Tonsillectomy

FOR CONSULTATION

13 February 2013
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1 Tonsillectomy

1.1 Scope of 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.

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) followed by sore throat due to recurrent throat infections.¹ SDB encompasses a range of obstructive disorders that increase in severity from primary snoring to obstructive sleep apnoea (OSA).² 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.²

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.² 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.³
1.3 Surgical Procedures, potential complications and alternative treatments

Tonsillectomy surgery 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 peri-operative complications including electrosurgery, cautery dissection, coblation and radiofrequency ablation. Techniques for partial removal of the tonsil which preserves 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. Several instruments have been used to perform partial removal including the microdebrider, the coblator and the traditional cold steel method.

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 usually takes an average of two weeks with loss of time from work or education. An inevitable episode of post-operative pain is associated with tonsillectomy lasting an average of 5 to 7 days. Life threatening complications of the conditions associated with tonsillectomy are rare and the main aim of surgery is to relieve symptoms. Risks include those associated with anaesthesia and general surgical complications.

The main complication associated with tonsillectomy itself is post-operative bleeding. Primary haemorrhage occurs within 24 hours of surgery in approximately 0.2 to 2.2% of patients. Secondary haemorrhage occurs more than 24 hours after surgery in approximately 0.1 to 3% of patients. Surgical technique can have an impact on post-operative bleeding. 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. 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.

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.
1.4 Current practice in Ireland

Patients with sore throats or tonsillar hypertrophy, for example, who require treatment 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 Inpatient Enquiry (HIPE) system reports that there were approximately 3,500 tonsillectomies coded as ‘all procedures’ or ‘principal procedures’ undertaken in 2011, see Table 1.1 for ICD codes used. Thirty-one percent of ‘all procedures’ were classified as private. The principal diagnosis listed for tonsillectomy with or without adenoidectomy (coded as ‘all procedures’) was chronic tonsillitis for children (< 16 years, see Table 1.2) and adults (> 16 years, see Table 1.3). This may vary between hospitals, for example, a tertiary referral centre for complex cases reported approximately 60% (tonsil and adenoid hypertrophy) and 40% (tonsillitis).

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

<table>
<thead>
<tr>
<th>Intervention code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>41789-00</td>
<td>Tonsillectomy without adenoidectomy</td>
</tr>
<tr>
<td>41789-01</td>
<td>Tonsillectomy with adenoidectomy</td>
</tr>
</tbody>
</table>

Table 1.2 HIPE recorded principal diagnoses for tonsillectomy coded as ‘all procedures’ (2011) for children (< 16 years).

<table>
<thead>
<tr>
<th>Principal diagnosis*</th>
<th>Code</th>
<th>Number of ‘all procedures’</th>
<th>% of total procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic tonsillitis</td>
<td>J350</td>
<td>2100</td>
<td>80.28</td>
</tr>
<tr>
<td>Hypertrophy of tonsils with hypertrophy of adenoids</td>
<td>J353</td>
<td>335</td>
<td>12.81</td>
</tr>
<tr>
<td>Hypertrophy of tonsils</td>
<td>J351</td>
<td>55</td>
<td>2.1</td>
</tr>
<tr>
<td>Obstructive sleep apnoea syndrome</td>
<td>G4732</td>
<td>19</td>
<td>0.73</td>
</tr>
<tr>
<td>Chronic mucoid otitis media</td>
<td>H653</td>
<td>18</td>
<td>0.69</td>
</tr>
<tr>
<td>Chronic disease of tonsils and adenoids; unspecified</td>
<td>J359</td>
<td>18</td>
<td>0.69</td>
</tr>
<tr>
<td>Hypertrophy of adenoids</td>
<td>J352</td>
<td>15</td>
<td>0.57</td>
</tr>
<tr>
<td>Other chronic diseases of tonsils and adenoids</td>
<td>J358</td>
<td>11</td>
<td>0.42</td>
</tr>
<tr>
<td>Acute tonsillitis; unspecified</td>
<td>J039</td>
<td>9</td>
<td>0.34</td>
</tr>
</tbody>
</table>

*Note: The remaining principle diagnoses contain 5 or less cases and should not be published.
Table 1.3  HIPE recorded principal diagnoses for tonsillectomy coded as ‘all procedures’ (2011) for adults (> 16 years).

