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REDUCING HARM TO PATIENTS IN THE NATIONAL HEALTH SERVICE. WILL THE GOVERNMENT'S COMPENSATION PROPOSALS HELP?

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Contents

EXECUTIVE SUMMARY

The provision of health care is inherently risky. Some procedures will lead to patient deaths however well the operation is performed. Some drugs will produce severe adverse effects in a number of patients even when the diagnosis is correct, the choice of the drug is correct, and the right dose is taken. However, errors may occur in the performance of an intervention or delivery of a drug which result in injury or death. Some of these will be preventable and only a subset of these will be the result of negligence (or "fault") on the part of clinicians.

At present under a negligence-based system only a small proportion of patients harmed by the NHS receive compensation. As a consequence the incentive for the NHS to tackle the causes of harm is reduced and information about preventable error generated from patient claims is lost.

The Government's proposals set out in the report "Making Amends" include helpful ways forward, in particular setting up a Redress Scheme for compensation in relation to small claims and birth injuries as an alternative to use of the courts. However, its proposals risk separating systems to achieve accountability for adverse events from those designed to compensate patients. We do not accept that the decoupling of accountability from mechanisms for compensating patients is a necessary or desirable component of reform. We believe that administrative mechanisms for improving patient safety can, and should, be linked to those aimed at

compensating patients who are harmed for two main reasons:

- patients seeking compensation for harm will report incidents from which the NHS can learn and information from patient compensation claims can be used to improve patient safety;
- there should be a clear financial link between a hospital's record in harming patients and the contribution that hospital has to make to compensation paid to patients so it has a financial incentive to invest in preventing errors.

We see benefits in moving from a fault-based system to one based on a looser notion of preventability, for two reasons. More people harmed by the NHS will receive compensation, and as a consequence more information will be generated about incidents that cause injury to patients. We think it is essential, however, in any systematic reform to link incident reporting mechanisms and patient compensation mechanisms, so avoiding the decoupling implied by Making Amends. We can also see merit in seeking to move compensation cases from the tort process to an administrative one. It could improve efficiency, especially in dealing with small claims. In our view the NHS should therefore be moving towards an administrative system of liability based on preventability – in effect a modified no-fault approach that nevertheless maintains a clear link between incident reporting and compensation and thus preserves the deterrent effects of compensation.

A movement towards liability based on preventability rather than fault can have significant benefits. Overall, both the small claims and birth injuries elements of the Redress Scheme are likely to increase the number of claims and the amount of compensation paid, at reduced administrative cost. These are positive developments, providing the NHS does not seek to reduce average payments by under-compensating people, is able to learn from the errors that give rise to the claims, and hospitals' contributions to the costs of the Redress Scheme reflect the harm they cause and the quality of their processes for identifying and preventing error.

The NHS Litigation Authority, which handles tort cases for the NHS and will administer the new Scheme, is currently charging contributions to hospitals that take account of their risk management processes but in addition hospitals' contributions need to reflect their record in harming patients. The NHS Litigation Authority must also provide information on claims to enable the errors that give rise to them to be tackled. Failure to pursue these changes will limit the accountability benefits of wider access to compensation.

1 INTRODUCTION

The UK government hopes that the proposals in the report of the Department of Health's Chief Medical Officer "Making Amends" (CMO, 2003) will make its NHS safer whilst ensuring that patients who are harmed get compensation more quickly and more efficiently than at present. The Making Amends proposals seek to achieve this by setting up administrative mechanisms for compensating patients. These will provide an alternative to the existing court based "tort" system, whereby patients sue doctors and hospitals for negligence in order to get compensation. These changes should be helpful. They will reduce administrative costs and lead to more patients injured by adverse events getting compensated[1]. However, the changes will only contribute to the overriding objective of reducing the number of NHS patients harmed in the future if the administrative mechanisms for compensating patients who are harmed are linked to those aimed at improving patient safety. It is not clear that the government's proposals will achieve this. Yet the link is essential for two reasons: so that information from patient compensation claims can be used to improve patient safety; and so that a hospital's record in harming patients costs it money, giving it a strong financial incentive to invest in preventing errors.

This paper sets out the context of the extent of medical error in the NHS and the current tort system for negligence, discusses the issues the government's proposals raise, and sets out how these proposals can be made more effective by ensuring a link between safety systems and compensation mechanisms.

[1] It is unclear if the proposals will provide as much compensation to individual patients as the existing tort system. However, as use of the new schemes are voluntary, patients will continue to use the tort system if the NHS seeks to cut compensation levels.

