms, costs: Costs and risks of tonsillectomy
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Although PSG results are not the only factor used in assessing OSA presence or severity and may not correlate with clinical symptoms, PSG is still the most objective study for diagnosis. Consensus by the development group that children with untreated OSA are at risk for future morbidity or impaired health status
- Intentional vagueness: The diagnostic criteria and definitions of severity for OSA are not specified, recognizing that there is variability among sleep laboratories and clinicians, with a broad range of values that may not correlate with surgical outcomes
- Role of patient preferences: Moderate
- Exclusions: Children who are high-risk surgical candidates, have significant comorbidities, or are interested in nonsurgical options
- Policy level: Recommendation
- Differences of opinions: None

**STATEMENT 8. EDUCATION REGARDING PERSISTENT OR RECURRENT OBSTRUCTIVE SLEEP-DISORDERED BREATHING:** Clinicians should counsel patients and caregivers and explain that obstructive

sleep-disordered breathing (oSDB) may persist or recur after tonsillectomy and may require further management. *Recommendation based on a randomized controlled trial and observational studies, case-control and cohort design, with a preponderance of benefit over harm.*

### Action Statement Profile 8

- Quality improvement opportunity: Increase awareness of possible residual oSDB after tonsillectomy (National Quality Strategy Domains: Person and Family Centered Care, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade B, randomized controlled trial, systematic reviews, and before-and-after observational studies
- Level of confidence in evidence: High
- Benefits: Improve patient expectations through education
- Risks, harms, costs: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception of inadequate counseling by clinicians and underappreciation that oSDB may persist or recur despite tonsillectomy
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: None

**STATEMENT 9. PERIOPERATIVE PAIN COUNSELING:** The clinician should counsel patients and caregivers regarding the importance of managing posttonsillectomy pain as part of the perioperative education process and should reinforce this counseling at the time of surgery with reminders about the need to anticipate, reassess, and adequately treat pain after surgery. *Recommendation based on randomized controlled trials with limitations and observational studies with a preponderance of benefit over harm.*

### Action Statement Profile 9

- Quality improvement opportunity: Raise awareness about the need to anticipate and manage pain after tonsillectomy and to provide patients and caregivers with effective strategies for preventing and treating pain (National Quality Strategy Domains: Person and Family Centered Care, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade B, randomized controlled trials and observational studies
- Level of confidence in evidence: Medium
- Benefits: Pain relief, improved and faster recovery; avoidance of complications from dehydration, inadequate food intake
- Risks, harms, costs: None

- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception by the panel that pain control is often underemphasized and inadequately discussed before and after tonsillectomy; importance of engaging the patient and caregiver and providing education about pain management and reassessment, which may result in increased patient and caregiver satisfaction
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: None

**STATEMENT 10. PERIOPERATIVE ANTIBIOTICS:** Clinicians should not 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.*

### Action Statement Profile 10

- Quality improvement opportunity: Reduce inappropriate use of perioperative (pre-, intra-, or post-operative) antibiotics for children undergoing tonsillectomy who have no other indication for antibiotic therapy (National Quality Strategy Domains: Patient Safety, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade A, randomized controlled trials and systematic reviews, showing no benefit in using perioperative antibiotics to reduce posttonsillectomy morbidity
- Level of confidence in evidence: High
- Benefits: Avoidance of adverse events related to antimicrobial therapy, including rash, allergy, gastrointestinal upset, and induced bacterial resistance
- Risks, harms, costs: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: The guideline update group felt that there remains a significant gap in care for this recommendation, despite reduced use of perioperative antibiotics after the original publication of this guideline recommendation in 2011. Antibiotic therapy is not recommended given the lack of demonstrable benefits in randomized controlled trials plus the well-documented potential adverse events and cost of therapy
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: Patients with cardiac conditions requiring perioperative antibiotics for prophylaxis; patients undergoing tonsillectomy with concurrent peritonsillar abscess