<table>
<thead>
<tr>
<th>Principal diagnosis*</th>
<th>Code</th>
<th>Number of ‘all procedures’</th>
<th>% of total procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic tonsillitis</td>
<td>J350</td>
<td>949</td>
<td>86.67</td>
</tr>
<tr>
<td>Hypertrophy of tonsils</td>
<td>J351</td>
<td>40</td>
<td>3.65</td>
</tr>
<tr>
<td>Acute tonsillitis; unspecified</td>
<td>J039</td>
<td>22</td>
<td>2.01</td>
</tr>
<tr>
<td>Other chronic diseases of tonsils and adenoids</td>
<td>J358</td>
<td>14</td>
<td>1.28</td>
</tr>
<tr>
<td>Malignant neoplasm of tonsils; unspecified</td>
<td>C099</td>
<td>11</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: The remaining principle diagnoses contain 5 or less cases and should not be published.

The numbers of tonsillectomies undertaken has declined slowly since 2005 (Figure 1.1). In addition to activity levels in public hospitals, tonsillectomy in private hospitals has also been funded through the public healthcare system via the National Treatment Purchase Fund (NTPF). Data on the numbers of additional procedures funded by the NTPF is also shown in Figure 1.1.\(^{(14)}\)

**Figure 1.1** HIPE reported trends for tonsillectomy and adenoidectomy procedures (2005 – 2011).

![Trends in procedures numbers](image)

Source: HIPE data accessed via ESRI HIPE Online Portal 28 Jan 2013, NTPF activity data received from the NTPF. Note: The HIPE data does not include the additional tonsillectomy procedures procured by the National Treatment Purchase Fund (NTPF), an estimated 1,452 additional tonsillectomy procedures were procured annually between 2005 and 2011.

The majority of tonsillectomies ('all procedures') in Ireland are carried out in children less than 16 years of age (2,616, 73%) with approximately 16% (574) in children less than 3 years of age.\(^{(12)}\) Tonsillectomies ('all procedures') are mainly undertaken by otolaryngologists (94%), also referred to as paediatric Ear Nose and Throat (ENT) consultants in HIPE (5%); the availability of this procedure is usually restricted to
facilities with an ENT service. Tonsillectomy rates vary across regions, see Table 1.4, some of which may be explained, for example, by the variation in the availability of an ENT service, hospital size or specialisation. Regional comparisons show that 52% (0.4% rate per 100,000 population) of the tonsillectomies in the North East region include an adenoidectomy, compared to 24% (0.2% rate per 100,000 population) in the Southern region. The average length of stay (ALOS) is 1.42 days (range 1.37-1.51 days per region) for ‘principal procedures’.

Table 1.4 HIPE data per health region (2011), ‘all procedures’.

<table>
<thead>
<tr>
<th>Health Region</th>
<th>Tonsillectomies</th>
<th>Rate per 1,000 population*</th>
<th>Adenoidectomy</th>
<th>Rate per 1,000 population*</th>
<th>% with adenoidectomy</th>
<th>Inpatient bed days</th>
<th>% day-case</th>
<th>Avg. age</th>
</tr>
</thead>
<tbody>
<tr>
<td>North East</td>
<td>778</td>
<td>0.76</td>
<td>404</td>
<td>0.40</td>
<td>52</td>
<td>1107</td>
<td>1</td>
<td>8.97</td>
</tr>
<tr>
<td>Mid East</td>
<td>1019</td>
<td>0.77</td>
<td>310</td>
<td>0.24</td>
<td>30</td>
<td>1740</td>
<td>6</td>
<td>12.81</td>
</tr>
<tr>
<td>Southern</td>
<td>964</td>
<td>0.83</td>
<td>235</td>
<td>0.20</td>
<td>24</td>
<td>1401</td>
<td>0</td>
<td>13.81</td>
</tr>
<tr>
<td>Western</td>
<td>836</td>
<td>0.77</td>
<td>354</td>
<td>0.33</td>
<td>42</td>
<td>1186</td>
<td>1</td>
<td>12.83</td>
</tr>
<tr>
<td>Total</td>
<td>3597</td>
<td>-</td>
<td>1303</td>
<td>-</td>
<td>37</td>
<td>5434</td>
<td>2</td>
<td>12.3</td>
</tr>
</tbody>
</table>

Note: This data excludes public patient activity purchased by the NTPF. This data will be added at a later stage. *Rates are based on area of residence, Census 2011. (15)

Although identified as being in the ‘Basket of 24 Procedures’, that is a range of elective surgical procedures for which there is a stated target of 75% to be undertaken as day case surgery, (16) HIPE data indicate that only 2% of tonsillectomies (coded as ‘all procedures’ or ‘principal procedures’) 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 or the complexity of the patient’s condition.

