Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

# Health Technology Assessment of Scheduled Surgical Procedures

# Grommet insertion and adenoidectomy for otitis media with effusion

**April 2013**

*Safer Better Care*

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# 1 Grommet insertion and adenoidectomy

## 1.1 Scope of this health technology assessment

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral thresholds for grommet insertion, a high volume scheduled surgical procedure within the publicly funded healthcare system in Ireland. The main indication for grommet (tympanostomy tube) insertion is restoration of hearing for children with otitis media with effusion (OME). Surgical management of OME may involve concomitant adenoidectomy and as such this procedure is also reviewed. The effectiveness of grommet insertion and adenoidectomy 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 provide advice on clinical referral and treatment thresholds that can be used in the assessment, referral and surgical management of patients for whom grommet insertion – with or without adenoidectomy – is being considered. Input from an expert advisory group (EAG), international guidelines, international policy documents and thresholds, and economic evaluations were reviewed to inform the referral criteria. Additionally the resource and budget impact and wider ethical or societal implications were assessed where appropriate.

## 1.2 Surgical indications

Otitis media with effusion (OME) or persistent middle ear effusion, known as 'glue ear', is a condition where the middle ear fills with a glue-like fluid instead of air because of Eustachian tube dysfunction. It is the most common cause of hearing loss in childhood with prevalence rates as high as 80% reported for one episode in children by four years of age.[2] While it is usually a self-limiting condition, the condition may be more persistent leading to educational, language and behavioural problems. OME is the main indication for insertion of grommets – ventilation tubes that correct the Eustachian tube dysfunction by allowing air into the middle ear.

Children with cleft palate are particularly susceptible to OME as are children with trisomy 21 (Down's syndrome) who have a high incidence of OME, mainly due to impaired immunity and mucosal abnormality resulting in a higher incidence of ear infection. The management of these children is more problematic because of potential diagnostic difficulties and because onset of OME is typically at an earlier age, has a prolonged course and has a greater risk of complications.[2]

Grommet insertion may also be indicated for prevention of recurrent acute otitis media (AOM) 'middle ear infections'. The natural history of AOM is spontaneous resolution in most cases[3] and is often treated with antibiotics.[4] However, OME may follow[5] with up to 10% of children having an effusion three months post AOM.[6] This review focuses on the main indication of otitis media with effusion (OME), which may occur with or without prior acute otitis media (AOM).[5]

## 1.3 Surgical procedures, potential complications and alternative treatments

Most cases of OME will resolve spontaneously, but some OME may persist over months or years potentially causing hearing loss (≥25dB) or speech impairment,[3] thus requiring surgical treatment.[2] Typical surgical management involves myringotomy (a small incision in the eardrum), suctioning of fluid present and then insertion of a small ventilation tube (grommet, which allows air into the middle ear), with or without adenoidectomy (removal of the adenoid tissue in the back of the nose). No non-surgical intervention has been proven to conclusively show benefit for OME. Clinical practice guidelines developed in 2008 by the National Institute of Health and Clinical Excellence (NICE)[‡] in the UK recommend that the following are not used to treat OME: antibiotics, topical or systemic antihistamines, topical or systemic decongestants, topical or systemic steroids, homeopathy, cranial osteopathy, acupuncture, dietary modification, including probiotics, immunostimulants or massage.[2] Alterative options for the management of OME include hearing aids for OME-related hearing loss where surgery is contraindicated.[2]

Grommet insertion and adenoidectomy surgery are widely perceived to be safe procedures. Surgical risks include those associated with anaesthesia and surgical complications. In a systematic review of the literature to support a clinical guideline published in 2008 by NICE, the incidence of complications associated with grommet insertion was estimated from a review of 134 articles.[2] Otorrhoea (26%),[*] focal atrophy[†] or retraction of the tympanic membrane (25% combined) and tympanosclerosis (32%)[‡] were noted to be relatively common complications of grommet insertion. Serious complications, such as perforation of the tympanic membrane, were noted to be more common with long-term grommet insertion (17%) than short-term grommet insertion (2%). Grommet insertion was associated with an increased risk of focal atrophy/retraction (RR 3.5; 95% CI 2.6 to 4.9) and

[‡] Now called the National Institute for Health and Care Excellence.
[*] Discharge from the external ear.
[†] Under-ventilation of the middle ear.
[‡] Condition caused by calcification of tissues in the middle ear.

tympanosclerosis (RR 1.7; 95% CI 1.1 to 2.7) compared to myringotomy or no surgery. It also reported that results from a well-conducted cohort study showed that children undergoing grommet insertion for OME, persisting for three months or more, have an increased risk of tympanic membrane pathological abnormalities and elevated hearing thresholds at 6 to 10 years following the surgery, compared to children who did not have tube insertion.[2] Finally, it reports that if concurrent adenoidectomy is also carried out, additional complications may rarely include severe bleeding,[7] and palatal insufficiency.

