

damage to the optic apparatus, causing visual impairment, has been reported in 3.4%⁷ and 24%⁸ of patients after radiosurgery at two years, and 30% patients developed temporal lobe damage.⁹ Optic neuropathy is related to the proximity of the tumour to the optic apparatus and limits the technique to small sellar lesions. In contrast, the risk of radiation induced visual impairment after conventional fractionated radiotherapy is 1-2%, with a tumour control rate of about 90% at 20 years for adenomas of all sizes.¹⁰ Radiosurgery of benign pituitary adenomas and meningiomas is associated with mortality ranging from 1.6%⁷ to 24%.¹¹ The deaths are a direct consequence of damage from high dose single fraction radiation and have not been reported after fractionated treatment.

Few effective treatments exist for brain metastases and malignant gliomas, and patients will accept any offer of hope. Radiosurgery is a non-invasive alternative to surgery for solitary brain metastases. The median survival is 6-12 months and is related to performance and the state of systemic malignancy.¹² Radiosurgery has no advantage over whole brain radiotherapy for patients with multiple brain metastases.¹³

Radiosurgery alone is not the appropriate primary therapy for malignant gliomas. However, a boost after conventional surgery and radiotherapy of malignant glioma is claimed to be associated with marginal prolongation of survival, but this may be explained by patient selection.¹⁴ Two multicentre randomised studies in the United States and Europe are currently examining this issue. Patients with malignant brain tumours should be encouraged to take part in trials to define the role of radiosurgery in treatment.

Radiosurgery as delivered by the gamma knife has major limitations. Each "shot" consists of a small radiation sphere 4-18 mm in diameter, and these need to be multiple for the treatment of larger lesions. In contrast, linear accelerator techniques offer the possibility of treating larger and moreirregular lesions with a technique described as conformal stereotactic radiotherapy. Single fraction radiation as delivered by the gamma knife in doses greater than 8 Gy to critical structures is associated with a high risk of injury. Giving treatment in multiple small doses (the principle of fractionation) allows for higher radiation doses to the tumour without increased risk of damaging the central nervous system. Conformal stereotactic radiotherapy coupled with fractionation is increasingly being explored as a potentially safer method of delivering high precision localised irradiation.

Activity is often equated with progress. The statement that "about 80 000 people have been treated with the gamma knife world wide"¹⁵ reflects uncontrolled spread of an unproved technique and the power of marketing. The limited information available suggests that radiosurgery should be fully evaluated in well designed prospective studies. On present evidence single fraction radiosurgery for brain tumours is associated with higher toxicity than is seen with fractionated irradiation, so far without the reassurance of long term efficacy.

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Points for pain: waiting list priority scoring systems

May be the way forward, but we need to learn more about their effects

Doctors have long worried that the British government's emphasis on the number of people on waiting lists, and the time they spend there, obscures the need to treat patients according to clinical urgency. This concern has been voiced most recently in a report from the BMA,^{1 2} though others have gone further and pointed to the futility of pursuing policies to reduce, or even abolish, waiting lists.^{3 4} The BMA

warns that additional funds earmarked for reducing NHS waiting lists and waiting times will provide an incentive for operating on large numbers of minor cases, leaving more urgent cases and potentially cost effective treatments to wait. The danger with such initiatives is that they provide only temporary relief and do not address the underlying problem of ensuring that waiting lists operate as an efficient and

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equitable non-price rationing mechanism. The BMA paper argues in favour of priority scoring systems, such as those developed for elective health care in New Zealand, Canada, and Sweden.^{5 6 7} The success of such systems seems, however, to be mixed.

In New Zealand an evaluation of the generic surgical priority criteria at Auckland Hospital showed wide variation and poor agreement between the surgeons' clinical judgment in assessing priority and the score patients obtained on the priority score.⁸ In Sweden a central register established to ensure guaranteed maximum waiting times for cataract surgery found that centres using formal priority scoring systems were more successful in adhering to maximum waiting time guarantees than centres without such systems.⁷

In the United Kingdom local authorities use priority scoring systems for allocating public housing.⁹ Such systems assess the relative priority of individuals or families based on current housing conditions, overcrowding, presence of dependent children, and medical or welfare circumstances. These allocation systems have proved controversial so that assessment of their efficiency and equity in the public housing sector (as yet not systematically evaluated) is essential to the debate as to whether waiting list priority scoring systems offer a way forward for the NHS. In particular, priority scoring systems used for allocating public housing differ between local authorities, as does the availability of public housing, leading to differences in waiting times for families in similar circumstances (V Burholt, personal communication).

In the United Kingdom consultants have always prioritised their waiting lists according to broad categories—urgent, soon, and routine. Pilot experiments with priority scoring systems for managing NHS waiting lists have been led by individual clinicians.^{10 11} At Guy's Hospital, for example, the top 22 conditions on a general surgical waiting list were ranked according to their expected net quality adjusted life year (QALY) gain per unit of bed and theatre resource.¹¹ At Salisbury and Carmarthen patients were initially ranked according to points awarded based on the following criteria: rate of progress of disease, pain or distress, disability or dependence on others, loss of occupation, and time already waited. Both approaches led to clustering of conditions, which posed difficulties for preparing balanced theatre lists. This problem has been overcome at Carmarthen through the introduction of a patient initial quotient to determine whether a patient should be placed on a waiting list, and an algorithm to reflect time waited, which has led to a more balanced case mix on prioritised waiting lists (B Davies, personal communication).

The main arguments in favour of introducing priority scoring systems are that they make the management of waiting lists transparent; the criteria by which priority is given to patients are explicit; and they should lead to patients being treated in order of clinical need, rather than according to arbitrary maximum waiting time guarantees. They also make it possible to set minimum thresholds of clinical need for referral onto waiting lists.

