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Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Technology Assessment of Scheduled Surgical Procedures

Tonsillectomy

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Safer Better Care

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1 Tonsillectomy

1.1 Scope of this health technology assessment

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral/treatment thresholds for tonsillectomy, a high volume scheduled surgical procedure within the publicly funded healthcare system in Ireland. The effectiveness of tonsillectomy may be limited unless undertaken within strict clinical criteria. This report is one of a series of HTAs of scheduled surgical procedures; details of the background to the request and general methodology are included in the separate 'Background and Methods' document.⁽¹⁾

The scope of this HTA is to recommend clinical referral and treatment thresholds to be used in the assessment, referral and surgical management of patients for whom tonsillectomy, with or without adenoidectomy, is being considered. Input from an expert advisory group, international guidelines, international policy documents and thresholds, and economic evaluations were reviewed to inform the referral criteria. Additionally the resource and budget impact were assessed where appropriate.

1.2 Surgical indications

The main indications for tonsillectomy (surgical removal of the tonsils) are sleep disorder breathing (SDB) due to enlarged tonsils (tonsillar hypertrophy) and sore throat due to recurrent throat infections.⁽²⁾ SDB encompasses a range of obstructive disorders that increase in severity from primary snoring to obstructive sleep apnoea (OSA).⁽³⁾ Complete or partial tonsillectomy may be indicated in children with SDB secondary to tonsillar hypertrophy. Adenoidectomy may also be indicated, particularly in patients with obstructive sleep apnoea, to relieve symptoms of obstruction.⁽³⁾ Over the last decade, international reports suggest that there has been a trend change so that SDB is now the most common indication for paediatric tonsillectomy, particularly in younger children.^(4;5)

Throat infections are defined as episodes of sore throat caused by a viral or bacterial infection of the pharynx (most commonly streptococcal pharyngitis), tonsils (tonsillitis), or both.⁽³⁾ They may be associated with pain, difficulty swallowing, headaches, ear pain, fever, chills, or tenderness of the jaw and throat. Tonsillectomy for recurrent tonsillitis typically requires complete removal of the tonsils and their capsules. Adenoidectomy may also be carried out. A severe complication of tonsillitis, arising mainly in adults, is peritonsillar abscess or quinsy, and this condition often requires hospital admission for treatment and pain control.⁽⁶⁾

1.3 Surgical procedures, potential complications and alternative treatments

The tonsillectomy procedure consists of two surgical stages: removal of the tonsils followed by haemostasis. The traditional technique for tonsillectomy consists of cold steel dissection of the tonsils with bleeding controlled by pressure and ligatures. This surgical strategy allows for complete removal of the tonsil and its capsule (extracapsular). Newer techniques have been introduced to reduce perioperative complications including electrosurgery, cautery dissection, coblation and radiofrequency ablation.⁽²⁾ Techniques for partial removal of the tonsil that preserve a rim of lymphoid tissue and tonsillar capsule (intracapsular) have also been introduced to reduce peri-operative complications. The preserved tissue may act as a buffer to aid an easier recovery and reduce haemorrhage rates, but at a risk of tonsil regrowth and potentially revision surgery.⁽²⁾ Several instruments have been used to perform partial removal including the microdebrider, the coblator and the traditional cold steel method.⁽²⁾

Tonsillectomy surgery is widely perceived to be a safe procedure. It typically requires a short stay in hospital and a general anaesthetic. Return to usual activities typically takes an average of two weeks with loss of time from work or education.⁽⁷⁾ An inevitable episode of post-operative pain is associated with tonsillectomy lasting an average of 5 to 7 days.⁽⁸⁾ Life threatening complications of the conditions associated with tonsillectomy are rare and the main aim of surgery is to relieve symptoms.⁽⁹⁾ Risks include those associated with anaesthesia and general surgical complications.

The main complication associated with tonsillectomy itself is post-operative bleeding.⁽²⁾ Primary haemorrhage occurs within 24 hours of surgery in approximately 0.2% to 2.2% of patients.^(2;3) Secondary haemorrhage occurs more than 24 hours after surgery in approximately 0.1% to 3% of patients.^(2;10) Surgical technique can have an impact on post-operative bleeding.⁽¹¹⁾ Several systematic reviews and guidelines have summarised randomised controlled trials (RCTs) on cold steel tonsillectomy versus diathermy, monopolar cautery, harmonic scalpel or coblation techniques with no significant difference in post-operative haemorrhage reported.^(2;9;12;13) The reported results are in many cases conflicting with no definite consensus regarding the optimal technique or optimal combination of techniques with the lowest morbidity rates.^(2;14)

Several non-surgical options for treatment of sore throat are available for children and adults. These include pain relief, throat sprays and antibiotic options. These alternatives are described in the SIGN guidelines and are not included here as they are beyond the scope of this HTA.⁽⁷⁾

1.4 Current practice in Ireland

Patients with recurrent sore throats associated with tonsillitis or tonsillar hypertrophy, who are possible candidates for tonsillectomy, are generally referred for an outpatient consultant appointment by their general practitioner (GP). Referral or treatment thresholds (similar to those discussed in Section 2 below) may be used by GPs and surgeons to identify eligible candidates for referral or treatment. However, it is unclear what thresholds are currently being used and how consistently they are being applied.

Tonsillectomy is a common surgical procedure within the publicly-funded healthcare system in Ireland. The Hospital In-patient Enquiry (HIPE) system reports that there were approximately 3,500 tonsillectomies undertaken in 2011. Tonsillectomy may be coded as the principal procedure or as a secondary procedure. For consistency and completeness, data are reported to include the principal and secondary procedures (i.e. 'all procedures') with all data presented on this basis. The International Classification of Diseases (ICD) intervention codes used to retrieve this data are listed in Table 1.1.