Despite frequent activity, tonsillectomy features on waiting lists due to limited capacity, requiring triaging of some patients particularly urgent cases. (13) A HSE report on outpatient data in 2012 noted that 4,061 patients were referred for ENT outpatient appointments in February 2012 with ‘did not attend’ (DNA) rates reaching a maximum of 58.9% in some hospitals. (17) 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 1,400 patients were waiting for tonsillectomies in September 2012, of which 233 (17%) were waiting for over six months, see Figure 1.2. (18) 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 all patients referred for outpatient surgical review are referred back to their GP without undergoing surgery or being referred for further testing.\(^{(14)}\) 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.

**Figure 1.2 National Treatment Purchase Fund (NTPF) waiting list times for tonsillectomy with adenoidectomy (Dec 2012).**

![NTPF Waiting list times](image)

*Source: Data received from the NTPF.*

### 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 the separate appendix accompanying this document, a summary of the results are included in Table 2.1.
Table 2.1  Included evidence sources to inform clinical referral thresholds.

<table>
<thead>
<tr>
<th>Publication Type</th>
<th>Number</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Guidelines</td>
<td>8</td>
<td>(2-4;19-23)</td>
</tr>
<tr>
<td>Systematic reviews</td>
<td>2</td>
<td>(5;24)</td>
</tr>
<tr>
<td>Clinical Studies</td>
<td>3</td>
<td>(24-26)</td>
</tr>
<tr>
<td>Cost effectiveness studies</td>
<td>3</td>
<td>(25;27;28)</td>
</tr>
</tbody>
</table>

2.2 Clinical evidence

2.2.1 Sore throat in children:

As discussed in section 1.4, HIPE data predicts that the majority of tonsillectomies are carried out in children. 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). These guidelines were informed by several RCTs including a study by Paradise et al which developed the widely accepted criteria for referral for surgery for recurrent sore throat and clinical features to define ‘recurrent sore throat’ in children.

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 >2 cm), or tonsillar exudate, or a positive culture for group A b-haemolytic streptococcus.

Watchful waiting is recommended for 'mild sore throats' in children based on RCTs and systematic reviews conducted by Burton et al., Buskens et al., Paradise et al. and Lock et al. or for fewer episodes of recurrent sore throat than the Paradise criteria above. This is to avoid unnecessary intervention in children who are likely to improve without surgery. 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. 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) adeno-/tonsillectomy 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.\(^{(5)}\) Less severely affected children who have adeno-/tonsillectomy 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.\(^{(5)}\)

A HTA conducted in 2010 by the NIHR (Lock et al.,) reported on a pragmatic RCT (\(n=268\)) with a parallel nonrandomised preference study (\(n=387\)) for children 4 to 15 years old.\(^{(25)}\) 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 2 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 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 have insurance reimbursement criteria for tonsillectomy, see Appendix 2, again these are consistent with Paradise criteria.

### 2.2.2 Sore throat in adults:

The SIGN guidelines apply the Paradise criteria to both children and adults.\(^{(4)}\) They state that evidence on which adults will benefit from tonsillectomy is not available.\(^{(4)}\) Additionally, Italian guidelines for children and adults recommend at least five episodes per year which are disabling and impair normal activity with symptoms for a minimum of one year.\(^{(21)}\) A Cochrane review by Burton et al., in 2009 reported that there is limited evidence of benefit of tonsillectomy in adults.\(^{(5)}\) Another study reports that apart from adults with proven recurrent group A streptococcal pharyngitis,\(^{(30)}\) 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

The second main indication for tonsillectomy is tonsillar hypertrophy.

A meta-analysis published in 2011 concluded that tonsillectomy is effective for treating sleep disorder breathing (SDB) in children with tonsillar hypertrophy\(^{(24)}\) and a recent clinical practice guideline has recommended tonsillectomy for this population.\(^{(2)}\) However, they also recommend 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.\(^{(13)}\) 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').\(^{(13)}\) If the tonsils are smaller and causing less obstruction, referral to a respiratory consultant may be more appropriate.\(^{(13)}\)

The current surgical treatment of choice for OSA in children is adenotonsillectomy.\(^{(31;32)}\) However, a recent Cochrane review did not find any strong evidence from randomised trials to support this.\(^{(33)}\) The American Academy of Paediatrics state that adenoidectomy or tonsillectomy alone may not be sufficient because residual lymphoid tissue may cause persistent obstruction.\(^{(32)}\)

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 ENT specialist.\(^{(23)}\) However, the evidence is weak with respect to this.\(^{(23)}\) OSA is multifactorial and a tonsillectomy may not alleviate symptoms. Deciding which of the varying options is most appropriate for the management of OSA depends on the severity of the condition and the characteristics of the patient.\(^{(23)}\) The SIGN recommended treatment for moderate or severe OSA is continuous positive airway pressure.\(^{(23)}\) Therefore, a patient with large tonsils may first be referred to a respiratory consultant.\(^{(13)}\)

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 ENT surgeon immediately.