However, priority scoring systems also raise a host of philosophical, technical, and managerial questions. Should scoring systems be condition or specialty specific or, could a set of generic or common criteria be

applied across several or all clinical specialties? What clinical and social criteria should be used to decide the relative priority of patients? Who among the many interested groups—consultants, general practitioners, health authority commissioners, patients, and the general public—should be asked to decide on such criteria and their relative weight?

Families seeking public housing have long had to accept that their case for housing or re-housing must be weighed against those of other families on local authority housing lists. Would the British public accept the introduction of explicit priority scoring systems in the NHS?

It has been argued that priority scoring systems would solve the clinical dilemma faced by consultants currently trying to operate according to clinical urgency and also meet maximum waiting time guarantees.¹¹ They may do this by providing a transparent and explicit indication of need. However, the explicit measurement of need may also lead to professional disharmony if aggregated priority or need scores are consistently different across clinical specialties and used as evidence for the reallocation of beds and theatre time. This might, in theory, improve the efficiency and equity of the management of waiting lists but would be dependent on confidence in interscorer consistency—that is, that a particular patient would be given the same or similar priority score by different doctors.

One of the most serious issues limiting the potential benefits of priority scoring systems is the potential for “gaming” by doctors, patients, and their families. Priority scoring systems would cease to discriminate constructively between high and low priority cases if sympathetic or harassed general practitioners or consultants—or patients wise to the system—exaggerated the case for priority. However, introduction of enforceable contracts linking broad urgency categories to a gradient of maximum waiting times in Victoria's public health system in Australia did not appear to lead to evidence of gaming in terms of the regrading of patients to meet maximum waiting time guarantees.¹²

As an alternative to a market system where price rations access to health care, as in the United States, there is much merit in using waiting lists as a rationing mechanism for elective health care if the waiting lists are managed efficiently and fairly. Priority scoring systems may offer the NHS an opportunity for policies that promote the treatment of patients in order of clinical need—and thus promote clinical effectiveness. Nevertheless, before their widespread introduction we need to evaluate their dynamic effects over time on case mix, distribution of waiting times, and patterns of resource use. This will involve looking within the “black box” of NHS waiting list management to find out far more about the beliefs and behaviour of those involved in the delivery and receipt of elective health care in the NHS.

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Breast implants: evidence based patient choice and litigation

The only safety lies in providing patients with full information

The American plaintiff lawyer ranks high in the hierarchy of demons that haunt the quiet areas of a doctor's mind, but the plaintiff lawyer serves a useful and essential social function in a society in which the safety net for those who suffer severe health problems is gossamer thin. Tough, well organised, aggressive plaintiff lawyers, especially acting as a group, are a formidable force and they have achieved some spectacular successes—most recently in sponsoring and leading action against tobacco companies, whom they have brought to the bar of justice in the one country where they seemed most unassailable.¹ Plaintiff lawyers can, of course, get things spectacularly wrong, as they did in the breast implant saga chillingly told by Marcia Angell in her book *Science on Trial*.²

The book reinforces all our worst fears about plaintiff lawyers, who, in pursuit of \$3bn for their clients and \$1bn for their fees, created an industry, including "experts" who flourished in the publicity and on the money provided by the plaintiffs' lawyers. Research foundations sprang up, and television appearances allowed those researchers to publicise rather than publish their findings and theories. Good quality evidence of harm was, so far as the scientific community was concerned, negligible, but the two class actions proceeded and Dow Corning, the company that made the implants, has now settled out of court.

In the United Kingdom the departments of health set up an independent review group which carried out a systematic review of the evidence—using italics in their text to distinguish their method from the "apparent selectivity" of some of the reviews that had previously been conducted. The review group published its report on the world wide web (<http://www.silicone-review.gov.uk>), a welcome innovation, as was the request to send comments by email (to mail@silicone-review.gov.uk). The review group concluded that there was no strong evidence to support the hypothesis that silicone gel breast implants were a major public health problem.

So much for the evidence. What about its implications for patient choice and litigation outside the United States? The review group wisely avoided the temptation to classify implants as "safe" but did state that silicone gel breast implants "are not associated with any greater health risk than other surgical implants." It did, however, emphasise that there is "no

evidence of an association with an abnormal immune response or typical or atypical connective tissue diseases or syndromes."

The report focuses on the need for evidence based patient choice, and perhaps the most interesting section, certainly for United Kingdom readers, is the chapter on "Consent to medical treatment"—which emphasises the need for full, clear, and written information. The reaction of those women who make the choice—the term "patient" seems inappropriate—was expressed and polarised in an exchange of letters in the *Guardian* in the summer between Maxine Heasman, founder of the Breast Implantation Information Society and author of *The Ultimate Cleavage*, and Yvonne Roberts.³ Ms Heasman saw the report as giving comfort to "thousands of women who have been worrying unnecessarily as a result of public scare-mongering... Now that women have been given the all clear, women can make an informed choice." Yvonne Roberts on the other side dismissed both Ms Heasman's faith in the medical establishment and her values. "How many times have we been given 'authoritative' medical opinion only to discover that these men are fallible human beings?" Her main argument is, however, not against the experts but based on the values of women who choose to have silicon gel breast implants.

There, hopefully, the debate will rest, in the United Kingdom at least. By clarifying the evidence the review group should keep the issue out of the courts, except where it can be shown that the woman has not been given sound written information—and this is perhaps the main consequence of this saga. For the first time the need for patients to have "full knowledge" has been explicitly described in a document of this type. As we move into an era in which knowledge will be the dominant commodity, the provision of best current knowledge to patients and carers⁴ will have to become standard practice.

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