Table 1.1 HIPE ICD-10AM/ACHI list of intervention codes for tonsillectomy

Intervention code	Description
41789-00	Tonsillectomy without adenoidectomy
41789-01	Tonsillectomy with adenoidectomy

In 2011, the principal diagnosis listed for tonsillectomy with or without adenoidectomy for both children (≤ 16 years) and adults (> 16 years) was chronic tonsillitis, accounting for 80% and 87% of cases, respectively (Tables 1.2 and 1.3).⁽¹⁵⁾ This is different to the emerging international trend of SDB as the most common indication for paediatric tonsillectomy; however there is evidence of variation between hospitals. For example, a tertiary referral centre for complex cases reported approximately 60% of cases being undertaken for a principal diagnosis of tonsil and adenoid hypertrophy with only 40% undertaken for chronic tonsillitis.⁽¹⁶⁾ Based on 2011 cost and activity data, tonsillectomy accounts for 42% of all otolaryngology procedures performed annually in the publicly funded healthcare system in Ireland, and makes up 44% of the overall otolaryngology surgical costs.⁽¹⁷⁾

Table 1.2 Principal diagnoses for tonsillectomy in children ≤ 16 years (HIPE data 2011)

Principal diagnosis	Code	Number of procedures	% of total procedures
Chronic tonsillitis	J350	2,100	80.28
Hypertrophy of tonsils with hypertrophy of adenoids	J353	335	12.81
Hypertrophy of tonsils	J351	55	2.1
Obstructive sleep apnoea syndrome	G4732	19	0.73
Chronic mucoid otitis media	H653	18	0.69
Chronic disease of tonsils and adenoids; unspecified	J359	18	0.69
Hypertrophy of adenoids	J352	15	0.57
Other chronic diseases of tonsils and adenoids	J358	11	0.42
Acute tonsillitis; unspecified	J039	9	0.34
Other*	-	36	1.42

HIPE: Hospital In-Patient Inquiry (HIPE) Scheme.

Data includes all activity in publicly funded hospitals including procedures in patients that used private health insurance.

**Note: The remaining principal diagnoses contain five or fewer cases per diagnosis code.*

Table 1.3 Principal diagnoses for tonsillectomy in adults > 16 years (HIPE data 2011)

Principal diagnosis	Code	Number of procedures	% of total procedures
Chronic tonsillitis	J350	949	86.67
Hypertrophy of tonsils	J351	40	3.65
Acute tonsillitis; unspecified	J039	22	2.01
Other chronic diseases of tonsils and adenoids	J358	14	1.28
Malignant neoplasm of tonsil; unspecified	C099	11	1
Other*	-	59	5.35

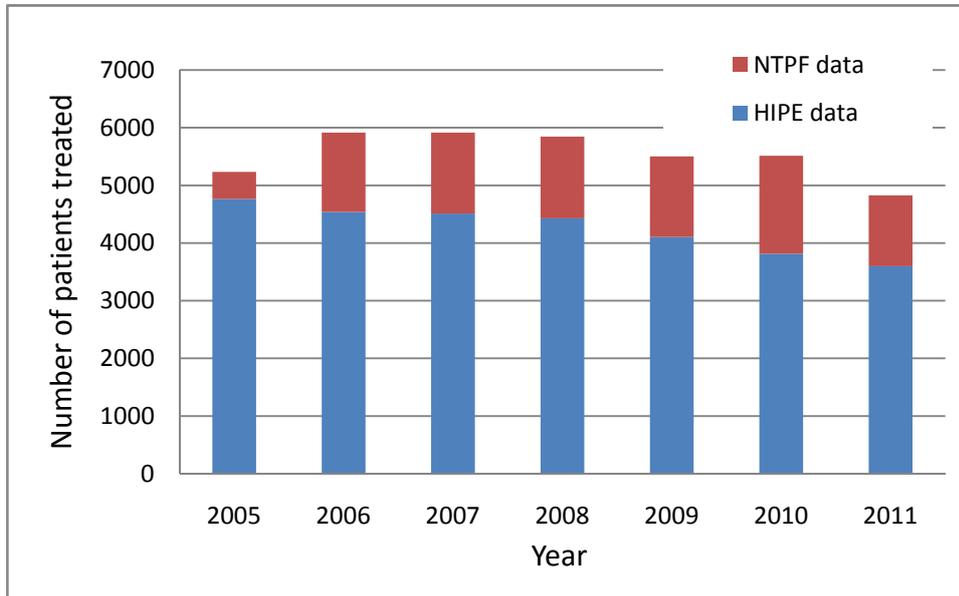
HIPE: Hospital In-Patient Inquiry (HIPE) Scheme.

Data includes all activity in publicly funded hospitals including procedures in patients that used private health insurance.

**Note: The remaining principal diagnoses contain five or fewer cases per diagnosis code.*

The numbers of tonsillectomies undertaken in the publicly funded healthcare system has declined since 2005 (Figure 1.1). In addition to activity levels in public hospitals, tonsillectomy in private hospitals has also been procured for the public healthcare system via the National Treatment Purchase Fund (NTPF).⁽¹⁸⁾ Data on the total number of procedures undertaken in the publicly funded system and including the additional procedures funded by the NTPF are shown in Figure 1.1.

Figure 1.1 Number of tonsillectomy procedures (with/without adenoidectomy) provided through the publicly funded healthcare system (2005 – 2011)

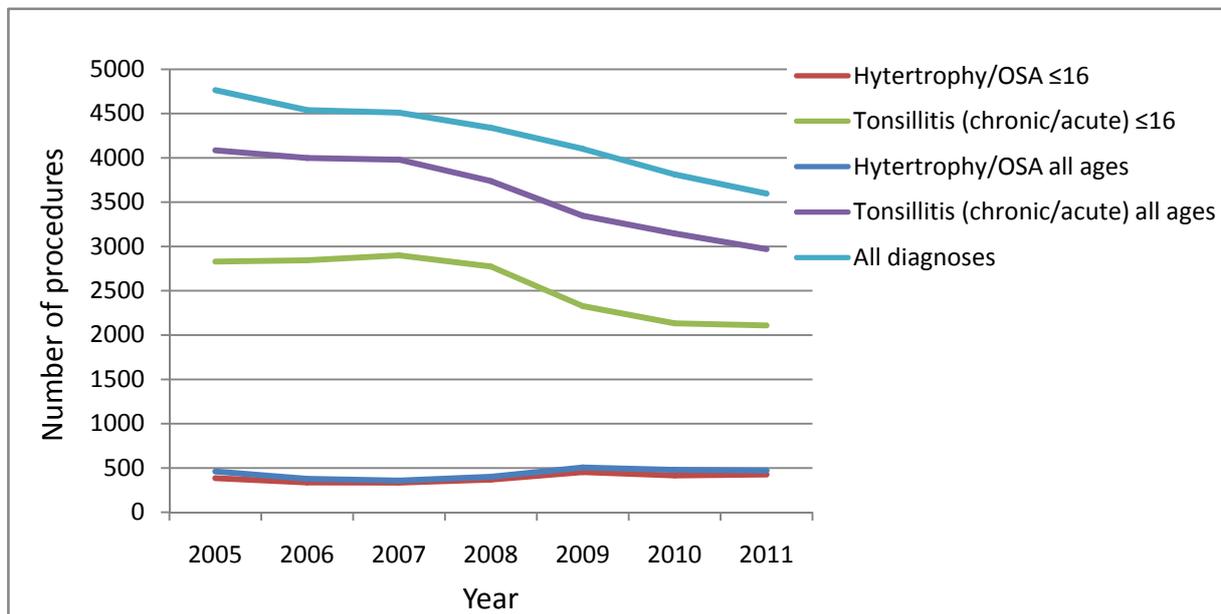


HIPE: Hospital In-Patient Inquiry (HIPE) Scheme; NTPF: National Treatment Purchase Fund. HIPE data includes all activity in publicly funded hospitals including procedures in patients that used private health insurance.