2 DEFINING ERROR

The provision of health care is inherently risky. Some procedures will lead to patient deaths however well the operation is performed. Some drugs will produce severe adverse effects in a number of patients even when the diagnosis is correct, the choice of the drug is correct, and the right dose is taken. However, errors may occur in the performance of an intervention or delivery of a drug which result in injury or death. Some of these will be preventable and some will be the result of negligence on the part of clinicians.

There is no agreement in the literature on the definitions of medical error, adverse event, avoidable medical error, and negligence. The definitions provided by the United States Institute of Medicine (IOM) in its report To Err is Human (Kohn et al, 2000) are:

- error is "the failure of a planned action to be completed as intended (i.e. an error of execution) or the use of a wrong plan to achieve an aim (i.e. an error of planning)";
- an adverse event is "an injury caused by medical management rather than the underlying condition of the patient";
- preventable adverse events are "adverse events that are attributable to error";
- negligent adverse events are a subset of preventable adverse events that satisfy the legal standard of each particular country for defining an act as negligent.

Injury to patients may therefore arise from three sources:

- a preventable adverse event (i.e. one caused by error, of which a subcategory are negligent errors) For us, preventability means there is some available technology or method of management that had it been adopted could have avoided the adverse event occurring. Error is therefore the failure to adopt this technology or method;
- an adverse event that is caused by the medical intervention but is not preventable, i.e. is a consequence of medical management but not of an error. It may, for example, be a complication arising from an intervention that is known to occur in some patients and for which there is no known method or technique available to avoid it happening;
- the underlying medical condition of the patient.

We can note that an error may not lead to harm (i.e. an adverse event) but be a "near miss". The IOM report also distinguishes between active and latent errors. Active errors "occur at the level of the frontline operator, and their effects are felt almost immediately." Latent errors or system failures "tend to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management and poorly structured organisations." They lead ultimately to an active error, but when examining the causes of an active error it is important to identify and tackle the latent errors or system failures.

Finally, and most importantly, while this taxonomy helps clarify the fact that not all adverse events *can* be prevented, it may not be particularly helpful in determining what adverse events *should* be prevented. Simply defining an event as being preventable does not automatically imply that it ought to be prevented; that will depend on how costly its prevention would be in relation to the harm caused by the event. Closing a ward in order to prevent a single mild infection is unlikely to be sensible. The management methods and available technologies may simply be too expensive to introduce relative to the health gain (in the form of harm avoided) that would be achieved. As economists, we believe it is an efficient use of scarce NHS resources to invest in cost-effective injury prevention, not to seek to avoid all preventable error.

3 THE SIZE OF THE PROBLEM

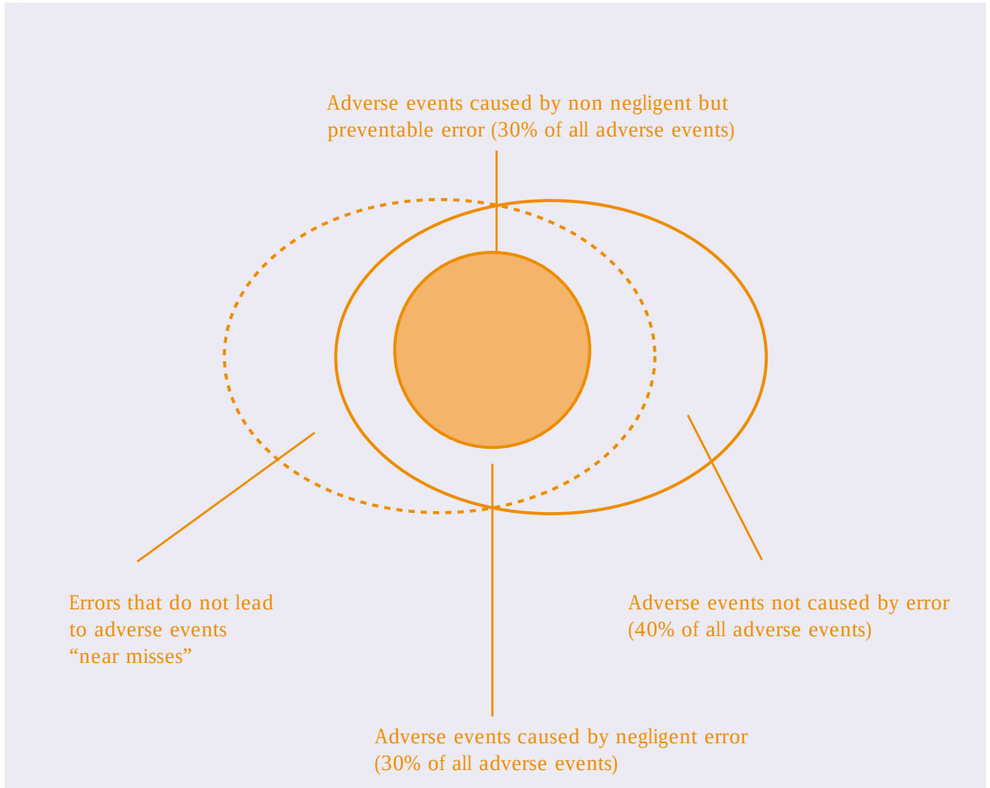
The study by Brennan et al (1991), often quoted as "the Harvard Medical Practice Study", found that 3.7 per cent of patients suffered some sort of adverse event during their hospitalisation. Error was judged as responsible for 58 per cent of the total of these unwanted injuries, with negligent care judged as responsible for a subset of 28 per cent. This leaves a 30 per cent gap, of injuries that are attributable to error, but cannot be judged as being a result of negligent care. Patients suffering this sort of injury are victims of preventable injuries, but are not entitled to compensation under tort law. However, negligence was present in 90.3 per cent of those adverse events that led to severe disability, meaning that compensation was in principle available through the courts for most severe injuries.

