limit on the maximum society is willing to pay for health gain, then it is even more likely that the sample size requirements for economic evaluation will be many times those required to show a clinical effect.[6]

The consequence is that piggyback economic evaluations will typically be underpowered for both the cost analysis and any cost effectiveness analysis, even if the main clinical comparison is appropriately powered. The dangers of underpowering studies are well documented in the clinical literature,[7] and this has led to the recommendation to use estimation rather than hypothesis testing when reporting results of clinical evaluations.[8] Exactly the same principle should be used in economic evaluation. The evaluative technique of cost minimisation analysis is often used unthinkingly to select the least costly intervention when no statistically significant difference in health outcome is detected. Yet this use of cost minimisation is built on the sandy foundations of hypothesis testing and the mistaken assumption that "absence of evidence is evidence of absence."[9] Similarly, it is inappropriate, given the likely low power to detect cost differences in a piggyback study, to interpret a statistically significant difference in clinical effect and an insignificant cost difference as evidence of cost effectiveness.

For these reasons, and in common with the recommendation for clinical evaluation, the focus of cost effectiveness studies should be on estimating cost effectiveness, even when either cost or effect differences lack conventional statistical significance. Low powered studies will be revealed in the wide confidence limits around results, and readers will not be misled.

In this issue Bower et al report that their study was designed as a cost effectiveness analysis.[2] However, they later report that there was no power calculation for costs, with the sample size for the study being determined by the main clinical outcome. Not surprisingly, therefore, it found no significant differences in cost between the treatments either at 4 or 12 months' follow up. As the authors emphasise, we must be careful in interpreting these results.

Health service decision makers will probably be most interested in the fact that, though there is no evidence of any long term treatment effect, the cost difference is not inconsistent with an additional cost to society of £458 for cognitive behaviour therapy or £952 for non-directive counselling, at conventional levels of significance. The authors chose not to present cost effectiveness results directly, although it is clear that any such estimate based on the data from this trial would have high variance.

Ideally, of course, studies that attempt to address economic questions should be powered on the economic variables. But then they would almost certainly be overpowered with respect to the clinical outcomes. Would this be a problem? Some might argue that the ethical basis of randomisation would be questionable and that it would be inappropriate to continue a trial beyond the point at which clinical superiority has been determined beyond reasonable doubt. Given current ethical committee guidance and the consent forms that patients sign on entering a clinical trial this is no doubt true. However, inquiry into the cost effectiveness of treatment interventions is a legitimate enterprise. Failure to recruit enough patients to give unequivocal treatment and policy recommendations could be seen as unethical, leading to delay in providing cost effective treatments, delay in curtailing cost ineffective treatments, and a consequent underachievement of potential health gain from available resources within the NHS.

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The failings of NICE

Time to start work on version 2

Despite the protestations of its boss, the National Institute for Clinical Excellence (NICE) is an instrument for rationing health care.[1,2] Unfortunately, it's not a very good one. A government with spine would learn from the failings of NICE and move on to version 2. Perhaps this is a job for after the next election, whoever wins.

NICE, which covers only England and Wales, began in 1999 with three main functions.[1,3–5] Firstly, it appraises new technologies, including drugs, and decides which should be encouraged in the NHS and which should be held back. Its other functions are to produce or approve guidelines and to encourage quality improvement. The biggest push for NICE came from political disapproval of "postcode prescribing:" patients on opposite sides of the same street may receive or be denied treatment because they fall under different health authorities, each with different policies on which treatments they will fund.

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NICE began with a blaze of publicity by deciding that zanamivir, a new drug for treating flu, would not be made available in the NHS.[6 7] Its decision was based on the lack of evidence that the drug was effective in older people and others most at risk of serious harm from flu. It glossed over the fact that the same could be said for many, even most, treatments currently available on the NHS. Zanamivir's manufacturers, Glaxo Wellcome, were furious, and the chief executive threatened to take the company's research abroad.[6] Last week, NICE reversed its decision on the drug, declaring that it would be available to at risk adults who present within 36 hours of developing symptoms when consultations for flu rise above 50 a week per 100 000 population.[8] Just how easy it will be to implement such complex advice remains to be seen, but NICE boasted that the reversal of its guidance showed its commitment to evidence. A pooled analysis by the manufacturers showed that the drug would reduce symptoms in those at high risk from 6 to 5 days.

It's easier to say yes than no

When NICE approves treatments—such as taxanes for cancer—then there's little fuss, although many cardiologists think that it oversold the use of intravenous glycoprotein IIb/IIIa inhibitors in high risk patients who have had a heart attack, perhaps because it was overinfluenced by the drug companies' secret evidence. NICE's problems begin when it tries to deny treatments. It decided against beta interferon for multiple sclerosis and promptly found itself facing hostile publicity and an appeal from both the manufacturers and patients' groups.[9] Its final decision will not be available until the new year.

One failing of NICE is that it's living a double lie. The first lie—which is as Orwellian as its name—is to deny that it's about rationing health care, which might be defined as "denying effective interventions." Denying ineffective interventions is not rationing; rather it's what the Americans call a "no brainer." The population is smart enough both to know that NICE is rationing health care and that rationing of health care is inevitable. The second, and related, lie is to give the impression that if the evidence supports a treatment then it's made available and if it doesn't it isn't. In other words, the whole messy problem of deciding which interventions to make available can be decided with some data and a computer. It's a technical problem. This lie corrupts the concept of evidence based medicine, which the BMJ has long championed. The evidence supports decision making, but the evidence can't make the decision. The values of the patient or the community must be part of the decision. Effective interventions have adverse effects. How can benefits be weighed against risks? How, for example, might an individual woman or society balance the probable cardiovascular benefits of hormone replacement therapy after the menopause against the increased risk of breast cancer? This is not a technical problem. Similarly treatments that are highly cost effective in those at high risk are also effective in those at low risk—but at a very high cost. Deciding where cost effectiveness ends is not a technical but an ethical judgement.

These failures with honesty may lead to the ultimate failure of NICE, which could be the inability to say no except in obvious cases. Beta interferon is effective in reducing the progression of multiple sclerosis in some patients, and donezepil is effective in slowing the progression of Alzheimer's disease in some patients. A body that is not about rationing and is concerned primarily with evidence might have to promote the wide use of both drugs within the NHS, whereas a body that was honestly about rationing might legitimately say no to both drugs. We shall see.

One off decisions unbalance system

Another failure with NICE is that it considers issues one at a time and is mostly concerned with what's new and expensive. A better system, like the one in Oregon, would look at all interventions. Otherwise a weak body that finds itself saying yes to most new technologies will encourage the traditional unjust rationing by delay (waiting lists), discrimination (against the elderly and mentally ill), dilution (two nurses on a geriatric ward at night when there should be four), and diversion (long term care moves to the social sector). Patients with Alzheimer's disease might receive donepezil but perhaps be worse off because they lose some of their nursing and social care.

Transparency is vital in an issue as difficult as rationing health care, and NICE has moved in the right direction by deciding to make its preliminary determinations public. Still, however, the process is far from transparent, and the suspicion is that political clout is as important as evidence in the final decision.

Probably NICE had to exist in order for us to begin to think about something better. A single body cannot "solve" the problem of rationing, but Britain would benefit from a body that admits it is about rationing, works openly, uses evidence, looks right across health care, incorporates ethical thinking systematically into its judgments, is more distant from politicians and the pharmaceutical industry, and is directly accountable to the public. Let's call it CHOR—the Committee for Honest and Open Rationing.

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