Source: HIPE data accessed via ESRI HIPE Online Portal 28 January 2013, NTPF activity data.

The decline in the number of procedures undertaken mainly relates to a decline in procedures for patients with a principal diagnosis related to tonsillitis. In contrast, there has been no change in the number of procedures undertaken for diagnoses related to hypertrophy of the tonsils/adenoids or obstructive sleep apnoea, so that these now account for a proportionally higher number of those undergoing surgery, particularly in the paediatric setting (Figure 1.2).

Figure 1.2 Number of tonsillectomy procedures (with/without adenoidectomy) for tonsillitis compared to hypertrophy/obstructive sleep apnoea (2005 – 2011)



The majority of tonsillectomies in Ireland are carried out in children less than 16 years of age (2,616, 73%) with approximately 16% (574) in children less than three years of age.⁽¹⁵⁾ However, tonsillitis can be a much more severe and debilitating condition in adults.⁽¹⁹⁾ HIPE data indicate that tonsillectomies are almost exclusively undertaken (99%) by otolaryngologists (5% referred to as paediatric ear nose and throat (ENT) consultants);⁽¹⁵⁾ the availability of this procedure is usually thus restricted to facilities with an otolaryngology service. Tonsillectomy rates vary across the four Health Service Executive (HSE) regions (Table 1.4). Some of this variability may be explained by the variation in the availability of an otolaryngology service, hospital size or specialisation. Regional comparisons show that 52% (0.4% rate per 100,000 population) of the tonsillectomies in the HSE Dublin North East region in 2011 included an adenoidectomy, compared to 24% (0.2% rate per 100,000 population) in the HSE South region. The average length of stay (ALOS) was 1.54 days (range 1.43 to 1.81 days per region) for tonsillectomy (with or without adenoidectomy).

Table 1.4 HIPE data per HSE region (2011)

HSE health region	Tonsillectomies					Adenoidectomy		% of tonsillectomies with adenoidectomy
	Number	Rate per 1,000 pop.*	Inpatient bed days	% day-case	Avg. age	Number	Rate per 1,000 pop.*	
Dublin North East	778	0.76	1,107	1	8.97	404	0.40	52
Dublin Mid East	1,019	0.77	1,740	6	12.81	310	0.24	30
South	964	0.83	1,401	0	13.81	235	0.20	24
West	836	0.77	1,186	1	12.83	354	0.33	42
Total	3,597	-	5,434	2	12.3	1303	-	37

*Note: This data excludes public patient activity purchased by the NTPF. *Population rates are based on area of residence, Census 2011.⁽²⁰⁾*

Although identified as being in the HSE 'Basket of 24 Procedures' – a range of elective surgical procedures for which there is a stated target of 75% to be undertaken as day case surgery⁽²¹⁾ – HIPE data indicate that only 2% of tonsillectomies in 2011 were undertaken as day case procedures. Variations in day case rates may be due to factors such as day case theatre availability, theatre closing times, capacity to manage complications such as haemorrhaging, the complexity of the patient's condition or social issues such as distance from hospital etc..

Despite frequent activity, tonsillectomy features on waiting lists due to limited capacity, requiring triaging of some patients particularly urgent cases.⁽¹⁶⁾ A HSE report on outpatient data in 2012 noted that 4,061 patients were referred for otolaryngology outpatient appointments in February 2012 with 'did not attend' (DNA) rates reaching a maximum of 58.9% in some hospitals.⁽²²⁾ DNAs may occur for several reasons. In the case of tonsillectomy, some DNAs may be due to the patient's symptoms resolving over time.

Data from the National Patient Treatment Register reflecting surgical and medical inpatient and day case waiting lists for all public hospitals, indicates that approximately 1,500 patients were on waiting lists for tonsillectomies in December 2012, of whom 63% were waiting less than three months, 27% between three and six months, and 10% for over six months.⁽²³⁾ It is unclear what proportion of patients who are referred for outpatient review with symptoms of tonsillitis or tonsillar hypertrophy are subsequently listed for surgery. Reports from the NTPF (2007 to 2011) indicate that 34% (2008) to 52% (2011) of patients referred for outpatient surgical review (across all surgical disciplines) are referred back to their GP without undergoing surgery or being referred for further testing.⁽²⁴⁾ This suggests that the use of clear referral criteria and treatment thresholds may help clarify the criteria

under which referral for surgery should take place and potentially limit the number of inappropriate referrals.

2 Clinical referral / treatment threshold

2.1 Review of the literature

A comprehensive review of the literature was conducted during January 2013 to identify international clinical guidelines, health policy documents describing treatment thresholds that are in place in other health systems, and economic evaluations for tonsillectomy. The approach and general search terms are described in Appendix 1 in the Background and Methods document; a summary of the results is included in Table 2.1.

