

Healthcare: who pays and how much?

In the second article of a series discussing issues in healthcare ethics and law, David Badcott and Joy Wingfield ask: what price a life?



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Last year, *The Times* (8 October 2007) published an article entitled: "What price a few more years?" Colin Howe, who is the subject of the article, has advanced kidney cancer. Treatment with sunitinib (Sutent) rather than interferon alfa offers the possibility of doubled survival times in some patients, but costs £3,500 per month. Initially, a request to Mr Howe's local primary care trust in Warwickshire to fund Sutent was rejected on the grounds that the PCT had to serve a population of some 900,000 — funds were limited and Mr Howe's circumstances did not justify bending the rules. With the help of family and friends and the support of a local newspaper, over £6,000 was collected to enable treatment to get under way. Warwickshire PCT eventually relented and agreed that they would take over funding provided that the cancer was no longer spreading. On 15 November, the *Rugby Advertiser* announced that Mr Howe's cancer had been reduced, heralding: "Victory as Colin gets cancer drug for free."

One might suppose that such problems are avoidable for those more able to contribute to the cost of their own treatment. Not so. In January, the *Northern Echo* carried an article headed "Cancer victim to take drug fight into court", which concerned further aspects of the somewhat hit-and-miss situation regarding access to new medicines. The article highlighted legal developments in the case of two women with breast cancer. Colette Mills and Debbie Hirst were both receiving NHS treatment but wished, in addition, to take bevacizumab (Avastin). (The evaluation of Avastin for the treatment of advanced and metastatic breast cancer by the National Institute of Health and Clinical Excellence is currently suspended.) The women were prepared to

self-fund the cost of this treatment but their health authorities, respectively South Tees Hospitals NHS Trust and the Royal Cornwall Hospitals Trust, had told them that if they went ahead they would no longer be eligible for treatment under the NHS.

In answer to a Parliamentary question on 18 December 2007 concerning self-funding, Alan Johnson the Secretary of State for Health stated: "A founding principle of the NHS enshrined in every single code of practice — most recently the 2003 code of practice — is that someone is either a private patient or an NHS patient. They can be a private patient and decide to resume their treatment as an NHS patient, but they cannot, in one episode of treatment, be treated on the NHS and then [be] allowed, as part of the same episode and the same treatment, to pay money for more drugs. That way lies the end of the founding principles of the NHS."¹

Mrs Mills and Mrs Hirst subsequently launched a legal action claiming that the health minister had failed his duty of care under the NHS Act 1977 and that their rights under several articles of the Human Rights Act 1998 would be breached if NHS treatment were withdrawn.

Ethical considerations

The fundamental questions arising from Colin Howe's story centre on rights and justice, but are severely polarised by limited resources. (We may take justice here roughly to equate with what is right, proper and impartial or simply being treated fairly rather than reflecting the legal exercise of authority.) These considerations can be generally grouped within what is often termed "distributive justice". Broadly, approaches to distributive justice fall into two categories:

- A largely utilitarian approach intended to maximise the overall benefit of the resources used (eg, by treating more people or the more serious diseases), irrespective of individual need (as illustrated by the QALY approach — see below)
- An egalitarian approach that aims at an equal share of benefit to all

In this article we have chosen to look only at the most obvious resource — money — and assume that most people would expect the NHS to put the treatment of life-threatening illnesses, such as cancer, before less serious ones. Thus our analysis is by no means comprehensive — it does not address other resources, such as opportunity costs, health professional time or use of equipment, nor aspects of equity, such as "fair" distribution and the objective assessment of need.

The implication of our title is to question just what monetary value are we, as individuals, society or government, prepared to place on a human life in terms of public expenditure? We could, of course, answer that life is simply beyond value and we cannot put a price on it. But in the real world we regularly do so, although generally in an impersonal and largely anonymised or statistical form. For example, those who drive motor cars should at least have third party insurance, which is concerned not with insuring the vehicle, but with compensation in the event of causing injury or death to others. Similarly,

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life insurance policies specify a monetary value for the life of the insured and the civil courts regularly place a value on the life of a patient who has been fatally harmed through medical negligence. What we as a society are prepared to pay for healthcare under the NHS reflects the cost of treatment to prevent disease, restore or maintain health, or alleviate suffering and does not directly relate to the monetary value of human life.

