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Response

NICE: A nightmare worth having?

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In their paper, Birch and Gafni argue that the increased involvement of economic evaluation in decision making (as personified by the National Institute for Clinical Excellence – NICE – in the United Kingdom) has, rather than being the economist's dream, turned out to be a nightmare. In particular, they track economists' involvement in two sets of methodological guidelines (NICE 1 and NICE 2), the development of the threshold (of maximum willingness-to-pay) and the consideration of equity. Finally, they suggest that, either intentionally or unintentionally, the involvement of economic evaluation and economists in the decision-making process has furthered the interests of technology manufacturers. Here I examine their arguments in turn.

The central thesis

I do not disagree with Birch and Gafni's central thesis, that 'any attempts to promote improvements in the efficiency of NHS resource use, must be based on the explicit use of opportunity cost' (this issue). I also agree that the procedures followed by NICE, including the use of an explicit or implicit cost-effectiveness threshold, are imperfect. It is also true that NICE has largely dodged issues of affordability and the consequences, at the local level, of implementing its recommendations.

However, for me the relevant question is not whether NICE is perfect, but whether it is leading us closer to an efficient allocation of resources than would otherwise be the case. Prior to the advent of NICE, decisions about the adoption (or non-adoption) of new health technologies were made largely at the local level. Consideration of the evidence on clinical effectiveness or cost effectiveness, was sparse. In primary care, general practitioners relied heavily on evidence provided by manufacturers, mainly pharmaceutical companies. Within

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hospitals, decisions on the adoption of new therapies were largely influenced by clinical specialists who had few incentives to consider cost effectiveness.

Of course, the advantage of decision making at the local level is that local circumstances, including opportunity cost, can be taken into account. There may also have been some recognition of the budget constraint. However, it is hard to believe (as Birch and Gafni acknowledge) that such procedures would lead to an efficient allocation of resources, except by chance.

If we do not want to return to what we had before NICE, how can we improve matters? Birch and Gafni's paper is heavy on diagnosis and light on treatment options. However, by following through their opportunity cost argument, several options emerge, none of which I claim to be original. One option would be to retract from the position of making NICE guidance (on technology appraisal) binding on the National Health Service. Then, local decision makers would be able to consider whether the recommendations for the adoption of new technologies justify the (local) opportunity cost. The risk is that local decisions will be driven by political pressures not closely related to opportunity cost, although, given the evidence on the patchy uptake of NICE guidance (Sheldon *et al*., 2004), I suspect that local decision makers are exerting their influence in any case.

Another option would be to force NICE to consider opportunity costs more explicitly. This could be done in a number of ways. First, in making a recommendation requiring additional resources, NICE could be asked to suggest disinvestments in the clinical area where the new technology is to be applied. (This assumes that the budgetary allocations to the various clinical areas are, in some sense, optimal, but it would be a start.) Secondly, NICE could be asked to operate a 'balanced budget' with respect to its guidance, on an annual basis. That is, in making a number of recommendations implying increased resource use, it should compensate by making other recommendations implying a corresponding reduction in resources, or an overall net increase in line with an agreed real increase in the health budget for the year in question.

Threshold, what threshold?

Birch and Gafni correctly identify the shifting position over the years with respect to the implicit threshold (of willingness-to-pay) for health technologies. Of course, it does not matter whether the threshold is explicit or not, since a threshold can be inferred from the decisions made, even if it is not stated explicitly. I do not know whether the current threshold (or threshold range) is the right one. Nor do I suspect that anyone else knows. Furthermore, it is not clear whether the same threshold, if one could be determined, should apply in all instances.

It is fairly clear that NICE is finding its way with respect to the criteria it uses for the rejection or acceptance of new technologies. Again, the question is

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whether it could do any better. Some suggestions for explicit consideration of opportunity cost were made above. In addition, NICE could resort to cost–benefit analysis, where attempts are made to value in full all the costs and benefits of health care interventions. It is not clear from their paper whether Birch and Gafni would advocate this. There is already research underway in the United Kingdom to estimate the societal value of a QALY. We have to see what this produces, but my view is that there remain several questions surrounding the methods used to assess the willingness-to-pay for improved health. Also, even if NICE performed cost–benefit analyses in support of its guidance, we would still need to be clear on whether decisions were to be made within the current budget, or whether increases in the health budget were envisaged. In reality the health budget in the UK is likely always to be determined exogenously.

NICE and equity considerations

Birch and Gafni point out that NICE's views on equity considerations have also changed over the years. Some of this is explained by the fact that, when NICE came into being, the top political issue was 'postcode rationing'. That is, individuals in some locations were gaining access to new, expensive, health technologies, whereas those in other locations were not. The objective of NICE was to produce evidence-based guidance that could be implemented, in a standardized way, throughout England and Wales.

