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REVIEW ARTICLE

The National Institute for Health and Clinical Excellence, and otolaryngology: review of the evidence

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Abstract

Background: The adoption of evidence-based practice is fundamental to good medical care; it ensures that intervention is clinically effective and safe. In a world of limited healthcare resources, consideration of cost-effectiveness must, unfortunately, restrict clinicians' choice. The National Institute for Health and Clinical Excellence has, for over 10 years, developed guidance to achieve a national consensus on best practice.

Objectives: This review describes the Institute's methodology, examines guidance relevant to otolaryngology and presents more recent research to update the evidence.

Key words: NICE; National Institute For Health And Clinical Excellence; Otolaryngology; Evidence-Based Practice; Decision Making, Organizational; National Health Programs; Technology Assessment, Biomedical; Quality Of Health Care; Academies And Institutes

Introduction

Critical appraisal of the available medical evidence underlies the practice of evidence-based medicine. It involves systematic evaluation of the evidence's validity, results and relevance to an area of work. This, coupled with the education of healthcare professionals (and patients), reduces ineffective, unduly costly or potentially hazardous interventions. Many countries strive to develop their own unique strategies or organisations to provide coherent evidence-based guidelines on treatment and management options. Examples include the Agency for Healthcare Research and Quality in the US,[1] and the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical.[2]

The UK national bodies, such as the National Institute for Health and Clinical Excellence (NICE),[3] the Scottish Intercollegiate Guidelines Network[4] and the Cochrane Collaboration,[5] play an important role in promoting the concept of evidence-based practice nationally and internationally. This review outlines the principles of NICE and the types of guidelines produced that are related to otolaryngology.

Institute role

The Institute is a Special Health Authority, funded by the Department of Health to serve the National Health Service (NHS). It was established in 1999 to address the UK regional variation in availability and quality of NHS treatments and care, often described as 'the postcode lottery'. Although often labelled 'the government watchdog' in the media, NICE functions independently to provide guidance for England and Wales.

The work of NICE encompasses four spheres of activity: guidance, performance indicators, information services and international activities.

Institute guidance

This includes: clinical guidelines (165 in total), technology appraisals (275), interventional procedure guidelines (381), public health promotions or guidelines (43), medical technology and diagnostic guidance (both still in their infancy), and cancer service guidance.

Clinical guidelines cover the best practice for a given disease state. Very few are of direct relevance to ENT, but many carry an important generic surgical message.

Despite the title, technology appraisals generally relate to medication. These are often highly controversial and publicised, as they tackle the difficult choices made in comparing the costs of drugs in oncology or chronic disease with cost-effectiveness and quality of life.

Many of the interventional procedure guidelines are relevant to otolaryngological practice. The guidelines

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apply to new techniques involving invasive surgery, ionising radiation or endoscope use. This guidance does not address cost issues, but concentrates on clinical effectiveness and safety issues. Curiously, the guidance does not even compare these procedures with established practice.

Cancer service guidance recommends methods to ensure the delivery of high quality care for cancer patients, from the diagnosis stage, through secondary care and subsequent community support, to the post-treatment surveillance stage.

Topics for evaluation may be referred by the Department of Health (clinical guidelines) or notified by individual clinicians (interventional procedure guidelines). The subsequent process typically involves stakeholder registration, specialist advice and a staged development from: the scoping exercise (determining what the guideline will cover), draft guidance with recommendations followed by a period of public consultation for comment, and finally published guidance.

Patient-friendly versions of the guidance are available to allow the patient to actively participate in managing their condition with their clinician.[6] The NICE guidance is freely accessible on the worldwide web, and there is even a relevant smartphone application.[7]

Performance indicators

The Institute's quality standards are a set of statements designed to drive and measure quality improvements within a particular area of care. These standards are used by commissioning bodies and frameworks (e.g. the Commissioning Outcomes Framework) to test compliance and incentivise provider performance.

Information services

The NHS Evidence search engine allows healthcare professionals to access clinical or non-clinical evidence, and best practice guidance through a web-based portal.[8]

International role

The introduction of NICE International in 2008 allowed the organisation to extend links to foreign countries (e.g. the Philippines and Vietnam) to improve healthcare systems.[9] It is a self-supporting, non-NHS funded organisation that also carries out research activities through international meetings.

The Institute and ENT

Accessing ENT-related guidance by navigating the NICE website can be challenging, as the current ENT guideline subsection only covers the ear and nose. Tonsillectomy guidance in the 'Mouth and Dental' section is reasonable, but also including endoscopic stapling of pharyngeal pouch in that section strays well beyond anatomical boundaries.

Tables I–III outline all NICE guidelines relating to ENT; these are discussed in more detail below.