Table 2.1 Included evidence sources to inform clinical referral thresholds

Publication Type	Number	References
Clinical guidelines	8	(3;6;7;25-29)
Systematic reviews	2	(8;30)
Clinical studies	3	(30-32)
Cost-effectiveness studies	3	(31;33;34)

2.2 Clinical evidence

2.2.1 Sore throat in children:

As discussed in Section 1.4, HIPE data indicate that the majority of tonsillectomies are carried out in children.⁽¹⁵⁾ The most recent and comprehensive guidelines retrieved are the American Academy of Otolaryngology Head and Neck Surgeons 'Tonsillectomy in children' (2011) and the Scottish Intercollegiate Guidelines Network 'Management of sore throat and indications for tonsillectomy' (2010, for children and adults).^(3;7) These guidelines were informed by several randomised controlled trials (RCTs) including a study by Paradise et al. which developed the widely accepted criteria for referral for surgery for recurrent sore throat and the clinical features to define 'recurrent sore throat' in children.⁽³⁵⁾ The criteria are: seven episodes of tonsillitis in the preceding year, five in each of the preceding two years, or three in each of the preceding three years. The clinical features for recurrent sore throat include sore throat plus the presence of one or more of the following to qualify as one episode: temperature greater than 38.3°C, or cervical lymphadenopathy (tender

lymph nodes or >2cm), or tonsillar exudate, or a positive culture for group A beta-haemolytic streptococcus.⁽³⁵⁾

Watchful waiting is recommended for 'mild sore throats' in children⁽⁷⁾ based on RCTs and systematic reviews conducted by Burton et al., Buskens et al., Paradise et al. and Lock et al.^(8;31;33;35) or for fewer episodes of recurrent sore throat than the Paradise criteria above.⁽³⁾ This is to avoid unnecessary intervention in children who are likely to improve without surgery.⁽³⁾ Several other international guidelines have been developed over the last number of years, all of which are based on these criteria, see Appendix 1 for details.

Appendix 2 includes details of the most relevant and recent Cochrane reviews and clinical studies retrieved from the literature. A Cochrane review by Burton et al. in 2009 reported that the benefits of surgery are greatest for those fulfilling the Paradise criteria.⁽⁸⁾ They report that good evidence about the effects of tonsillectomy is only available for children and the majority relates to the first year after surgery.

For more severely affected children (fulfilling the Paradise criteria) tonsillectomy (with or without adenoidectomy) will avoid one unpredictably timed episode of moderate or severe sore throat in the first year post-surgery at a cost of an additional episode of predictable postoperative pain.⁽⁸⁾ Less severely affected children who have tonsillectomy (with or without adenoidectomy) may not have another sore throat anyway, the chance being slightly reduced with surgery. The authors note that one reason that the impact of surgery is so modest is because many patients in the control group get better spontaneously. Further conclusions include that doubt remains about whether or not removing the adenoids has an effect on the frequency and/ or severity of sore throats.⁽⁸⁾

A HTA conducted in 2010 in the UK by the National Institute for Health Research (NIHR) (Lock et al.,) reported on a pragmatic RCT (n=268) with a parallel non-randomised preference study (n=387) for children aged 4 to 15 years old.⁽³¹⁾ They reported that during both years of follow-up, children randomised to surgical management were less likely to record episodes of sore throat than those randomised to medical management; the incidence rate ratios in years 1 and 2 were 0.70 [95% confidence interval (CI) 0.61 to 0.80] and 0.54 (95% CI 0.42 to 0.70), respectively. They reported clinical benefits of tonsillectomy that persist for at least two years with a reduction of 3.5 episodes of sore throat.

In the UK, there are 146 primary care trusts (PCTs) charged with service delivery for the National Health Service (NHS). Many of these PCTs have generated treatment thresholds for elective surgery (including tonsillectomy) that are linked to the funding of these interventions. PCT policies identify interventions that are 'not normally

funded' or that must meet specified criteria for funding to apply. The criteria for tonsillectomy are generally evidence based and are consistent with the Paradise criteria and guidelines from the Scottish Intercollegiate Guidelines Network (SIGN). Examples of two PCT policies are included in Appendix 2. The US also has insurance reimbursement criteria for tonsillectomy (Appendix 2), again these are consistent with the Paradise criteria.

2.2.2 Sore throat in adults:

The SIGN guidelines apply the Paradise criteria to both children and adults.⁽⁷⁾ They state that evidence on which adults will benefit from tonsillectomy is not available.⁽⁷⁾ Additionally, Italian guidelines for children and adults recommend at least five episodes per year that are disabling and impair normal activity with symptoms for a minimum of one year.⁽²⁷⁾ A Cochrane review by Burton et al. in 2009 reported that there is limited evidence of benefit of tonsillectomy in adults.⁽⁸⁾ Another study reports that apart from adults with proven recurrent group A streptococcal pharyngitis,⁽³⁶⁾ evidence that adults will benefit from tonsillectomy is not available. Both of these studies are discussed in the SIGN guidelines.

2.2.3 Tonsillar hypertrophy in children

In Ireland, the second most common indication for tonsillectomy is tonsillar hypertrophy.⁽¹⁵⁾

A meta-analysis published in 2011 concluded that tonsillectomy is effective for treating sleep disorder breathing (SDB) in children with tonsillar hypertrophy⁽³⁰⁾ and a recent clinical practice guideline has recommended tonsillectomy for this population.⁽³⁾ However, it also recommends that, in addition to tonsillar hypertrophy, there should be evidence of abnormalities of respiratory pattern or adequacy of ventilation during sleep including, but not limited to, snoring, mouth breathing, and pauses in breath. There is some debate as to the diagnosis of obstructive sleep apnoea (OSA) in children and the need for extensive diagnostic tests to make an appropriate diagnosis. However, access to these diagnostics tests is limited in Ireland⁽¹⁶⁾ and obtaining an appointment for a polysomnography (sleep study) also features on the waiting lists.⁽³⁷⁾ In the meantime, such children should be referred for further investigation and consideration for tonsillectomy particularly if the tonsillar enlargement is sufficient to cause airway obstruction ('kissing tonsils'[‡]).⁽¹⁶⁾ If the tonsils are smaller and causing less obstruction, referral to a respiratory consultant may be more appropriate.⁽¹⁶⁾

[‡] Tonsils are graded in size from 1 to 4, with the largest commonly called 'kissing tonsils' because they are so large they bump each other.

