

Clinical Practice Guideline: Tonsillectomy in Children (Update)

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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

Otolaryngology–
 Head and Neck Surgery
 2019, Vol. 160(1S) S1–S42
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 Surgery Foundation 2018
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sagepub.com/journalsPermissions.nav
 DOI: 10.1177/0194599818801757
<http://otojournal.org>



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 oSDB. (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 ≥ 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 ≥ 1 of the following: temperature $> 38.3^\circ\text{C}$ (101°F), cervical adenopathy, tonsillar exudate, or positive test for group A beta-hemolytic streptococcus.

Differences from Prior Guideline

- (1) 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.
- (2) There were 1 new clinical practice guideline, 26 new systematic reviews, and 13 new randomized controlled trials included in the current guideline update.
- (3) Inclusion of 2 consumer advocates on the guideline update group.
- (4) 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).
- (5) 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).
- (6) Addition of an algorithm outlining KASs.
- (7) Enhanced emphasis on patient and/or caregiver education and shared decision making.

Keywords

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

Received June 26, 2018; revised August 13, 2018; accepted August 30, 2018.

Tonsillectomy 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.¹ Indications for surgery include recurrent throat infections and obstructive sleep-disordered breathing (oSDB),² 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.^{3,4} 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 an abnormal polysomnography (PSG) with an obstructive apnea-hypopnea index (AHI) ≥ 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.⁵
- 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 1**) that include or were influenced by a reduction in the use of routine postoperative antibiotics⁶ as well as a Food and Drug Administration (FDA) black box warning on the use of codeine in children posttonsillectomy.⁷

Additionally, there have been published guidelines on the diagnosis and treatment of OSA by the American Academy of Pediatrics,⁸ the American Academy of Sleep Medicine,⁹ and the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF).¹⁰ 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 1 to 18 years of age who 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 tonsillotomomy or intracapsular tonsillectomy) is frequently performed, we decided not to include it in this guideline because the evidence base is found predominantly in 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.¹¹

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>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. <u>Recommendation</u></p> | <p>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. <u>Strong recommendation</u></p> | Change to “Strong recommendation” |
| <p>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. <u>Recommendation</u></p> | <p>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. <u>Recommendation</u></p> | Change to “>1 peritonsillar abscess” |
| <p>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. <u>Recommendation</u></p> | <p>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. <u>Recommendation</u></p> | Changed to obstructive sleep-disordered breathing throughout the document. “Asthma” added to the list of comorbid conditions |
| <p>STATEMENT 8. PERIOPERATIVE ANTIBIOTICS: Clinicians should not routinely administer or prescribe perioperative antibiotics to children undergoing tonsillectomy. <u>Strong recommendation against</u></p> | <p>STATEMENT 10. Perioperative antibiotics: 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>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. <u>Recommendation</u></p> | <p>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. <u>Recommendation</u></p> | Updated statement emphasizes patient and/or caregiver counseling and education in the perioperative period |

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

Data in 1993 from the National Hospital Discharge Survey noted a decrease >50% in inpatient tonsillectomy rates from 1977 to 1989.¹³ 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.^{2,14} 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.¹⁴⁻¹⁶

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.¹⁷ 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, for caregivers, loss of time from work.^{17,18}

Treatment of oSDB is associated with an increase in health care utilization and cost. Children with oSDB versus 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.¹⁸ Failure to thrive is reported in 27% to 62% of pediatric OSA cases.¹⁹ Children with tonsillar disease, including children 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.²⁰

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%,²¹⁻²³ while as many as 10% of children have primary snoring.²⁴ Up to 40% of children with oSDB exhibit behavioral problems that include enuresis,²⁵ hyperactivity, aggression, anxiety, depression, and somatization.²⁶ OSA is also associated with poor school performance and a decrease in QoL.²⁷ The QoL of children with OSA is comparable to that of children with other chronic conditions, such as asthma and juvenile rheumatoid arthritis.²⁸

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 (AHRQ) 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.²⁹

Although tonsillectomy for recurrent throat infections in severely affected children was shown, in a randomized controlled trial,³⁰ 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.^{30,31} Observational studies, however, showed improved disease-specific and global QoL after tonsillectomy for recurrent or chronic sore throat, as measured by validated instruments.³² 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.³³⁻³⁵

Evidence supporting tonsillectomy as an effective treatment for oSDB³⁶ is based on tonsillar hypertrophy being the principal cause of crowding of the oropharynx. A

meta-analysis of case series³⁷ and another study³⁸ showed that tonsillectomy was effective at improving or resolving oSDB in the majority of children. The Childhood Adenotonsillectomy Trial (CHAT) showed that, as compared with a strategy of watchful waiting, surgical treatment for OSA in school-aged 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 as compared with 7 months of observation.³⁹ The AHRQ review also demonstrated that tonsillectomy can lead to short-term improvement in sleep outcomes when compared with no surgery in children with oSDB (moderate strength of evidence).²⁹ There is also evidence that behavioral parameters, school performance, and QoL improve after resolution of oSDB.²⁷

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%.³ Bleeding 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.⁴ 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, 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 in children <3 years of age.⁴⁰⁻⁴⁴

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.⁴⁵ 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, respectively,^{46,47} 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.⁴⁵ About one-third of deaths are attributable to bleeding, while the remainder are related to aspiration, cardiopulmonary failure, electrolyte imbalance, or anesthetic complications.^{3,48} Similarly, airway compromise is the major cause of death or major injury in malpractice claims after tonsillectomy.⁴⁹

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.⁵⁰ As a result, the tonsils are most prominent during this period of childhood and subsequently demonstrate age-dependent involution.⁵¹

The epithelium of the tonsils is cryptic and reticulated and contains a system of specialized channels lined by “M” cells.⁵² 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.⁵²

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.⁵³ 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.⁵² 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

demonstrated minor alterations of Ig concentrations in the serum and adjacent tissues following tonsillectomy.^{54–57} Nevertheless, there are no studies to date that demonstrate a significant clinical impact of tonsillectomy on the immune system.⁵⁸

Methods

General Methods

In developing this update of the evidence-based clinical practice guideline, the methods outlined in the AAO-HNSF’s “Clinical Practice Guideline Development Manual, Third Edition” were followed explicitly.⁵⁹

A draft of the original “Tonsillectomy in Children” guideline⁶⁰ 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 the Cumulative Index to Nursing and Allied Health Literature.

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.⁵⁹ 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.⁶¹

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.⁶² 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 on the basis of 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, to minimize harm, and to reduce inappropriate variations in clinical care. 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 are listed in **Tables 2** and **3**.⁶³⁻⁶⁵

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 might be expected with a “recommendation.” “Options” offer the most opportunity for practice variability.⁶⁵ 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.⁶⁵ 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,⁶⁶ 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 participants’ previously established “stake” in an issue.⁶⁷

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.^a

| Grade | CEBM Level | Treatment | Harm | Diagnosis | Prognosis |
|-------|------------|---|--|---|---|
| A | 1 | Systematic review ^b of randomized trials | Systematic review ^b of randomized trials, nested case-control studies, or observational studies with dramatic effect | Systematic review ^b of cross-sectional studies with consistently applied reference standard and blinding | Systematic review ^b of inception cohort studies ^c |
| 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 ^c |
| 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).

^aAdapted from Howick and coworkers.⁶³

^bA systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

^cA 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.⁶⁸ 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). ^a 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). ^a 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) ^a or well-done studies (grade A, B, or C) ^a 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. |

^aAmerican Academy of Pediatrics' classification scheme.⁶⁴

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

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 without tonsillectomy. Watchful waiting does not imply inaction. Rather, patients should be closely monitored by regular clinic visits 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. The clinical characteristics of each episode should be recorded, including the symptoms, physical findings, rapid antigen detection testing, and/or 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.

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 ≥ 1 of the following: temperature $>38.3^{\circ}\text{C}$ (101°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] ≥ 10 obstructive events/hour, oxygen saturation nadir $<80\%$, or both). | Recommendation |

(continued)

Table 4. (continued)

| Statement | Action | Strength |
|---|---|-------------------------------|
| I3. Postoperative ibuprofen and acetaminophen | Clinicians should recommend ibuprofen, acetaminophen, or both for pain control after tonsillectomy. | Strong recommendation |
| I4. 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 |
| I5a. 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 |
| I5b. Posttonsillectomy bleeding rate | Clinicians should determine their rate of primary and secondary posttonsillectomy bleeding at least annually. | Recommendation |

While tonsillectomy can reduce the recurrence rate of sore throat, missed school days, and health care utilization, this effect does not extend beyond the first year postoperatively, and benefits are significantly lessened for children with a mild disease burden.²⁹ QoL outcomes improve with time regardless of surgery.⁶⁹ Less affected children also experienced increased episodes of moderate to severe sore throat after surgery as compared with controls.⁷⁰ As a result of these findings, tonsillectomy is not cost-effective and does not provide clinically meaningful improvements in children who do not meet the “Paradise criteria” (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).

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 that 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).

History <12 Months. There are currently no randomized controlled trials investigating the efficacy of tonsillectomy for patients experiencing recurrent tonsillitis over a period <12 months. Randomized controlled trials assessing the efficacy of tonsillectomy differ in study entry requirements (ie, the frequency and severity of recurrent pharyngotonsillitis), but all required a minimum number of sore throats in the preceding 12 months.⁷⁰ For example, in the study by Paradise et al,³⁰ 62 (33%) of the 187 children who satisfied the Paradise criteria had ≥ 7 throat infections in the preceding 12 months. It is possible that all the reported infections occurred in a period shorter than 12 months, but these data were not reported. Furthermore, 1 study⁷¹ 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 may reasonably be considered for the procedure under the following circumstances: a history of recurrent severe infections requiring hospitalization; complications of infection, such as ≥ 2 peritonsillar abscesses or Lemierre’s syndrome (thrombophlebitis of the internal jugular vein); a personal or family history of rheumatic heart disease; or numerous repeat infections in a single household (“ping-pong spread”). However, caregivers should be educated on the likelihood of spontaneous improvement and the modest magnitude of benefit conferred by tonsillectomy for 12 months after surgery.

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 $>38.3^{\circ}\text{C}$ (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 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.

Supporting Text

The purpose of this statement is to ensure that patients with recurrent throat infection who are candidates for tonsillectomy have a severity of illness (**Table 5**) consistent with

descriptions of disease found in well-designed clinical trials. The preponderance of evidence suggests that in the most severely and frequently affected children, tonsillectomy results in a modest degree of improvement only in the first year after tonsillectomy, with little or no difference in QoL when compared with those treated with watchful waiting.⁶⁹

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 on the referring clinician to accurately describe individual episodes of throat infection and to document the frequency of these events. Supportive documentation in children who meet criteria for tonsillectomy may include absences from school, spread of infection within the family, and a family history of rheumatic heart disease or poststreptococcal glomerulonephritis.

