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

one perforation, 1480 to prevent one gastric outlet obstruction, and 493 to prevent either. The numbers may be smaller in high risk patients. Although this study was in patients with rheumatoid arthritis, its results can be generalised to include all older patients requiring a non-steroidal anti-inflammatory drug, regardless of the diagnosis.

Should we then be prescribing prophylactic misoprostol to all patients over 65 who are taking non-steroidal anti-inflammatory drugs? Given the quite large number of patients who would need to be treated to prevent one serious side effect, and the suggestion from another study that taking regular prophylactic misoprostol may worsen the quality of life for some patients,[5] such a policy seems difficult to justify except in those at highest risk. Nor could it be entirely justified on grounds of cost.[6]

In patients at highest risk a more cautious approach to using non-steroidal anti-inflammatory drugs seems prudent. If such drugs are absolutely necessary, those whose main effect is on inducible cyclo-oxygenase may be the best choice. Another option may be to use essential fatty acids as pharmacological agents, since they have been shown to modify synthesis of cytokines if given in high enough doses.[7] Clinical trials of both strategies are, however, necessary.

In conclusion, prophylaxis with misoprostol should be considered in any patient over 75 requiring a non-steroidal anti-inflammatory drug who has a history of peptic ulcer or gastrointestinal bleeding, or cardiovascular disease. During the first six months of use misoprostol reduces the risk of gastrointestinal perforation but not of bleeding. Compliance may be poor because of the high incidence of side effects.

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Doctors and medical politics

Why don't they get involved?

Although membership of the BMA has risen to its highest level ever, and continues to rise, doctors' enthusiasm to join the organisation is not reflected in participation in its work. Likewise, the Royal College of Physicians of London is seeking greater participation from members[1] and proposals to reform the way in which its fellows elect the ruling council and the president have been mooted. The president's working party of the General Medical Council is exploring ways to improve the participation of doctors in its elections. Yet the vast majority of doctors take no active part in any of these organisations. Nominations for the BMA's Council are sought in this issue of the Journal (see p 1576) amid increasing concern about the level of participation of doctors in the bodies that govern the profession.

Last year's BMA council elections illustrate the problem: 32 of the elections for the 43 directly elected constituencies were uncontested and two seats were left vacant. Yet the BMA's council is the equivalent of a trade union executive (the BMA is a registered trade union), and also serves as the board of directors of a limited company (which the BMA also is.) This year, the association's annual representative meeting was attended by only 433 representatives out of a possible 560, and 70 of the 280 divisions were not represented at all, reflecting the fact that many are moribund. The committees serving both junior doctors[2,3] and general practitioners[4] have been accused of being unrepresentative and out of touch.

The proportion of BMA members that participates in postal ballots compares favourably with both the Royal College of Nursing and the Law Society—25-30% of members in all three organisations vote in national elections. Only 10 of the last 61 elections for the Law Society's ruling council have been contested, and many branches of the Royal College of Nursing are minimally active.

Postal ballots have their problems: the candidates are unlikely to be known to the electors, and in a non-party political election it may be more important not to alienate potential voters than to appear to be in favour of any particular course of action. Yet it is controversy that generates interest, debate, and participation. In a recent Personal View in the *BMJ*, the General Medical Council's postal ballot was criticised for not giving enough information for electors to choose between the candidates.[5] The authors' solution—relying on their 8 year old daughter's visual prejudices—is understandable but probably not the best way of appointing the body responsible for standards of professional practice in Britain.

Participating in a postal ballot is hardly the epitome of political involvement, but the disincentives to committee work are obvious. According to one politicial theorist,[6] rational individuals do not work towards the common good without selective incentives that directly benefit them at an individual level. For example, the BMA aims to further the interests of the medical profession in Britain, but members join in order to have access to contractual advice and to receive the BMJ each week. The disincentives to committee work are obvious. It is time consuming and involves a lot of travel. A generational divide seems to be opening in the profession, with younger members much less inclined to see their work as a vocation, and more inclined to make time for their family and leisure.

Cynics may suggest that the whole point of committee work is to escape from clinical duties, and even possibly one's family, but in fact committee members are almost entirely in active practice, and are most often motivated by their convictions and a desire to shape the future.

The structures that currently exist for doctors to express their political will are democratic, if obscure. The BMA could