when a patient has undergone immediate breast reconstruction, as even when radiotherapy is delivered over a longer period than normal it has a deleterious effect on the final cosmetic outcome.

Breast conserving treatment is usually offered only to patients with single tumours measuring less than 4 cm in diameter, because the cosmetic outcome of excising larger tumours is poor. However, in up to 80% of patients with large operable breast cancers and roughly 25% of patients with locally advanced breast cancers, breast conservation is possible if the size of the tumour is reduced by a course of primary systemic treatment.[13 14] This so called neoadjuvant therapy usually consists of combination chemotherapy, although hormonal treatment can also lead to significant reduction in the size of tumours if they have oestrogen receptors.[15] If the patient has a complete clinical response after primary systemic treatment, the question then is whether she needs surgery or whether radiotherapy alone would be sufficient. The answer at the present time is that patients should have both surgery and radiotherapy for the following reasons. Firstly, over three quarters of patients with complete clinical responses have residual microscopic disease,[13] which is sometimes extensive. Secondly, local recurrence after radiotherapy alone seems to be higher than that after surgery and radiotherapy.[16] Thirdly, the histological status of lymph nodes at the end of primary systemic treatment is the most useful predictor of long term survival.[17]

Although there is no definite evidence that better local control is associated with improved survival, by reducing the rate of local recurrence in patients with operable breast cancer, local treatments do have an impact on patients' quality of life. The recent overview raises the possibility that, if deaths due to causes other than breast cancer can be limited better control of local disease might be translated into better overall survival.[4]

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Brachial plexus neuropathy after radiotherapy for breast cancer

Lower doses and surgical management of the axilla may be the answer

It is tragic when patients are permanently harmed by a complication of treatment. One such complication, which has recently received publicity, is brachial plexus neuropathy after radiotherapy for early breast cancer.[1] A group of women who perceived themselves damaged in this way formed a pressure group called RAGE (Radiotherapy Action Group Exposure). In response the Royal College of Radiologists commissioned an independent survey by two senior oncologists funded by the NHS Executive.[2]

The committee of RAGE received more than 1000 letters after publicity surrounding litigation and formed an action group with 800 members. Of 556 women who thought they had sustained nerve damage the college contacted those who had been treated at 15 representative centres. These women were asked if they would agree to have their medical records reviewed in order to establish whether they were suffering from a condition related to the disease process or to previous treatment, or both. It was essential to identify factors in the delivery of the radiotherapy or its association with surgery or chemotherapy that might have contributed to the neuropathy.

Against advice from their solicitors, 126 of the women agreed to have their records examined, and 48 (38%) of them were found to have brachial plexus neuropathy due to radiotherapy. These patients had been treated during a 14 year period (1980-93) at 15 radiotherapy departments in England and Wales. These centres gave radiotherapy to about 65 000 women with operable breast cancer during this period. (It is not known how many of these also developed side effects.) Although 41 cases occurred during 1980-6, only seven patients had received treatment since 1986. Since the median delay between treatment and the start of symptoms was 27 months, this implies a decline in incidence of neuropathy.

An extensive review of the factors associated with radiotherapy in breast cancer—associated surgery, chemotherapy, radiation dose, fractionation regimes, the position of the patient, the radiotherapy fields, and the treatment schedule—laid the main blame for the neuropathy on the planned movement of the patients' arms and bodies between radiotherapy to the breast and radiotherapy to the axillary and supraclavicular lymph nodes. Thirty four of 47 patients (72%) moved in this way developed neuropathy, compared with only 12 of 51 (24%) who were not moved. The high doses used to treat the axilla in the past were a secondary cause.[3]

While radiotherapy has an important effect in preventing local recurrence and thus improving quality of life, a recent overview shows no significant impact on 10 year survival.[4] Indeed, a 5% reduction in deaths from breast cancer seems to be counterbalanced by an increase in deaths from other causes. However, studies with longer follow up have shown a significant trend towards improved survival, suggesting that

modern radiotherapy may have a value beyond the clearly established improvements in local control.[5] A 5% improvement in survival due to radiotherapy would rank in impact with that from adjuvant chemotherapy and hormone treatment. Surgical management of the axilla is used increasingly. This largely avoids the need for radiotherapy to that area and so prevents brachial plexus neuropathy due to radiotherapy, while a good cosmetic result is still achieved by irradiating the retained breast.