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. In children with recurrent sore throat whose throat swabs for GABHS are repeatedly positive, it is desirable to rule out streptococcal carriage with concurrent viral infections, as carriers are unlikely to transmit GABHS or develop suppurative complications or nonsuppurative sequelae such as acute rheumatic fever.^{69,72,73} In practice, streptococcal carriage is strongly suggested by positive strep cultures or other strep tests when the child lacks signs or symptoms of acute pharyngitis.

Efficacy and Effectiveness of Tonsillectomy for Recurrent Throat Infection. Studies^{74,75} suggest a modest but statistically significant reduction in frequency of throat infection among severely affected patients undergoing tonsillectomy for 1 year but no longer.³¹

In the most frequently cited and most meticulous trial, Paradise and colleagues³⁰ included patients only if their episodes of throat infection met the strict criteria outlined in **Table 5**, including contemporaneous clinical documentation of each episode. The following study results were obtained, which reflect in part the natural history of recurrent pharyngitis in that fewer episodes occur in subsequent years with watchful waiting:

- 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. In the control group without tonsillectomy, patients also experienced a mean rate reduction of 0.5 to 1 episodes per year as compared with their preenrollment frequency of infection.
- For episodes of moderate or severe throat infection, the control group experienced 1.2 episodes in the first year versus 0.1 in the surgical group. The rate

Table 5. Paradise Criteria for Tonsillectomy.³⁰

| Criterion | Definition |
|---|---|
| Minimum frequency of sore throat episodes | <ul style="list-style-type: none"> • Seven or more episodes in the preceding year, OR • Five or more episodes in each of the preceding 2 y, OR • Three or more episodes in each of the preceding 3 y |
| Clinical features ^a | <ul style="list-style-type: none"> • Temperature >38.3°C (>101°F), 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 | <ul style="list-style-type: none"> • 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^b |

^aSore throat plus the presence of ≥ 1 qualifies as a counting episode.

^bThis 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.

reductions diminished over the subsequent 2 years of follow-up.

- Mean days with sore throat in the first 12 months were not statistically different between the tonsillectomy and watchful waiting groups.

A Cochrane review on the efficacy of tonsillectomy for recurrent tonsillitis also concluded that cases may resolve without surgery and that, after the first year, there were no or minimal differences between groups.⁷⁰ A systematic review confirming earlier work⁷⁶ reported that in all studies, the control group showed a spontaneous reduction of rates of recurrent infection.⁷⁷ A systematic review commissioned by the AHRQ reached essentially identical conclusions—that benefits of tonsillectomy did not persist over time and that strength of evidence for differences was low for short- and long-term missed school days and low for QoL differences.⁶⁹ Multiple case series provide further evidence about the favorable natural history of recurrent pharyngotonsillitis. These studies demonstrated that a significant proportion of children awaiting tonsillectomy no longer met criteria for surgery⁷⁸⁻⁸⁰ or had fewer episodes of tonsillitis in the months preceding surgery.^{81,82}

Balance of Benefit vs Harm for Tonsillectomy in Severe Recurrent Throat Infection. Caregivers and patients who meet the appropriate criteria for tonsillectomy as described here should be advised of only modest anticipated benefits of tonsillectomy, as weighed against the natural history of resolution with watchful waiting, as well as the risk of surgical morbidity and complications and the unknown risk of general anesthesia exposure in children <4 years of age.⁸³ In considering the potential harms, the guideline panel agreed that there was not a clear preponderance of benefit over harm for tonsillectomy, even for children meeting the Paradise criteria.³⁰ Instead, the group felt there to be a balance that

allows either tonsillectomy or watchful waiting as an appropriate management option for these children and 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 that there is a substantial role for shared decision making with the child's caregiver and primary care clinician.

Limitations of the available randomized controlled trials must also be considered when assessing the benefits and harms of surgery. Paradise and colleagues³⁰ 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 next study by these investigators,³¹ wherein 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, as the same conclusion was reached in a Cochrane review⁷⁵ and in the AHRQ review.⁶⁹ However, the panel did downgrade the aggregate evidence level from A (randomized trials) to B (randomized trials with limitations).

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

Supporting Text

The purpose of this statement is to encourage discussion and shared decision making between providers and caregivers regarding the modifying factors that may ultimately favor tonsillectomy, separate from consideration focused solely on the frequency of recurrent tonsillitis. Such conditions may be especially important in situations for which, in general, the benefits and risks of surgery are closely matched but compelling individual features (eg, 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**).³⁰ 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 poorly

tolerated by the child, if the child has extensive medication 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 <5 years of age. The illness does not usually last >5 days; it recurs at regular intervals of 3 to 6 weeks (ie, at least 3 documented episodes); and it is characterized by the sudden onset of fever, pharyngitis plus tender cervical lymphadenopathy or aphthous ulcers.⁸⁴ While the use of steroids usually leads to prompt termination of an episode, the interval between episodes shortens.⁸⁴ 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.^{85,86} In 2014, a Cochrane review compared these articles, being the only 2 randomly controlled trials applicable, and found a significant beneficial effect of tonsillectomy versus no surgery on both immediate and complete symptom resolution (number needed to treat to benefit = 2) and a substantial reduction in the frequency and severity (length of episode) of any further symptoms experienced.⁸⁷ Tonsillectomy may be considered per the frequency of illness, the 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 history of peritonsillar abscess.⁸⁸ When peritonsillar abscess is treated with needle aspiration or incision and drainage, the need for subsequent tonsillectomy is about 10% to 20%.^{89,90} This rate may not merit routine tonsillectomy unless a patient also has a history of frequent prior throat infections, especially when culture positive for GABHS. Some authors advocate "quinsy" tonsillectomy, which is performed in the setting of an active peritonsillar abscess, especially if general anesthesia is required for drainage (eg, uncooperative child) and there is a history of tonsil disease.⁹⁰

Tonsillectomy has been considered for treating pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS), but evidence is anecdotal and the entity poorly understood.⁹¹ A recent systematic review found no recommendations either for or against performing tonsillectomy specifically to treat PANDAS.⁹²

The last category contains a series of poorly validated indications for tonsillectomy that have not been tested in any controlled trials or case series: chronic tonsillitis, febrile seizures, muffled ("hot potato") speech, halitosis, malocclusion of teeth, tonsillar hypertrophy, cryptic tonsils, and chronic pharyngeal carriage of GABHS. There is a substantial role for shared decision making with caregivers when considering tonsillectomy for ≥ 1 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.

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

Supporting Text

The purpose of this statement is to (1) help clinicians and caregivers make informed decisions about tonsillectomy in children with clinically diagnosed oSDB and (2) highlight the importance of eliciting a history about modifying factors that affect the decision to proceed with surgery.

oSDB is characterized by recurrent partial or complete upper airway obstruction during sleep, resulting in

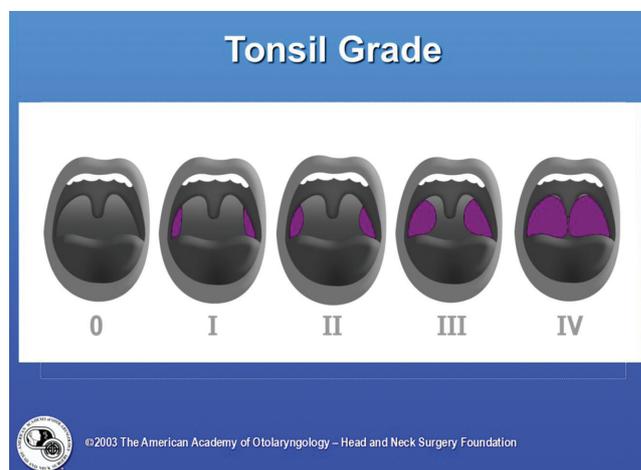


Figure 1. Subjective tonsil grading scale.

disruption of normal oxygenation/ventilation and sleep patterns.⁵ The diagnosis of oSDB in children may be based on history, physical examination, audio/videotaping, pulse oximetry, and limited or full-night PSG. History and physical examination are the most common initial methods for oSDB diagnosis.

Tonsillar and adenoid hypertrophy is recognized as the most common cause of oSDB in children. Tonsil size is readily identified with a tonsil grading scale,⁹³ with tonsillar hypertrophy defined as grades 3+ and 4+ (**Figure 1**). Tonsillar size alone does not correlate with the severity of oSDB,⁹⁴ although the combined volume of the tonsils and adenoids more closely correlates with oSDB severity.^{95,96} It is likely that the severity of oSDB 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.⁹⁷

oSDB is known to increase the risk for externalizing behaviors (eg, aggression, hyperactivity) and internalizing behaviors (eg, depression) in some children, leading to symptoms of attention-deficit/hyperactivity disorder.^{27,98-100} Problems with memory and attention, often associated with oSDB, may lead to poor school performance.¹⁰¹ Studies found that the QoL in children with oSDB is worse than that of controls.¹⁰²

Several studies showed that up to 50% of children with oSDB have secondary enuresis.¹⁰³⁻¹⁰⁷ Primary enuresis identifies a child who has never had control of nighttime urination, whereas secondary enuresis identifies a child who has had a regression in nighttime control. Since secondary 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 should be aware of the association between oSDB and secondary enuresis.

oSDB can also lead to failure to thrive and should be considered in children evaluated for growth failure¹⁰⁸ It

remains unknown whether growth failure is a result of hormonal changes caused by oSDB or simply excessive energy expenditures to overcome the airway obstruction.

Several studies have shown improvement or resolution of these modifying factors following tonsillectomy for oSDB in children. Behavioral and neurocognitive problems have been shown to improve significantly after tonsillectomy for oSDB by both objective testing^{98,99,109} and subjective testing.¹¹⁰ This improvement in behavior has been shown to continue for at least 2 years after tonsillectomy.¹¹¹ School performance has also been shown to improve significantly in children with oSDB following tonsillectomy as compared with those who do not undergo surgical intervention.¹⁰¹ There is also a dramatic improvement in QoL in children after tonsillectomy for oSDB,^{102,112,113} and this improvement is maintained for up to 2 years after surgery.¹⁰²

Enuresis has been shown to resolve or improve in the majority of children with oSDB after tonsillectomy. A systematic review of 14 studies concluded that oSDB is associated with nocturnal enuresis and that tonsillectomy is associated with a significant improvement.¹¹⁴ Another systematic review and meta-analysis of studies that evaluated height and weight changes after tonsillectomy for oSDB¹⁰⁸ reported that height, weight, and growth biomarkers increased significantly after tonsillectomy, concluding that oSDB, secondary to tonsil and adenoid hypertrophy, should be considered when screening, treating, and referring children with growth failure.