TABLE I
ENT-RELATED CLINICAL GUIDELINES

CG3	Pre-operative tests
CG27	Referral for suspected cancer
CG32	Nutrition support in adults: oral nutrition support, enteral tube feeding & parenteral nutrition
CG46	Venous thromboembolism (surgical)
CG60	Surgical management of otitis media with effusion
CG64	Prophylaxis against infective endocarditis
CG74	Surgical site infection
CG89	When to suspect child maltreatment
CG92	Venous thromboembolism – reducing risk
CG96	Neuropathic pain – pharmacological management
CG104	Metastatic malignant disease of unknown primary origin
CG112	Sedation in infants, children & young people

CG = clinical guideline

Clinical guidelines

Surgical management of otitis media with effusion. This clinical guideline (number 60, Table I) addresses surgical management of this condition in children aged less than 12 years old based on the best available evidence in 2008. The guideline recommends that clinical diagnosis involves clinical history taking, examination, audiometry and tympanometry. Surgical intervention (ventilation tubes) is recommended for those children with persistent bilateral otitis media with effusion (OME) documented over a period of 3 months, with a hearing level in the better ear of 25–30 dB HL or worse, averaged over 0.5, 1, 2 and 4 kHz (core criteria). Surgical intervention is also recommended for children not meeting those audiological criteria in whom OME has a significant impact upon developmental, social or educational status. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.

Treatments not recommended include antibiotics, topical or systemic antihistamines, decongestants or steroids, and such alternative measures as homeopathy, cranial osteopathy or acupuncture.

An earlier publication by the Scottish Intercollegiate Guidelines Network (2003), which related to the diagnosis and management of childhood OME in primary care, concurred with the non-recommendations produced by NICE but did suggest that autoinflation may be of benefit in some patients.[10]

A recent retrospective case note review analysed practice in five UK centres before and after the introduction of the NICE guidelines.[11] This showed that 87 per cent of children with OME had ventilation tubes inserted in accordance with the NICE guidelines. It also showed that a significant number had surgery based on the non-core criteria, suggesting that there is a persisting trend for clinicians to personalise treatment to the individual child.

Cancer service guidance (head and neck). This guidance (2004) aims to improve outcomes for patients with head and neck cancers. It recommends which

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TABLE II
ENT-RELATED INTERVENTIONAL PROCEDURE GUIDELINES*

IPG009	Coblation tonsillectomy (normal)
IPG022	Endoscopic stapling of pharyngeal pouch (normal)
IPG028	Customised titanium implants for orofacial reconstruction (currently revising)
IPG032	Endoscopic transsphenoidal pituitary adenoma resection – guidance (normal)
IPG036	Radiofrequency volumetric tissue reduction of turbinate hypertrophy (special)
IPG042	Cyanoacrylate instillation for occlusion of parotid sinuses (special)
IPG108	Auditory brainstem implants (normal)
IPG113	Endoscopic dacryocystorhinostomy (normal)
IPG124	Radiofrequency ablation of soft palate for snoring (special)
IPG130	Collagen injection for vocal fold augmentation (normal)
IPG149	Division of ankyloglossia (tongue-tie) for breastfeeding (normal)
IPG150	Electrosurgery (diathermy & coblation) for tonsillectomy – guidance (normal)
IPG178	Tonsillectomy using ultrasonic scalpel (normal)
IPG186	Tonsillectomy using laser (normal)
IPG187	Catheterless oesophageal pH monitoring (normal)
IPG196	Patient safety & reduction of Creutzfeldt–Jakob disease transmission risk via interventional procedures
IPG218	Therapeutic sialendoscopy (normal)
IPG240	Soft palate implants for simple snoring (research only)
IPG241	Soft palate implants for obstructive sleep apnoea (do not use)
IPG255	Intra-operative nerve monitoring during thyroid surgery (normal)
IPG259	Interstitial photodynamic therapy for malignant parotid tumour (special)
IPG273	Balloon catheter dilatation of paranasal sinus ostia for chronic sinusitis (normal)
IPG328	Suction diathermy adenoidectomy (normal)
IPG409	Balloon dilatation of eustachian tube (research only)
IPG422	Incisionless otoplasty (special)
IPG425	Endoscopic balloon dilatation for subglottic or tracheal stenosis (special)
IPG426	Micropressure for refractory Ménière's disease (special)
IPG434	Radiofrequency cold ablation for respiratory papillomatosis (special)

*Text in parentheses indicates National Institute for Health and Clinical Excellence recommendations (wherein 'normal' refers to 'normal arrangements' and 'special' to 'special arrangements'). IPG = interventional procedure guideline

TABLE III
ENT-RELATED TECHNOLOGY APPRAISALS

TA7	Proton pump inhibitors for dyspepsia
TA139	Continuous positive airway pressure for sleep apnoea
TA145	Cetuximab for head & neck cancer
TA166	Cochlear implants for hearing impairment

TA = Technology appraisal

healthcare professionals should be involved and where treatment is best delivered. It specifies that cancer networks should identify the units tasked with this objective and that multidisciplinary teams should have patient responsibility. Rapid diagnosis and support services, including long-term community care, are also stressed. The guidance calls for data collection and research input. The document is a systematic review, of remarkable quality, of the evidence base for head and neck cancer management, from surveillance through to post-discharge review and support.