## 1.4 Current practice in Ireland

In the absence of national guidelines, the Clinical Guidelines from NICE in the UK on the surgical management of OME in children are considered relevant for the management of children in Ireland.[2] Patients with OME who require treatment due to hearing loss are generally referred by their general practitioner (GP) to an audiologist to measure the patients hearing.[8] If there are issues with the child's speech this typically warrants direct referral to an otolaryngologist (ear, nose and throat [ENT]) consultant. The Health Service Executive (HSE) operates regional hearing clinics and has clinical management guidelines in place which include, for example, criteria for referral to an otolaryngologist based on persistent hearing losses with symptoms of OME.[7]

Obtaining an appointment is difficult, particularly with paediatric audiologists as there are limited numbers practising in Ireland. A separate HSE document has reported on this issue.[9] A prolonged 'watchful waiting' period may inherently occur due to difficulties in accessing an appointment with an audiologist or otolaryngologist.[7] Time to appointment and completion of the audiology report may be long; once complete, it is sent back to the GP. An otolaryngology appointment may then be required if there is evidence of hearing impairment. Due to the difficulty obtaining audiology appointments, some patients are referred directly to an otolaryngologist. However, these patients will have to be subsequently referred by the otolaryngologist to an audiologist for a hearing test. Although most otolaryngology units have audiology available on the day of patient review, it has been noted that this is not always the case and can result in additional delays in the patient's assessment.[7;8] In younger children, it can be difficult to get ear-specific, frequency-specific information; a decision on the appropriateness for grommet insertion may have to be based on clinical criteria.[7] Once complete, the patient is scheduled for a return visit to the otolaryngologist. Typically, two audiograms three months apart are required prior to consideration for surgery, although exceptions may be made in a limited number of children to prevent further developmental issues. While hearing aids may be

considered as an alternative to surgery, there are similar issues in obtaining timely access to assessment for these.[7]

### 1.4.1 Grommet insertion

Grommet insertion 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 3,400 grommet insertions undertaken in 2011. Grommet insertion 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. It should be noted that patients may have grommets inserted on more than one occasion. The principal diagnosis listed for grommet insertion in 2011 was chronic mucoid otitis media for both children (≤16 years, see Table 1.2) and adults (>16 years, see Table 1.3).[10] Based on 2011 diagnosis-related group (DRG) cost and activity data, 'myringotomy and tube insertion' accounts for 25% of all otolaryngology procedures performed annually in Ireland, and makes up 8% of the overall otolaryngology surgical costs.[11]

**Table 1.1 HIPE ICD-10AM/ACHI list of intervention codes for grommet insertion**

| Intervention code | Description |
|---|---|
| 41632-00 | Myringotomy with insertion of tube, unilateral |
| 41632-01 | Myringotomy with insertion of tube, bilateral |

**Table 1.2 Principal diagnoses for grommet insertion in children ≤ 16 years (HIPE data 2011)**

| Principal diagnosis | Code | Number of procedures | % of total procedures |
|---|---|---|---|
| Chronic mucoid otitis media | H653 | 1,392 | 46.85 |
| Otitis media; unspecified | H669 | 337 | 11.34 |
| Chronic tonsillitis** | J350 | 223 | 7.51 |
| Nonsuppurative otitis media; unspecified | H659 | 195 | 6.56 |
| Hearing loss; unspecified | H919 | 185 | 6.23 |
| Hypertrophy of adenoids | J352 | 146 | 4.91 |
| Other chronic nonsuppurative otitis media | H654 | 74 | 2.49 |
| Hypertrophy of tonsils with hypertrophy of adenoids | J353 | 65 | 2.19 |
| Impacted cerumen | H612 | 47 | 1.58 |
| Chronic serous otitis media | H652 | 41 | 1.38 |
| Other* | - | 266 | 8.78 |

**Note: the top ten diagnoses are included. The remaining diagnoses contain five or fewer cases per diagnosis code.*
***Note: data gathered for 'all procedures'; therefore grommet insertion may have been undertaken in addition to another procedure, such as tonsillectomy. The recorded principal diagnoses may relate instead to the other procedure that was undertaken.*

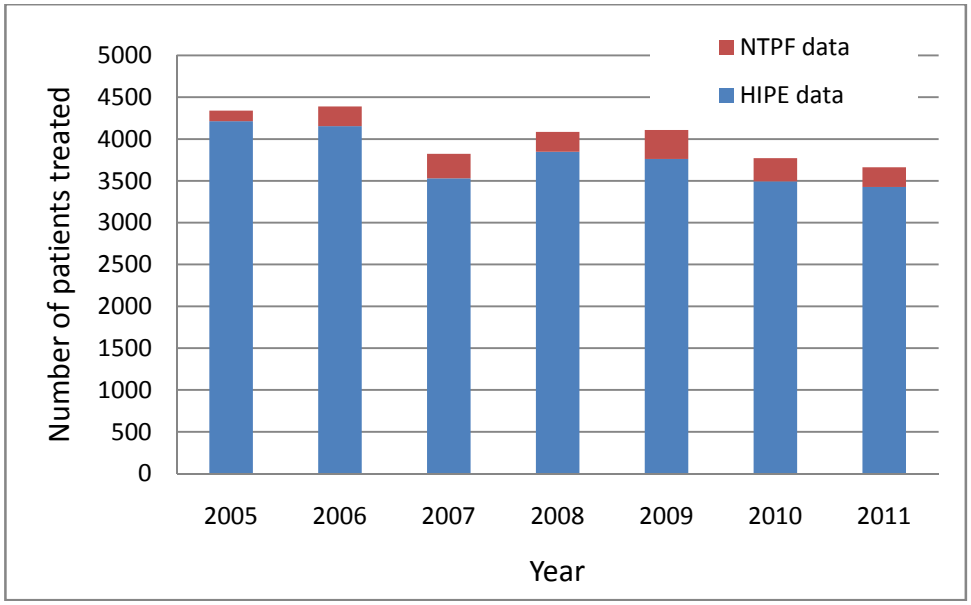
**Table 1.3 Principal diagnoses for grommet insertion in adults > 16 years (HIPE data 2011)**