Asthma outcomes have also been shown to improve after tonsillectomy. In a systematic review of 4 qualified studies, markers of asthma severity—including respiratory medication use, emergency room visits for asthma-related symptoms, overall asthma symptoms, and asthma-related exacerbations—were all significantly reduced following tonsillectomy.^{115,116}

While contemporary studies largely support the use of tonsillectomy for oSDB, further randomized controlled trials are needed across multiple age groups to better understand which subsets of children may benefit from surgical and nonsurgical strategies.

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

Supporting Text

The purpose of this statement is to improve the quality of care and assist with clinical treatment plans in children with oSDB who are at increased risk for surgical or anesthetic complications because of comorbid conditions that include obesity, neuromuscular or craniofacial disorders, Down syndrome, mucopolysaccharidoses, and sickle cell disease.^{43,117-119} Obtaining PSG prior to tonsillectomy in young children or those with any of the conditions mentioned will benefit clinicians and patients by improving diagnostic accuracy in high-risk populations and defining the severity of OSA to optimize perioperative planning (**Table 6**).

Although there is a paucity of studies investigating the role of preoperative PSG in the group <2 years of age, the overwhelming consensus was to confirm the diagnosis of OSA prior to surgical intervention for this age group since the risk of complications is higher¹²⁰ and clinical examination does not predict the presence of OSA.^{39,121,122} An analysis of 880 children who underwent a tonsillectomy revealed that those who were <14 kg were more likely to have a respiratory complication.¹²³ Most children <2 years of age weigh <14 kg. Also, although younger children do not have a higher risk of a posttonsillectomy bleeding (PTB), the safety index is narrower due to their smaller blood volume.

Table 6. Role of PSG in Assessing High-Risk Populations before Tonsillectomy for oSDB.

| Role of PSG | Rationale |
|---|---|
| Avoid unnecessary or ineffective surgery in children with primarily nonobstructive events | Identify primarily nonobstructive events or central apnea that may not have been suspected prior to the study and may not benefit from surgery |
| Confirm the presence of obstructive events that would benefit from surgery | The increased morbidity of surgery in high-risk children requires diagnostic certainty before proceeding |
| Define the severity of oSDB to assist in preoperative planning | Children with severe OSA may require preoperative cardiac assessment, pulmonary consultation, anesthesia evaluation, or postoperative inpatient monitoring in an intensive care setting |
| Provide a baseline PSG for comparison after surgery | Persistent OSA despite surgery is more common in high-risk patients than in otherwise healthy children |
| Document the baseline severity of oSDB | High-risk patients are more prone to complications of surgery or anesthesia |

Abbreviations: OSA, obstructive sleep apnea; oSDB, obstructive sleep-disordered breathing; PSG, polysomnography.

We specifically mention obesity, neuromuscular or craniofacial disorders, Down syndrome, mucopolysaccharidoses, and sickle cell disease as the comorbidities for the population of children to obtain PSG; however, this does not exclude PSG referral for other children who have elevated anesthetic or surgical risks. The most common comorbidity in this group is obesity. Obesity is defined as *body mass index (BMI) ≥ 95 th percentile*. The BMI percentile for age and sex is used because the amount of body fat changes with age and differs between girls and boys.¹²⁴ Children are categorized into normal weight (BMI, 5th to < 85 th percentile), overweight (BMI, 85th to < 95 th percentile), and obese (BMI, ≥ 95 th percentile). For the purpose of the discussion in this guideline, recommendations are directed at obese children (eg, an 8-year-old boy, height 4 ft 10 in /1.4 m, would have to weigh ≥ 100 lb / ≥ 45 kg), not overweight children. BMI percentiles can be calculated by entering a child's height and weight into a calculator at <https://www.cdc.gov/healthyweight/bmi/calculator.html>.¹²⁴ The prevalence of oSDB in obese children is unknown. Obese children are more likely to have severe oSDB¹²⁵⁻¹²⁸ and respiratory complications following tonsillectomy.^{129,130} A prospective study on obese children between the ages of 8 and 17 years emphasizes the importance of performing preoperative PSG. In this study of 20 children, a baseline PSG was performed with follow-up PSG on the night of their tonsillectomy and revealed persistent severe OSA.¹³¹ Another retrospective study revealed that obese adolescents (ages 12-17 years) who underwent PSG were more likely to have OSA. Of note, 41% of the obese children had severe OSA.¹³² A recent meta-analysis demonstrated that tonsillectomy was frequently not curative. Between 33% and 76% of obese children had evidence of persistent but improved OSA following tonsillectomy.¹³³ The patient characteristics and definition of OSA varied for each study, as reflected in the surgical outcomes. Preoperative PSG therefore assists in planning perioperative care and with long-term management.

In the action statement profile, the role of patient preference is listed as high. This specifically applies to obesity and, to a lesser extent, children with Down syndrome or children < 2 years old. With the increasing prevalence of obesity, more children are presenting with oSDB. Due to regional differences in access to PSG, delay in treatment, and procedural costs, some families, after a shared decision-making dialogue with their provider, may opt to bypass PSG. Currently, many pediatric otolaryngologists are not performing PSG prior to tonsillectomy in obese children.¹³⁴ As previously stated, clinical assessment is a poor predictor of OSA. Since many obese children have severe OSA and surgical intervention does not resolve the OSA on the first postoperative day,¹³¹ it is prudent to admit any obese child following a tonsillectomy if PSG has not been obtained to quantify the severity of oSDB.

The role of patient preference in obtaining PSG is less in children with Down syndrome, although many pediatric otolaryngologists do not routinely obtain preoperative PSG.¹³⁴ In a retrospective chart review of 122 children with Down syndrome, the parental accuracy of predicting OSA was low, while OSA prevalence was high (66%). Almost half of these children had severe OSA (AHI ≥ 10 /hour and/or $O_2 < 80\%$).¹³⁵ Another retrospective study had similar findings.¹³⁶ Also, persistent but improved OSA after tonsillectomy is much higher in Down syndrome versus nonsyndromic children. A meta-analysis revealed only moderate success in improving PSG parameters following a tonsillectomy. In the pooled analysis of 3 studies, the mean AHI decreased only by 51%.¹³⁷ Maris et al had a cure rate (AHI < 2 /hour) of 18% and a success rate (AHI < 5 /hour) of 53%.¹³⁸ There were 34 children in this cohort, and 2 of them had an isolated adenoidectomy. A larger Down syndrome cohort (n = 75) who had pre- and post-PSG within 6 months of tonsillectomy had a cure rate of 21% (AHI < 2 /hour) and a success rate (AHI < 5 /hour) of 48%.¹³⁹ The information obtained from the PSG confirms indications and appropriateness of tonsillectomy, helps plan perioperative management, and provides

a baseline of OSA severity for a procedure that is unlikely to normalize the sleep disorder.

Neuromuscular diseases (neuropathies, cerebral palsy, congenital myopathies, muscular dystrophies, myotonias, and myasthenia gravis) form a heterogeneous group based on the etiology of the individual disorder. These patients often manifest other forms of SDB in addition to oSDB, including central apneas and hypoventilation, that are important to distinguish on preoperative PSG.¹⁴⁰ In children with predominantly nonobstructive events, tonsillectomy may not be indicated, and other management options should be explored.

For children with craniofacial disorders, mucopolysaccharidoses, sickle cell disease, and moderate to severe congenital heart disease, there are no high-quality case-control studies on the perioperative course following a tonsillectomy. However, several publications indicate that children with these disorders are at either increased risk for anesthetic complications or require special precautions.¹⁴¹⁻¹⁴⁵ For high-risk populations, preoperative PSG will confirm that the child has significant OSA and will optimize perioperative planning.

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

Supporting Text

The purpose of this statement is to help clinicians decide when to request PSG prior to tonsillectomy in children without any of the conditions in Key Action Statement 5. Advocating for PSG refers to encouraging or arguing in favor of using PSG to assist in decision making when the need for surgery is uncertain or there is discordance between the physical examination and the reported severity of oSDB. Although the tonsil size does not predict the severity of OSA, one is less certain of the diagnosis when tonsil hypertrophy is absent. The clinician may fulfill the requirement of advocating for PSG by (1) documenting in the medical record that PSG was discussed and encouraged, (2) providing an informational brochure or handout that describes the benefits and rationale of PSG in this circumstance, or (3) referring the patient for PSG or to a sleep specialist.

There is some controversy regarding the role of PSG in children without the risks described in Key Action Statement 5 but with symptoms of oSDB. The American Academy of Sleep Medicine recommends obtaining PSG in all patients undergoing tonsillectomy for oSDB.⁹ The American Academy of Pediatrics recommends obtaining PSG for children undergoing tonsillectomy for oSDB. In circumstances when the service is not readily available, it recommends referral to an otolaryngologist or a sleep medicine specialist.⁸

In some children who are candidates for tonsillectomy to treat oSDB, there may be controversy among clinicians, caregivers, or both regarding the need for surgical intervention. Examples include differing opinions or observations among caregivers, primary care clinicians, and surgeons. This is an opportunity for shared decision making. In addition, at times, the severity of oSDB by history is inconsistent with the physical examination by the clinician: children

with small tonsils may have severe symptoms suggesting oSDB, or children without apparent oSDB symptoms may have tonsillar hypertrophy or nasal airway obstruction that appears highly significant. In these situations, information obtained from PSG should help clarify the presence and severity of oSDB and to assist in decision making.

Recent investigations have demonstrated the potential for long-lasting health consequences if oSDB remains untreated. A recent meta-analysis demonstrated a significant increase in height, weight, and growth biomarkers after tonsillectomy.¹⁰⁸ Although some children may not be experiencing growth failure, they may also not be meeting their full potential. The implications of untreated oSDB may be worse for children with borderline neurocognitive functioning prior to developing a sleep disturbance. Multiple studies in younger children with oSDB have shown an intelligence quotient (IQ) loss of >5 points.¹⁴⁶ For perspective, the exposure to lead-based paint is associated with an average IQ point loss of <4 points.¹⁴⁷

Treatment of oSDB has been shown to improve behavior,^{38,148-150} attention,¹⁴⁹ QOL,^{38,151} neurocognitive functioning,¹⁵² enuresis,^{104,153} parasomnias (unusual events that occur while asleep),¹⁵⁴ and restless sleep.¹⁵⁵ Even when a clinician strongly suspects oSDB, some families require objective information to facilitate a clinical decision. In these situations, PSG should be requested.