Interventional procedure guidelines

These evaluate the safety and efficacy of the new invasive procedures used for diagnosis and treatment; many of these guidelines are relevant to otolaryngology (Table II). Topics selected must be in use in the UK; they should be novel enough to merit study, yet carry sufficient peer-reviewed published evidence to allow evaluation.

The guidance given is based on clinical efficacy (whether it works well enough for routine use) and safety. Final recommendations can range from 'do not use' to 'normal arrangements', which are both self-evident. Where evidence for safety and efficacy is limited in quantity and/or quality (e.g. small case series, lack of long-term follow up and/or flawed study methodology), the alternative recommendations are: 'research only', where the protocol and ethical approval process will govern further work; or 'special arrangements' for audit, clinical governance and the consent process, reflecting the uncertainty. For the latter, an audit tool is published and the recommendation is reviewed every three years, thereby allowing new evidence to be considered.

Endoscopic stapling of pharyngeal pouch. The Institute recommends normal arrangements concerning this procedure. The interventional procedure guideline (number 22, November 2003) notes that this technique allows a more rapid recovery and a shorter stay in hospital (1–2 days) than open surgery. However, the procedure should be performed in specialist centres by specifically trained otorhinolaryngologists. Although deemed safe, evidence is based on small case series and therefore more research is welcomed.

A recently published meta-analysis of 585 patients from 15 retrospective case series reported over the last 15 years has confirmed the safety of this procedure.[12] It showed good outcomes, with 92 per cent of patients resuming oral intake by the second post-operative day, and more than 90 per cent of patients reporting symptom resolution or significant

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improvement. An overall perforation rate of 4.8 per cent was reported.

It has been suggested that pharyngeal pouch procedures should only be undertaken by otolaryngologists with a primary head and neck interest. This recommendation was based on a single-centre retrospective review of practice.[13]

Endoscopic transsphenoidal pituitary adenoma resection. The Institute supports the use of this procedure. The interventional procedure guideline (number 32, December 2003) reports efficacy comparable to conventional surgery. It notes shorter operating times, shorter hospital stay and lower risks of serious complications compared with microscopic resection.

A systematic review, covering 11 studies from 1989 to 2009, showed no difference in major outcome measures (tumour resection extent or change in hormone levels) compared with traditional techniques.[14] However, complications, time in operating theatre and in hospital, and patient discomfort were all significantly improved with the endoscopic approach. A recent single-unit, retrospective analysis of 171 cases reported an 85 per cent total tumour resection rate with this technique.[15]

A 10-year follow-up study involving a retrospective case series of 301 patients showed that the total complication rate, which was heavily weighted towards endocrine problems, was relatively high at 26.9 per cent.[16] There were no comparisons with data from conventional techniques. Surprisingly, there is little high-level evidence comparing traditional microsurgery with endoscopic surgery, with the majority of available data coming from single-institution case series.

Radiofrequency volumetric tissue reduction for turbinate hypertrophy. In this interventional procedure guideline (number 36, January 2004), NICE concluded that there was inadequate evidence to support the use of this procedure routinely, and that usage requires special measures for consent, audit and clinical governance.

A prospective, randomised, controlled trial (RCT) of 30 patients, which compared this technique with microdebrider submucosal resection in 2008, showed no difference in efficacy between the two techniques.[17]

A systematic review of current knowledge on effectiveness and complications (published in 2009) revealed that most of the published studies on nasal radiofrequency ablation were observational, with relatively short follow up.[18] This further emphasises the need for double-blind, placebo-controlled randomised trials.

Level 1 evidence supporting radiofrequency volumetric tissue reduction has been published (in February 2013) in the form of a prospective, randomised, single-blinded crossover trial ($n = 22$).[19] This study presented statistically significant data, showing an advantage for radiofrequency volumetric tissue reduction compared with placebo. The primary outcome measures were based on patient and clinician subjective assessments, as well as rhinomanometry; long-term outcomes were not reported. However, the results of a study that did examine longer-term outcomes seemed to corroborate these findings.[20] Neither study reported any intra-operative or post-operative complications.

Further research in this area is warranted.

Cyanoacrylate instillation for occlusion of parotid sinuses. This interventional procedure guideline (number 42, February 2004) states that parotid-skin sinuses, which complicate 10–15 per cent of parotid gland resections, can be managed by injection of lipiodol and cyanoacrylate adhesive. This procedure often follows a period of bandaging and watchful waiting, and is an alternative to radiotherapy and excision of the deep lobe of the gland. In theory, this procedure can be repeated on recurrence. The evidence for both efficacy and safety is inadequate, with only one case report to document its feasibility, and there has been no addition to the literature.