A study following a similar methodology was conducted by Studdert et al (2000) in Utah and Colorado. Another analysis of the same data set looked at the number of "preventable" adverse events occurring (Thomas et al, 2000). The studies conducted in Utah and Colorado found that adverse events occurred at an annual rate of 2.9 per cent of non-psychiatric discharges. They judged 58 per cent of these adverse events as preventable with 27 per cent deemed as being caused by negligent behaviour. According to the data collected in Utah and Colorado, we are thus left with a proportion of non-preventable adverse events mounting to 42 per cent of the total number of injuries.

The figures obtained in both studies are coincident and other studies are also broadly consistent with these numbers. From the analysis of these data we may deduce that roughly 60 per cent of adverse events are a result of error (half of them deemed as negligent), and the remaining 40 per cent are caused neither by failures of planning, nor slips in execution. The 60 per cent arising out of error is thus the "preventable" fraction of the total number of medical injuries. We show this in Figure 1, which shows the intersection of the set of all adverse events (solid line) with the set of all preventable errors (dashed line). Within that intersection is the set of adverse events caused by negligence.

Making Amends reports on two UK pieces of work that are consistent with these results. Research commissioned for the report (Fenn et al, 2002) found that 4.85 per cent of people interviewed reported illness, injury or impairment within the last 3 years which they thought was caused by their medical care. 57.5 per cent of these arose in hospital, implying that 2.8 per cent of respondents reported an adverse event arising from hospital treatment. In addition, a pilot study for the NHS (Department of Health, 2000) found around half of inpatient episodes leading to harmful adverse events were preventable (as compared to the 60 per cent figure from the US studies).

Figure 1



To get some overall sense of the implications for NHS patients, if we assume 3 per cent[2] of hospital inpatients are harmed, then, given 15 million inpatient episodes in the UK[3] (OHE Compendium, 2003) in 2002, we might have expected some 450,000 adverse events to have occurred, of which 270,000 were avoidable with a subset of 135,000 being due to negligence. The Harvard Medical Practice Study (Brennan et al, 1991) reported a death rate of 14 per cent among people suffering adverse hospital events, implying a figure of 63,000 deaths in the UK from the 450,000 adverse events. Assuming that the proportions set out in Figure 1 above, then 38,000 of these deaths were preventable and 19,000 of the preventable deaths were due to medical negligence. Currently fewer than 5,000 patients a year receive compensation from the tort process for harm suffered whilst being an NHS patient. This is less than 4 per cent of those we estimate to have been subject to negligent error, and only around 1 per cent of those experiencing adverse events for whatever reason. Only around twice this number even begin action. It follows that only a relatively small proportion of patients harmed by the NHS currently make a successful claim for compensation. Most get no redress for the suffering the NHS causes them. This has two unfortunate consequences for efforts to reduce the overall numbers of patients harmed by NHS treatment. Firstly, it reduces the financial pressure to tackle the problem of error and, secondly, much information about error that would be generated from patient claims is lost.