PSG can also assist in tonsillectomy candidates when there is discordance between tonsillar size and the reported severity of oSDB. When a child with tonsils that do not appear hypertrophic nonetheless has symptoms of oSDB, normal PSG results would lead to reassessing the need for surgery and a recommendation for observation. Conversely, abnormal PSG results would support the need for surgery and can assist in the decision-making process, as tonsillectomy has been shown to resolve OSA even when tonsils are not hypertrophic.³⁸

Another clinical scenario involves a child with markedly hypertrophic tonsils and mild symptoms of oSDB reported by the caregiver. Caregiver reports of snoring, witnessed apnea, or other nocturnal symptoms may be unreliable if the caregiver does not directly observe the child while sleeping or observes the child in only the early evening. Since oSDB is most severe in rapid eye movement (REM) sleep and there is more REM in the second half of the night, caregiver reports of symptoms poorly correlate with PSG findings. In this situation, PSG may help detect OSA that may otherwise have been overlooked and could be improved after tonsillectomy. Similarly, caregivers may be unaware of, or underappreciate the impact of, oSDB on their child's daytime functioning or behavior (eg, hyperactivity, poor school performance) or nighttime symptoms (eg, enuresis, sleep terrors, sleepwalking, frequent awakenings).

The clinical benefits of treated oSDB in children are well established,^{38,104,148-156} but the threshold for intervention is not. Clinicians must provide caretakers with the information necessary to make an informed decision. This requires

advocating for PSG when the diagnosis is uncertain. The objective information obtained from PSG will help direct care and minimize the risk of overtreatment or failing to accurately diagnose oSDB.

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

Supporting Text

The purpose of this statement is to promote tonsillectomy as the primary surgical intervention for OSA in children. This recommendation is in agreement with the guidelines published by the American Academy of Pediatrics⁸ and the American Academy of Sleep Medicine.⁹ This statement differs from the recommendation in the first version of this guideline, which stated that clinicians should counsel caregivers about tonsillectomy as a means to improve health in children with abnormal PSG. The change from counsel to recommendation for tonsillectomy for OSA reflects more recent evidence in randomized controlled trials and systematic reviews showing that tonsillectomy versus observation results in significantly greater improvements in polysomnographic outcomes, symptoms, QoL, and behavior. Overnight PSG is recognized as the most reliable and objective test to assess the presence and severity of OSA.⁸ Normative polysomnographic data in children have been reported in numerous studies.¹⁵⁷⁻¹⁵⁹ Adenotonsillar hypertrophy is the main contributor to OSA in the majority of healthy children; therefore, tonsillectomy is the first-line surgical treatment. Most sleep specialists consider PSG to be abnormal in children if AHI is >1 , pulse oximetry levels are $<92\%$, or both.¹⁶⁰ Furthermore, although there is no universal consensus on cutoffs for OSA severity, several studies used an AHI of 1 to 4.9 for mild OSA, 5 to 9.9 for moderate OSA, and ≥ 10 for severe OSA.^{126,132,156} There is recognition that any decision to recommend tonsillectomy should not be based solely on PSG findings but also on clinical history, examination, and the likelihood that tonsillectomy will improve sleep and lead to improvements in day- and nighttime symptoms.

The results of the CHAT were published as a primary paper³⁹ in 2013 and in several secondary papers subsequently.¹⁶¹⁻¹⁶³ The CHAT was a well-designed and rigorously conducted randomized controlled trial with wide geographic and racial representation and high follow-up rates.³⁹ It included 464 children (ages 5-10 years) with OSA randomized to tonsillectomy or watchful waiting with supportive care (observation).³⁹ Polysomnographic, cognitive, behavioral, and health outcomes were assessed at baseline and 7 months.³⁹ The study reports significantly greater improvements in the tonsillectomy versus observation groups (with moderate to large effect sizes).³⁹ This included improvement in symptoms, behavior, QoL, and polysomnographic outcomes.³⁹ However, there were no differences in attention and executive function between the groups.³⁹ Normalization of PSG was also much higher in the tonsillectomy groups versus the observation group (79% vs 46%).³⁹

Battacharjee et al reported on a multicenter retrospective study of 578 children in 6 pediatric sleep centers in the United States and 2 in Europe who had a tonsillectomy for OSA with pre- and postoperative PSG.¹⁶⁴ Approximately 50% of the children were obese. Tonsillectomy resulted in a significant reduction in AHI from a mean 18.2 to 6.4.

However, 27% had complete resolution of OSA. Older age (>7 years) and obesity were the main contributors to persistent OSA. Again, tonsillectomy was associated with a significant improvement in OSA in the majority of children.

There is an ongoing debate about the efficacy of tonsillectomy for mild OSA (AHI <5). Trosmann et al studied children with mild OSA, with some having a variety of comorbidities, including obesity, craniofacial disorders, and hypotonia. Of 62 children, 19 had a tonsillectomy, and the rest were observed.¹⁶⁵ Tonsillectomy resulted in a significant improvement in AHI over observation especially in the nonsyndromic, nonobese children. Observation did not lead to improvement and resulted in worsening AHI in several patients. Volsky et al studied children with mild OSA and compared 30 who underwent tonsillectomy with 34 in the observation group.¹⁶⁶ Outcomes were measured with QoL instruments. Baseline QoL measures were worse in the tonsillectomy groups versus the observation group but improved significantly 4 months after surgery. There was no change for the observation group, and 6 (18%) crossed over to the tonsillectomy group. Interestingly, at 8 months, the tonsillectomy group maintained the improvement in QoL scores, but the observation group also showed a significant improvement from baseline. There is evidence that nasal steroids and oral montelukast can improve mild OSA,^{167,168} but in neither of these studies was the observation group given a standard treatment. Thus, tonsillectomy for mild OSA is associated with improvements in PSG and QoL outcomes, but this is based on small studies with short-term follow-up.

Two meta-analyses on outcomes of tonsillectomy for OSA were recently published.^{169,170} In a meta-analysis of 3 studies on outcomes of tonsillectomy for OSA (including the CHAT), Chinnadurai et al reported a 4.8-point improvement in AHI and significant improvements in symptoms, QoL, and behavior after surgery versus observation.¹⁶⁹ Venekamp et al reported on 3 studies with 562 children but were unable to combine the results because the trials differed substantially and evaluated different groups of children.¹⁷⁰ They reported significant improvements following tonsillectomy versus observation but primarily from the CHAT, as already discussed in this text.

Tonsillectomy for OSA can improve sleep outcomes in the majority of children as compared with observation. The effect is seen most clearly in healthy, normal-weight children. However, these benefits may be modified by comorbid conditions, such as craniofacial, neuromuscular, genetic, and metabolic disorders. There is a paucity of outcomes data in children with significant comorbidities, and it remains unknown if tonsillectomy should be a first-line treatment in these children, especially when OSA is mild. Demographic characteristics, particularly obesity, can lead to more severe baseline OSA and a less significant response to tonsillectomy.¹³³ There is additional concern that tonsillectomy for OSA can lead to weight gain especially in obese children.¹⁷¹ Although tonsillectomy is recommended

Table 7. Tonsillectomy and oSDB Caregiver Counseling Summary.

1. Enlarged tonsils are the most common reason that children develop oSDB.
2. oSDB is not solely due to enlarged tonsils; muscle tone also plays a role.
3. Obesity plays a major role in oSDB.
4. PSG is considered the best test to confirm that a child has OSA that would benefit from surgery. It also provides baseline information in case there are persistent symptoms after surgery.
5. PSG 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. For an otherwise healthy child with a strong history of struggling to breathe with daytime symptoms and enlarged tonsils, PSG is typically not performed unless the parents want to confirm the diagnosis.
6. The success of tonsillectomy is variable. The age, weight, ethnicity, OSA severity, and associated medical conditions all affect the success. Younger, normal-weight, non-African American children may have a resolution of oSDB of 80%.
7. For obese children, tonsillectomy produces complete resolution of oSDB <50% of the time.
8. Caregivers need to be aware that their children may require additional interventions to cure their oSDB, which can vary from weight loss, medications, or wearing a special mask while sleeping that will keep their airway open. Some children may be candidates for more advanced sleep surgery procedures.

Abbreviations: OSA, obstructive sleep apnea; oSDB, obstructive sleep-disordered breathing; PSG, polysomnography.

as a first-line treatment in obese children, noninvasive ventilation, such as continuous positive airway pressure (CPAP), may be a reasonable alternative.¹³³ Future studies are needed (1) to define the group of children who are most likely to benefit from tonsillectomy over observation, (2) to develop better patient-focused outcome measures, and (3) to measure objective and subjective outcomes beyond 12 months.

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

Supporting Text

The purpose of this statement is to emphasize that oSDB may persist after tonsillectomy, despite perceptions by caregivers and clinicians that surgery is curative. As a result, clinicians should counsel or educate caregivers of all patients (**Table 7**). Counseling may be accomplished by (1) discussing the reasons why oSDB 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 oSDB may have other underlying medical conditions, such as obesity, which contribute to their symptoms and persist after tonsillectomy.¹²⁶ PSG is considered the gold standard for evaluating patients with suspected oSDB and is the most reliable objective 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.

Clinical studies show that tonsillectomy has a variable effect on resolving oSDB as measured by PSG; however, most pediatric otolaryngologist do not obtain either pre- or postoperative PSG. An American Society of Pediatric Otolaryngology survey reported that <6% of respondents referred a child with oSDB for PSG prior to surgery “most of the time” and fewer requested postoperative studies. The referral rate was higher for children with comorbidities.¹³⁴ The CHAT, which is the first randomized clinical trial for tonsillectomy versus observation, reported that the overall success rate (AHI <2 events/hour) for surgery was 79%. Children with obesity, certain ethnicities, and those with an AHI >4.7 events/hour were less likely to be cured.³⁹ A meta-analysis of normal-weight and obese children who

underwent tonsillectomy reported an improvement in oSDB in most children but a cure in 60% to 70% of subjects.³⁶ The percentage of children in whom oSDB has resolved is dependent on the proportion of children in the study population who are overweight or obese. In a large multicenter study, 27% of children had OSA cure (AHI <1 event/hour) after tonsillectomy. Cure was less likely in children who had the following characteristics: asthma, age >7 years, obesity, or more severe baseline disease.¹⁶⁴

Despite the perceptions by caregivers and clinicians that surgery is curative, clinicians should counsel or educate caregivers of children who may require further management. Of specific concern is an association between tonsillectomy and weight gain that may lead to a persistence or recurrence of OSA.^{163,172} Multiple studies report a variable success rate for tonsillectomy at curing OSA.^{36,39,164} Especially for children who are at high risk for residual OSA, one should have a low threshold to perform postoperative PSG. Counseling families that oSDB may persist or recur after tonsillectomy is important so that families can make an informed decision for a procedure that may not cure oSDB.