Auditory brainstem implants. The Institute concluded (in interventional procedure guideline number 108, January 2005) that this procedure is suitable for the small proportion of patients who have complete deafness in both ears caused by damage to the vestibulocochlear nerve, as a result of tumour or surgery, and in whom there is no alternative treatment. The data are limited to case series reports on a small number of patients and no long-term data are available. Based on current evidence on safety and efficacy, it is recommended that the procedure is only undertaken by experienced surgical teams.

Since the publication of this guideline, a study of 61 patients who received such devices showed encouraging, long-term results (up to 8 years).[21] A 10-year follow-up study also observed a high efficacy rate for auditory brainstem implants.[22] It should be noted that a recent case of bacterial meningitis secondary to stapes footplate malformation was reported in a child with an auditory brainstem implant.[23]

Recent review articles suggest that results are poor compared with cochlear implants, and that auditory brainstem implants are possibly overused in patients who could still benefit from a cochlear implant.[24,25] It was recommended that auditory brainstem implants are used only in severe cochlear hypoplasia or aplasia cases.

Endoscopic dacryocystorhinostomy. The Institute concluded (in interventional procedure guideline number 113, February 2005) that this procedure is now established practice. Efficacy rates are comparable to conventional treatment and there is good evidence to support faster healing rates following endoscopic dacryocystorhinostomy. Complication rates are low, with adverse events found to occur at similar rates

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with or without the use of lasers. The Institute found little evidence to support the use of silicone tubes to maintain patency.

A subsequent prospective, randomised study of 173 patients supports this guideline; its findings suggested that silicone tube stenting does not increase success rates.[26] It reported success rates of 96 per cent with silicone stenting, and 91 per cent without (over a one-year follow-up period); these results were not statistically significant. The overall success rate of 94 per cent is better than previous findings.

Clinical tools such as the Lacrimal Symptom Questionnaire can be beneficial in evaluating surgical outcomes.[27]

Radiofrequency ablation of the soft palate for snoring. According to this interventional procedure guideline (number 124, May 2005), reduction of the volume of palatal tissue by means of radiofrequency ablation is an attractive procedure for patients and clinicians alike, and it can potentially be done as an out-patient procedure under local anaesthesia. Although the evidence base is limited to two small randomised studies, subjective assessment seems to support its efficacy. Objective sleep assessment, however, yielded no significant difference between the ablation and the control groups. Further evidence is limited to case series, with similar results of high patient satisfaction, but low evidence of efficacy on objective assessment.

Comparative studies looking at radiofrequency ablation and laser-assisted uvulopalatoplasty and uvulopalatopharyngoplasty have found pain duration to be significantly shorter following radiofrequency ablation. Bleeding risk was around 2 per cent in a case series of 60 patients.[28] There are no documented complications of speech or swallowing difficulties. Specialist advisors had no major concerns about the safety of radiofrequency ablation, but noted potential risks of haemorrhage, secondary infections and palatal ulceration. For these reasons, this procedure should not be carried out without special arrangements in place, and specific consideration should be given to patient selection.

More recently, a systematic review of 30 articles, including two RCTs, concluded that radiofrequency ablation is superior to placebo in snoring treatment efficacy.[29] Reduced post-operative pain was also reported compared with conventional procedures. Once again, the limitations of subjective assessment and lack of long-term outcomes preclude useful conclusions from this review. Prospective studies looking at longer-term outcomes showed between 25 per cent[30] and 37 per cent[31] success rates long-term (follow up was 20 months and 3 years respectively). Although radiofrequency ablation is relatively safe and easy to carry out, patients must be informed regarding the uncertainty of long-term outcomes.

Collagen injection for vocal fold augmentation. The Institute reports (in interventional procedure guideline number 130, June 2005) that this procedure is effective in patients requiring short-term benefit, but evidence on long-term efficacy is lacking.

Subsequent research has suggested that age may influence outcome.[32] Fifty-nine patients with unilateral vocal fold paralysis underwent vocal fold augmentation with collagen injections. Three months later, these patients were divided into an improved phonation group ($n = 44$) and unimproved phonation group ($n = 15$). The improved group was significantly younger than the unimproved group. This same study revealed that the size of the posterior glottic gap had a significant effect on outcome.

Injection laryngoplasty as a stopgap measure in recoverable vocal fold paralysis has also been favourably reported.[33] The need for medialisation laryngoplasty has been shown to be lower in patients initially treated with injection laryngoplasty.[34]

A US multicentre retrospective review, conducted in 2010, found injection augmentation to be a safe and effective treatment with a high rate of success, whether performed in the awake or asleep patient.[35]

Division of ankyloglossia for breastfeeding. As indicated in this interventional procedure guideline (number 149, December 2005), NICE felt that the division of ankyloglossia (tongue-tie) raised no major safety concerns and could improve breastfeeding. It should however only be performed by properly trained, registered healthcare professionals. Adverse effects are rare, but include bleeding, infection, damage to the submandibular ducts and recurrence.