Of course, such standardization is a myth, since, whilst it might be possible for NICE to standardize which technologies are adopted, it is not possible to standardize which technologies are abandoned, at the local level, to fund the new treatments. Of course, if NICE did make recommendations for disinvestments, there may be more standardization, although local decision makers may still wish to exercise their own judgments. Indeed, a major tension, which only emerges on occasions in Birch and Gafni's paper, is that between local and centralized decision making. One might argue that local decision makers have a better idea of the opportunity costs at the local level, yet there may still be a need for a national decision in a national health service. One thing we can be clear on is that there are economies of scale in reviewing the evidence at the national level, although it is known that the cost effectiveness of health technologies varies from location to location (Sculpher *et al*., 2004).

The other main point about equity considerations is that they have several dimensions. Whilst the original concern of NICE was with geographical equity, other concerns include the equity between the rich and the poor, between those suffering from health conditions of different severity and between those suffering from common and rare diseases.

Like Birch and Gafni, I feel that if such equity concerns are important, the trade-offs between equity and efficiency need to be approached in an explicit

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fashion (Williams and Cookson 2004). At this point I do not feel that we have enough information (for example, on the calculation of equity weights) to determine the best way forward. However, I do sense a growing dissatisfaction with equal weighting of QALYs, no matter to whom they accrue (Drummond *et al.*, 2007). In my view, exploration of the ways of incorporating equity considerations should be a priority for research.

Conflicts of interest and technology manufacturers

Birch and Gafni point out that economists participating in the development of NICE economic evaluation guidelines did not adequately declare conflicts of interest and that 'instead of challenging the pharmaceutical industry to show value for money, NICE has become their "golden goose"'. I agree that, now that economists have become more closely associated with the decision-making process, they should be much more careful about declaring competing interests. However, I was somewhat puzzled as to why conflicts of interest are a particular problem in the development of the NICE economic evaluation guidelines. Is the suggestion that economists would somehow construct guidelines that give their friends in industry an easy ride? I suspect that the opposite is likely to be true. Namely, economists participating in guidelines development may get the hurdle high, thereby generating more requests for analytic assistance from industry!

Of course, it is possible that, now manufacturers have a better idea of what the willingness-to-pay threshold is, they will set prices so as to extract the maximum economic rent. It is also true that, within the context of a fixed budget, the activities of NICE involved a reallocation of resources towards the producers of those technologies recommended by NICE and away from other unidentified programmes.

Rightly or wrongly, NICE has adopted a policy of broad stakeholder involvement in its decision-making processes, including manufacturers, patient advocacy groups, and clinical societies. The precise influence of the various groups is unclear. However, the agenda for NICE is still set by the Department of Health, rather than the Institute itself.

Furthermore, not all NICE recommendations are positive. Whilst it is true that outright rejections of new technologies are rare, restrictions on the use of treatments are much more common. NICE often determines that a new technology can be used in the NHS, but only for certain patient sub-groups. Contrast this with the situation before the advent of NICE, when clinicians were taking their guidance for use of new drugs primarily from the pharmaceutical industry itself. Whilst British clinicians are traditionally conservative in their use of new technologies, there was no incentive for the industry to highlight uses for which a technology is not very cost-effective.

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I do not believe that the pharmaceutical, and other healthcare, industries welcomed the advent of NICE. Indeed, several of the major pharmaceutical companies in the United Kindgom spent a considerable amount of time trying to get the government to change its mind. However, I do agree that manufacturers have learned to work with and seek to influence, NICE, in the same way that they have learned to work with and seek to influence, the Food and Drug Administration and the European Medicines Evaluation Agency.

How manufacturers have reacted to the threshold is unclear. It is true that many evaluations submitted by companies show cost per QALY ratios in the £20,000–£30,000 range, although it is hard to tell whether this is a result of price expectations being revised upwards or downwards. Also, the pricing of a new health technology is usually subject to international considerations, so the influence of the NICE threshold may not be as strong as some people think. Finally, it has to be remembered that many NICE appraisals involve two or more competitor products, so manufacturers need to keep one eye on their product's cost effectiveness in relation to the competitor, as well as its relation to the threshold.

A nightmare worth having?

Birch and Gafni are right in suggesting that, in many ways, the increased involvement of economic evaluation and economists in NICE has turned out to be a nightmare. Perhaps we should have predicted this, since all that has happened is that the difficulties of making rationing decisions in health care have been made more explicit.

Birch and Gafni end their paper with a quote from Smith (2000), who said that 'Failures with honesty may lead to the ultimate failure of NICE, which could be the inability to say no except in obvious cases'. I think that this quote is wrongly directed at NICE, because it is probably the most transparent public decision-making body in the world. This is why it has been so widely studied and scrutinized, by Birch and Gafni, and others.

However, it is important that economists are honest and open about their role in NICE. Has the involvement of economic evaluation in NICE's decision making done more good than harm? I believe so, although improvements are clearly required. Is an increased role in public decision making a nightmare worth having? As an applied economist, I am much clearer on the answer to that question.

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