is still widely used in some countries to control mosquitoes.

Temporal trends in breast cancer rates are difficult to relate to changes in exposure to suspected risk factors because the rates are affected by complex variations in the known risk factors for breast cancer such as age at menarche, age at first birth, parity, and age at menopause. In several developed countries, however, breast cancer mortality rates were high before any widespread exposure to DDT or polychlorinated biphenyls, and the rates have not risen strikingly since these chemicals were introduced.

The International Agency for Research on Cancer has classified DDT as "possibly carcinogenic" to humans, largely because it can cause liver cancer in experiments on animals.[8] Another reason for suggesting that DDT from the environment might cause breast cancer is that DDT is oestrogenic. This is a very theoretical risk; even in large doses DDT is only weakly oestrogenic in animals, and it has not been shown to have oestrogenic effects in women. Oestrogen replacement therapy, which has clear oestrogenic effects, may increase the risk of breast cancer by about 30% after 15 years of use,[9] so any small oestrogenic effect of DDT in the environment would probably be impossible to detect by epidemiological studies.

Polychlorinated biphenyls have been classified by the International Agency for Research on Cancer as "probably carcinogenic" to humans, with a possible association with cancers of the liver and biliary passages.[10] Polychlorinated biphenyls are sometimes referred to as oestrogenic, but in fact some show antioestrogenic activity, and no oestrogenic effects of polychlorinated biphenyls have been established in women.[11,12] There is, therefore, no strong reason to expect polychlorinated biphenyls to cause breast cancer rather than any other cancer.

Putting all this evidence together, we conclude that it is unlikely that DDT in the environment increases the risk of breast cancer. However, all published epidemiological evidence comes from the six studies cited—based on only 301 women with breast cancer and 412 women without. The question is so important that it seems justified to examine it further in at least the same number of women again, using specimens collected before the women develop breast cancer. For polychlorinated biphenyls there is no evidence for an association with breast cancer risk, and there seems to be no need to pursue this question further.

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Cycle helmets and the law

Even when the science is clear policy decisions may still be difficult

Any discussions of the law and the use of bicycle helmets will be helped by focusing on three questions. Firstly, how much do cycle helmets affect the risk of injury in a crash? Secondly, how much do laws requiring cyclists to wear helmets affect casualties? And, thirdly, should wearing of bicycle helmets be required by law?

Answers to the first two questions have objective answers that can be sought from specific empirical studies and what is already known about traffic safety.[1] Three unrelated sources of evidence consistently show that cycle helmets reduce risk substantially in a crash. The science of biomechanics shows that a helmet reduces the peak acceleration forces that are associated with injury. Many published epidemiological studies, including that by Maimaris and colleagues in this issue of the *BMJ* and the references it cites,[2] find that helmets reduce injury and the risk of death. Such studies fall short of the methodological ideal of comparing harm in matched treatment and control populations—so less direct methods must necessarily be used.

For example, examining the ratio of head injuries to non-head injuries in cyclists wearing and not wearing helmets indicates that helmets reduce the risk of head injury by more than half. One important way in which these studies fall short of the ideal is due to selective recruitment,[1,3] the tendency of people who wear protection devices to differ in many ways from those who do not. Estimates of effectiveness will be biased if they ignore the reasonable expectation that crashes will be more severe for cyclists who do not wear helmets than for those who do.[1,3] The third source of evidence is the analogy with motorcycle helmets. The effectiveness of a motorcycle helmet has been determined by comparing outcomes for a driver and a passenger riding the same motorcycle, and thereby having the same crash, but one wearing and the other not wearing a helmet.[1,4] The large sample sizes available in data from the United States gave a precise estimate of the effectiveness in reducing death of 28% (SE 8%).

Similar effectiveness was found for drivers and passengers and for men and women. Independent examination of the ratio of head to non-head injuries provides results comparable to those in pedal cyclists—suggesting similar effectiveness for bicycle and motorcycle helmets. A universal property of all protection devices is that effectiveness declines as severity increases,[1,3] so bicycle helmets are less effective for the higher severities that result from crashes with other vehicles.

Even if cycle helmets protect in a crash casualties need not necessarily decline if more cyclists use them. There is

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.[5] 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 year[2]—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