Reviews on ankyloglossia division indicate that this is a safe and efficacious procedure, corroborating the findings of NICE.[36] Most recently, a retrospective study of 91 patients found a high level of maternal satisfaction.[37] Eighty per cent of mothers questioned strongly believed that frenotomy benefited their child's ability to breast feed. Maternal satisfaction rates increased to 86 per cent in cases where the procedure was performed in the first week of life.[37]

Electrosurgery for tonsillectomy. In addition to the NICE-commissioned systematic review, data were also analysed from the Wales Single-Use Instrument Surveillance Programme (3690 patients) and the National Prospective Tonsillectomy Audit (33 921 patients). As reported in this interventional procedure guideline (number 150, December 2005), NICE concluded there was adequate evidence for the safety and efficacy of electrosurgery, with avoidance of excessive diathermy, during tonsillectomy. The guideline notes that the use of coblation can result in higher rates of haemorrhage than those seen in other techniques. Surgeons should be trained in both cold-steel and ligature, and electrosurgical techniques. In addition, it is helpful if diathermy equipment can record the total energy usage during each operation to allow for future research.

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A subsequent study has compared pain scores in children undergoing coblation and electrocautery.[38] Duration of severe pain was shorter and overall pain scores were better in the coblation group. However, when compared with the traditional 'cold' technique, coblation had no pain score benefit.[39]

Haemorrhage rates in coblation tonsillectomy were addressed in a meta-analysis published in 2011.[40] Twenty-four prospective, randomised and controlled studies were included, revealing an overall haemorrhage rate of 4.1 per cent; this rate was comparable to similar techniques.

Tonsillectomy using ultrasonic scalpel. Ultrasonic energy is used to vibrate a disposable blade, allowing the simultaneous dissection and sealing of blood vessels. This is done using lower temperatures than thermal methods.

Three randomised studies were analysed for this interventional procedure guideline (number 178, June 2006). One study's comparative data suggested that post-operative pain duration was shortened with the use of this technique versus diathermy (120 patients). Another suggested that cold-steel dissection lessened this time further. Four other studies looked at the time taken to return to a normal diet. All four found that the ultrasonic scalpel shortened this time compared with both cold-steel and diathermy techniques.

The retrospective studies referred to in the guideline, with total sample sizes of 400 patients, reported primary bleed rates of 1 per cent for ultrasonic scalpel use and 3 per cent for diathermy. It is worth pointing out, however, that these numbers are not in keeping with the larger studies mentioned in the interventional procedure guideline number 150. In these retrospective studies, additional techniques (such as bipolar diathermy or ligatures) were utilised concomitantly with an ultrasonic scalpel to achieve haemostasis.

Secondary haemorrhage data are less robust, with small sample sizes and no statistically significant results between ultrasonic and diathermy groups. These studies agreed with the findings of the National Prospective Tonsillectomy Audit, in that the cold-steel technique with ligatures yielded the lowest secondary re-bleed rates.[41]

Tonsillectomy using laser. Several types of laser are used for tonsillectomy, including carbon dioxide, potassium titanyl phosphate ('KTP') and contact diode lasers. This interventional procedure guideline (number 186, July 2006) looks at laser vaporisation tonsillectomy, but does not consider laser-assisted tonsillectomy.

Five studies examined post-operative pain and showed that laser tonsillectomy was associated with a higher pain rating than traditional cold-steel methods. Three of those studies also looked at healing and again found worse results for laser treatment. Overall, laser therapy had a higher bleeding rate. However, the types of laser, the power settings and the techniques used were heterogeneous; it is therefore difficult to generalise from the findings of these studies.

A subsequent randomised, controlled comparison of radiofrequency tonsillectomy with laser tonsillectomy revealed little difference in post-operative pain between the two patient groups.[42]

Catheterless oesophageal pH monitoring. The procedure involves placing a capsule under endoscopic guidance, which is secured onto the oesophageal wall by means of a vacuum. This interventional procedure guideline (number 187, July 2006) was based on a 'rapid review' of the literature and is not deemed to be a definitive assessment of the procedure. Small studies in the literature review failed to come to a consensus regarding the efficacy of the procedure, although it did seem to be better tolerated than conventional monitoring. There was too little evidence to produce robust guidance.

Therapeutic sialendoscopy. Treatment for obstruction of the salivary glands can include medical therapy, extracorporeal or endoscopic lithotripsy, and sialadenectomy or sialendoscopy. For this interventional procedure guideline (number 218, May 2007), NICE looked at five case series and found that treatment was successful in 82–87 per cent of cases. As with all interventional procedure guidelines, NICE did not compare this therapy with other treatments. The procedure was generally safe, but the case reports did highlight complications, such as ductal wall perforation and lingual nerve damage. This procedure continues to evolve.