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

Supporting Text

The purpose of this statement is to improve pain management and decrease morbidity following tonsillectomy based on a perception by the panel that the role of pain control may be underestimated or inadequately discussed with the patient and/or caregiver. The main cause of morbidity after tonsillectomy is oropharyngeal pain resulting in decreased oral intake, dehydration, dysphagia, sleep disturbance, behavioral changes, or readmission to the hospital. This section deals with measures seeking to educate and empower patients and caregivers.

Clinicians should educate caregivers about the need to manage and reassess pain because caregivers have the most frequent contact with the child and are often best suited to monitor the child frequently after tonsillectomy. 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 describe how this was accomplished, including verbal discussion, written information, educational brochure, or web-based resources. Pain management is primarily the responsibility of parents or caregivers, who may have misconceptions regarding safe and effective pain management.¹⁷³

Preprocedure studies have identified preoperative pain education and treatment plans as valuable to children and caregivers prior to tonsillectomy.¹⁷³⁻¹⁷⁵ Research on postoperative pain management at home for children is affected by multiple factors, including parental attitudes, misconception about pain medication, side effects, knowledge deficits, cultural background, parental anxiety, socioeconomic status, ability to assess pain, and health literacy.¹⁷⁶⁻¹⁷⁹

A contributing factor to poorly controlled postoperative pain may be noncompliance by patients and caregivers. Many studies have examined the inadequacy of caregiver compliance with the administration of analgesics following tonsillectomy.^{174,178-182} Rony and colleagues¹⁷⁹ found that parents undertreated their children's pain in terms of dosage and frequency of analgesics. Study results showed the median number of analgesic doses on the first postoperative day was 1 and that 26% of parents provided no analgesics. Only 17% of parents provided ≥ 4 doses of analgesics the day after surgery. Ninety-five percent of parents reported that they did receive specific instructions regarding analgesics at home. Of these parents, 69% administered the specific prescribed analgesic medication; 55% administered the prescribed dosage; but only 35% administered the prescribed number of doses. Reasons reported for not administering prescribed medication included the child's refusal to take medication, the bad taste of the medication, and the

Table 8. Patient Information: Posttonsillectomy Pain Management for Children—Education for Caregivers.**How long is the recovery after surgery?**

Pain after tonsillectomy on average lasts 7-10 days but can last as long as 2 weeks. Your child may complain of throat pain, ear pain, and neck pain. The pain may be worse in the morning; this is normal. You should ask your child every 4 hours if he or she is having any pain, remembering that children may not say that they are in pain.

Will my child be taking pain medication?

Yes, your child will be prescribed pain medications such as ibuprofen or acetaminophen. Ibuprofen can be used safely after surgery. Pain medication should be given on a regular schedule. You may be asked to give pain medication around the clock for the first few days after surgery, waking your child up when he or she is sleeping at night. Alternating medication such as ibuprofen and acetaminophen may be recommended. Rectal acetaminophen may be given if your child refuses to take pain medication by mouth. Ask your child if her or his pain has improved after taking pain medication.

Do children need to restrict their diet after surgery?

No, your child can maintain his or her normal diet as tolerated. Make sure your child drinks plenty of fluids. Offer frequent small amounts of fluids by bottle, sippy cup, or glass. Staying hydrated is associated with less pain. Encourage your child to chew and eat food, including fruit snacks, popsicles, pudding, yogurt, or ice cream.

Will other things besides pain medication help my child's pain?

Yes, there are things other than medication that can be utilized. You can distract children by playing with them, having their favorite toys or video games available, and applying a cold or hot pack to the neck and/or ears; you and your child can also blow bubbles, do an art project, color, watch television, or read a book together.

What should I do if I cannot manage my child's pain?

Call your health care provider if you are unable to adequately control your child's pain.

child's refusal to swallow anything. Longard et al found variability in parents' report of their children's pain following tonsillectomy, from mild to considerable pain and distress.¹⁸¹ All parents administered some type of analgesic, including morphine, paracetamol, and ibuprofen, but there was variability in their medication use.¹⁸¹

Patient and caregiver education and counseling on posttonsillectomy care should include verbal and written information prior to the day of surgery, and clinicians should reinforce postoperative instructions on the day of surgery. Education interventions for patients and their caregivers should focus on increasing their knowledge on how to assess pain and achieving adequate pain management utilizing pharmacologic and nonpharmacologic interventions.

Patient and caregiver education on how to assess pain should utilize a validated age-appropriate pain scale. The Wong-Baker FACES scale, in which patients choose the cartoon face that correlates with their level of pain, is validated for children ≥ 3 years.¹⁸³ The FLACC postoperative pain tool is validated for children 2 months to 7 years of age. FLACC utilizes numeric scores for the face, legs, activity, cry, and consolability categories. The FLACC scale was found to be a valuable way of quantifying posttonsillectomy pain in children.¹⁸⁴ Older children can utilize a numeric scale, with 0 being no pain and 10 being worst pain.¹⁸⁵

Nonpharmacologic pain management following tonsillectomy includes relaxation, distraction, imagery, cold or heat application, touch, massage, eating, drinking, chewing gum, emotional support, creating a comfortable environment that minimizes noise, reading, playing with favorite toys and video games, and watching television.^{174,180} Helgadottir and Wilson found that educating parents about the deliberative use of distraction in addition to pain

medication decreased pain behavior in 3- to 7-year-old children after tonsillectomy.¹⁷⁵

In summary, patients and caregivers should be educated on the perioperative events associated with tonsillectomy (Tables 8 and 9), but specifically, education on the assessment of pain is important and may improve compliance with medication administration. Nonpharmacologic interventions should supplement and not replace pharmacologic agents for posttonsillectomy pain. Failure to control the pain should prompt the caregiver to call the clinician to seek additional assessment and treatment.

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

Table 9. Patient Information: Tonsillectomy and Obstructive Sleep-Disordered Breathing—Education for Caregivers.**What is obstructive sleep-disordered breathing?**

Obstructive sleep-disordered breathing (oSDB) is airway obstruction during sleep. It can be caused by enlarged tonsils/adenoids and obesity. Children with oSDB may be sleepy during the day, and they often have behavioral problems, poor school performance, nighttime bed wetting, and growth failure.

How is oSDB diagnosed?

The best test for diagnosing oSDB is a sleep study or polysomnography. It is not always needed, and the study is performed in a sleep laboratory. A technician will tape or gel small discs on your child's head and body. Your child's heart rate, body movements, blood oxygen levels, and airflow through the mouth and nose will be measured.

Will a tonsillectomy cure my child's oSDB?

Tonsillectomy is not curative in all cases of oSDB in children, especially in children with obesity. Tonsillectomy is effective for oSDB in 80% of normal-weight children with tonsillar hypertrophy. Tonsillectomy is effective in oSDB in only 20% to 30% of obese children.

What if I have more questions?

Contact your health care provider if you have any further questions regarding oSDB or a polysomnography study.

- **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

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. In addition, the purpose is to provide an update on studies that reported on the outcomes of reducing routine use of perioperative (pre-, intra-, or postoperative) antibiotics since the publication of the 2011 tonsillectomy guideline.⁶⁰

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.

Historically, early randomized controlled trials of antibiotic therapy had largely shaped the delivery of care by otolaryngologists, suggesting improved recovery after tonsillectomy when antibiotics were prescribed.^{186,187} In fact, up to 79% of polled otolaryngologists in the United States once used antibiotics in patients undergoing tonsillectomy to reduce postoperative morbidity.¹⁸⁸ The accumulated body of evidence in the 21st century brought into question these early suggestions of benefit due to methodological limitations in older trials and because newer trials, in aggregate, did not support any benefit for routine antimicrobial therapy in the perioperative period.

A Cochrane review of 10 randomized controlled trials suggests that antibiotics do not reduce pain, the need for pain medication, or bleeding.¹⁸⁹ In the pooled analyses, antibiotics had no impact on rates of secondary bleeding (of any severity; 7 trials) or on significant secondary bleeding (requiring readmission, blood transfusion, or return to the operating room; 3 trials).¹⁸⁹ An additional pooled analysis (2 trials) showed a reduced incidence of fever >99.9°F with antibiotics, but 2 other trials (not suitable for pooled analysis) showed no benefit.¹⁸⁹ 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.¹⁸⁹

In the Cochrane review, 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.¹⁸⁹ 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.¹⁸⁹ In addition, multiple studies have shown no significant change in pain, emergency room encounters, or hospitalization.^{29,190-194}

Any real or theoretical benefit of antibiotics on recovery after tonsillectomy must be balanced against the known risks, harms, and adverse events of therapy.¹⁹⁵ Aside from the direct costs of acquiring the medications, adverse events include rash, allergy, and gastrointestinal upset or diarrhea.

Adverse events from antibiotics account for about 20% of all medication-related emergency department visits in the United States, most of which are attributable to allergic reactions.¹⁹⁵ 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.¹⁸⁹

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. There is insufficient evidence to support the routine use of antibiotics to reduce morbidity after pediatric tonsillectomy.

