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critical appraisal.<sup>5-7</sup> Moreover, learners have different learning needs and styles, and these differences must be reflected in the educational experiences provided.

Just as the intervention has proved difficult to define, its evaluation has been challenging. Effective interventions involving evidence based medicine produce a wide range of outcomes. Changes in knowledge and skills are relatively easy to detect and demonstrate. Changes in attitudes and behaviours are harder to confirm. Still more challenging is detecting changes in clinical outcomes.

By questioning the evidence for evidence based medicine are we asking the right question? Providing evidence from clinical research is a necessary but not sufficient condition for the provision of optimal care. This has created interest in knowledge translation—the scientific study of the methods for closing the gap between knowledge and practice—and the analysis of barriers and facilitators inherent in this process.<sup>8</sup> Proponents of knowledge translation have identified that changing behaviour is a complex process requiring comprehensive approaches directed towards patients, doctors, managers, and policy makers, and providing evidence is but one component.<sup>9</sup> Moreover, it may be too soon to tell if evidence based medicine changes clinical performance and outcomes because advocates think that it requires lifelong learning, and this is not something that can be measured over the short term.

The *BMJ* will publish a theme issue on “What’s the evidence that evidence based medicine changes anything?” in October 2004. We see this as an opportunity to reflect on the challenges of practising

and teaching evidence based medicine, highlighting the work that has been done in this field and providing an opportunity to point the way forward. We invite contributions from researchers, patients, health professionals, policy makers, and other stakeholders, to reach us by 15 April 2004. Submissions should be made to [www.submit.bmj.com](http://www.submit.bmj.com), and the editorial contact is Giselle Jones ([gjones@bmj.com](mailto:gjones@bmj.com)).

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## Efficiency, equity, and NICE clinical guidelines

*Clinical guidelines need a broader view than just the clinical*

The stated purpose of clinical guidelines from the United Kingdom's National Institute for Clinical Excellence (NICE) is to “help healthcare professionals and patients make the right decisions about healthcare in specific clinical circumstances.”<sup>1</sup> However, what constitutes “the right decisions” depends on your point of view. For individual patients the right decision is that which maximises their wellbeing, and this is properly the concern of the clinician. Yet in resource constrained healthcare systems this will not always coincide with the right decisions for patients in general or society as a whole, thereby leading to some understandable tensions. NICE is a national policy making body whose responsibility is clearly broader than the individual patient.<sup>2</sup> This wider viewpoint is reflected in NICE's technology appraisals by the central role afforded to cost effectiveness. We argue that the methods currently used by the NICE clinical guideline programme confuse these two viewpoints.

Cost effectiveness analysis allows decision makers to improve efficiency by spending the limited healthcare budget on those activities that generate the greatest health benefits per pound spent.<sup>3</sup> Such efficiency considerations are a key part of NICE technology appraisals, and NICE's remit demands that

the same principles of assessing societal wellbeing should apply to clinical guidelines work.

Clinical guidelines themselves are not a new concept,<sup>4-5</sup> but the NICE clinical guideline programme is different. Rarely have clinical guidelines been intended to operate at a national level, incorporate both clinical and cost effectiveness, and provide instructions that are mandatory within the NHS (though, unlike technology appraisals, there is no requirement for funding to be provided).<sup>1-6</sup> Currently, development of guidelines is commissioned by NICE from development teams via several national collaborating centres that are largely based at the royal colleges. These teams produce evidence reviews that are presented and considered by guideline development groups, who then produce the guideline recommendations based on the best available evidence.

Guideline development groups consist substantially of senior clinicians with special interest in the disease area.<sup>7</sup> Undoubtedly the understanding of clinical evidence is enhanced by the inclusion of such experts, but the incentives for members of these groups to recommend cost effective practices may clash with their feelings of responsibility to patients and fellow professionals within this disease area. Each development

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group has to include only one member, a health economist, whose role is to promote the social viewpoint. The health economists are often relatively junior, new to the disease area, and struggling with a lack of economic evidence. For cost effectiveness to underpin NICE guidelines in these circumstances is particularly challenging.

Recommendations made within a clinical guideline are graded according to the strength of the evidence on which they are based. The highest grades are afforded to recommendations based on meta-analysis of randomised controlled trials and the lowest grade to recommendations based on expert opinion, including the view of the development group. This classification also has the effect of reducing the impact of cost effectiveness considerations: health economic evidence is often sparse in established clinical areas and, where it does exist, is of variable quality. Rarely is economic evidence based entirely on clinical trials: most economic analyses require additional data sources or assumptions. Members of the guideline development group, who may wish to downplay economic evidence, can use the grading system to this end by claiming that clinical evidence is of a higher grade. Qualitative evaluation has identified exactly this tendency in the Netherlands.<sup>8</sup>

We applaud the efforts of NICE and the guideline development groups to consider cost effectiveness. However, the absence of evidence on the cost effectiveness of guideline recommendations is not an adequate rationale for issuing guidelines as though they had no implications for resources. One solution might be for NICE to delineate clearly the individual viewpoints of patients and society and allocate expertise to tasks that are appropriate in the light of this distinction. In this scenario, collaborating centres would be commissioned to produce wholly clinical guidelines, at arm's length from NICE. This work would provide a crucially important foundation for subsequent cost effectiveness assessment undertaken by specialist academic units. Clinical guidelines that carry the NICE stamp of approval—and its associated weight in the NHS—should be produced by guideline appraisal com-

mittees, analogous to NICE technology appraisal committees, based on consideration of the best available evidence on clinical and cost effectiveness. A membership that includes expertise in a broad range of clinical specialties, health economics, public health, and statistics, together with representatives of NHS organisations, can be expected to make better recommendations that truly reflect the societal viewpoint that NICE must reflect.

Such an approach would promote consistency between the appraisal and guidelines functions of NICE, make the basis for recommendations transparent, and avoid accusations that NICE guidelines are wish lists created by panels of clinical experts that threaten the efficient and equitable use of scarce NHS resources.<sup>9</sup>

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## Smoking and blindness

*Strong evidence for the link, but public awareness lags*

While most people and many patients attending eye clinics recognise many adverse health hazards of tobacco smoking, they remain largely unaware of its link with blindness. Although smoking is associated with several eye diseases, including nuclear cataract<sup>w1</sup> w2 and thyroid eye disease,<sup>w3</sup> the most common cause of smoking related blindness is age related macular degeneration, which results in severe irreversible loss of central vision. Current treatment options are of only partial benefit to selected patients. Identifying modifiable risk factors to inform efforts for prevention is a priority.

A risk factor is generally judged to be a cause of disease if certain causality criteria are fulfilled.<sup>w4</sup> Applying commonly used criteria<sup>w4</sup> to available evidence provides strong evidence of a causal link between tobacco smoking and age related macular degenera-

tion. The strength of association is confirmed in a pooled analysis of data from three cross sectional studies, totalling 12 468 participants, in which current smokers had a significant threefold to fourfold increased age adjusted risk of age related macular degeneration compared with never smokers.<sup>1</sup> By way of comparison, although the relative risks associated with smoking for lung cancer and chronic obstructive pulmonary disease are in excess of 20, the relative risk for ischaemic heart disease in men is only 1.6.<sup>w5</sup> Consistency of effect is demonstrated as smoking was the strongest environmental risk factor for age related macular degeneration across these three different