Since the publication of this guideline, a sizeable single-centre study of 1154 patients was carried out in Germany.[43] The authors treated over 1000 submandibular and parotid calculi, a significant number of which were removed by sialendoscopy alone. The findings revealed long-term success rates of 90 per cent. Meta-analysis data also support the use of sialendoscopy with regard to efficacy rates, safety and gland-preserving factors.[44]

Advances in sialendoscopy have meant that this technique can now be used in paediatric populations, with good evidence for its safety and outcome.[45]

Soft palate implants for simple snoring. In this interventional procedure guideline (number 240, March 2007), NICE concluded that although there are no major safety concerns regarding this procedure, there is a lack of evidence on efficacy, with small case series data only and a lack of well-controlled comparative data. All studies reviewed showed snoring to improve over short periods of follow up, with no serious adverse events reported. The Institute called for further research, particularly on quality of life outcomes and patient selection data.

A subsequent cohort study of 26 patients compared snoring outcomes before and after soft palate implants (at 52 weeks and 4 years post-implant).[46] This showed significant improvements in snoring scale scores at 52

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weeks compared with pre-operative scores. However, there was deterioration in snoring scale scores between 52 weeks and 4 years, suggesting that the efficacy of implants may deteriorate over time. The study size was small, and only 23 of the 26 patients were followed up for the full 4 years.

Soft palate implants for obstructive sleep apnoea. No safety concerns are reported in this interventional procedure guideline (number 241, March 2007). However, the evidence for efficacy is lacking. As there are other treatments for this potentially serious condition, the current recommendation is to not use this procedure in the treatment of obstructive sleep apnoea (OSA).

A recent meta-analysis (of seven studies) supports the use of soft Pillar implants for mild to moderate OSA, but notes that high-level evidence is still lacking.[47]

Intra-operative nerve monitoring during thyroid surgery. Nerve damage during thyroid surgery is a major concern as it can lead to breathing and vocalisation difficulties. This interventional procedure guideline (number 255, March 2008) concerns nerve monitoring carried out via electrodes attached to the endotracheal tube.

A large, non-randomised trial of almost 30 000 patients compared the rates of nerve damage associated with: not identifying the recurrent laryngeal nerve, identifying it visually or using intra-operative nerve monitoring. The results showed no significant difference between these groups. Smaller studies appeared to show a trend towards a benefit from intra-operative nerve monitoring, but this was not statistically significant. Specialist advisors commented that intra-operative nerve monitoring is of value in proving nerve integrity should litigation arise post-operatively.

A US multi-institutional survey reported that 80 per cent of ENT surgeons who carry out thyroid surgery use intra-operative nerve monitoring technology, with 40 per cent of surgeons choosing to use it in every case.[48]

The most recent evidence comes from a single-centre study in Greece, which looked at revision thyroidectomy ($n = 91$).[49] This showed no significant difference in rates of recurrent laryngeal nerve injury for intra-operative nerve monitoring use compared with non-use. Furthermore, the study found a statistically significant increase in intra-operative time associated with its use.

The most robust evidence is probably that from the International Neural Monitoring Study Group, who reported a review of the literature and their own experience of intra-operative nerve monitoring over 15 years.[50] The consensus document recommended standards for equipment set-up and endotracheal tube placement, and for dealing with loss of signal. In addition, the authors derived an algorithm for intra-operative problem solving.

Interstitial photodynamic therapy for malignant parotid tumour. This procedure is used for parotid tumour that is recurrent or locally persistent, despite surgery and adjunctive chemotherapy and/or radiotherapy. For this interventional procedure guideline (number 259, April 2008), NICE looked at a total of two case reports and concluded that the procedure should only be used with special arrangements because of the lack of evidence.

Balloon catheter dilatation of paranasal sinus ostia for chronic sinusitis. This interventional procedure guideline (number 273, March 2008) is based on published evidence from one non-randomised controlled trial and three large case series. The Institute concluded that the short-term efficacy of this procedure is adequate, with no major safety concerns. The procedure should be carried out only by surgeons with experience of complex sinus surgery and specific training in the technique. Publications of long-term outcomes are welcomed.

Subsequent retrospective case note reviews of 27 consecutive patients were conducted, in which subjective improvement and sinonasal outcome test ('SNOT-22') scores were measured. The results revealed that dilatation was successful in 98 per cent of sinuses in which this procedure was attempted, but subjective improvement was only reported for 62 per cent of patients.[51] It was concluded that this technique, although valuable, has limited applications; the cost of the procedure also needs to be considered.

Following this, a systematic review of the technique called for more RCTs to determine its efficacy over conventional treatment modalities.[52]

Low-level evidence was provided in the form of a retrospective, controlled study of 85 patients who were followed up using a questionnaire.[53] The findings suggested that those with chronic rhinosinusitis related comorbidity, or occupational exposure, had a better outcome with traditional endoscopic sinus surgery than with balloon sinuplasty. The study also described a statistically higher rate of antibiotic usage and maxillary sinus puncture after balloon sinuplasty.