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

Supporting Text

The purpose of this statement is to evaluate the use of a single intraoperative dose of steroids to reduce postoperative morbidities. One of the most important morbidities associated with pediatric tonsillectomy is PONV. PONV occurs independent of dissection technique¹⁹⁶ and in >70% of children who do not receive prophylactic antiemetics.¹⁹⁷⁻¹⁹⁹ PONV can itself be uncomfortable and enhance overall pain perception. PONV can necessitate overnight hospital admission to provide intravenous hydration and analgesic administration and is associated with decreased patient satisfaction and increased use of hospital resources.²⁰⁰⁻²⁰²

For several decades, evidence has accumulated that the administration of a single intraoperative dose of dexamethasone in children undergoing tonsillectomy results in decreased PONV.²⁰³ A systematic review from the Cochrane Collaboration showed that children receiving dexamethasone were half as likely to vomit in the first 24 hours than were children receiving placebo (risk ratio, 0.49; 95% CI, 0.41-0.58; $P < .00001$) and more likely to advance to a soft or solid diet on posttonsillectomy day 1 (risk ratio, 1.45; 95% CI, 1.15-1.83; $P = .001$).²⁰³ Routine use in 5 children would be expected to result in 1 fewer patient experiencing posttonsillectomy emesis (risk difference, -0.24 ; 95% CI, -0.32 to -0.15 ; $P < .00001$).²⁰³

The mechanism of efficacy of dexamethasone is unknown but may be related to its anti-inflammatory properties that reduce pain and swelling.²⁰⁴⁻²⁰⁶ Most published studies used a dexamethasone dose of 0.5 mg/kg²⁰⁷; however, lower doses may be equally effective.²⁰⁸⁻²¹⁰ In 1 systematic review of randomized controlled trials, for example, doses ranged from 0.15 to 1.00 mg/kg, with a maximum range of 8 to 25 mg.²⁰³

Additional comorbidities after tonsillectomy include pain and poor oral intake. In addition to having a beneficial effect on PONV, dexamethasone decreases throat pain after tonsillectomy and time to resumption of oral intake.²¹¹⁻²¹⁴

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.^{203,215} The results of a trial that was published after this review found increased postoperative bleeding in children who were randomized to receive 0.5 mg/kg of dexamethasone.²⁰⁷ However, this was a secondary outcome that was not adjusted for other risk factors and that lost significance when primary bleeding cases, which are largely related to surgical technique, were excluded from the analysis.²¹⁶ Increased bleeding with dexamethasone has not

occurred in any other published trials, and the significance of this single report has been challenged.²¹⁵⁻²¹⁷

Several systematic reviews and meta-analyses of the use of perioperative dexamethasone in children <18 years of age undergoing tonsillectomy were not associated with an increase in postoperative bleeding. Increasing doses of dexamethasone were not associated with increased odds of bleeding.²¹⁸⁻²²⁰

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] ≥ 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

Supporting Text

The purpose of this statement is to promote an appropriate, monitored setting after tonsillectomy for children who are at an increased risk of complications in the immediate and early postoperative periods. Age and OSA severity are associated with an increased risk to have a postoperative respiratory complication requiring intervention.^{120,221} In particular, children who are aged <3 years,²²² have complicated medical histories,²²³ or have severe OSA benefit from inpatient hospital admission and monitoring after surgery.^{120,221,224} Postoperative care should include continuous pulse oximetry and the availability of more intensive levels of care, including respiratory support (intubation, supplemental O₂, CPAP).

Children aged <3 years with oSDB symptoms are at increased risk of respiratory compromise after tonsillectomy as compared with older children. In a review of 2315 children aged <6 years, 9.8% of children aged <3 years experienced a respiratory complication postoperatively, as compared with 4.9% of older children.¹²⁰ In a study of >300 children, those <3 years of age were found to have a major respiratory complication 29.2% of the time.²²² A recent study evaluating perioperative respiratory complications following tonsillectomy demonstrated that lower weight (≤ 14 kg) was associated with more complications.¹²³ However, at least 1 retrospective study suggested that postoperative admission for children <3 years of age may not be necessary in all cases.²²⁵

Although the action statement does not specifically address children with complicated medical histories (because of the difficulty in defining these children), clinicians should have a low threshold to observe these children overnight. The literature suggests that the following children may benefit from observation in an inpatient setting: (1) children with complicated medical histories, including cardiac complications of OSA, Down syndrome, neuromuscular disorders, failure to thrive, craniofacial anomalies, and current/recent respiratory infection; (2) obese children (BMI >95th percentile for age/sex) without PSG to quantify OSA severity; and (3) children with behavioral factors that predict poor oral intake or difficult pain management postoperatively.⁸

While no validated severity scales are currently available for PSG in children, several publications^{10,43,221,224,226,227} support defining severe OSA as having an oxygen saturation nadir <80% or an AHI ≥ 10 obstructive events. In contrast, normal PSG outcome has oxygen nadir saturation >92% and an AHI <1. The panel does acknowledge that opinions do differ among experienced clinicians regarding what constitutes “severe” sleep apnea. The panel would like to be clear that if a clinician believes a child to have “severe” OSA based on other criteria or if the sleep laboratory that performed the study interprets the OSA as “severe,” it would be prudent to admit the child for observation.

Children with OSA who are considered high risk for respiratory compromise require overnight inpatient monitoring postoperatively in a setting where signs of respiratory depression and airway obstruction can be recognized and prompt intervention can be implemented.^{8,43,221,226,228-230} Postoperative respiratory complications occur in 5.8% to 26.8% of children with OSA undergoing tonsillectomy,^{224,231} as opposed to 1.3% to 2.4% in a general pediatric population.^{117,232} A meta-analysis of tonsillectomy complications revealed that children with OSA had nearly 5 times more respiratory complications after surgery as compared with children without OSA.²³³ Between 2.4% and 31% of children with OSA suffered from major or minor complications (respectively) requiring medical intervention, including supplemental oxygen, CPAP, or reintubation.^{43,221,224,228,230,232}

More severe problems, such as worsening OSA, pulmonary edema, and death, have all been attributable to respiratory complications in the immediate postoperative period in children with severe OSA. If opioids are used in the immediate postoperative period, they should be used at reduced doses with careful titration and continuous pulse oximetry.²³⁴ High-risk patients should undergo surgery at a center capable of monitoring and treating complex pediatric patients.⁸ Although tonsillectomy often resolves or significantly improves OSA in the majority of children, they may continue to experience upper airway obstruction and oxygen desaturation in the early postoperative period (the initial hours/days after surgery).^{235,236} Most interventions required during the postoperative period include administration of oxygen or repositioning; however, in several studies, children with OSA required more significant interventions with pediatric intensive care unit (PICU) admission.^{43,224,228,230}

There is consensus in the literature on postoperative inpatient monitoring of children with OSA after tonsillectomy. However, some controversy exists regarding the criteria for the general care area versus a step-down unit versus a PICU admission. Oximetry monitoring in the recovery room during the initial postoperative period is reported in many publications as a routine part of postoperative care among hospitalized children. Admission to the PICU may be considered for children with very severe OSA (AHI >30), for associated desaturation events, and for those with comorbidities with a known difficult airway or a syndrome potentially predisposing them to postoperative airway obstruction.²²⁸ The location of monitoring (general care area vs a step-down unit vs a PICU admission) may vary among hospitals based on capabilities and staffing. Documentation of mild or moderate OSA should not prevent the clinician from overnight monitoring of a patient who has clinically significant obstruction or desaturation after surgery. In addition, postoperative admission may be considered in children with comorbid conditions that, independent of OSA severity, increase their risk of postoperative complication.

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

Supporting Text

The purpose of this statement is to inform surgeons, other health care providers, and consumers of nonopioid alternatives for optimal pain control to decrease morbidity after tonsillectomy in children.

The main cause of morbidity after tonsillectomy is oropharyngeal pain, which may result in decreased oral intake, dysphagia, dehydration, and weight loss. Oral intake may improve over time but is highly variable among children.²³⁷⁻²⁴¹

Nonsteroidal anti-inflammatory drugs (NSAIDs) can provide adequate analgesia without significant side effects in the posttonsillectomy pediatric patient. In a multicenter randomized double-blind placebo-controlled trial involving 161 children aged 6 to 17 years undergoing tonsillectomy, patients given intravenous ibuprofen versus placebo (control) were found to have significantly reduced fentanyl use. There were no differences in the incidence of serious adverse events, surgical blood loss ($P = .622$), incidence of postoperative bleeding, or a need for surgical reexploration between the intravenous ibuprofen and placebo (control) groups.²⁴² In 2013, Riggan et al completed a systematic review and meta-analysis of 18

randomized controlled trials involving 1747 children comparing NSAIDs with placebo or opioids posttonsillectomy.²⁴³ The use of NSAIDs in children was not associated with an increased risk of bleeding, secondary bleeding, readmissions, or need for reoperation due to bleeding. Results suggest that NSAIDs can be considered a safe method of analgesia among children undergoing tonsillectomy.²⁴³

A review from the Cochrane Collaboration that included 1100 children in 15 studies found that NSAIDs did not significantly increase the risk of bleeding as compared with placebo or other analgesics, did not significantly alter the number of perioperative bleeding events requiring nonsurgical intervention, and resulted in less vomiting.²⁴⁴ Mudd et al reviewed 6710 children who underwent tonsillectomy.²⁴⁵ A total of 222 children required surgical control of PTB; in addition, 166 had ibuprofen and 62 did not. Ibuprofen was not a risk factor, while age (≥ 12 years) and preoperative diagnosis of recurrent tonsillitis were independently associated with PTB.²⁴⁵ The authors report that bleeding severity was significantly increased with ibuprofen use when transfusion rate was used as a surrogate marker for severity, but this was based on a low transfusion rate (15 of 6710 children).²⁴⁵

Pfaff et al reviewed 6014 children: 3317 treated with acetaminophen and codeine and 2697 treated with ibuprofen for posttonsillectomy analgesia.²⁴⁶ The incidence of readmission for PTB was 3.4% in the acetaminophen/codeine group and 3.6% in the ibuprofen group. When adjusted for age, there was no significant increase in PTB among patients treated with ibuprofen.²⁴⁶

Ketorolac is an NSAID. It is not associated with common opioid side effects, such as respiratory depression, nausea/vomiting, urinary retention, or sedation.^{247,248} The use of ketorolac in tonsillectomy patients remains limited due to concerns of increased bleeding postoperatively.²⁴⁷⁻²⁴⁹ Anesthesia providers and surgeons have been reluctant to use ketorolac in patients undergoing tonsillectomy, arguing that ketorolac may contribute to postoperative bleeding secondary to an alteration in the normal clotting mechanism through inhibition of platelet aggregation.²⁴⁸ However, a 2013 review from the Cochrane Collaboration²⁴⁴ comparing ketorolac with other NSAIDs found no increased risk of bleeding. Studies in children have not found a significant risk for PTB in those administered ketorolac as compared with adults.^{249,250} Ketorolac use with tonsillectomy remains controversial and dependent on provider preference.