| Principal diagnosis | Code | Number of procedures | % of total procedures |
|---|---|---|---|
| Chronic mucoid otitis media | H653 | 140 | 30.3 |
| Hearing loss; unspecified | H919 | 65 | 14.07 |
| Otitis media; unspecified | H669 | 33 | 7.14 |
| Nonsuppurative otitis media; unspecified | H659 | 27 | 5.84 |
| Other specified disorders of tympanic membrane | H738 | 24 | 5.19 |
| Other chronic nonsuppurative otitis media | H654 | 22 | 4.76 |
| Chronic serous otitis media | H652 | 17 | 3.68 |
| Tympanosclerosis | H740 | 10 | 2.16 |
| Other specified disorders of ear | H938 | 10 | 2.16 |
| Other* | - | 114 | 24.75 |

**Note: the top nine principal diagnoses are included; the remaining diagnoses contain eight or fewer cases per diagnosis code.*

The number of grommet insertions undertaken has declined since 2005 (Figure 1.1). In addition to activity levels in public hospitals, grommet insertion in private hospitals has also been funded for the public healthcare system via the National Treatment Purchase Fund (NTPF).[12]

**Figure 1.1 Number of grommet insertion procedures provided through the publicly funded healthcare system (2005 – 2011)**




*HIPE: Hospital In-Patient Inquiry (HIPE) Scheme, this 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 majority of grommet insertions in Ireland are undertaken in children 16 years of age and younger, (2,971, 87%), with 36% (1,248) in children less than 3 years of age.[10] This procedure is mainly undertaken by otolaryngologists (96%), also referred to as paediatric otolaryngologists in HIPE (3%);[10] the availability of this procedure is usually restricted to facilities with an otolaryngology service. Grommet insertion rates vary slightly across the four HSE regions (Table 1.4). Some of this variation may be explained by the availability of otolaryngology services and the number, size and specialisation of hospitals within the regions.

Grommet insertion is identified as being in the HSE '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.[13] HIPE rates for 2011 indicate that approximately 91% of principal procedures were carried out as day cases. Any variation in day case rates may be due to factors such as day case theatre availability or theatre closing times. For the 9% of procedures undertaken as an inpatient, the average length of stay (ALOS) per HSE region for grommet insertion when coded as the 'principal procedure' was 1.56 days (range: 1.24-2.08 days).

**Table 1.4 HIPE data per HSE region for grommet insertion (2011)**

| HSE health region | Number* | Percentage | Rate per 1,000 population** | Inpatient bed days | % day case | Avg. age |
|---|---|---|---|---|---|---|
| Dublin North East | 892 | 26.02 | 0.87 | 331 | 79.3 | 6.73 |
| Dublin Mid East | 950 | 27.71 | 0.72 | 673 | 80.4 | 10.7 |
| South | 751 | 21.91 | 0.65 | 208 | 83.1 | 10.91 |
| West | 835 | 24.36 | 0.77 | 351 | 79.4 | 12.7 |
| Total | 3428 | 100 | - | 1563 | 80.5 | 10.2 |

**Note patients may undergo grommet insertion on more than one occasion. This table excludes the additional activity procured for the publicly funded system by the NTPF in private hospitals.*
*** Rates are based on area of residence, Census 2011.*[12]

Despite frequent activity, grommet insertion features on waiting lists due to limited capacity; requiring triaging of some patients, particularly urgent cases.[8] A HSE report on outpatient data in 2012 stated 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 one hospital.[14] Data from the national Patient Treatment Register which collates waiting list data for day case and inpatient surgical referrals in public hospitals indicate that approximately 291 patients were waiting for grommet insertions in December 2012, 86% of whom had been waiting less than three months, 11% between three and six months, and 3% of whom were waiting for over six months.[15] There are no reliable data on the percentage of patients referred to otolaryngology clinics that proceed to surgery; however, it is estimated that 50% of these patients who attend an otolaryngology consultation will go on to have a grommet insertion.[8] 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.

### 1.4.2 Adenoidectomy

As noted, surgical management of OME often involves concomitant adenoidectomy and as such, this data is also reviewed. Approximately 711 adenoidectomy procedures were performed in Ireland in 2011 (see Table 1.5 for ICD codes used).[10] The principal diagnosis recorded for adenoidectomy in both children and adults was hypertrophy of the adenoids (Tables 1.6 and 1.7, respectively).[10]

**Table 1.5 HIPE ICD-10AM/ACHI list of intervention codes for adenoidectomy**

| Intervention code | Description |
|---|---|
| 41801-00 | Adenoidectomy without tonsillectomy |

### Table 1.6 Principal diagnoses for adenoidectomy in children ≤ 16 years (HIPE data2011)

| Principal diagnosis | Code | Number of Procedures* | % of total Procedures |
|---|---|---|---|
| Hypertrophy of adenoids | J352 | 344 | 50.66 |
| Chronic mucoid otitis media | H653 | 87 | 12.81 |
| Chronic tonsillitis | J350 | 87 | 12.81 |
| Otitis media; unspecified | H669 | 31 | 4.57 |
| Non-suppurative otitis media; unspecified | H659 | 22 | 3.24 |
| Hearing loss; unspecified | H919 | 18 | 2.65 |
| Mouth breathing | R065 | 17 | 2.5 |
| Other specified disorders of nose and nasal sinuses | J348 | 15 | 2.21 |
| Other** | - | 58 | 8.56 |

