abundant evidence that human behaviour can reduce, negate, or even invert the expected outcomes of changes in traffic systems.¹ The mass of evidence, mainly from laws governing the use of safety belts in cars, shows that any change in risk taking by drivers is small and there is more likely to be a reduction in risk if wearing seat belts is mandatory.¹ For laws on cycle helmets the evidence is difficult to interpret because of small sample sizes and the absence of the sudden increases in rate of use generated by some belt wearing laws. One good evaluation found reductions in casualties associated with the law in Victoria, Australia.³ Although an ideal evaluation has not been possible for laws on cycle helmets, an event in the United States provided a unique opportunity to evaluate a law on motorcycle helmets. Under pressure from the federal government nearly all 50 states passed laws making motorcycle helmets mandatory in the mid-1960s. Congress removed that pressure in 1976, and soon after about half of the states repealed their laws. This made possible a near optimum natural experiment, the results of which showed that repeal led to a 25% (4%) increase in deaths of motorcyclists.¹

This effect is, if anything, larger than expected, thus ruling out the possibility that wearing helmets leads to any large increase in risk taking. Laws on wearing motorcycle helmets had the expected effect, and it seems hard to imagine plausible reasons why the case for cycle helmets would be all that different. The evidence is fairly compelling that passing a law making the wearing of cycle helmets mandatory will result in appreciable reductions in casualties.

Accepting that a law would reduce casualties does not inexorably require that such laws ought to be passed. Many unappealing laws could reduce traffic casualties. Successfully prohibiting passengers from travelling in front seats of cars while any rear seat remained unoccupied would prevent many casualties because of the substantially lower risk in rear seats.¹ The advantages of social interaction and a better view make it unlikely that any such law will find support. Being compelled to wear a bicycle helmet does not incur such large negatives, but it does require a diminution in freedom. No scientific

investigation can ever lead to the conclusion that a law ought to be passed. Such questions should properly be decided through the political process, the appropriate forum for taking into account disparate interests, values, and alternative approaches (p 1534).⁶ It would be presumptuous for me to express a preference for whether Britain should or should not pass a law making the wearing of cycle helmets mandatory—my experience goes back more than 30 years to commuting by bicycle without wearing a helmet, as was then the universal custom, to universities in Belfast and Oxford.

My plea is that the discussion of whether or not to pass a law should take full account of the scientific information that research has uncovered. Robert Oppenheimer and Edward Teller disagreed passionately over whether to develop thermonuclear weapons, but they had no disagreement over the physics on which they were based. Discussions on whether to require cyclists to wear helmets would become more productive if everyone would accept that it is well established that helmets substantially reduce risk in a crash, and that passing laws making wearing them mandatory would substantially reduce casualties.

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Managing clinical risk

Makes sense, but does it work?

The number of negligence claims made against health authorities rose dramatically during the 1980s.¹ Since Crown Indemnity was introduced in 1990 the responsibility for meeting these claims has shifted from defence organisations to health authorities and NHS trusts. Settling these claims in England currently costs an estimated £75m a year²—money that could otherwise be spent on patient care. What can NHS trusts do to minimise these costs?

The NHS Executive has recently issued *Risk Management in the NHS*, which recommends to chief executives that "risk management . . . is no longer an optional extra."³ Four categories of risk management are identified: risks that relate to clinical care; non-clinical risks to patient safety, such as security and fire hazards; risks to the health of the workforce; and organisational risks, such as failure to safeguard confidential information and unlicensed use of computer software.

But how does risk management relate to clinical care? It aims at reducing adverse events (incidents that under optimal conditions are not a normal consequence of a patient's disease or treatment) that might lead to negligence claims. It also helps to resolve claims that do arise.⁴ There are four phases in

this process: identification, analysis, control, and funding.³ To identify and analyse risks, NHS trusts can audit to monitor adverse events—perhaps through incident reporting or screening case notes—and analyse complaints and claims data. Risk control includes the introduction of guidelines and protocols, continuing education, and organisational change. Incident reporting plays a key part in risk control by allowing a rapid response to an adverse event, including timely and appropriate communication with the patient and family, support for staff, and thorough record taking. Risk funding ensures financial protection against successful negligence claims. This may be through the creation of a central fund, as recently proposed by the NHS Executive, or through insurance (though trusts are discouraged from this option).²