- Policy level: Strong recommendation against
- Differences of opinions: None

#### STATEMENT 11. 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.*

##### Action Statement Profile 11

- Quality improvement opportunity: Promote appropriate use of intraoperative steroids as a safe and effective intervention to improve recovery after tonsillectomy (National Quality Strategy Domains: Patient Safety, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade A, randomized controlled trials and multiple systematic reviews, for preventing postoperative nausea and vomiting (PONV); Grade A, randomized controlled trials and systematic review for decreased pain and shorter times to oral intake
- Level of confidence in evidence: High
- Benefits: Decreased incidence of PONV up to 24 hours posttonsillectomy, decreased time to first oral intake, and decreased pain as measured by lower pain scores and longer latency times to analgesic administration
- Risks, harms, costs: No adverse events in all randomized controlled trials; direct cost of medication
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Decreased PONV and postoperative pain likely to result in increased patient and caregiver satisfaction; decreased incidence of overnight hospital admission associated with lower total health care costs as compared with costs of medication administration
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: Patients in whom steroids are contraindicated
- Policy level: Strong recommendation
- Differences of opinions: none

#### STATEMENT 12. INPATIENT MONITORING FOR CHILDREN AFTER TONSILLECTOMY:

Clinicians should arrange for overnight, inpatient monitoring of children after tonsillectomy if they are <3 years old or have severe obstructive sleep apnea (OSA; apnea-hypopnea index [AHI]  $\geq 10$  obstructive events/hour, oxygen saturation nadir <80%, or both). *Recommendation based on observational studies with a preponderance of benefit over harm.*

#### Action Statement Profile 12

- Quality improvement opportunity: Facilitate early detection and management of oxygen desaturation, airway compromise, or other adverse events after tonsillectomy in patients who are more likely to have them based on young age, OSA severity, or both (National Quality Strategy Domains: Patient Safety, Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade B, observational studies on age, meta-analysis of observational studies regarding complications
- Level of confidence in evidence: Medium
- Benefits: Improve patient safety and patient satisfaction after tonsillectomy that would allow prompt detection and management of respiratory complications among high-risk children
- Risks, harms, costs: Unnecessary admission of children who are at low risk for respiratory complications, occupying a hospital bed in limited resource settings, risk of iatrogenic injury, cost of hospital care
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Despite the lack of consistent data on what constitutes severe OSA on polysomnography or appropriate age for admission, the panel decided that some criteria, based on consensus, should be provided to guide clinical decisions; perception by the panel that inpatient monitoring after tonsillectomy is underutilized for children with severe OSA or age <3 years
- Intentional vagueness: None
- Role of patient preferences: Low
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: There was a difference of opinion regarding the definition of severe OSA by 2 panel members who felt that there is a lack of expert consensus regarding the AHI cutoff (10 vs a higher AHI) and that additional sleep study parameters may be useful to define severe OSA

#### STATEMENT 13. POSTOPERATIVE IBUPROFEN AND ACETAMINOPHEN:

Clinicians should recommend ibuprofen, acetaminophen, or both for pain control after tonsillectomy. *Strong recommendation based on systematic review and randomized controlled trials with a preponderance of benefit over harm.*

##### Action Statement Profile 13

- Quality improvement opportunity: Promote awareness that ibuprofen is a safe and effective analgesic for use after tonsillectomy, when used alone or in combination with acetaminophen (National Quality

Strategy Domains: Patient Safety, Effective Communication and Care Coordination)

- **Aggregate evidence quality:** A; based on systematic review and randomized controlled trials
- **Level of confidence in evidence:** High
- **Benefits:** To ensure adequate pain control, to potentially avoid the use of opioids for pain control, to make it clear that it is safe and appropriate to administer ibuprofen after tonsillectomy
- **Risks, harms, costs:** Direct cost of the medication, adverse events related to these medications, possible inadequate pain control
- **Benefits-harm assessment:** Preponderance of benefit
- **Value judgments:** Despite systematic reviews showing the safety of ibuprofen after tonsillectomy, some providers are not using ibuprofen for pain control after tonsillectomy because of perceived concerns regarding increased postoperative bleeding
- **Intentional vagueness:** None
- **Role of patient preferences:** Medium
- **Exclusions:** Children with contraindications to these medications
- **Policy level:** Strong recommendation
- **Differences of opinions:** None