**Note: this table excludes the additional activity procured in private hospitals by the NTPF for the publicly funded system.*
*** The remaining principal diagnoses contain five or fewer cases per diagnosis code. Data were gathered for 'all procedures'; therefore, adenoidectomy may have been undertaken in addition to another procedure, such as tonsillectomy so that certain recorded diagnoses may relate instead to these principal procedures.*

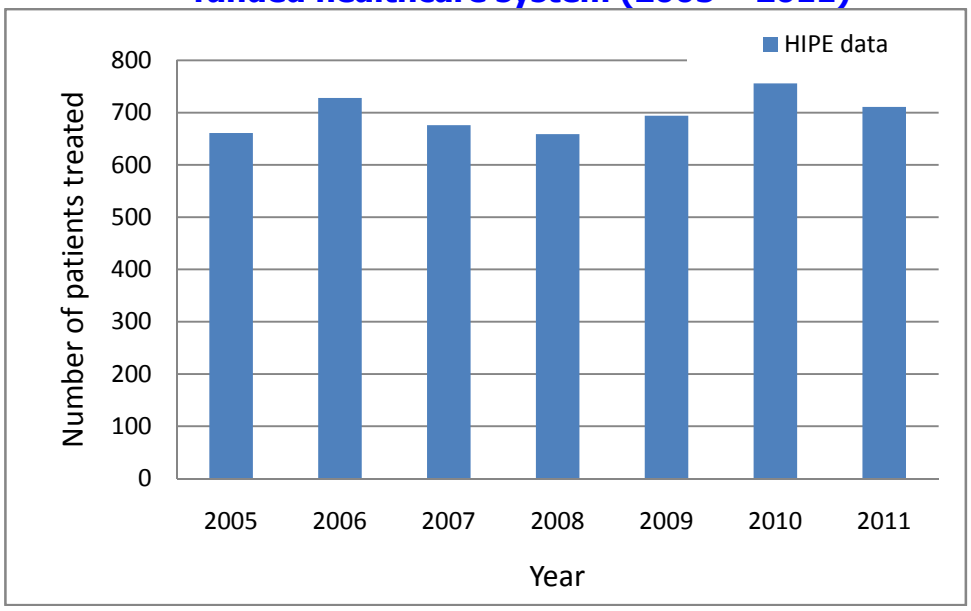
### Table 1.7 Principal diagnoses for adenoidectomy in adults > 16 years (HIPE data 2011)

| Principal diagnosis | Code | Number of Procedures* | % of total procedures |
|---|---|---|---|
| Hypertrophy of adenoids | J352 | 17 | 42.5 |
| Chronic tonsillitis | J350 | 5 | 12.5 |
| Other** | - | 18 | 45 |

**Note: this table excludes the additional activity procured in private hospitals by the NTPF for the publicly funded system.*
***Note: the remaining principal diagnoses contain five or fewer cases per diagnosis code.*

The number of adenoidectomies undertaken has remained relatively steady since 2005 (Figure 1.2). In addition to activity levels in public hospitals, adenoidectomy in private hospitals has also been funded for the public healthcare system through the NTPF. However, the data for adenoidectomy alone cannot be extracted because of coding issues.

**Figure 1.2 Number of adenoidectomies provided through the publicly funded healthcare system (2005 – 2011)**




*HIPE: Hospital In-Patient Inquiry (HIPE) Scheme, this includes all activity in publicly funded hospitals including procedures in patients that used private health insurance.*
*HIPE source: HIPE data accessed via ESRI HIPE Online Portal 28 January 2013. Note NTPF trends are not included here as the code is combined with tonsillectomy.*

The majority of adenoidectomies are undertaken in children 16 years of age or younger (679, 96%) with 26% (182) in children less than three years of age.[10] This procedure is mainly undertaken by otolaryngologists (95%), also referred to as paediatric otolaryngologists in HIPE (4.5%);[10] the availability of this procedure is usually restricted to facilities with an otolaryngology service. Adenoidectomy rates vary slightly across the four Health Service Executive (HSE) regions (Table 1.8).

Adenoidectomy is identified as being in the HSE '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.[13] However, HIPE data indicate that only 50% of adenoidectomies in 2011 were undertaken as day case procedures. Any variation in day case rates may be due to factors such as day case theatre availability or theatre closing times. Generally adenoidectomy is carried out in tandem with another procedure (tonsillectomy or grommet insertion) and this principal procedure may have an effect on whether an overnight stay is required; this is particularly relevant for concomitant tonsillectomy as only 2% of tonsillectomies are currently undertaken as day case surgery in Ireland. The average length of stay (ALOS) per region is 1.73 days ranging from 1.46 to 4.09 days when coded as the 'principal procedure'.