The current surgical treatment of choice for OSA in children is adenotonsillectomy.^(38;39) However, a recent Cochrane review did not find any strong evidence from randomised trials to support this.⁽⁴⁰⁾ The American Academy of Paediatrics states that adenoidectomy or tonsillectomy alone may not be sufficient because residual lymphoid tissue may cause persistent obstruction.⁽³⁹⁾

2.2.4 Tonsillar hypertrophy in adults:

SIGN guidelines for management of OSA in adults agrees that large tonsils in an adult should prompt referral to an otolaryngologist.⁽²⁹⁾ However, they note that the evidence is weak with respect to this.⁽²⁹⁾ OSA is multifactorial and a tonsillectomy may not alleviate symptoms. Deciding which of the treatment options is most appropriate for the management of OSA depends on the severity of the condition and the characteristics of the patient.⁽²⁹⁾ The SIGN recommended treatment for moderate or severe OSA is continuous positive airway pressure.⁽²⁹⁾ Therefore, a patient with large tonsils may first be referred to a respiratory consultant.⁽¹⁶⁾

2.2.5 Other indications:

Other indications for tonsillectomy include peritonsillar abscess or suspected tumour. Suspected malignancy is an absolute indication for tonsillectomy and patients should be referred to an otolaryngologist immediately.^(16;41;42)

There is limited evidence for tonsillectomy for peritonsillar abscess;⁽²⁵⁾ however, the American Academy of Otolaryngology Head and Neck Surgeons notes that some authors advocate 'quinsy' tonsillectomy when an abscess is present, especially if general anaesthesia is required for drainage (e.g., uncooperative child) and there is a prior history of tonsil disease.⁽³⁾ It notes that the role of tonsillectomy in managing peritonsillar abscess remains controversial, but the threshold for surgery is lowered when a child with recurrent throat infection develops, or has a past history of, peritonsillar abscess. It states that clinicians should assess a child with recurrent throat infection who does not meet the Paradise criteria, but has modifying factors, such as peritonsillar abscess, favouring tonsillectomy.⁽³⁾ HIPE data indicates that the numbers of patients undergoing surgery for this indication is very low (<1% of adults and children). A recent evidence-based review of peritonsillar abscess reported that overall, the recurrence rate of peritonsillar abscess is poorly defined but estimated as 9% to 22%.⁽⁴³⁾ Patients presenting with a peritonsillar abscess and a history of tonsil disease should be considered for referral for further investigation.

2.3 Cost-effectiveness evidence

The British Association of Otorhinolaryngologists (ENTUK) estimates that 35 million days are lost from school or work due to sore throats in the UK with GP consultations

for sore throat costing approximately £60 million annually.⁽⁶⁾ No relevant economic evaluations based on, or generalisable to, Irish costs were identified. Appendix 3 summarises a sample of cost-effectiveness studies retrieved; these studies are in agreement with the recommendations provided above. However, a Belgian study completed a study from a societal perspective and indicated that watchful waiting results in a higher cost to society compared to tonsillectomy, given the cumulative costs of parents' absenteeism.⁽³⁴⁾ The guidelines for economic evaluation of health technologies, including surgery, in Ireland require that evaluations are conducted from the perspective of the payer, that is the publicly-funded healthcare system, although additional relevant costs should be highlighted, as appropriate.⁽⁴⁴⁾

2.4 Budget impact and resource implications

The estimated average cost of a tonsillectomy in Ireland in 2011 is included in Table 2.2. This equated to an approximate cost of €11,293,000 based on 3,500 cases of which approximately 2% were conducted as day surgery.⁽¹⁵⁾

Table 2.2 Cost of HSE inpatient and day case surgery summarised by diagnosis-related group (based on 2011 costs and activity)

DRG code	Description	Cost/case (€)
D11Z	Tonsillectomy, Adenoidectomy (inpatient)	3,261
D11	Tonsillectomy, Adenoidectomy (outpatient)	1,539
-	Outpatient appointment	130

Data summary from the HSE National Casemix Programme based on activity and costs reported by 39 participating hospitals.

Reports suggest that up to 50% of those referred to outpatient clinics for tonsillectomy are not suitable candidates for surgery at that time.⁽¹⁶⁾ Across all specialities, approximately 30% to 50% of individuals seen in surgical outpatient clinics between 2005 and 2011, through the NTPF, were referred back to their GP without undergoing surgical treatment.⁽²⁴⁾ This suggests that a proportion of those referred for surgery do not meet the minimum clinical criteria for surgery in terms of the number or severity of episodes of tonsillitis they have experienced. This may include patients whose symptoms are expected to resolve over time and for whom watchful waiting is appropriate. Therefore, it is predicted that the use of transparent clinical referral criteria has the potential to reduce the number of patients being referred for outpatient review for whom non-surgical management is recommended. This would help optimise the patient journey, ensuring the right patients are referred and treated at the right time, allowing more efficient use of available resources.

International data and guidelines suggest that paediatric tonsillectomy may be performed safely in a day case setting.⁽²⁾ Increasing the proportion of procedures

undertaken as day case surgery has the potential to reduce the overall cost of care, if resources can be realigned to ensure that patient safety is not compromised.

2.5 Advice on clinical referral / treatment threshold

The literature indicates that there is a general agreement with the Paradise criteria for referral with recurrent sore throat. Therefore, the following criteria are advised in line with this:

Referral for recurrent sore throat is recommended for children and adults if:

- ≥ 7 episodes of tonsillitis in the preceding year, **OR**
- ≥ 5 in each of the preceding two years, **OR**
- ≥ 3 in each of the preceding three years.

The clinical features include sore throat plus the presence of ≥ 1 of the following qualifies as a counting episode:

- temperature $> 38.3^{\circ}\text{C}$, **OR**
- cervical lymphadenopathy (tender lymph nodes or >2 cm), **OR**
- tonsillar exudate, **OR**
- a positive culture for group A b-haemolytic streptococcus.

AND

Episodes of sore throat are disabling preventing normal function (e.g. school or work attendance)

OR

Children and adults who are immunocompromised, or have other medical conditions (e.g. diabetes, cystic fibrosis), which would leave them at risk of severe complications as a result of tonsillitis.

Other indications for immediate referral to an otolaryngologist (ENT specialist):

- suspected tonsillar malignancy in children and adults
- tonsillar enlargement sufficient to cause airway obstruction in children
- peritonsillar abscess in patients with a history of tonsil disease or peritonsillar abscess.