#### STATEMENT 14. POSTOPERATIVE CODEINE:

Clinicians must not administer or prescribe codeine, or any medication containing codeine, after tonsillectomy in children younger than 12 years. *Strong recommendation against administering or prescribing based on observational studies with dramatic effect and supporting high-level pharmacogenetic studies with a preponderance of benefit over harm.*

#### Action Statement Profile 14

- **Quality improvement opportunity:** Reduce harmful therapy (National Quality Strategy Domains: Patient Safety, Effective Communication and Care Coordination)
- **Aggregate evidence quality:** Grade B, based on observational studies with dramatic effect and supporting high-level pharmacogenetic studies
- **Level of confidence in evidence:** High
- **Benefits:** Avoiding severe or life-threatening complications in children who are ultra-rapid metabolizers of codeine who might be first exposed to this medication after tonsillectomy
- **Risks, harms, costs:** There is a potential for inadequate pain control if alternative appropriate medications are not recommended
- **Benefits-harm assessment:** Preponderance of benefit
- **Value judgments:** None
- **Intentional vagueness:** None
- **Role of patient preferences:** None
- **Exclusions:** None
- **Policy level:** Strong recommendation against

- **Differences of opinions:** The majority of the panel supported this statement as written, but 5 members favored expanding the age limit to 18 years because codeine can cause significant harm to children at all ages and safer alternatives exist

#### STATEMENT 15A. OUTCOME ASSESSMENT FOR BLEEDING:

Clinicians should follow up with patients and/or caregivers after tonsillectomy and document in the medical record the presence or absence of bleeding within 24 hours of surgery (primary bleeding) and bleeding occurring later than 24 hours after surgery (secondary bleeding). *Recommendation based on observational studies with a preponderance of benefit over harm.*

#### STATEMENT 15B. POSTTONSILLECTOMY BLEEDING RATE:

Clinicians should determine their rate of primary and secondary posttonsillectomy bleeding at least annually. *Recommendation based on observational studies with a preponderance of benefit over harm.*

#### Action Statement Profile 15A and 15B

- **Quality improvement opportunity:** Encourage clinicians to systematically obtain follow-up data regarding bleeding for their tonsillectomy patients and to facilitate calculation of clinician-specific bleeding rates for comparison with national benchmarks (National Quality Strategy Domains: Patient Safety, Person and Family Centered Care, Effective Communication and Care Coordination)
- **Aggregate evidence quality:** Grade C, observational studies and large-scale audit showing variability in postoperative bleeding rates and some association with surgical technique; Grade C, observational studies showing bleeding as a consistent sequela of tonsillectomy with heterogeneity among studies and providers
- **Level of confidence in evidence:** High for tonsillectomy bleeding as a complication for tonsillectomy; medium for bleeding rates because of concerns regarding the accuracy and consistency of reporting
- **Benefits:** Improve self-awareness of outcomes for the surgeon and improve the confidence of patients and referring physicians, the ability to compare personal outcomes with national metrics, encourage quality improvement efforts
- **Risks, harms, costs:** Administrative burden
- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Perceived heterogeneity among clinicians regarding knowledge of their own bleeding rates after tonsillectomy; potential for clinicians to reassess their process of care and improve quality
- **Intentional vagueness:** Specifics of how to determine the bleeding rate are left to the clinician; the process of follow-up is at the discretion of



the clinician but should include a good-faith effort to contact the patient through some form of communication

- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: The majority of the panel supported this statement as written, but 2 members of the group were concerned that the need to contact every patient could be difficult and may not be feasible in every practice setting

## Disclaimer

This clinical practice guideline is not intended as an exhaustive source of guidance for managing tonsillectomy in children. 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 diagnosing and managing this program of care. As medical knowledge expands, and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates. These do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The AAO-HNSF emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care, or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

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