**Table 1.8 HIPE data per HSE region for adenoidectomy (2011)**

| HSE health region | Number | Percentage | Rate per 1,000 population* | Inpatient bed days** | % day case | Avg. age |
|---|---|---|---|---|---|---|
| Dublin North East | 182 | 25.6 | 0.18 | 207 | 69.8 | 4.82 |
| Dublin Mid East | 139 | 19.55 | 0.11 | 128 | 33.1 | 7.34 |
| South | 152 | 21.38 | 0.13 | 101 | 43.4 | 7.57 |
| West | 238 | 33.47 | 0.22 | 113 | 54.6 | 7.17 |
| Total | 711 | 100 | - | 549 | 51.9 | 6.69 |

** Rates are based on area of residence, Census 2011.[12] **Note: This table excludes the additional activity procured in private hospitals by the NTPF for the publicly funded system.*

As with grommet insertion, despite frequent activity, 'adenoidectomy without tonsillectomy' features on waiting lists due to limited capacity. Triaging of more urgent or severe cases occurs. However, the absence of clear referral criteria may lead to these patients experiencing delays for an outpatient appointment in the first instance.[8] Data from the national Patient Treatment Register which collates waiting lists for elective surgical procedures for all public hospitals indicate that approximately 108 patients were waiting for adenoidectomies (without tonsillectomies) in December 2012, 79% of whom were waiting less than three months, 19% between three and six months and 2% of whom were waiting more than six months.[15]

It is uncertain what proportion of patients referred for outpatient surgical review proceeds to surgery. Limited data across all surgical disciplines indicate that 30% to 50% of patients referred for surgical outpatient review (across all disciplines) are referred back to their GP without undergoing a procedure or further activity.[16] This suggests that the use of clear referral 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 grommet insertions. The approach and general search terms are described in

Appendix 1 in the Background and Methods chapter and a summary of the results are included in Table 2.1.

**Table 2.1 Included evidence sources to inform clinical referral and treatment thresholds**

| Publication Type | Number | References |
|---|---|---|
| Clinical guidelines | 4 | (2;3;17;18) |
| Systematic reviews | 4 | (19-22) |
| Clinical studies | 0 (some included in systematic reviews above) | – |
| Cost-effectiveness studies | 2 | (2;23) |

The main international guidelines retrieved for grommet insertion and adenoidectomy are summarised in Appendix 1. The Royal College of Surgeons in Ireland (RCSI) references guidelines from a range of international institutions reflecting current clinical recommendations on the management of common surgical problems; for the surgical management of OME in children, the UK NICE Clinical Guidelines are referenced.[2]

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 grommet insertion and adenoidectomy) 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. Examples of two PCT policies are included in Appendix 2.

## 2.2 Clinical evidence

A comprehensive review of the literature retrieved several international guidelines for grommet insertion and adenoidectomy. The most comprehensive guidelines were from NICE in the UK 'Surgical management of otitis media with effusion in children,[2]' the Scottish Intercollegiate Guidelines Network (SIGN) 'Diagnosis and management of childhood otitis media in primary care[3]' and the American Academy of Paediatric guideline 'Otitis media with effusion'.[17] These guidelines were informed by several randomised controlled trials (RCTs), see Appendix 2 for details.

The NICE guideline includes a systematic review to determine the appropriate time for intervention, the factors predicting benefit from and the effectiveness of surgical intervention.[2] It references a systematic review by Rosenfeld et al., see Appendix 2, and states that the evidence shows that a period of observation for three months will allow resolution of many cases and eliminate the need for clinical intervention and

therefore it recommends this. The American Academy of Paediatrics report improvement of newly detected OME in 55% of children, with one third having a relapse within the next three months based on Rosenfeld's study.[17;20] This is also reported in a Quality Improvement Scotland evidence note.[24] A recent Cochrane review (2010) of the evidence for grommet insertion for hearing loss associated with OME in children reported that the effects of grommet insertion on hearing are small and diminish after six to nine months, by which time natural resolution leads to improved hearing for those undergoing non-surgical treatment.[19]

The NICE guideline notes that the presence of bilateral disease predicts a higher risk of more severe hearing impairment with longer persistence, and therefore such patients should be considered for surgical treatment.[2] It references a meta-analysis by Rovers et al. (Appendix 2) to determine which children would benefit more from surgery compared to watchful waiting. It reports that children attending day-care or school with bilateral hearing loss of 25 dB or greater persisting for three months might benefit from grommet insertion. It also states that children with persistent bilateral OME documented over three months with a hearing level in the better ear of 25 to 30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available) should be considered for surgical intervention. It states that evidence shows that insertion of grommets is effective in correcting hearing loss due to OME as long as they remain in place and function. This is in line with a previous SIGN guideline[3] and with an American Academy of Paediatric guideline (Appendix 1).[17] A Cochrane review in 2010 noted that more severely affected children did not seem to have significantly different results based on published and unpublished data from a 2001 TARGET trial.[19] However, a trial conducted by the British Association of Otorhinolaryngologists – ENT UK reported that 50% of children with bilateral hearing loss of at least 20dB are likely to recover normal hearing with no treatment in the first three months and that the remaining 50% with persistent hearing loss, concerns about speech, language or other associated problems are potentially eligible for surgery. It also noted that, at the time, no study was completed on children with established speech, language, learning or development problems, so no conclusions were drawn for this cohort.[25]

Grommet insertion may also be indicated for prevention of recurrent acute otitis media (AOM). The natural history of AOM is for spontaneous resolution in most cases;[3] however, OME may follow[5] with up to 10% of children having an effusion three months post-AOM.[6] The SIGN guideline states that there is limited evidence for recommendations for AOM and base its recommendation on expert opinion and previous guidelines. It recommends that children with frequent episodes (more than

four episodes in six months) of acute otitis media, or complications such as mastoiditis or facial nerve paresis, should be referred to an otolaryngologist .[3]