3 Discussion

Referral thresholds have been recommended based on a comprehensive review of the literature with the aim to treat the right patients at the right time and to avoid unnecessary interventions, particularly in those who are likely to improve without

surgery. This referral threshold is not new to the Irish system; it is currently being used by many primary care practitioners and surgeons, but not necessarily consistently.⁽¹⁶⁾ As noted, there is evidence of regional variation in treatment practices and there is evidence that a substantial number of those referred for OPD review either do not attend (perhaps because of symptom resolution) or are considered not suitable candidates for surgery when first seen. It is suggested that the practice of early referral is caused by the long waiting lists for outpatient appointments and surgery, with primary care practitioners resorting to referring their patients earlier than necessary in the anticipation that the patient's condition will have persisted with ongoing episodes of tonsillitis so that they warrant surgery by the time they are reviewed. However, this ultimately makes the waiting lists less efficient. The Council of Europe's report on managing waiting lists states that patients should not be added to a waiting list to reserve a place against the possibility that in the future treatment might be warranted.⁽⁴⁵⁾

As noted in Section 1.4, there has been a decline in the number of tonsillectomy procedures undertaken in the publicly funded system in recent years, particularly for procedures with a principal diagnosis of chronic tonsillitis. This may reflect a change in referral and treatment practices or a difficulty in accessing surgery for these patients. Clinicians may be prioritising access for patients with diagnoses related to tonsillar hypertrophy, particularly in the paediatric setting as these now account for 16% of all paediatric procedures (2011) compared to 11% of procedures in 2005. This is consistent with international trends where tonsillar hypertrophy is a more common indication for paediatric tonsillectomy than infection, particularly in younger children. Given these factors, the implementation of treatment thresholds may not lead to a substantial reduction in the number of tonsillectomies undertaken in all health areas as the threshold will only impact patients referred for recurrent sore throat associated with tonsillitis. However, the implementation of referral thresholds is relevant: the benefit of such criteria is that there will be improved clarity for the GP and patients and it will allow for standardisation of care. Patients would only be referred to a hospital when appropriate, remaining under the care of their primary care practitioner until then. This could potentially streamline the patient journey through reducing the number of unnecessary hospital appointments, leading to a reduction in waiting times for these appointments, improving access for those with the greatest clinical need and allowing for more efficient use of resources, without causing harm or reducing benefit.

Although beyond the scope of this HTA, feedback was obtained from the EAG members and through public consultation in relation to the significant concerns regarding the ability of the HSE to effectively implement referral and treatment thresholds that will allow the timely treatment of patients in need of surgery given

the significant capacity constraints in the system. Concern was also expressed regarding the need for clinical discretion if a patient is on the borderline of the threshold, particularly if the lengthy waiting lists for outpatient review and surgery persist. Concern was expressed that implementation of referral criteria may lead to an increase in primary care visits for the purpose of ensuring that the number of episodes of sore throat and the severity of these are documented to fulfil the Paradise criteria. The need of continuity of care for patients between providers was also highlighted in terms of this documentation.

A recent study audited the clinical indications for tonsillectomy in the UK (two rounds, n=17, n=100) to determine if consultants were adhering to guidelines.⁽⁴⁶⁾ They found that otolaryngologists' tonsillectomy decisions were justified, but were inadequately documented. This may be the case in Ireland also – currently no audit data is available to support requirements for surgery and it remains unclear as to the absolute impact any thresholds would have on the number undergoing surgery. However, based on information with respect to outpatient activity, it appears that guidelines could help triage patients at primary care level, reducing the number of referrals to surgical outpatient clinics.⁽¹⁶⁾

Finally, although beyond the scope of this HTA, it was noted that there may be scope for improvement in the number of tonsillectomies undertaken as day case procedures, resulting in a more efficient use of resources. Expert feedback highlighted that proper planning and resources are required to safely provide tonsillectomy as day case surgery, but that the cost of this could be offset through realignment of existing care pathways. The proportion of surgeries undertaken as day case surgery is audited by the HSE through HealthStat.⁽²¹⁾

In conclusion, the suggested referral and treatment criteria reflect international evidence-based best practice. They also represent existing best practice in Ireland. Applying these consistently throughout the system should bring greater transparency, ensure greater equity of access based on clinical need and allow maximal benefit to be gained from existing resources.

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Appendix 1 – International clinical referral thresholds

Guideline	Scope	Tonsillectomy Thresholds for sore throat and other indications	Evidence
French Society of ENT and Head and Neck Surgery (SFORL) (2012) ⁽²⁵⁾ France	Indications: Tonsillar hypertrophy, recurrent tonsil infection Population: Paediatric	Recurrent acute tonsillitis: ≥ 3 such episodes of infection per year over a 3 year period or 5 over 2 years Other indications: Chronic tonsillitis: low level of evidence Recurrent peri-tonsillar abscess (low level of evidence)	Literature review: Systematic Grading system: Oxmen et al. Key references: Not listed.
American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) (2011) ⁽³⁾ US	Indications: Sore throat, SDB, quinsy. Population: Children (1-18 y)	(1) Watchful waiting for recurrent throat infection if < 7 episodes in past year or < 5 episodes per year in past 2 years or < 3 episodes per year in past 3 years; (2) Assessing child with recurrent throat infection who do not meet criteria above for modifying factors that may favour tonsillectomy, which may include (not limited to) multiple antibiotic allergy/intolerance, periodic fever, aphthous stomatitis, pharyngitis and adenitis, or history of peritonsillar abscess; Other indications: Diagnosis of SDB with documentation of all of following: Tonsillar hypertrophy; AND abnormalities of respiratory pattern or adequacy of ventilation during sleep, including (not limited to) snoring, mouth breathing, and pauses in breathing; AND a condition related to SDB (not limited to growth retardation, poor school performance, enuresis, behavioural problems) that is likely to improve after tonsillectomy. OR A diagnosis of SDB for a child < 3 years of age with documentation of: Tonsillar hypertrophy; AND SDB is chronic (> 3 months in duration); AND Child's parent or caregiver reports regular episodes of nocturnal choking, gasping, apnoea, or breath holding. OR A diagnosis of OSA with documentation of: Tonsillar hypertrophy; AND A polysomnogram with an Apnoea-Hypopnea Index (AHI) > 1.0. OR They note that some authors advocate "quinsy" tonsillectomy when an abscess is present, especially if general anaesthesia is required for drainage (eg, uncooperative child) and there is a prior history of tonsil disease.	Literature review: Systematic Grading system: AAP scale Key references: SIGN 117, ⁽⁷⁾ Paradise et al. ⁽³⁵⁾
Scottish Intercollegiate Guidelines Network (SIGN) 117 (2010) ⁽⁷⁾ UK	Indications: Sore throat. Population: Children (4-16 y) Adults	1) Watchful waiting more appropriate than tonsillectomy for children with mild sore throats (<i>Grade A</i>) 2) Tonsillectomy recommended for recurrent severe sore throat in adults (<i>Grade A</i>) 3) Indications for tonsillectomy consideration for recurrent acute sore throat (children and adults) (<i>Grade D</i>): a. Sore throat due to acute tonsillitis b. Episodes of sore throat are disabling and prevent normal function c. ≥ 7 well documented, clinically significant, adequately treated sore throats in preceding year or d. ≥ 5 such episodes in each of preceding 2 years or e. ≥ 3 such episodes in each of preceding 3 years	Literature review: Systematic Grading system: SIGN scale Key references: SIGN 34, ⁽⁴⁷⁾ Paradise et al., ⁽³⁵⁾ Lock et al., ⁽³¹⁾ Burton et al., ⁽⁸⁾ Buskens et al., ⁽³³⁾