In the UK, funds are invariably limited because all government expenditure is raised through taxation and the cake has to be divided to cover education, armed forces, the police, healthcare and everything else. In pursuit of a simple, unequivocal and universal parameter, some health economists and others have proposed various formulae or calculations to put a price on a life. Morrow and Bryant,² Edgar,³ and Greener and Guest⁴ provide useful introductions to how economists, philosophers and pharmacists might address "effective and equitable distribution of limited health care resources"⁴ using the most common quality of life indicators. Among the approaches that have been applied are:

- The DALY (disability adjusted life year), which takes account of social preference values and is used by the World Health Organization to produce periodic reports on the global burden of disease
- The Ghana approach, which focuses on years of healthy life gained or lost
- The QALY (quality adjusted life year), which is the basis of the system adopted by NICE (see below).²

The QALY is a cost-utility index, combining both duration and quality of life, that can be used for comparative purposes. Perfect health is equivalent to a QALY of one, and death is zero-rated, with various health states being represented on a fractional basis. Hence estimates of cost/QALY can be used to devise an indication of the relative value of different treatments.

Politicians, economists and healthcare analysts, however, have expressed reservations concerning NICE and, more especially, various aspects of the use of QALYs. In particular, John Harris, joint editor in chief of the *Journal of Medical Ethics*, argues: "There are two ways in which QALYs can be used . . . to determine which of rival therapies to give to a particular patient or which procedure to use to treat a particular condition, in short which of two different treatments is the more cost-effective, better for patients, better for society. . . . QALYs are also used, however, to determine not which of rival treatments to give to a particular patient or group of patients, but whether or not to offer any treatment at all to some patients, or whether to offer a particular treatment to some patients even when no alternatives are preferred".⁵

It is this latter approach to which Professor Harris, understandably, objects on moral grounds and exemplifies by reference to treatment of patients with Alzheimer's disease,

where he claims: ". . . it is clear that it is not the drugs that have been judged not to be cost-effective when compared [with] rival treatments, it is the patients who are being condemned as not cost-effective to society. . . . Each citizen has an equal claim on the protection of the community as expressed by its public healthcare system and this means that each is entitled to an equal chance of having their necessarily individual and personal, and hence different, needs respected by any publicly funded healthcare system."

Serious reservations are also expressed by Maurice McGregor of McGill University Health Centre, Montreal,⁶ who with reference to the work of Erik Nord at the National Institute of Public Health, Oslo,⁷ says: ". . . the assumption of 'distributive neutrality' [individual considerations are not taken into account] that underlies the QALY frequently violates societal concerns for fairness in allocation of healthcare resources. For example, in general, society does not consider a unit of health gained by a severely ill individual to be of equal value to a unit of health gained by an individual who is less severely ill."

Legal considerations

The NHS Act 2006 specifies (as did earlier Acts and parallel Acts in Scotland) that it is the duty of the Secretary of State (for Health) to promote, in England and Wales, a comprehensive health service free of charge except where otherwise specified in law. However, case law has established that secretaries of state and health bodies are entitled to take into account resource constraints when making their decisions on allocation of funding. Further, although an article published by Wrightington, Wigan and Leigh NHS Trust suggests that "hospitals are under a duty to take positive steps to safeguard a patient's right to life and, therefore, need to consider the implications of Article 2 [of the Human Rights Act; HRA] before refusing life-saving treatment to a patient,"⁸ a question and answer document on the HRA from the Department of Health⁹ asserts that under the Act a person cannot compel the NHS to give him treatment or an operation except through the courts.

So we can conclude that there is no statutory legislation that will be of assistance to patients who insist on access to medicines under the NHS or any certainty that a court case will be decided in their favour. Indeed, Nigel Griffin QC was quoted in *The Times* (14 November 2007) as saying that he could see no legal barrier to patients, denied access to drugs in England, buying them for themselves and insisting that they could be used as part of a course of treatment, and he could see no evidence in law or in any directions from any health secretary to justify refusals from primary care trusts or doctors.