A recent Cochrane review (2010) of adenoidectomy in OME in children reported a significant benefit of adenoidectomy for resolution of middle ear effusion in children with OME, but that the benefit to hearing is small and the effects on changes in the tympanic membrane are unknown.[22] It notes that the risks of operating should be weighed against the potential benefits.[22] NICE also reported that the literature does not show that adjunctive adenoidectomy improves hearing levels and that the practice of adenoidectomy for OME is not backed by sufficiently precise scientific evidence.[2] A recent case-control study reported that children less than five years of age treated with adenoidectomy without tonsillectomy are more likely to require a repeat procedure.[26]

UK primary care trusts (PCTs) have developed referral criteria for grommet insertion and adenoidectomy that are linked to the funding of these procedures. These criteria are generally evidence based and are consistent with the NICE guideline. Examples of criteria from two PCTs are included in Appendix 2.

## 2.3 Cost-effectiveness evidence

No relevant economic evaluations based on, or generalisable to Irish costs were identified. Appendix 3 summarises a sample of the most recent cost-effectiveness studies retrieved. The most relevant study is from NICE which developed an economic model as part of their guideline development process. This suggested that insertion of grommets is a cost-effective treatment for persistent bilateral OME. The cost for grommet insertion (typically a day case procedure) was estimated at £1,208 based on the National Tariff 2006/7 (England).

## 2.4 Budget impact and resource implications

### 2.4.1 Grommet insertion

The cost of a grommet insertion procedure in Ireland is included in Table 2.2 below.[11] This equates to an approximate total cost of €3,600,000 in 2011 based on the surgical treatment of 3,400 patients, 91% of which were undertaken as day cases.[10] It is reported that patients typically may be seen up to three times as an outpatient between assessment and post-operative review; the HSE Casemix unit estimates the cost of an OPD appointment (not ENT specific) at €130.[7;11]

**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 (€) |
|---|---|---|
| D13Z | Myringotomy + tube insertion (inpatient) | 3,109 |
| D13 | Myringotomy + tube insertion (outpatient) | 868 |

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

### 2.4.2 Adenoidectomy

The cost of an adenoidectomy procedure in Ireland is difficult to estimate as the diagnosis related group (DRG) code includes tonsillectomy. However, HIPE data indicated that only 2% of tonsillectomies are undertaken as day case surgery, while expert opinion indicates that adenoidectomy in the absence of tonsillectomy is almost always undertaken as day case surgery.[8] Using a DRG code D11, the cost of adenoidectomy as a day case is estimated at €1,690.

As with grommet insertion, it is unclear what proportion of patients referred for surgical outpatient review subsequently undergoes surgery. Across all surgical specialities, there is limited data to suggest that 30% to 50% of patients referred for surgical outpatient review are referred back to their GP without undergoing surgical treatment or being referred for further testing.[16] This indicates that a proportion of the patients referred are not appropriate for surgery at the time of review or that the patient's symptoms are predicted to resolve over time, in which case watchful waiting is appropriate. It is predicted that the use of transparent clinical referral criteria has the potential to reduce the number of patients for whom non-surgical management is recommended from being referred for outpatient review. This is important from a resource consideration given the considerable waiting lists for outpatient appointments and the estimated average cost of an outpatient appointment (across all disciplines) of €130.[11] Streamlining the referral of patients for surgical review has the potential to shorten the patient's elective surgical journey by ensuring the right patients are treated at the right time and to optimise the use of available resources without causing harm or reducing benefit.

As noted, grommet insertion and adenoidectomy are considered procedures that may be safely performed in a day case setting. The HSEs HealthStat for Hospitals guide lists grommet insertion as one of a basket of 24 procedures which target a group day case rate of 75%.[13] For patients who meet the recommended referral threshold that go on to have surgery, there could be a potential for increasing the day case rate if

resources were realigned to ensure that the quality and safety of patient care is not compromised.

## 2.5 Advice on clinical referral / treatment threshold

The following referral/treatment threshold is advised:

Persistence of bilateral otitis media with effusion (OME) and hearing loss should be confirmed over a three month period before referral for intervention is considered. The child's hearing should be re-tested at the end of this time.[§]

Children with persistent bilateral OME documented over three months with a hearing level in the better ear of 25–30 dBHL or worse should be referred to an otolaryngologist for consideration for surgery.

Children with persistent bilateral OME with a hearing loss < 25–30 dBHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant should be referred to an otolaryngologist for consideration for surgery.

Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.

# 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. Introduction of clinical referral and treatment criteria should potentially clarify or streamline the patient journey and allow for more efficient use of resources. As discussed in Section 1.4, the caveat is that there is currently limited access to paediatric audiologists, particularly for primary care practitioners. Therefore, these referral thresholds may be difficult to implement unless this is resolved. A recent

[§] Implementation of the threshold is dependent on timely adequate direct access to paediatric audiology for GPs and this may not be available in all areas of the country, this is currently under review by the HSE.

report has discussed the issues of access to audiology[9] and a further GP report is in progress, discussing GP access to diagnostics.[8]

Although beyond the scope of this HTA, feedback was also obtained 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 existing capacity constraints in the system and the lengthy waiting lists for outpatient review and surgery. Issues may be encountered when a patient is on the borderline of a threshold: 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 period of watchful waiting will correspond with the delay in obtaining an appointment, so that the patient will meet the criteria for 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.[27]

A study published by Al-Hussaini et al. in 2012, reported on the effect of UK guidelines to reduce inappropriate grommet insertion on grommet day case rates over 10 years.[28] A review of UK health databases predicted that the guidelines significantly improved day case rates, reduced waiting times, but did not affect the number of grommet insertions. Daniel et al., reported on whether NICE guidelines on the surgical management of OME are being followed or if they have changed practice using a retrospective review of case notes.[29] They found that 87% of children have grommets inserted in accordance with NICE guidelines providing exceptional cases are included, but only 32.2% comply with the core criteria. A significant number have surgery due to the invoking of exceptional criteria, suggesting that clinicians are customising the treatment to each individual child.