<p>Scottish Intercollegiate Guidelines Network (SIGN) 73 (2003)⁽²⁹⁾ UK</p>	<p>Indications: OSA. Population: Adults</p>	<p>The presence of large tonsils in a patient with diagnosed OSA should prompt referral to an ENT surgeon for consideration of tonsillectomy.</p>	<p>Literature review: Systematic Grading system: SIGN scale Key references:</p>
<p>Royal Australasian College of Physicians and The Australian Society of OHNS (2008)⁽²⁸⁾ Australia</p>	<p>Indications: Upper Airway Obstruction with OSA, Frequent Recurrent Acute Tonsillitis, Peritonsillar Abscess, Suspected Neoplasm, Uncommon indications Population: Children</p>	<p>For frequent recurrent acute tonsillitis. Tonsillectomy per Paradise criteria supported. Tonsillectomy/adenotonsillectomy indicated for episodes of:</p> <ul style="list-style-type: none"> a. Recurrent acute tonsillitis. As a guide, 7 episodes in preceding 12 months, OR b. 5 in each year for 24 months, OR c. 3 per year for 3 years; <p>Account should be taken of the clinical severity of episodes and that this may result in as little as 1 less episode of sore throat with fever per year.</p> <p>Other indications: The indications for tonsillectomy/adenotonsillectomy are:</p> <ul style="list-style-type: none"> a. Upper Airway Obstruction in Children with OSA b. Frequent Recurrent Acute Tonsillitis c. Peritonsillar Abscess d. Suspected Neoplasm e. Uncommon indications 	<p>Literature review: Literature search Grading system: NHMRC Key references: Paradise et al.,⁽³⁵⁾ SIGN 34⁽⁴⁷⁾ Burton et al., (1999)</p>
<p>Sistema Nazionale Linee Guida (SNLG15) (2008)⁽²⁷⁾ Italy</p>	<p>Indications: OSA, severe recurrent tonsillitis Population: Children and adults</p>	<p>1) Recurrent tonsillitis meeting all of the following criteria (Level II/A evidence): ≥ 5 episodes per year; episodes disabling and impairing normal activities; symptoms last for minimum of 1 year. At least 6-month of watchful waiting recommended to assess pattern of symptoms, using a clinical diary. In less severe cases, not meeting cited criteria and responding to antibiotics, watchful waiting recommended.</p> <p>2) VI/B Cited criteria should be used less strictly in presence of: Significant laterocervical adenopathy (> 2 cm) due to recurrent tonsillitis and persisting after administration of antibiotics; one or more episodes of peritonsillar abscess; febrile convulsions; deformities of respiratory tract or of cardio circulatory system, or other severe pathologies.</p> <p>3) IV/B Adenoidectomy associated with tonsillectomy should be carried out only if clinical indications justifying combined surgery are present.</p> <p>Adenotonsillectomy is the recommended treatment in children with OSAS due to adenotonsillar hypertrophy. (Level III/A) Simple adenoidectomy is not recommended, considered the high risk of re-intervention due to OSAS persistence (Level III/A)</p>	<p>Literature review: Systematic Grading system: PNLG Method Key references: Paradise et al.,⁽³⁵⁾ SIGN 34⁽⁴⁷⁾ Burton et al., (2002)</p>
<p>Ministry of Health</p>	<p>Indications: Recurrent tonsillitis,</p>	<p>Recurrent tonsillitis: i) The symptom of sore throat is due to inflammation of the tonsils.</p>	<p>Literature review: Evidence based review</p>

<p>Malaysia (2003)⁽²⁶⁾ Malaysia</p>	<p>peritonsillar abscess or quinsy Population: Children and adults</p>	<p>ii) > 6 episodes of tonsillitis over a 12-month period. iii) Duration of symptoms should be over a 12-month period. iv) The symptoms interfere with the patient's normal daily function. All the above criteria must be met before tonsillectomy is performed for recurrent tonsillitis (Level III). Peritonsillar abscess or quinsy i) Tonsillectomy indicated when the abscess has failed to respond to appropriate antibiotics together with incision and drainage. This is rarely required (Evidence level III). It is an accepted surgical practice that all abscesses should be drained. ii) Tonsillectomy is indicated if patients develop quinsy and has a history of recurrent tonsillitis (Evidence level III). However, one episode of quinsy and no significant history of tonsillitis is not an indication for surgery.</p>	<p>Grading system: U.S. / Canadian Preventative Services Task Force method Key references: SIGN 34,⁽⁴⁷⁾ Paradise et al.,⁽³⁵⁾</p>
<p>ENT UK Position paper (2009)⁽⁶⁾ UK</p>	<p>Indications: Recurrent tonsillitis, severe tonsillitis or peritonsillar abscess (quinsy) Population: Adults and children.</p>	<p>Patients should meet all of the following criteria: · sore throats are due to tonsillitis · ≥ 5 episodes of sore throat per year · symptoms for at least a year · episodes of sore throat are disabling and prevent normal functioning Those with very frequent infection (>8 per annum) or who are hospitalised with extremely severe tonsillitis or peritonsillar abscess (quinsy) may seek intervention within a year of symptom onset.</p>	<p>No literature review but references SIGN 34.⁽⁴⁷⁾</p>

