■ EDITORIAL

NICE work

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This editorial examines the influence of the National Institute for Clinical Excellence (NICE) on the conduct of orthopaedic surgery. It proffers criticism and suggests ways of improvement.

In 1999, the government set up the National Institute for Clinical Excellence (NICE), the role of which was clarified in the 2004 White Paper 'Choosing health: making healthier choices easier'.¹ In 2005, it merged with the Health Development Agency to form the National Institute for Health and Clinical Excellence, also known as NICE.

It is a government-funded organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. It has offices in London and Manchester and guidance is developed by independent advisory groups consisting of health professionals, National Health Service (NHS) workers, patients, their carers and the public. It is headed by a Board which holds six public meetings each year, in different locations across the country.

The National Institute for Health and Clinical Excellence produces four types of guidance: clinical guidelines, technology appraisals, public-health guidance and assessments of new interventional procedures. All of these apply to the NHS in England. In Wales, Scotland and Northern Ireland public-health guidance does not apply and in Scotland the clinical guidelines are not mandatory. Once NICE has produced a clinical guideline, hospital Trusts must review their current management and consider the resources and time needed to implement the guideline. In response to a technology appraisal, Trusts should fund and resource the medicines and treatments recommended, usually within three months. Individual clinicians are required to check whether NICE has issued guidance before carrying out a new procedure. If there is none, the clinician must seek prior approval from the clinical governance committee of their Trust.

Several different groups suggest topics for NICE guidance. For a public-health intervention, technology appraisal or clinical guideline health professionals, the Department of Health's National Clinical Directors and policy teams, patients, carers and the general public suggest topics. The National Horizon Scanning Centre deals with emerging health technology. Topics for guidance concerning interventional procedures are usually notified to NICE directly by clinicians. The Department of Health makes the final decision as to whether NICE should develop a guidance.

Orthopaedic surgeons may become involved in developing NICE guidelines in several ways. The British Orthopaedic Association (BOA) has a representative on the New Interventional Procedures Committee, which nominates experts to advise on individual procedures. NICE co-opts orthopaedic surgeons on to committees and, finally, the BOA and specialist societies can register as stakeholders in individual NICE guidance.

NICE has provided a number of guidance documents on matters of orthopaedic interest and a summary of these can be found on the BOA website.²

So much for the theory. In practice, from an orthopaedic point of view the recommendations of NICE are often imperfect. For example, the interventional assessment for devices for intramedullary lengthening does not distinguish between the modern Intramedullary Skeletal Kinetic Distractor,³ which appears to have good results, and older designs which have been withdrawn from use as a result of complications. Nor does NICE differentiate between femoral and tibial lengthening, although better results and fewer complications have been obtained with the former technique.

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In addition to errors resulting from a lack of orthopaedic insight, there have also been mistakes in statistical and investigational methods. For example, when studying intramedullary lengthening, the authors bemoaned the lack of prospective, randomised trials in which the appropriate statistical method was used whereas there are a number of prospective studies of the technique, its outcome and complications. In addition, NICE has quoted the complications of intramedullary lengthening in isolation without comparing them with those of other interventions which might have achieved the same clinical end-point.

Similar methodological bias and orthopaedic naivety have been seen in the draft NICE proposals for the prevention of venous thromboembolism after orthopaedic surgery. However, NICE chose to ignore all except prospectively, randomised studies, and then made a number of *ad hoc* statistical assumptions allowing them to come to rigid conclusions on the basis of apparently sparse data. They also combined all 'major' orthopaedic procedures. Most orthopaedic surgeons would probably not agree with the NICE proposals and the BOA has therefore issued a robust response. Details of our continuing discussions with NICE on this matter can be found on the BOA website.²

Roberts, Esler and Harper⁴ in this issue, highlight another area where NICE guidelines are apparently not being followed by the profession, namely the use of uncemented total hip replacements (UTHRs), including hybrid devices. NICE has concluded that "there is currently more evidence of the long-term viability of cemented prostheses, which, in many cases, occupy the lower end of the range of prostheses cost, than there is for uncemented and hybrid prosthesis."⁵ Roberts et al⁴ have shown that in spite of this conclusion, surgeons in the Trent Region have continued to use UTHRs and actually increased their usage.

They draw two conclusions. The first is the fact that the failure of surgeons to implement NICE guidelines calls into question the value of NICE and, secondly, that the introduction of 'Payment by Results'⁶ may limit the ability of surgeons to choose more expensive UTHR devices in the absence of NICE endorsement. Both of these conclusions are correct. NICE guidelines are indeed of limited value in

orthopaedic surgery for the reasons outlined above and yet they may well have a considerable impact on orthopaedic practice in the future.

How should we react to this problem? I believe that as a profession we need to engage more closely with NICE. The decision of the President of the BOA to appoint a lead councillor for NICE should aid this process. NICE often suggest that further evidence is required for the full assessment of new orthopaedic interventions. We should co-operate in the collection of appropriate data nationally and the BOA is currently investigating ways in which this may be facilitated. In addition, we need a stronger voice on NICE appraisal committees. The statistics and research methods of orthopaedic surgery are often arcane and it is essential that we convince NICE that, as a profession, we are scientifically competent.

Most importantly, we need to convince NICE and the British government that a major reason for the lack of evidence of the results of new interventions in a specialty which progresses with great rapidity is a lack of appropriate research funding. We need to use the evidential problems of orthopaedic surgery to convince funding bodies that considerably more resources should be given to investigations of the efficacy of new orthopaedic interventions and the treatment of orthopaedic disease and its complications.

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