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Editorial Review

Evidence based medicine in Otolaryngology

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It has become increasingly apparent that the National Health Service is being moved towards a formal evidence-based approach with pronouncements from ministers and publications from the NHS Executive promoting this concept. In October 1995 both Mr Alan Langlands, Chief Executive of the NHS, and Mr Stephen Dorrell, the Secretary of State for Health, spoke very strongly in favour of an evidence-based health service at a London conference on the scientific basis of health services. The central message of this conference, as reported in an Editorial in the British Medical Journal (Smith, 1995), was that health services need both research that will develop new ideas and treatments, and research that will help evaluate them and ensure that those that are effective are introduced rapidly into treatment.

In a recent article in The Journal of the Royal Society of Medicine, Sackett and Rosenberg (1995) indicated that 'Evidence-based Medicine' (EBM) is a short hand term for five linked ideas:

(1) that our patient management decisions should be based on the best patient- and population-based evidence as well as on laboratory studies;
(2) that the problem determines the nature of the evidence to be sought;
(3) that we need to integrate information from many sources, including biostatistical and epidemiological as well as from personal and pathophysiological standpoints;
(4) that this information needs to be applied to patient care and
(5) that we need to constantly evaluate our performance in applying these ideas.

In practising EBM the randomized control trial (RCT) has become, along with meta-analysis of relevant published studies, the 'Gold Standard', although this view has been challenged by Black (1996) who has stated the case for observational studies as long as they are evaluated with scientific rigour. Reassuringly Sackett *et al.* (1996) comment that the practice of evidence-based medicine means the integration of individual clinical expertise with the best available external clinical evidence from systematic research and that it is not 'cookbook' medicine.

How does this affect the otolaryngologist?

As a discipline we must apply ourselves to patient care utilizing the most up-to-date, relevant and effective treatment available. In addition, we are being constantly challenged by our purchasers to justify treatments in their quest for cost-effectiveness, or, as many clinicians suspect, for cost reduction. Our views were challenged four years ago with the publication of the *Effective Health Care Bulletin* (1992) on otitis media with effusion, one of the first evidence-based challenges to confront us. In fact, that publication presented much useful information but was unfortunately taken out of context, certainly by the media but also to a lesser extent by many within our own community.

A symposium held in Nottingham in April last year addressed a number of the issues related to EBM in Otolaryngology and highlighted areas we need to develop in order to practise informed decision making. Dr Muir Gray from the Centre for Evidence-based Medicine at Oxford gave a definition of evidence-based practice as 'conscientious, explicit and judicious use of the best evidence available', he felt, however, that this was not the only factor to influence clinical practice. Patient management depends on the evidence available, the resources available and the needs and values of the individual patient. He felt that 80 per cent of practice *is* evidence-based.

A further area for research is that of outcome measures; Professor Janet Wilson noted that correlates of patient satisfaction are not the same as outcomes as measured by physicians and surgeons. Even within the individual fields within the broader discipline of ear, nose and throat surgery different outcome criteria are required, for example, between rhinoplasty, (FESS) endoscopic sinus surgery and the surgery of inverted papilloma.

Williams *et al.* (1995) have commented on the challenges facing surgeons designing or using outcome measures for research or audit. They stressed various areas to be addressed including reduction of symptoms, improvement of well-being and change in health-related quality of life (HRQOL); study design and the importance of case-mix are other relevant factors to be considered. Ryan *et al.* (1996) used a simple measure of identifying the primary goal of surgical treatment as a means of monitoring outcome of surgical procedures in otolaryngology. Robinson

et al. (1996) have used the Glasgow benefit inventory (GBI) as a patient oriented measure; they studied five different ENT interventions and found that the GBI has a high sensitivity to each of the interventions studied.

In considering a specific rhinological issue, Drake-Lee (1996) notes that, in the absence of science, magic is important in reporting the results of endoscopic sinus surgery until proper clinical trials are carried out!

Clearly, quality of life is an important outcome measure whether this be applied to benign or malignant conditions; the former may include consideration of benign tumours as discussed by Van Leeuwen *et al.* (1996) who compared the outcome of different surgical approaches to the management of acoustic neuromas. Morton (1995, 1996) discussed quality of life mainly as applied to malignant disease and raised several issues stressing that otolaryngologists risk having their clinical practice directed by others unless we contribute to the design and implementation of quality of life assessment in our specialty.

At the Nottingham conference Professors Browning and Summerfield discussed specific issues, the former raising questions related to the management of otitis media with effusion, or confusion, the latter dealing with the evaluation of cochlear implantation. In both cases considerable costs have been involved in the evaluation.