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\(^{1}\) 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.
There is limited evidence for tonsillectomy for peritonsillar abscess,\(^{(19)}\) however, the American Academy of Otolaryngology Head and Neck Surgeons note 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.\(^{(2)}\) They note 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. They state that a clinician 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.\(^{(2)}\)

HIPE data indicates that the numbers of patients with 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 9-22%.\(^{(34)}\) 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) estimate 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.\(^{(3)}\) 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 compared to tonsillectomy, given the cumulative costs of parents' absenteeism.\(^{(28)}\) 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.\(^{(35)}\)

### 2.4 Budget impact and resource implications

The estimated average cost of a tonsillectomy operation in Ireland in 2010 is included in Table 2.2. This equated to an approximate cost of €10,300,000 based on 3,597 patients of which approximately 2% were conducted as day cases.\(^{(12)}\)
Table 2.2  Ready reckoner data reported in 2012 (based on 2010 activity).

<table>
<thead>
<tr>
<th>DRG code</th>
<th>Description</th>
<th>Cost/case (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D11Z</td>
<td>Tonsillectomy, Adenoidectomy (inpatient)</td>
<td>2,895</td>
</tr>
<tr>
<td>D11</td>
<td>Tonsillectomy, Adenoidectomy (outpatient)</td>
<td>1,690</td>
</tr>
<tr>
<td>-</td>
<td>Outpatient appointment</td>
<td>139</td>
</tr>
</tbody>
</table>

Reports suggest that up to 50% of those referred to outpatient clinics for tonsillectomy are not suitable candidates for surgery at that time.\(^{(13)}\) Across all specialties, approximately 30-50% of individuals seen in surgical outpatient clinics, through the NTPF, were referred back to their GP without undergoing surgical treatment.\(^{(14)}\) 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.\(^{(1)}\) Increasing the proportion of procedures undertaken as day case surgery has the potential to reduce to 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:

- \(\geq 7\) episodes of tonsillitis in the preceding year, OR
- \(\geq 5\) in each of the preceding 2 years, OR
- \(\geq 3\) in each of the preceding 3 years.

The clinical features include sore throat plus the presence of \(\geq 1\) of the following qualifies as a counting episode:
• temperature > 38.3°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 ENT specialist:

• Suspected tonsilar malignancy in children and adults
• Tonsilar 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 may be being applied irregularly. The benefit of a stated referral threshold is that there will be improved clarity for the GP and patient and allow for standardisation of care. This could potentially streamline the patient journey and allow for more efficient use of resources, without increasing harm or reducing benefit.

However, there may be some issues encountered if a patient is on the borderline of the threshold, particularly if the lengthy waiting lists for outpatient review and surgery persist. Also, it is important that there is continuity of care for the patient in terms of documenting the number of episodes of sore throat and the severity of these to fulfil the Paradise criteria.

A recent study audited the clinical indications for tonsillectomy in the UK (2 rounds, n=17, n=100) to determine if consultants were adhering to guidelines. 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 is clear that
guidelines could help triage patients at primary care level, reducing the number of referrals to surgical outpatient clinics.\textsuperscript{(13)}

Finally, there may be scope for improvement in the number of tonsillectomies undertaken as day case procedures. This is beyond the scope of this HTA and is being assessed by the HSE through Healthstat.\textsuperscript{(16)}
References


(12) HIPE. *Hospital In-Patient Enquiry (HIPE) Portal data.* 2013.


(17) HSE. Outpatient Data Quality Programme Update February 2012 [Online].

(18) National Treatment Purchase Fund (NTPF). Personal communication. 2012.