Acetaminophen is another choice for a nonopioid analgesic to reduce mild to moderate pain with no anti-inflammatory side effects. Studies have found acetaminophen, as the sole pain medication, limited in its ability to control posttonsillectomy pain.^{174,177} Liu and Ulualp reviewed 583 patients, ages 1 to 18 years, who received alternating doses of acetaminophen (10 mg/kg) and ibuprofen (5 mg/kg) every 3 hours posttonsillectomy.²⁵¹ They found that the use of alternating doses of ibuprofen and acetaminophen provided effective control of posttonsillectomy pain in a majority of children and did not increase the rate of bleeding.²⁵¹ Also, for optimization of pain control, it is advisable to use

multimodal analgesic treatment on a set schedule for each child.^{176,251,252} Recommended prescribing of ibuprofen is 5 to 10 mg/kg/dose every 6 to 8 hours. Acetaminophen is 10 to 15 mg/kg/dose every 4 to 6 hours, with a maximum dose of 75 mg/kg/d or 4000 mg, whichever is less.^{253,254}

Finally, clinicians should document the formulation and review of a postoperative pain management plan with the caregiver prior to surgery. The pain management plan should be reviewed again immediately after surgery. Parents and caregivers should be instructed to begin assessing for pain and administering pain medication as needed starting on the day of surgery. Accurate documentation in the patient's medical record should indicate that verbal instructions were provided and questions were answered and the family understood and agreed with the patient's postoperative pain management. As well, relevant written material concerning postoperative pain management should be available to reinforce postoperative pain instructions. Instructions should include administering medication at home; properly using nonopioid alternatives, such as acetaminophen and ibuprofen, alone or in combination; adhering to prescribed intervals for administration of pain medications; assessing pain at regular intervals; encouraging oral intake and advancing diet as tolerated; and using nonpharmacologic interventions for pain relief. In summary, studies have demonstrated that NSAIDs decrease postoperative pain, nausea, and vomiting and are a viable alternative to opioids.

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

Supporting Text

The purpose of this statement is to inform surgeons that the prescription or administration of codeine, or any medication containing codeine, is not recommended in children <12 years of age after tonsillectomy.^{7,255} In 2013, the FDA issued a boxed warning, the FDA's strongest warning, concerning the risk associated with codeine for use in postoperative pain management in children following tonsillectomy.⁷ This strong recommendation was emphasized with issuance of a contraindication in the US prescribing information sections on warnings/precautions, pediatric use, and patient counseling information.⁷ The added contraindication in April 2017 warns that "codeine should not be used to treat pain or cough . . . in children younger than 12 years."²⁵⁵ Additionally, the FDA recommends against the use of codeine in adolescents between 12 and 18 years who are obese or have conditions such as OSA, which supports the American Academy of Pediatrics' recommendations to avoid codeine use in children.²⁵⁶ The panel recognized that codeine poses significant harm to children of all ages for any procedure/surgery but that the strength of the published data are especially strong for children aged <12 years.

The boxed warning follows the identification of codeine-related fatalities in the FDA's Adverse Event Reporting System database from 1969 to 2015.^{7,255} Of 24 reported deaths, 21 occurred in children <12 years old from respiratory depression after receiving multiple doses of codeine-containing medicines for pain control, including posttonsillectomy and/or adenoidectomy pain management, cough, and cold.²⁵⁵ Ten pediatric deaths and 3 overdoses were identified and associated with codeine administration in children ranging in age from 21 months to 9 years.⁷ Of these 13 reported cases, 8 children had undergone tonsillectomy and received appropriate doses of codeine. Another 2 deaths were identified in a survey of morbidity and mortality following tonsillectomy conducted by the American Academy of Otolaryngology–Head and Neck Surgery.⁷ In most cases, the child had a genetic predisposition to rapidly metabolize codeine to morphine (ultra-rapid metabolizer), resulting in high blood levels of morphine.^{7,255} This genetic variant combined with a diagnosis of OSA increased the risk of respiratory depression.^{7,255}

Alternative medications are recommended to manage postoperative pain after tonsillectomy in children with OSA. Screening for cytochrome P450 2D6 (CYP2D6) genetic polymorphisms to identify those at risk for a respiratory event is unreliable because some patients with normal metabolism may be induced to become ultra-rapid metabolizers.²⁵⁷ In addition, caution must be exercised with other

common opioid medications, such as tramadol and hydrocodone, which are significantly metabolized by the CYP2D6 pathway and share inherent risks of respiratory depression.¹⁷⁷ Tramadol is specifically contraindicated in children <12 years of age for the treatment of pain and <18 years for postoperative tonsillectomy pain control, after 9 reported cases of respiratory depression, including 3 fatalities from 1969 to 2016.²⁵⁵ Tramadol undergoes metabolism to its active form, O-desmethyltramadol, via CYP2D6.^{177,255,257} However, oxycodone and morphine are minimally metabolized (CYP2D6) and metabolized by an alternate metabolic pathway (UGT2B7), respectively, and are less dependent on the metabolite to provide analgesia.¹⁷⁷ Based on pharmacogenomics, these last 2 alternative analgesics seem less prone to unintended sedation given their phenotypic expression and reliability to provide pain relief and sedation.^{177,257}

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

Supporting Text

The purpose of these statements is to encourage self-assessment and accurate documentation by clinicians who perform tonsillectomy, to determine how their personal rates of bleeding compares with expected rates based on audit data and published reports. This allows communication of more accurate and surgeon-specific surgical risk during the informed consent discussion with caregivers and patients. It may also identify circumstances in which a surgeon needs to reassess his or her technique and process of care for quality improvement opportunities. While rates of PTB are relatively low, the burden and seriousness of this complication necessitate that clinicians who perform tonsillectomies document and track PTB rates in their practice. The panel recognized that some otolaryngologists may not do a sufficient number of pediatric tonsillectomies to make an annual determination of PTB statistically meaningful and may need to look at their data every 2 to 3 years. The panel felt that a recommendation was justified based on the fact that bleeding posttonsillectomy is variable, related to technique, and potentially fatal. As such, it justifies measurement and introspection. Each surgeon should know her or his specific rate of PTB that can be discussed with the caregiver and patient prior to tonsillectomy. This approach was preferable to recommendations regarding choice of surgical technique. A future goal would be to see how active measurement and reporting of PTB might influence future measurement of outcomes.

PTB may be categorized as primary or secondary. *Primary bleeding* 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 bleeding range from 0.1% to

5.8%.²⁹ *Secondary bleeding* occurs >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 bleeding range from 0.2% to 7.5%.²⁵⁸ The average reported rate of primary and secondary PTB is approximately 4.2%.²⁵⁸ There is a wide spectrum of PTB rates that reflects how bleeding is recorded in each study. The caregiver may observe a minor bleed at home, while a severe bleed may necessitate a blood transfusion and cautery under general anesthesia in the operating room. As such, studies have often included different patient populations, and this heterogeneity has limited the pooling and comparison of outcomes data.

Determination of PTB complicating tonsillectomy is important. Clinicians should inquire about bleeding following tonsillectomy (primary and secondary) and whether further treatment was necessary. This can be accomplished at the time of a postoperative visit or with telephone, written, or electronic communication.^{259,260} The panel felt that communication with the caregiver and patient is practice dependent and should be determined by the surgeon. However, a good-faith effort to obtain these data should be part of routine clinical practice. In addition, all patients should be counseled, as part of their pre- and/or postoperative education, to contact the surgeon in the event of PTB regardless of the treatment setting (eg, emergency department, urgent care, or primary care provider).

The severity of PTB may be difficult to accurately quantify. Minimal bleeding is frequently short-lived and managed at home with observation. However, 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. Information such as emergency room and/or hospital admission, requirement for further treatment, and surgery for PTB should be documented by the primary surgeon or designee. Good communication between the primary surgeon and the family promotes continuity of care that 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 often considered the standard from which to compare the effectiveness and safety of 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) were intended to reduce intraoperative bleeding, postoperative morbidity, and risk of bleeding. The heat produced by these techniques produces hemostasis during tonsil dissection and reduces intraoperative bleeding. However, there is concern that newer techniques increase PTB rates.^{261,262}

There is conflicting evidence regarding whether different surgical techniques are associated with different PTB rates. Two recent meta-analyses determined that frequencies of PTB were similar between cold dissection (3.8%) and coblation (3.3%).^{29,258} In a systematic Cochrane review of 9 trials that compared coblation and other techniques for tonsillectomy, there was no significant difference between techniques with respect to PTB rates.²⁶³ A case series of 1997 children undergoing coblation tonsillectomy from January 2000 to June 2004 showed similar rates of primary and secondary bleeding as compared with electrocautery tonsillectomy.²⁶⁴ In contrast, the National Prospective Tonsillectomy Audit reported on PTB in 33,921 patients undergoing tonsillectomy in England and Northern Ireland over a 14-month period from 2003 to 2004.²⁶¹ “Hot” surgical techniques for dissection and hemostasis (diathermy or coblation) increased the risk of secondary bleeding by 3-fold when compared with cold steel tonsillectomy alone without any “hot” technique for cautery.

There have been numerous studies, systemic reviews, and meta-analyses that evaluate the risk of PTB with one technique over another,^{29,258,265-273} but these studies are limited by low sample sizes, heterogeneity, and inconsistent definitions of bleeding. As a result of conflicting findings, there is insufficient evidence, at this time, to support the superiority of one technique over another to reduce PTB.

Other Factors Influencing PTB. The National Prospective Tonsillectomy Audit demonstrated that there was a higher risk of postoperative bleeding with increasing patient age, male sex, and history of recurrent acute tonsillitis (3.7%) and previous peritonsillar abscess. The rate was highest in quinsy patients (5.4%) versus patients with pharyngeal obstruction and OSA (1.4%).²⁶¹

Implementation Considerations

The complete updated guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery*, and an executive summary will be simultaneously published in the main journal. A full-text version of the guideline will also be accessible free of charge at www.entnet.org, the AAO-HNSF website, and will include decision tools and patient aids. The updated guideline was presented as a panel presentation to AAO-HNS members and attendees at the AAO-HNSF 2018 Annual Meeting & OTO Experience. Existing AAO-HNSF printed and online patient information will be updated to reflect the updated guideline recommendations.

The panel identified several potential areas of the guideline where obstacles to implementation might occur based on the updated recommendations and current practice patterns. In the first version of this guideline, a recommendation was made for clinicians to counsel caregivers about tonsillectomy for children with an abnormal PSG outcome. This has been changed in the new guideline to indicate that clinicians should recommend, rather than counsel, tonsillectomy for children with OSA. This reflects recent studies (eg, new randomized trials and systematic reviews) that have

shown a significant improvement in sleep parameters and symptom relief after tonsillectomy as compared with a period of watchful waiting. Continuing medical education will be needed to focus on this subtle but important change so that it becomes part of routine clinical practice.