Clinical risk management and clinical audit overlap—both seek to improve the quality of care, but risk management is concerned with the quality of care only as much as better quality care might reduce negligence claims. Epidemiological evidence from the United States suggests that this is not necessarily so. The Harvard medical practice study, which screened the case notes of a stratified random sample of

patients admitted to hospitals in New York State in 1984, estimated that 1% of admissions were complicated by an adverse event due to negligent care. Fewer than 1 in 50 of these, however, led to malpractice claims.⁵ Furthermore, out of the 47 malpractice claims that were identified in the study population, only eight were clearly associated with substandard care. This is consistent with a review of medico-legal cases in the United Kingdom that found that 44 out of 100 claims were not associated with any serious clinical error.⁶ It seems, therefore, that many patients who are injured as a result of poor care do not sue their doctor. Paradoxically, many patients who start legal proceedings do so without clear evidence of error. Unsurprisingly, communication and record keeping, cornerstones of clinical risk management, are identified as key issues in minimising litigation.⁷

Does managing clinical risk work? The United States has considerable experience of risk management techniques, but their effect on the cost of negligence claims has rarely been subjected to formal evaluation.⁸ Such evaluation is difficult because claims are rare and resolving them can take a long time. A comparison of 40 hospitals in Maryland found that hospitals with specific risk management programmes had fewer claims made against them than those that did not.⁹ A study in California assessing incident reporting systems found that claims were resolved more rapidly if an incident report was made.¹⁰ This was despite the incident reports involving more serious injuries. Neither study was randomised, and confounding factors may have accounted for the apparent effect of risk management. In the Maryland study hospitals that provided better quality care may also have been more likely to have a risk management programme; in the Californian study characteristics of events that were not reported (for example, a late complication after hospital discharge) may have made claims more difficult to resolve. Given the substantial differences in both the health care and legal systems between the United States and the United Kingdom, the findings may be of limited relevance to the NHS.¹¹

Despite the lack of evidence of the effectiveness of clinical risk management, any attempt to minimise malpractice claims and improve patient safety must be taken seriously. So how should doctors and managers respond to the intuitive appeal of clinical risk management? Given its overlap with clinical audit it should be closely linked to existing audit procedures. Risk management programmes that are set up should be carefully evaluated. The NHS Executive has urged that purchasers should assess the effectiveness of a clinical treatment before buying it.¹² The same criteria should apply to management interventions.

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Treating hypertension after stroke

Hold off for 10 days unless hypertensive encephalopathy, aortic dissection, or intracerebral bleeding is present

Hypertension is the most important potentially reversible risk factor for cerebrovascular disease in all age groups. A continuous relation exists between increasing blood pressure and the likelihood of stroke, such that a 7 mm Hg increment in diastolic blood pressure is associated with a doubling of the relative risk of stroke.¹ The preventive role of antihypertensive treatment in reducing morbidity and mortality from stroke is well established: treatment that produces a long term reduction in diastolic blood pressure of 5-6 mm Hg results in a 35-40% fall in the risk of stroke.^{2,3}

About four fifths of patients with stroke have raised blood pressure on admission to hospital and about one third have a history of hypertension.⁴ Raised blood pressure usually falls spontaneously within a few days⁵: 10 days after an ischaemic stroke two thirds of patients are normotensive.⁶ Doctors are therefore faced with the problem of deciding in whom and when to treat raised blood pressure.

There is conflicting evidence about the prognostic significance of hypertension immediately after acute stroke. Using multivariate analysis, Carlberg and colleagues found that previous hypertension most strongly predicted raised

initial blood pressure in patients admitted to an acute stroke unit.⁷ Hypertension preceding stroke is, however, not invariably associated with an adverse prognosis in terms of either early fatality or functional recovery.⁸⁻¹⁰ Although early studies suggested that hypertension immediately after stroke was associated with increased fatality and poor functional recovery,^{11,12} more recent work has suggested that raised blood pressure early after cerebral haemorrhage or infarction is related to 30 day fatality only in patients with impaired consciousness,¹³ which is the single most important adverse prognostic factor for survival after stroke.¹⁴ In addition, Levy and colleagues found no association between blood pressure at admission and recovery in a series of patients with acute stroke.⁸ These results explain the controversy surrounding the early use of hypotensive treatment after acute stroke.^{15,16}

In health, cerebral circulation is kept constant by autoregulation at a mean systemic arterial pressure (diastolic + (systolic - diastolic)/3) between 55 and 125 mm Hg. This capacity to regulate cerebral blood flow is reduced in elderly people.¹⁷ In patients with chronic hypertension autoregulation begins at a higher systemic pressure, and below