Currently no audit data is available to support requirements for surgery and it remains unclear as to the absolute impact any treatment thresholds would have on the number undergoing surgery in Ireland. As noted above, the overall number of grommet insertions in the UK did not decline with the implementation of treatment thresholds by PCTs. However, information from otolaryngologists with respect to outpatient department (OPD) referrals suggest that the use of stated referral thresholds could help triage patients at primary care level reducing the number of patients referred to OPD clinics that do not proceed to surgery or further testing.[8] However, this would only be possible in the context of appropriate access by general practitioners to paediatric audiology services.

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# Appendix 1 – International clinical referral thresholds

| Guideline | Scope | Grommet insertion thresholds for OME | Evidence |
|---|---|---|---|
| NICE CG60 (2008)[2]<br>**UK** | **Indications:**<br>Suspected OME<br>**Population:**<br>Children (<12 y) including children with cleft palate, Down's syndrome | 1) Persistence of bilateral OME and hearing loss should be confirmed over a three month period before intervention is considered. The child's hearing should be re-tested at the end of this time.<br><br>2) During the active observation period, advice on educational and behavioural strategies to minimise the effects of the hearing loss should be offered.<br><br>3) Children with persistent bilateral OME documented over three months with a hearing level in the better ear of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available) should be considered for surgical intervention.<br><br>4) Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25–30 dBHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.<br><br>5) Once a decision has been taken to offer surgical intervention for OME in children, the insertion of grommets is recommended. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.<br><br>6) Before grommets are offered as an alternative to hearing aids for treating OME in children with Down's syndrome, the following factors should be considered: severity of hearing loss, age of child, practicality of grommets insertion, risks associated with grommets, likelihood of early extrusion of grommets.<br><br>7) Insertion of grommets at primary closure of the cleft palate should be performed only after careful otological and audiological assessment and should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss. | **Literature review:**<br>Systematic<br>**Grading system:**<br>NICE<br>**Key references:**<br>Rosenfeld RM, Rovers MM et al., Lous J, (Rosenfeld and Kay 1645-57;Rovers et al. 480-85;Lous et al. CD001801) |
| SIGN Guidelines (2003)[3]<br>**UK** | **Indications:**<br>Acute otitis media (AOM), OME referral requirements<br>**Population:**<br>Children | 1) Children <3 years of age with persistent bilateral OME and hearing loss of ≤25 dB, but no speech and language, development or behavioural problems, can be safely managed with watchful waiting. If watchful waiting is being considered, the child should undergo audiometry to exclude a more serious degree of hearing loss.<br>2) Children with persistent bilateral OME who are >3 years of age or who have speech and language, developmental or behavioural problems should be referred to an otolaryngologist. | **Literature review:**<br>Systematic<br>**Grading system:**<br>SIGN scale<br>**Key references:**<br>Rover et al.,(Rovers et al. E42) Paradise et al.,(Paradise et al. 1179-87) |

| | | | |
|---|---|---|---|
| AAP CPG (2004)[17]<br>**US** | **Indications:**<br>OME<br>**Population:**<br>Children (2m – 12y) with or without development disabilities or underlying conditions that dispose to OME | 1) Document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME,<br>2) Distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME and more promptly evaluate hearing, speech, language, and need for intervention in children at risk, and<br>3) Manage the child with OME who is not at risk with watchful waiting for three months from the date of effusion onset (if known) or diagnosis (if onset is unknown).<br>4) Hearing testing be conducted when OME persists for three months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME,<br>5) Children with persistent OME who are not at risk should be re-examined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum<br>or middle ear are suspected. (They note that risk factors that make spontaneous resolution less likely include a hearing loss > 30-dB HL in the better hearing ear), and<br>6) when a child becomes a surgical candidate (tympanostomy tube insertion is the preferred initial procedure).<br>Adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis); repeat surgery consists of adenoidectomy plus myringotomy with or without tube insertion. Tonsillectomy alone or myringotomy alone should not be used to treat OME. | **Literature review:**<br>Systematic<br>**Grading system:**<br>AAP scale<br>**Key references:**<br>Rosenfeld RM,[20] |
| British Columbia Medical Association (2010)[18]<br>**Canada** | **Indications:**<br>OME, AOM<br>**Population:**<br>Healthy children > 6m presenting with AOM or OME | When OME has been present for at least 12 weeks, observation is advised at three month intervals until the resolution of effusion. If there are concerns of 'significant' hearing loss or structural abnormalities of the tympanic membrane, a formal hearing evaluation and referral to an otolaryngologist is recommended. | No literature review but references AAP.[17] |