The TARGET trial of glue ear treatment being conducted under the auspices of the MRC Institute of Hearing Research uses a variety of outcome measures. Most clinicians are aware in their daily clinical practice that assessing the outcome of treatment of glue ear purely on the results of pure tone audiometry may at best be disappointing and at worst misleading; parental reports of the effect of such treatments on the quality of life are probably at least as important as measuring hearing thresholds. Otopathological outcome is another measure of which purchasers remain unaware. Other factors to be considered in the assessment of glue ear treatment are possibly much longer term measures, such as quality of life issues, general health and behavioural outcomes. None of these is routinely used in clinical practice but nonetheless such measures need to be analysed. The TARGET trial includes such assessments. Such trials are not cheap nor do they produce quick results as they must of necessity involve assessment of long-term outcomes. The cost of the TARGET trial will be in the order of one million pounds; because of need for multiple outcomes and repeated measures due to the fluctuating nature of the condition a pragmatic trial of this magnitude is expensive.

Summerfield and Marshall (1995) have published their report on cochlear implantation with the results adopted by the Department of Health of the UK Government. The costs of the cochlear implant trial evaluation, approximately £0.5 million represented approximately one per cent of the implant budget. The outcome of this trial presents good evidence on which to base practice; it remains to be seen whether purchasers will heed the evidence! It is the author's experience that even now some purchasing authorities are ignoring these outcomes and refusing to purchase cochlear implants for adults, or restricting their purchasing of such treatments.

Both of the trials referred to above have involved considerable cost; in the one instance the study was of a high volume condition utilizing relatively low unit treatment costs, the other was of a high unit cost low volume treatment. There is a clear message to be transmitted to purchasers of our services – we as a discipline are prepared to carry out the necessary studies to provide the evidence on which to base practice but we need funding in order to do so.

That message was also contained in an Effective Health Care Bulletin in December 1994, '*Implementing Clinical Practice Guidelines*', – 'Resources should be made available to help provide the evidence base which can be incorporated into guidelines'.

The topic of clinical guidelines was discussed at the Nottingham conference by Patrick Bradley, Chairman of the BAO - HNS group on guidelines, who stressed that guidelines could only be applied once a diagnosis was made and that diagnosis depended on the quality of the doctor, the patient and the doctor - patient relationship. He also noted that the validity and effectiveness of guidelines had not as yet been tested. Tonsillectomy is an operation whose benefit has been questioned but Mr Bradley noted that the Scottish Tonsillectomy audit, now published (Blair *et al.*, 1996) had reported a 98 per cent patient satisfaction.

At the evidence-based Otolaryngology conference Dr Kim Ah See presented the results of a literature survey carried out in Edinburgh, reviewing the output of five otolaryngology journals, *Annals of Otology, Rhinology and Laryngology, Archives of Otolaryngology – Head and Neck Surgery, Laryngoscope, Clinical Otolaryngology and Otology* and *Head and Neck Surgery*. Of a total of 4938 articles in these journals between 1990 and 1994 only 72 reported randomized controlled trials (1.5 per cent); the only English journal referenced reported RCTs in four per cent of its articles.

It is clear that our discipline needs to expand its use of evidence-based practice. In many areas there is evidence on which to base practice, either already established or in the process of being collated. However, there remain areas where the evidence for current changes in practice, for example the uses of FESS as against conventional surgery is not available. We also need to look continually and critically at established practice. Whilst we are able to argue that lack of evidence does not mean lack of effectiveness that route may not be open to us indefinitely and in the 'new' NHS we will surely be called to account for our actions ever more closely.

Whilst Otolaryngology-Head and Neck Surgery is a surgical discipline a considerable amount of our time is spent in the outpatient department and only about 20 per cent of patients seen in the clinics are admitted for surgery. We, therefore, need also to

target our resources towards an analysis of outpatient workload and activity. It would be of major interest to note the reason for referral of patients to an Otolaryngology outpatient department - is it for diagnosis, medical treatment or surgical treatment or is the referral purely for patient (or general practitioner!) reassurance? If the referral is for management then not only should we be directing our efforts towards assessing surgical outcome but also towards auditing and evaluating non-surgical methods of treatment.

In summarizing our needs as a discipline perhaps we should ask our own professional organization to commission sub-groups to research the evidence relevant to various areas of practice and to disseminate that evidence. That process has already been started with the commissioning of a group to consider guidelines; it needs to be given the means to produce results.

As individual clinicians we need to ensure that we adopt practices that stand up to scrutiny and be prepared to assist in the gathering of the evidence required for evidence-based practice. We also need to maintain a dialogue with the purchasers of our services not only to try to ensure that we provide a service that is relevant to the local as well as the wider community but also to try to mould their thinking and to ensure that clinical priorities prevail.

Information needs to be readily available and accessible, a fact being increasingly recognized by some of the newer journals being introduced, including *ENT News, The Otolaryngology Journal Club Journal* and, hopefully, a new journal shortly to be launched in the United Kingdom '*CME Bulletin – Otorhinolaryngology, Head and Neck Surgery*'. Other sources of relevant information may include further *Effective Health Care Bulletins* and the *Drug and Therapeutics Bulletin*. Although not an ENT journal the *Journal of Evidence-Based Medicine* is another vehicle for disseminating evidence.

Finally, perhaps Editors of our own specialty journals should instruct reviewers to assess papers on the basis of their EBM content.

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