## Appendix 1  Clinical referral thresholds from guidelines

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Scope</th>
<th>Tonsillectomy Thresholds for sore throat and other indications</th>
<th>Evidence</th>
</tr>
</thead>
</table>
| **French Society of ENT & Head & Neck Surgery (SFORL) (2012)**<sup>(18)</sup> **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:** O/xmen et al.  
**Key references:** Not listed. |
| **American Academy of Otolaryngology Head & Neck Surgery (AAO-HNS) (2011)**<sup>(21)</sup> **US** | **Indications:** Sore throat, SDB, quinsy, tonsillar malignancy.  
**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 & 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  
Suspicion of tonsillar malignancy.  
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,<sup>(19)</sup> Paradise et al.<sup>(24)</sup> |
| **Scottish Intercollegiate Guidelines Network (SIGN) 117 (2010)**<sup>(6)</sup> **UK** | **Indications:** Sore throat.  
**Population:** Children (4-16 y) Adults | 1) Watchful waiting more appropriate than tonsillectomy for children with mild sore throats (<em>Grade A</em>)  
2) Tonsillectomy recommended for recurrent severe sore throat in adults (<em>Grade A</em>)  
3) Indications for tonsillectomy consideration for recurrent acute sore throat (children & adults) (<em>Grade D</em>):  
   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,<sup>(17)</sup> Paradise et al.,<sup>(28)</sup> Lock et al.,<sup>(25)</sup> Burton et al.,<sup>(5)</sup> Buskens et al.<sup>(27)</sup> |
| **Scottish Intercollegiate** | **Indications:** OSA. | The presence of large tonsils in a patient with diagnosed OSA should prompt referral to an ENT surgeon for consideration of tonsillectomy. | **Literature review:** Systematic |

<sup>(18)</sup> French Society of ENT & Head & Neck Surgery (SFORL) (2012)  
<sup>(19)</sup> Literature review: Systematic  
<sup>(20)</sup> Grading system: O/xmen et al.  
<sup>(21)</sup> Key references: Not listed.  
<sup>(22)</sup> American Academy of Otolaryngology Head & Neck Surgery (AAO-HNS) (2011)  
<sup>(23)</sup> Literature review: Systematic  
<sup>(24)</sup> Grading system: AAP scale  
<sup>(25)</sup> Key references: SIGN 117, Paradise et al.  
<sup>(26)</sup> Scottish Intercollegiate Guidelines Network (SIGN) 117 (2010)  
<sup>(27)</sup> Literature review: Systematic  
<sup>(28)</sup> Literature review: Systematic  
<sup>(29)</sup> Grading system: SIGN scale  
<sup>(30)</sup> Key references: SIGN 34, Paradise et al., Lock et al., Burton et al., Buskens et al.
| Guidelines Network (SIGN) 73 (2003) UK | Population: Adults | Indications: Upper Airway Obstruction with OSA, Frequent Recurrent Acute Tonsillitis, Peritonsillar Abscess, Suspected Neoplasm, Uncommon indications | For frequent recurrent acute tonsillitis. Tonsillectomy per Paradise criteria supported. Tonsillectomy/adenotonsillectomy indicated for episodes of: 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; 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. | Grading system: SIGN scale Key references: | Literature review: Literature search Grading system: NHMRC Key references: Paradise et al. (29) SIGN 34 (37) Burton et al., (1999) |
| Royal Australasian College of Physicians & The Australian Society of OHNS (2008) Australia |  |  |  |  |
| Sistema Nazionale Linee Guida (SNLG15) (2008) Italy | Population: Children and adults | 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 & responding to antibiotics, watchful waiting recommended.. 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. 3) IV/B Adenoidectomy associated with tonsillitis should be carried out only if clinical indications justifying combined surgery are present. 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) | Literature review: Systematic Grading system: PNLG Method Key references: Paradise et al. (29) SIGN 34 (37) Burton et al., (2002) |
| Ministry of Health Malaysia (2003) Malaysia | Population: Children and adults | Indications: Recurrent tonsillitis, peritonsillar abscess or quinsy | Recurrent tonsillitis: i) The symptom of sore throat is due to inflammation of the tonsils. 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 | Literature review: Evidence based review Grading system: U.S. / Canadian Preventative Services Task Force method Key references: SIGN 34 (37) Paradise et |
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.

| ENT UK Position paper (2009) UK | **Indications:** | 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. |

| **Population:** | Adults and children. | No literature review but references SIGN 34. [37] |

al. [29]
### Appendix 2 Summary of main recent systematic reviews and RCTs, sample of UK PCTs and US reimbursement criteria