In an attempt perhaps to avoid direct involvement in these complex arguments, the Government set up NICE in 1999 and gave it powers to appraise and disseminate guid-

ance on the clinical and cost-effectiveness of new and existing health technologies (including drugs) and other interventions in England, Wales and, since July 2006, in Northern Ireland. The Scottish Medicines Consortium (SMC) performs a similar function in Scotland. So far as cost-effectiveness is concerned, NICE has used (among many other considerations) the concept of QALYs and a notional upper limit of £30,000 per QALY since it was established, although Appleby *et al* claim: ". . . the uncomfortable truth is that NICE's threshold has no basis in either theory or evidence".¹⁰ The House of Commons Health Committee report on NICE of December 2007 noted that much time was given to interviewing expert witnesses concerning the use of QALYs, and although use of the QALY approach itself was not questioned, the threshold range was strongly criticised for being unclear and not being evidence-based. In particular, there were claims that the QALY range was arbitrary, and Professors Devlin and Parkin told the committee that "the threshold has no explicit basis or location in evidence. . . . By whatever means the threshold is determined, it should be adjusted over time."

Legal challenge Most challenges in relation to the allocation of NHS resources are brought against the budget-holding trust. A challenge to NICE itself arose from guidance issued in November 2006 that limited access to donepezil, galantamine and rivastigmine to patients with moderate Alzheimer's disease symptoms. Previous guidance had indicated treatment for early to moderate disease. The NICE decision immediately brought claims that the action would disadvantage a group of highly vulnerable people. Eisai, a company holding a marketing authorisation for Aricept (donepezil), supported by Shire Pharmaceuticals (galantamine) and the Alzheimer's Society as an interested party, requested a judicial review in order to delay implementation of the guideline by requiring NICE to allow their cost-effectiveness model as used in an independent Technology Assessment Report to be subjected to further independent assessment.¹¹ The hearing resulted in a judgment given on 10 August 2007. The findings are summarised by Burdon *et al*: "The court found that NICE had not been unreasonable or procedurally unfair in making the recommendations outlined in the guidance. However, the court did find that the wording of the guidance was so inflexible that it might lead to discrimination against certain groups of sufferers. NICE's use of one particular diagnostic test to ascertain the severity of Alzheimer's disease could have led to treatment being withheld despite patients having a moderate form of the disease. NICE was ordered to change the guidance accordingly".¹²

Subsequent to a judicial review, the claimant Eisai has been given leave to appeal the judgment. The basis of the appeal is likely to centre on the court's support for NICE's



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lack of transparency over cost-effectiveness calculations — NICE did not disclose the fully executable model of the methodology. Keith Syrett at the University of Bristol examined the judgment in detail. He also questions the wisdom of NICE's claim that the court's ruling in its favour "strengthens NICE by endorsing our approach to evaluating drugs".¹³ He maintains that the courtroom is not the place to validate barriers to acceptability and the "... conflict between the values which underpin cost-effectiveness analysis and those held by society. ... [Rather] this issue would be better addressed by means of public debate upon the values which should underpin decisions upon the coverage offered by the NHS, given that not every new medical technology which is developed can be afforded."

Relevance to pharmacy

Resource allocation in the NHS is one of the most fraught sources of ethical dilemmas in healthcare. Pharmacists are involved in, and frequently direct, the policies and guidelines adopted within NHS trusts and PCTs to inform cost-effective prescribing by their prac-

tioners. Although pharmacists can provide a wealth of evidence-based clinical data to inform resource decisions, it is important that they are also aware of the impact of the Human Rights Act, case law and ethical discourse on the sustainability of those decisions.

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Resources

- For an interesting discussion of some aspects of valuing life, see Bayles MD. The price of life. *Ethics* 1978;89:20–34.]
- For a full account of judicial review and other law relating to health resources see chapter 11 of 'Mason and McCall Smith's law and medical ethics' (London: Butterworths;1999) or chapter 5 of Newdick's 'Who should we treat?' (Oxford: Oxford University Press; 2005).

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