Study	Description	Sample size (n)	Finding
<p>Burton et al. (2009)⁽⁸⁾</p>	<p>Cochrane review included 5 studies</p>	<p>719 (children) 70 (adults)</p>	<p>Children (severe recurring tonsillitis): benefit was a reduction in number of sore throats by 3 episodes in first postoperative year, 1 of those episodes being moderate to severe. The reduction in sore throats in the severe group is accompanied by 1 episode of sore throat as a direct consequence of the surgery itself. In the case of less severely affected children, the benefit of adeno/tonsillectomy is more modest, with a reduction by 1 episode of sore throat in first postoperative year, reducing the number of sore throat days from 22 to 17 on average. Some children get better without any surgery, removing the tonsils will always prevent 'tonsillitis', the impact of the procedure on 'sore throats' due to pharyngitis is much less predictable. There is insufficient data to evaluate if there is any added benefit of adeno-tonsillectomy over tonsillectomy in reducing the frequency or severity of sore throats.</p>
<p>Lock et al. (2010)⁽³¹⁾</p>	<p>Pragmatic RCT with parallel non-randomised preference study</p>	<p>268 (trial), 461 (cohort study) children (4-15y)</p>	<p>Estimated effect of surgery over 2 years of follow up was reduction of 3.5 episodes of sore throat (95% CI 1.8 to 5.2) compared to medical management (not statistically significant). Participants more likely to express preference for tonsillectomy if they experienced more severe symptoms of sore throat. Strong parental preference for tonsillectomy. Findings support careful use of 'watchful waiting' and medical management in both primary and secondary care until clear-cut evidence of effectiveness is available.</p>

Wilson et al. (2012) ⁽³²⁾	Pragmatic RCT (n=268) plus parallel non-randomised patient preference group (n=461)	Children (4-15y)	Tonsillectomy saved 3.5 sore throats, whereas the as-treated model suggested an average reduction of more than 8 sore throats in 2 years for surgery within 10 weeks of consultation, falling to only 3.5 twelve months later due to the spontaneous improvement in the medical therapy group.
Friedman et al. (2009) ⁽³⁰⁾	Systematic review	Children, mean age 6.5y (n=1079)	Random-effects model estimated the treatment success of adenotonsillectomy was 66.3%, when cure was defined per each individual study. When "cure" was defined as an apnea-hypopnea index (AHI) of <1 (k = 9 studies), random-effects model estimate for OSA treatment success with adenotonsillectomy was 59.8%.

UK PCT examples of thresholds	Scope	Threshold	Evidence
North West London PCT (2012) ⁽⁴¹⁾	<p>Indications: Malignancy, sore throat, peri-tonsillar abscess, co-existing complications, failure to thrive, sleep apnoea</p> <p>Population: Children and adults</p>	<p>Referral for tonsillectomy should be considered for the following indications.</p> <ol style="list-style-type: none"> Suspected or confirmed malignancy – this is an absolute indication to refer. Recurrent severe sore throat in adults where Group A Streptococcal infection is suspected. Recurrent acute sore throat <u>in children</u> where the following conditions are met. <ol style="list-style-type: none"> sore throats are due to acute tonsillitis the episodes of sore throat are disabling and prevent normal functioning ≥ 7 well documented, clinically significant, adequately treated sore throats in the preceding year or ≥ 5 such episodes in each of the preceding 2 years or ≥ 3 such episodes in each of the preceding 3 years. Two or more quinsy's (peri-tonsillar abscesses) which have not usually resulted in hospital stay. Co-existing complications such as neck abscess or tonsillar enlargement causing upper airway obstruction. Failure to thrive where recurrent tonsillitis is considered a contributory factor. Sleep apnoea. Tonsillectomy will be considered where one or more of the following apply: <ol style="list-style-type: none"> A positive sleep study Demonstratable significant impact on quality of life A strong clinical history suggestive of sleep apnoea 	<p>Key references: SIGN 117⁽⁷⁾</p>
Herefordshire PCT (2011) ⁽⁴²⁾	<p>Indications: Recurrent acute sore throat, peri-tonsillar abscess, tonsillar enlargement, malignancy</p> <p>Population:</p>	<p>In both children and adults with recurrent acute sore throats:</p> <ol style="list-style-type: none"> ≥ 7 well documented, clinically significant, adequately treated sore throats in the preceding year OR ≥ 5 such episodes in each of the preceding 2 years OR ≥ 3 such episodes in each of the preceding 3 years OR, AND Sore throats are due to acute tonsillitis, AND The episodes of sore throat are disabling and prevent normal functioning (e.g. such as school attendance or work) <p>Other funded indications include:</p> <ol style="list-style-type: none"> Peri-tonsillar abscess with a history of recurrent tonsillitis, OR Tonsillar enlargement in children sufficient to cause airway obstruction – confirmed by overnight pulse 	<p>Key references: SIGN 117⁽⁷⁾</p>

	Children and adults	oximetry interpreted by a respiratory paediatrician, OR h. Suspected or proven malignancy When in doubt as to whether a tonsillectomy would be beneficial, a 6 month period of watchful waiting is recommended	
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US insurance criteria for reimbursement	Scope	Threshold	Evidence
Clinical UM Guideline (2012) US	Indications: Insurance criteria for reimbursement. Population: Children (< 18 y)	History of recurrent throat infection with frequency of at least: 7 episodes in the past year; or 5 episodes per year for 2 years; or 3 episodes per year for 3 years; AND Documentation in medical record for each episode of sore throat which includes at least 1 of following: Temperature > 38.3°C (100.94 °F); or Cervical adenopathy; or Tonsillar exudates or erythema; or Positive test for Group A β-hemolytic streptococcus (GABHS). OR History of recurrent throat infections not meeting criteria above, but individual has additional factors that favour tonsillectomy, including but not limited to: Multiple antibiotic allergy/intolerance; or PFAPA (Periodic fever, aphthous stomatitis, pharyngitis, and adenitis) syndrome; or Peritonsillar abscess; or Parapharyngeal abscess.	No literature review.

Appendix 2 – Cost-effectiveness studies for tonsillectomy

Study (year)	Type (country)	Population	Findings
Buskens et al. (2007) ⁽³³⁾	RCT (n=300) (The Netherlands)	Children (2-8 y)	Tonsillectomy is not cost-effective for children with mild to moderate sore throat and did not result in significant clinical benefit.
Lock et al. (2010) ⁽³¹⁾	Pragmatic RCT (n=268) plus parallel non-randomised (n=461) (UK)	Children (4-15y)	No evidence of difference in cost-effectiveness between surgery and non-medical management. ICER £261 per sore throat avoided (95% CI £161-£586). Incremental cost per QALY ranged from £3,129 to £6,904 per QALY gained.
Leupe et al. (2012) ⁽³⁴⁾	Cost analysis (Belgium)	Children	From societal perspective, a tonsillectomy costs the equivalent of 1.4 times the cost of a severe throat infection. This indicates that in children suffering from recurrent acute tonsillitis, watchful waiting results in a higher cost compared to tonsillectomy, given the cumulative costs of parents' absenteeism.

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