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Sample size (n)</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burton et al. (2009)(^{53})</td>
<td>Cochrane review included 5 studies</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Lock et al. (2010)(^{25})</td>
<td>Pragmatic RCT with parallel non-randomised preference study</td>
<td>268 (trial), 461 (cohort study) children (4-15y)</td>
<td>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.</td>
</tr>
<tr>
<td>Wilson et al. (2012)(^{26})</td>
<td>Pragmatic RCT (n=268) plus parallel non-randomised patient preference group (n=461)</td>
<td>Children (4-15y)</td>
<td>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.</td>
</tr>
<tr>
<td>Friedman et al. (2009)(^{24})</td>
<td>Systematic review</td>
<td>Children, mean age 6.5y (n=1079)</td>
<td>Random-effects model estimated the treatment success of adenotonsillectomy was 66.3%, when cure was defined per each individual study. When &quot;cure&quot; was defined as an apnea-hypopnea index (AHI) of &lt;1 (k = 9 studies), random-effects model estimate for OSA treatment success with adenotonsillectomy was 59.8%.</td>
</tr>
</tbody>
</table>

### UK PCT examples of thresholds

<table>
<thead>
<tr>
<th>Scope</th>
<th>Threshold</th>
<th>Evidence</th>
</tr>
</thead>
</table>
| North West London PCT (2012)\(^{38}\) | Indications: Malignancy, sore throat, peri-tonsillar abscess, co-existing complications, failure to thrive, sleep apnoea | Referral for tonsillectomy should be considered for the following indications.  
  a. **Suspected or confirmed malignancy – this is an absolute indication to refer.**  
  b. Recurrent severe sore throat in adults where Group A Streptococcal infection is suspected.  
  c. Recurrent acute sore throat in children where the following conditions are met.  
    i. sore throats are due to acute tonsillitis  
    ii. the episodes of sore throat are disabling and prevent normal functioning  
    iii. ≥ 7 well documented, clinically significant, adequately treated sore throats in the preceding year  
    iv. or ≥ 5 such episodes in each of the preceding 2 years  
    v. or ≥ 3 such episodes in each of the preceding 3 years. | Key references: SIGN 117\(^{34}\) |
Population: Children & adults

d. Two or more quinsy’s (peri-tonsillar abscesses) which have not usually resulted in hospital stay.

e. Co-existing complications such as neck abscess or tonsillar enlargement causing upper airway obstruction.

f. Failure to thrive where recurrent tonsillitis is considered a contributory factor.

g. Sleep apnoea. Tonsillectomy will be considered where one or more of the following apply:

   I. A positive sleep study
   II. Demonstratable significant impact on quality of life
   III. A strong clinical history suggestive of sleep apnoea

Herefordshire PCT (2011)(38)

Indications: Recurrent acute sore throat, peri-tonsillar abscess, tonsillar enlargement, malignancy

Population: Children & adults

In both children and adults with recurrent acute sore throats:

   a. \( \geq 7 \) well documented, clinically significant, adequately treated sore throats in the preceding year OR

   b. \( \geq 5 \) such episodes in each of the preceding 2 years OR

   c. \( \geq 3 \) such episodes in each of the preceding 3 years OR, AND

   d. Sore throats are due to acute tonsillitis, AND

   e. The episodes of sore throat are disabling and prevent normal functioning (e.g. such as school attendance or work)

Other funded indications include:

   f. Peri-tonsillar abscess with a history of recurrent tonsillitis, OR

   g. Tonsillar enlargement in children sufficient to cause airway obstruction – confirmed by overnight pulse 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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<table>
<thead>
<tr>
<th>US insurance criteria for reimbursement</th>
<th>Scope</th>
<th>Threshold</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical UM Guideline (2012) US</td>
<td>Indications: Insurance criteria for reimbursement.</td>
<td>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</td>
<td>No literature review.</td>
</tr>
</tbody>
</table>
| Population: Children (< 18 y) | 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. | }
## Appendix 3 Cost-effectiveness studies for tonsillectomy

<table>
<thead>
<tr>
<th>Study (year)</th>
<th>Type (country)</th>
<th>Population</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buskens et al. (2007)(27)</td>
<td>RCT (n=300) (The Netherlands)</td>
<td>Children (2-8 y)</td>
<td>Tonsillectomy is not cost-effective for children with mild to moderate sore throat and did not result in significant clinical benefit.</td>
</tr>
<tr>
<td>Lock et al. (2010)(25)</td>
<td>Pragmatic RCT (n=268) plus parallel non-randomised (n=461) (UK)</td>
<td>Children (4-15y)</td>
<td>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.</td>
</tr>
<tr>
<td>Leupe et al. (2012)(28)</td>
<td>Cost analysis (Belgium)</td>
<td>Children</td>
<td>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.</td>
</tr>
</tbody>
</table>