| Study | Description | Sample size (n) | Finding |
|---|---|---|---|
| Browning et al. (2010)[19] | Cochrane review | 1728 (children) | Grommets mainly beneficial in first six months by which time natural resolution lead to improved hearing in the non-surgically treated children also.<br>Only one high quality trial that randomised children (N = 211) reported results at three months; the mean hearing level was 12 dB better (95% CI 10 to 14 dB) in those treated with grommets as compared to the controls.<br>Meta-analyses of 3 high quality trials (N = 523) showed a benefit of 4 dB (95% CI 2 to 6 dB) at six to nine months. At 12 and 18 months follow up no differences in mean hearing levels were found.<br>Data from three trials that randomised ears (N = 230 ears) showed similar effects to the trials that randomised children. At four to six months mean hearing level was 10 dB better in the grommet ear (95% CI 5 to 16 dB), and at 7 to 12 months and 18 to 24 months was 6 dB (95% CI 2 to 10 dB) and 5 dB (95% CI 3 to 8 dB) dB better.<br>No effect was found on language or speech development or for behaviour, cognitive or quality of life outcomes. |
| Rosenfeld et al. (2003)[20] | Systematic review, meta-analysis | | OME after untreated AOM had 59% resolution by one month (95% CI, 50-68%) and 74% resolution by three months (95% CI, 68-80%). OME of unknown duration had 28% spontaneous resolution by three months (95%, CI 14-41%), rising to 42% by six months (95% CI, 35-49%). In contrast, chronic OME had only 26% resolution by six months and 33% resolution by 1 year. |
| Rovers et al. (2005)[21] | Meta-analysis | n = 1234 | Trials treating both ears: only significant interaction between day-care and surgery, occurring where mean hearing level was the outcome measure. No other baseline variables showed interaction effect with treatment to justify subgrouping.<br>Trials treating one ear: baseline hearing level showed a significant but not pervasive interaction with treatment-that is, only with a cut-off of 25 dB HL. |
| van den Aardweg et al. (2010)[22] | Cochrane review | n= 2712 children | Adenoidectomy in combination with a unilateral tympanostomy tube has a beneficial effect on the resolution of OME [risk difference (RD) 22% (95% CI 12% to 32%) and 29% (95% CI 19% to 39%) for the non-operated ear at six and 12 months, respectively (n = 3 trials)] and a very small (< 5 dB) effect on hearing, compared to a unilateral tympanostomy tube only.<br>However, the benefit to hearing is small and the effects on changes in the tympanic membrane are unknown. |

| UK PCT examples of thresholds | Scope | Threshold | Evidence |
|---|---|---|---|
| North West London PCT (2012)[30] | **Indications:** OME **Population:** Children | Referral for grommet insertion should be considered for the following:<br>▪ OME has persisted, following a period of watchful waiting, for three months from diagnosis in primary care; **AND**<br>▪ The child suffers from at least one of the following:<br>- ≥5 recurrences of acute OME in a year<br>- evidence of delay in speech development educational / behavioural problems due to persistent hearing impairment<br>- with hearing loss of at least 25dB, particularly in the lower tones<br>- a second, relevant health problem, e.g. Down's syndrome, cleft palate. | **Key references:** Lous et al., NICE CG60, (National Collaborating Centre for Women's and Children's Health;Lous et al. CD001801) |
| | **Indications:** Adenoidectomy **Population:** Children, adults | Adenoidectomy is of limited clinical effectiveness and will not be routinely funded. NHS NWL will fund adenoidectomy only for children who meet the following criteria:<br>▪ Children who meet the criteria for grommets and will also be getting both grommets and adenoidectomy at the same time.<br>▪ Adenoidectomy in adults will only be considered via the IFR route in exceptional cases. | **Key references:** Lous et al., NICE CG60, (National Collaborating Centre for Women's and Children's Health;Lous et al. CD001801) |
| Herefordshire PCT (2011)[31] | **Indications:** OME **Population:** Children | Unless one or more of the following criteria are met grommets are not normally funded for children with OME:<br>▪ ≥5 documented episodes of acute otitis media (in the same ear) in the previous 12 months **OR**<br>▪ Persistent bilateral OME documented over a period of three months, with a hearing level in the better ear of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available) **OR**<br>▪ Persistent bilateral OME with a hearing loss less than 25–30 dBHL in the better ear but where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant. | **Key references:** Lous et al., NICE CG60, (National Collaborating Centre for Women's and Children's Health;Lous et al. CD001801) |

# Appendix 2 – Cost-effectiveness studies

| Study (year) | Type (Country) | Population | Findings |
|---|---|---|---|
| NICE CG60 (2008)[2] | Economic evaluation (UK) | Children (<12 y) | Evidence shows that insertion of grommets is effective in correcting the conductive hearing loss from OME as long as they stay in place and functioning. An economic model developed as part of the NICE guideline suggested that insertion of grommets is a cost-effective treatment for persistent bilateral OME. The cost for grommet insertion was estimated at £1,208 based on the National Tariff 2006/7 (England). |
| Hartman et al. (2001)[23] | Economic evaluation (The Netherlands) | Children (19m) | Mean duration of effusion was 9.2 months in watchful waiting group and 4.7 months in grommet group. Language development was comparable in both groups. Mean costs per child during one year of follow-up were $454 in the grommet group and $120 in the watchful waiting group. On average, an additional investment of $334 per patient was needed for grommet insertion (societal perspective). |

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