Pain control after tonsillectomy is essential for minimizing postoperative morbidity. The new guideline reaffirms a prior recommendation that clinicians should advocate for pain management after tonsillectomy and educate caregivers about the importance of managing and reassessing pain. The new guideline adds 2 strong recommendations. The first is for use of ibuprofen, acetaminophen, or both for pain control after tonsillectomy. The second is a strong recommendation against the use of codeine or any medication containing codeine after tonsillectomy (there is an FDA black box warning against codeine use in children after tonsillectomy). There remains concern about increased postoperative bleeding with the use of ibuprofen, which is unsupported by systematic reviews of randomized trials. Equally, there is concern that ibuprofen and acetaminophen provide inadequate pain control after tonsillectomy without the addition of an opiate. Educational materials and brochures will be needed to promote the use of ibuprofen and acetaminophen for pain control and to avoid the routine use of opiates after tonsillectomy.

The majority of tonsillectomy procedures are performed with same-day discharge. There is considerable variation in the criteria used for overnight observation after tonsillectomy. The guideline recommends that clinicians should arrange for overnight inpatient monitoring of children after tonsillectomy if they are <3 years old or have severe OSA (AHI ≥ 10 obstructive events/hour, oxygen saturation nadir <80%, or both). Continuing medical education will be needed to explicitly focus on the rationale for this recommendation to promote adoption in routine clinical practice.

The new guideline reaffirms a prior recommendation suggesting that clinicians determine their rates of primary and secondary PTB at least annually. The updated guideline adds that clinicians should follow up with individual patients and/or caregivers after tonsillectomy and document in the medical record the presence or absence of bleeding. This revised recommendation imposes an administrative burden in acquiring these data. The guideline update group showed strong consensus and support for this recommendation as a means to improve quality of care for children and to provide more accurate information about PTB rates to referring physicians and caregivers. Educational material and brochures, in addition to reinforcement, will be needed to implement this strategy into routine clinical practice.

As a supplement to clinicians, an algorithm of the guidelines action statements is provided (**Figure 2**). The algorithm allows for a more rapid understanding of the guidelines logic and the sequence of the action statements. The guideline update group hopes that the algorithm can be adopted as a quick reference guide to support the implementation of the guideline's recommendations.

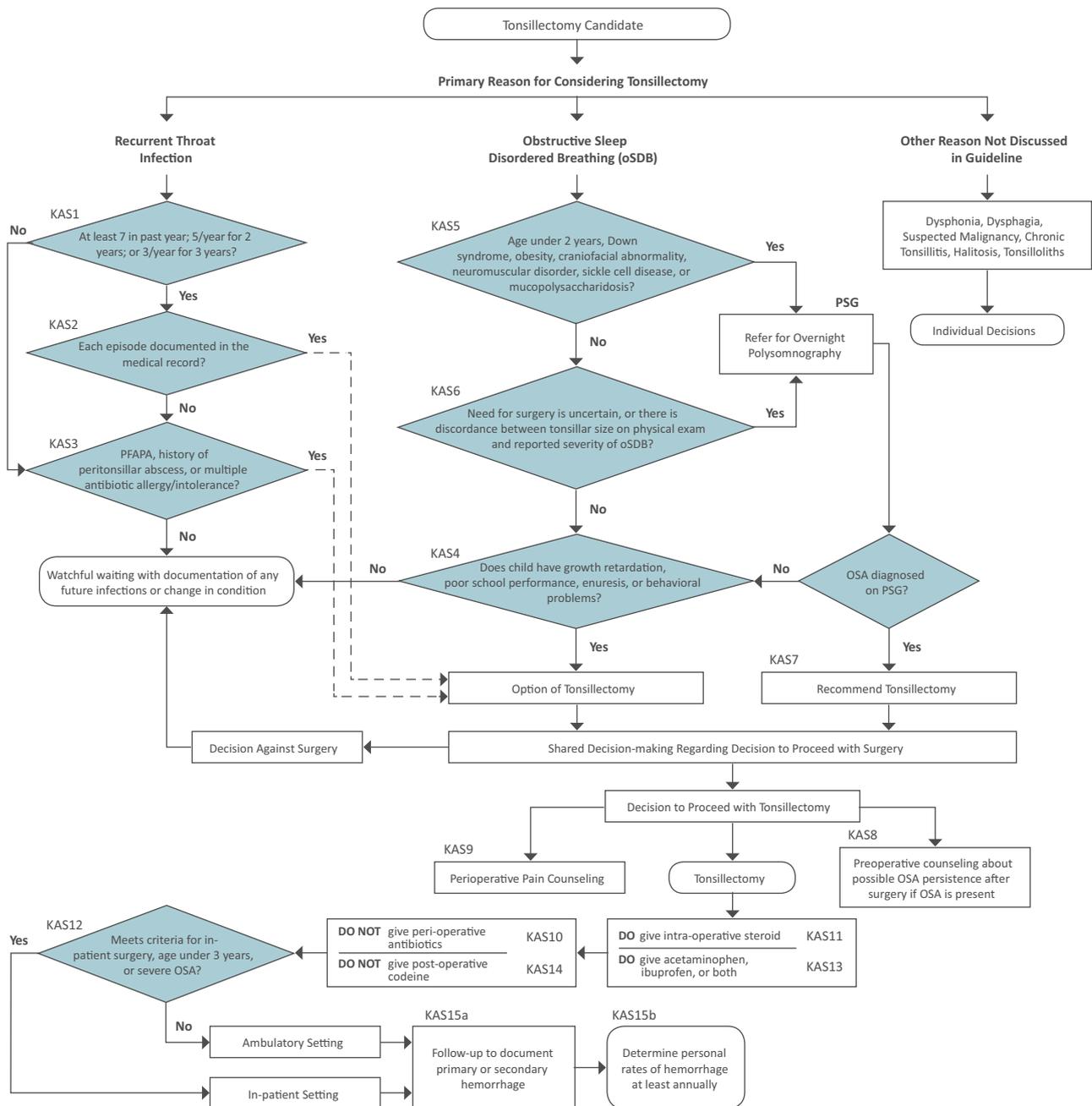


Figure 2. Tonsillectomy in children: clinical practice guideline algorithm. KAS, key action statement; OSA, obstructive sleep apnea; PFAPA, periodic fever, aphthous stomatitis, pharyngitis, and adenitis; PSG, polysomnography.

Research Needs

While there is a body of literature from which guidelines were drawn, significant gaps remain in knowledge about pre-, intra-, 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 (<12 and >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 oSDB and other comorbidities.
3. Measure QoL and school performance (not just missed school days) following tonsillectomy in children with mild oSDB and those with recurrent infections whose history does not meet the Paradise criteria.

4. Determine if the 12-month watchful waiting period causes unnecessary morbidity based on QoL and school performance measures.
5. Determine the optimal follow-up schedule for oSDB following tonsillectomy.
6. Determine when postoperative polysomnogram is indicated after tonsillectomy for oSDB.
7. Determine when a preoperative polysomnogram is indicated.
8. Determine percentage of patients who have full resolution, partial resolution, or no resolution of OSA posttonsillectomy in the short and long term.
9. Assess how future weight gain or obesity play a role in failure to respond following tonsillectomy for OSA.
10. Assess the immunologic 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. To increase the value of future research, key stakeholders need to develop a unified set of core outcomes that are important to children and those who care for them after tonsillectomy.
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 on the postoperative coordination between the primary care provider and otolaryngologist.
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.
19. Defining the polysomnographic parameters that predispose children to having respiratory complications.
20. Self-monitoring of postoperative bleeding rates yearly.
21. Studies are required to determine if the risk of postoperative complications can be stratified to the patient's disease severity as defined by PSG. This is important not only for otherwise healthy children but also for patients with Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, mucopolysaccharidoses, and obesity.
22. The degree to which overweight and/or obesity correlates with OSA severity as measured by PSG should be determined. PSG parameters that correlate with respiratory compromise perioperatively in obese children undergoing tonsillectomy should also be examined.
23. A large-scale prospective study should be conducted to determine the ability of PSG to predict surgical outcomes—specifically, to determine whether PSG parameters reliably predict the resolution of OSA after surgical intervention. This type of study would also be beneficial for predicting when tonsillectomy would be ineffective or potentially dangerous in the management of OSA.
24. Develop validated severity scales for PSG to benefit inpatient hospital admission and perioperative monitoring in children with severe OSA.
25. Study the impact of PSG findings (severity, including normal) on the need for additional pre- and postoperative evaluation and testing of children with or without OSA. Studies are needed to determine who would benefit from postoperative PSG.
26. Study the relationship between PSG findings (severity) and the perioperative management of children with OSA.
27. Outcomes study to determine the optimal anesthetic management to reduce the rate of postoperative complications in light of PSG findings (severity).
28. Study the role of portable monitoring in children with oSDB. This is of particular importance to patients who may lack access to a sleep laboratory and to those children who have difficulty sleeping in a foreign environment.
29. Additional studies of intraoperative anesthetic parameters such as end tidal CO₂ may show promise in predicting postoperative respiratory complications in patients with SDB.
30. Studying the appropriate in-hospital monitoring setting among monitored bed, intensive care unit, and extended postanesthesia care unit stay.

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.

Acknowledgments

We gratefully acknowledge the support provided by Jackie Cole, from the AAO-HNSF, for her assistance with this guideline's graphic designs and Janene Batten for her assistance with the literature searches. In addition, we acknowledge the work of the original guideline development group, which includes Reginald F. Baugh, MD; Ron B. Mitchell, MD; Sanford M. Archer, MD; Richard M. Rosenfeld, MD, MPH; Raouf Amin, MD; James J. Burns, MD; David H. Darrow, MD, DDS; Terri Giordano, MSN, CRNP, CORLN; Ronald S. Litman, DO; Kasey K. Li, MD, DDS; Mary Ellen Mannix, MRPE; Richard H. Schwartz, MD; Gavin Setzen, MD; Ellen R. Wald, MD; Eric Wall, MD, MPH; Gemma Sandberg, MA; and Milesh M. Patel, MS.

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Disclosures

Competing interests: Stacey L. Ishman, consultant for Medtronic. Sarah Coles, salaried employee at Bonner University Medical Group, Arizona Nexus research grant. Norman R. Friedman, intellectual property rights (sleep study and diagnosis of sites of obstruction projects) and Home Sleep Apnea Test (HSAT) research collaborator. Lorraine C. Nnacheta, salaried employee of the AAO-HNSF.

Sponsorships: AAO-HNSF.

Funding source: AAO-HNSF.

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