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

presumed negligent.[14] Though justifiable in terms of improved quality (and uniformity) of clinical care, the experimental scheme was in fact adopted in order to retain clinical services such as obstetrics, anaesthetics, and emergency medicine that were under threat because of the high risk of malpractice actions.

Common law courts in other jurisdictions have called for the development of practice guidelines,[15 16] whilst also retaining the power to overrule them.[17] American fears that guidelines will fuel a bonanza for litigators have so far proved unfounded. A recent survey of American actions for medical malpractice found that guidelines play "a relevant or pivotal role in the proof of negligence" in only 6.6% of actions.[18]

Clinical guidelines offer the courts explicit though not incontestable examples of clinical standards across a wide range of medical practice. Notwithstanding the experience of one doctor before the British General Medical Council's professional conduct committee, who concluded that "guidelines drawn up by the establishment" were used as a "means of punishing dissenters,"[19] there are grounds for believing that British courts will not be uncritically swayed by these statements but will question their authority and status as embodiments of customary care.[20] Nevertheless, it would be sensible to heed the view of a distinguished professor of medical law in Britain who has predicted that "the role of protocols and guidelines will become more and more significant in determining whether a doctor has violated the law."[21]

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Misoprostol in patients taking non-steroidal anti-inflammatory drugs

Best reserved for elderly patients at high risk

The past decade has seen considerable improvements in attempts to prevent the gastrointestinal complications of non-steroidal anti-inflammatory drugs. Increased awareness of the problems that these compounds cause and more careful prescribing have had an appreciable effect, although better access to diagnostic facilities and the availability of drugs both to treat and to prevent gastroduodenal ulceration have also contributed. However, progress in preventing the relatively rare but potentially life threatening complications such as perforation and gastrointestinal haemorrhage has until recently been disappointing.

The availability of misoprostol, a synthetic analogue of prostaglandin, has provided some cause for optimism. Endoscopic studies show that misoprostol reduces the frequency of asymptomatic gastric and duodenal ulceration induced by non-steroidal anti-inflammatory drugs, while ranitidine reduces only the frequency of duodenal ulcers but is better tolerated. [1 2] The extent of benefit from proton pump inhibitors such as omeprazole is being evaluated. A more pressing and important question is whether prophylactic use of such drugs can reduce the frequency of the severe gastrointestinal complications of non-steroidal anti-inflammatory drugs.

This issue has been addressed in a well conducted double blind placebo controlled trial of patients taking non-steroidal anti-inflammatory drugs.[3] Silverstein *et al* randomised 8843 patients with rheumatoid arthritis to receive either misoprostol 200 μg four times daily or placebo for six months. Patients with previous peptic ulceration were included but only if the ulcer had been inactive in the prior month. All gastrointestinal events were evaluated by an independent panel consisting of a rheumatologist, a gastroenterologist, and an epidemiologist, all of whom were unaware of the randomisation. The panel was required to reach consensus on whether the event was related to non-steroidal anti-inflammatory drugs and to assign the complication to one of 11 predefined categories, the first six of which were classified as serious and included perforation, gastric outlet obstruction, and bleeding.

The mean age of the patients studied was 68, but the range was from 52 to over 75. Twenty eight per cent of the patients taking misoprostol withdrew because of side effects, compared with 20% taking placebo. An intention to treat analysis showed no reduction in mortality in patients taking misoprostol, but the number of deaths due to proved gastrointestinal events was small. Sixty seven serious complications arose, of which 42 were in patients taking placebo. Risk factors identified for serious complications included age over 75, a history of peptic ulcer or gastrointestinal bleeding, and cardiovascular disease. Gastrointestinal bleeding occurred in 56 patients and was no less common in those taking misoprostol. Misoprostol, however, led to fewer cases of perforation (placebo 7, misoprostol 1) and gastric outlet obstruction (placebo 3, misoprostol 0). Of the eight cases of perforation, three were in the duodenum and four above the pylorus, while the site of one was unspecified. The authors concluded that misoprostol led to an overall 40% reduction in serious gastrointestinal complications from non-steroidal anti-inflammatory drugs.

How should we interpret these results to make them applicable in clinical practice? In a previous issue of this journal Cook and Sackett made a persuasive case for using "the number needed to treat" when presenting data, since it is a meaningful measure for clinical decision making.[4] It can be calculated from these data as the inverse of the absolute risk reduction: 741 patients would need to be treated to prevent