Suction diathermy adenoidectomy. In this interventional procedure guideline (number 328, December 2009), NICE concluded that the current evidence on the safety and efficacy of suction diathermy adenoidectomy is adequate to support the use of this procedure under normal arrangements. However, the procedure should be carried out by surgeons with specific training in the use of diathermy for adenoidectomy, because possible thermal damage to surrounding tissues can rarely cause Grisel's syndrome (subluxation of the atlanto-axial joint).

The NICE guidance is based on over 6000 patients' results from five papers, including one meta-analysis

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for which the level of evidence was concluded to be robust. The studies showed that the efficacy of suction diathermy was similar to that of the traditional 'cold' curettage technique in relieving symptoms, but the former procedure was superior in terms of adenoidal tissue removal, bleeding complications and length of hospital stay.

A subsequent postal questionnaire sent to consultant members of ENT UK in 2010 showed that suction diathermy ablation was the preferred routine adenoidectomy technique for only 8.1 per cent of these individuals.[54]

In 2011, a prospective cohort study was conducted (as part of the National Prospective Tonsillectomy Audit) that compared suction adenoidectomy and traditional curette in patients undergoing adenotonsillectomy.[55] The findings indicated that the use of suction diathermy had a similar safety profile to the conventional technique.

The use of suction diathermy has also been described as a treatment for chronic nasopharyngitis[56] and as a teaching tool.[57]

Balloon dilatation of eustachian tube. This interventional procedure guideline (number 409, November 2011) states that current research evidence is inadequate (in both quality and quantity) to assess the procedure's safety and efficacy. Hence, this procedure should only be used in the context of research.

Preliminary studies have since been carried out, with variable results. One study reported improved symptoms in 71 per cent of 70 adults studied, with one complication reported.[58] However, there have been documented cases of adverse catheter placement, which would appear to limit the use of balloon dilatation. In addition, in a cadaver study, attempts to pass the same tube in the reverse direction, from the tympanum towards the nasopharynx, highlighted the risk of carotid canal damage.[59]

Incisionless otoplasty. The technique, which is used to correct protruding ears, is adopted to avoid the complications associated with standard incision, such as anterior skin necrosis or keloid scar formation. This interventional procedure guideline (number 422, March 2012) describes a total of 24 patients from two retrospective case series. Both cases series were published over 12 years ago, and neither study had an adequate period of follow up. The Institute concluded that the technique seems to show good cosmetic results, but more recent and robust research is required.

Endoscopic balloon dilatation for subglottic or tracheal stenosis. In this interventional procedure guideline (number 425, April 2012), NICE concluded that the current evidence on safety and efficacy is inadequate in terms of quality and quantity. The published evidence was found to be related to a variety of different techniques, some of which are no longer used. A few patients experienced some symptomatic relief following this procedure (often after a number of dilatations). However, more data are required.

Micropressure therapy for Ménière's disease. Ménière's disease is thought to be caused by raised endolymph pressure in the inner ear. Micropressure therapy may stimulate endolymph flow via low pressure air pulses through the tympanic membrane.

This interventional procedure guideline (number 426, April 2012) looks at two RCTs that showed a significant improvement in functional level and a reduction in the number of vertigo attacks in the group treated with micropressure versus the group who received a sham treatment. However, there was no long-term follow up beyond two years. Furthermore, it is difficult to interpret these results, as Ménière's disease naturally relapses and remits. The NICE panel concluded that the evidence for efficacy was limited and suggested further research, particularly into long-term outcomes and the need for subsequent surgical treatment.

A subsequent preliminary study showed a statistically significant reduction in vertiginous symptom frequency (compared with pre-treatment) with the use of either the tympanic membrane massage device or the Meniett® device.[60] Follow up was for 12 months. Patient groups were limited to a maximum of 15 patients.

Technology appraisals

Technology appraisals (Table III) are recommendations on the use of new and existing medicines and treatments within the NHS. The appraisals might focus on medicines, devices (e.g. hearing aids), diagnostic techniques, surgical procedures and health promotion issues. The guidance is based on a review of the clinical and economical evidence, but has rarely tackled ENT-related issues. Recommendations in a technology appraisal are based on the quality and quantity of evidence for safety and efficacy.

Continuous positive airway pressure for sleep apnoea. For this technology appraisal (number 139; issued March 2008, reviewed November 2010), NICE looked at 48 RCTs on the effectiveness of continuous positive airway pressure (CPAP) for OSA. A meta-analysis of these studies showed a statistically significant reduction in daytime sleepiness when CPAP was used by those with moderate to severe OSA, and an improvement in blood pressure for patients with severe OSA. It also showed that road safety improved with the use of CPAP. Adherence to treatment was in the range of 65–85 per cent, dropping with time. The treatment is recommended for use in moderate to severe OSA (as determined by the Apnoea–Hypopnoea Index), and in mild OSA cases where symptoms have had a detrimental effect on quality of life and lifestyle measures have failed. The NICE costing team calculated a cost of between £4000 and £9000 per

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quality-adjusted life year gained, depending on apnoea severity.