How big is the problem? The Royal College of Radiologists survey reviewed a self selected group of women who perceived themselves damaged, and thus the report cannot assess the absolute size of the risk. However, the report states that radiotherapy to the breast has dramatically improved in recent years. Written patient information, pain relief clinics, lymphoedema protocols, and palliative care services are now routinely available, and the aim is to manage patients in a multi-disciplinary team of breast specialists with a wide knowledge of the disease.

What more can be done now ? A further multi-disciplinary committee of the college, chaired by Dr Jane Maher, has produced a report enumerating management plans for patients who have brachial plexus neuropathy.[6] It lists named clinical oncologists at each radiotherapy centre who would act as a contact for such patients. In addition independent cancer support groups have formalised advice for patients who are concerned about late side effects of radiation.

A recent issue of *Clinical Oncology* described the audit of early breast cancer management by radiotherapy.[7] The report from the college suggests proposals for research. The time has come for a national study to identify the optimum dose fractionation technique for appropriate, safe, effective, and economic management of early breast cancer. Clinical oncologists are anxious to continue to provide improved clinical outcomes for breast cancer patients. The Royal College of Radiologists has a nationally agreed protocol for assessing different radiotherapy regimes in early breast cancer, including quality assurance. This initiative must be funded.

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Clinical guidelines and the law

What is the legal status of guidelines?

Fifty years ago the regius professor of physic at the University of Cambridge wrote in praise of medicine that its satisfaction lay "in the personal and individual character of its practice: the latitude with which a qualified doctor may exercise his own judgement, express his own opinions and practise his own art."[1] In the same year (1946) the BMA, sensing a threat to this latitude from proposals to establish a national health service, declared that "the medical profession should remain free to exercise the art and science of medicine according to its traditions, standards and knowledge . . . without interference."[2]

Yet clinical practice is now governed by a vast array of regulations in the form of protocols, practice policies, clinical guidelines, and codes of practice. Their current ascendancy is not simply due to state intervention. It reflects a change in the balance of power within the framework adopted for the delivery of health care. Professional stewardship of clinical standards, health services, and the deployment of medical resources has been replaced by quasi-market mechanisms and civil regulation.

Lomas has argued that clinical guidelines and protocols should be understood as policy rules designed to change and control the behaviour of clinicians and institutions.[3] A colloquium of the National Health Lawyers Association in the United States was convened recently to "crystalize the tensions that exist between many people affected by practice guidelines." It concluded that the main role for guidelines lay in the rationing of health care.[4]

While the evidential basis and clinical effectiveness of many guidelines can be questioned, so also can their legal status. Are doctors who deviate from clinical guidelines more likely to be found negligent if patients suffer injury as a result? Could compliance with guidelines protect health care workers from liability? The standard of clinical care required by law is generally that judged reasonable and proper by a body of responsible doctors as ascertained in court from expert testimony.[5] As evidence of accepted and customary standards of care a witness may refer to protocols or guidelines, but they cannot usually be introduced into court as a substitute for expert testimony.[6,7] Because written guidelines cannot be cross examined they are classed as hearsay evidence, so British courts cannot decide what is reasonable and proper care simply by referring to them.

However impressive the organisation that sponsored the guidelines, or its process for developing them, the fact that a protocol exists for a particular condition does not mean that what it proposes is true. Nor does it guarantee that the protocol accurately represents customary practice.[8] Two important legal cases indicate that British judges do not automatically equate established guidelines with reasonable and proper medical practice.[7,9] Questioning may address the scope of the guideline,[10] how it was developed and adopted,[7,9] the mandatory force of its recommendations,[6,11] the existence of known exceptions to its application,[9] and whether any school of medical thought rejects it and adopts a different approach to treatment.[12]

In the United States, there have been calls for courts to defer to standards of care embodied in clinical guidelines[13] to ensure that doctors who comply with them are shielded against liability in negligence cases. A pilot project in Maine has created legally validated clinical guidelines. Doctors who comply with them can use their compliance as a complete defence against a malpractice claim, but those who fail to comply with the same guideline cannot automatically be