Cetuximab for head and neck squamous cell cancer. In this technology appraisal (number 145; issued June 2008, reviewed March 2011), cetuximab, in combination with radiotherapy, is currently recommended for patients with locally advanced head and neck cancer, in whom platinum-based chemotherapy is contraindicated. The patient must also have a good performance status score.

The NICE panel took into account information provided by Merck Pharmaceuticals, the manufacturers of cetuximab. The manufacturers supplied RCT evidence in which cetuximab plus radiotherapy was compared with radiotherapy alone, with 200 patients in each arm. This trial (the Bonner Trial) commenced at a time when chemotherapy was not standard treatment for locally advanced squamous cell cancer. The trial showed longer median survival times and prolonged control of the disease for patients in the cetuximab group. However, NICE noted that patient performance status varied widely prior to treatment, and many of those in the trial were actually suitable for conventional chemotherapy.

The Institute did not initially approve cetuximab, as it did not prove cost effective in this trial. However, on appeal, it was approved for those with a good performance status score (i.e. Karnofsky scores over 90 per cent). The Institute then invited Merck Pharmaceuticals to perform a literature review. However, there was no evidence at the time for cetuximab versus chemoradiotherapy. A recent meta-analysis of four trials comparing cetuximab plus radiotherapy with platinum-based chemoradiotherapy showed no difference in endpoints between the two treatments.[61] Interim results of the Radiotherapy (intensity-modulated radiation therapy), Erbitux® And CHemotherapy for unresectable carcinomas of head and neck ('REACH') trial, which examined the safety and efficacy of cetuximab plus chemoradiotherapy, are now available but the full findings have not yet been published.[62]

Cochlear implants for severe to profound deafness. For this technology appraisal (number 166; issued January 2009, reviewed February 2011), the committee looked at the devices currently available on the market. The appraisal recommends that unilateral implants are used in children and adults who do not benefit from acoustic hearing aids, and that simultaneous bilateral implants are used in those who are blind or rely on auditory stimuli as their primary sensory mechanism. Sequential bilateral implants are not recommended, and upgrading a unilateral implant to a bilateral implant is only indicated if a benefit can be proven.

The NHS buys cochlear implants from several companies on long-term contracts, via the national procurement contract. The manufacturers offer discounts on larger orders (e.g. 10 units or more), but often only give discounts for bilateral implants if they are being implanted simultaneously.

A literature review was carried out by NICE on the efficacy of cochlear implants. Thirty-three studies were found, but they were too heterogeneous to carry out a meta-analysis. Only two implant systems (produced by the same manufacturer) noted in the literature were actually available on the NHS contract. The review revealed significant benefits for children fitted with either unilateral or bilateral implants, but the benefit of bilateral implants in adults was less clear, with some studies even suggesting a worsening of symptoms (e.g. tinnitus). The committee was unable to give guidance on whether a second device should be implanted into a patient who already has a unilateral cochlear implant.

A more recent systematic review showed that even elderly patients gain an improved quality of life after a cochlear implant.[63]

Bilateral implants offer better sound localisation compared with unilateral implants, but there is high inter-individual variability in terms of outcome following the second implant. A second implant can still be beneficial even after a substantial time following the first implant,[64] but more research is needed into the cost-effectiveness of this strategy.

Conclusion

Our enthusiasm for new technologies and procedures, understandable in surgeons so familiar with invasive treatments, must be tempered by an understanding of the demands of evidence-based practice. Surgical specialties have been relatively spared from the highly publicised debates about funding for new expensive miracle drugs of controversial effectiveness, for chronic or life-threatening conditions, for which there is no existing evidence-based effective therapy. Instead, we have, for centuries, practised invasive procedures for which there is no high-level evidence; a randomised, controlled trial on appendicectomy, the repair of an abdominal aortic aneurysm after midnight or the drainage of an extradural abscess associated with mastoiditis seem, at best, impractical.

When we surgeons want to introduce new procedures, we must at least pause to think. The Institute has sanctioned those ENT procedures approved for normal arrangements. The fund holders, the commissioners of healthcare, must support such. The challenge arises with regard to procedures felt promising, but currently lacking an evidence base. In times of economic hardship, is the recommendation of special arrangements an excuse to withhold funding for what is, by definition, an unproven treatment? Clinical governance arrangements in the UK have transformed the traditional custom of attending a hands-on training course and then applying the lessons learnt on return.[65]

Otolaryngology had been considered as underrepresented by NICE, but it is increasingly on the

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agenda. Otolaryngology journals continue to publish ground breaking work, such as that on radiofrequency ablation for paediatric lymphatic malformations.[66] Such procedures are still in their evidence infancy, but are surely topics for the future.

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