[2] Vincent et al (2001) find a higher rate of 10.8 per cent in a pilot study in the NHS. They estimate that about half of these events were preventable. We use 3 per cent as a more conservative estimate based on the 3.7 per cent of the Harvard study, the 2.9 per cent of the Utah and Colorado study and the 2.8 per cent of the Fenn et al (2002) survey.

[3] Strictly Scotland, Northern Ireland and Wales use deaths and discharges, which we equate to episodes.

4 GOVERNMENT RECOMMENDATIONS FOR CHANGE

Two recent reports have addressed how to tackle these errors. The National Patient Safety Agency (NPSA) was established following the recommendations of the first of these reports, An Organisation with a Memory (Department of Health, 2002), which looked at how the NHS can learn from adverse events and near misses which cause or could have caused harm to patients. Box 1 reviews the report and the NPSA. Prior to this the main external mechanism for encouraging NHS hospitals and doctors to avoid error has been the tort process, whereby patients can sue doctors and hospitals in the courts for negligence.

Box 1
Organisation with a Memory

This expert group chaired by the Chief Medical Officer reported in 2000. It noted estimates of between 300,000 and 1.4 million adverse events in UK hospitals with a high cost (£2 billion) in terms of additional hospital stays, (five times the cost of litigation for clinical negligence) as well as in terms of human and wider economic costs.

It found that research on adverse events inside and outside of health care suggested a complex interaction between human behaviour, technology, socio-cultural factors and a range of organisational and procedural weaknesses. However, the focus was often on blaming an individual when an incident occurred. Whilst human error often precipitated the failure, there were usually systemic factors at work (or latent conditions) which could have prevented or mitigated the effect of the error. This mirrors the distinction between active and latent error made in the IOM report "To Err is Human" which we discuss in section 2. The report argues that the NHS had to change the conditions under which people work so as to make them less error provoking. This didn’t mean people should not be held accountable for unsafe acts (which they define as "slips, lapses, mistakes or procedural violation"). Indeed, there needed

to be a "just culture", in which there was an atmosphere of trust but not a total absence of blame, so people provided safety related information, but where a clear line was drawn between acceptable and unacceptable behaviour. In some cases the report recognised that action will be required arising out of incidents to deal with poor professional performance.

The report concluded that learning had to be "active" so that when lessons were identified they were acted upon so that an organisation's culture and practice was altered. This involves creating an informed or safety culture rather than a "blame culture". Similarly the NHS "needs to move away from a position where the automatic response to complaints and claims is often very defensive, towards one which is more open" (paragraph 4.33). This involves admitting mistakes and giving apologies.

The report goes on to say that the NHS overall does not have a systematic approach to recording and reporting adverse events or "near misses". Information from the complaints system and from health care litigation are underexploited as a learning resource. In summary "The NHS has no reliable way of identifying serious lapses of standards of care, analyzing them systematically, learning from them and introducing change which sticks so as to prevent similar events from recurring." (paragraph 1.12).

The report concludes that the NHS needs:

- unified mechanisms for reporting and analyzing when things go wrong, including when to hold an inquiry. This includes clear definitions of adverse events and near misses, a mandatory reporting scheme for Trusts, and linkages between different sources of information, with better use of information on learning opportunities from complaints and clinical negligence claims;
- a more open, questioning or learning culture where errors and service failures, including "near misses" can be reported (confidentially if preferred) and discussed;
- mechanisms for ensuring lessons are learned, and changes are put into practice;
- a wider appreciation of a system approach to learning from and preventing error with a single national NHS organisation to oversee identification and dissemination of lessons, and an explicit focus on identifying and addressing very specific categories of recurring serious adverse event;
- more basic research into the incidence and causes of adverse events in the NHS.

In response, the Department of Health created the National Patient Safety Agency (NPSA) as a Special Health Authority with a remit to improve patient safety in the NHS, promote a more open approach to risk, and increase the priority given to patient safety. The main aims of the NPSA are to

- establish and manage a national reporting and learning system for incidents that affect patient safety;
- encourage all healthcare staff to report incidents without undue fear of personal reprimand;
- collect reports from throughout the country and initiate preventative measures, so that the whole country can learn from each case, and patient safety throughout the NHS can be improved;
- design solutions that prevent harm, set targets and monitor progress;
- promote research into the causes of adverse events;
- promote an open and fair culture in the NHS.

The second report is Making Amends, the report of a working group set up in July 2001 to "undertake a wide ranging review of possible reforms to the way cases of clinical negligence are handled and to make proposals for improvement" (chapter 1 paragraph 18). It was set up as a direct result of the Bristol Royal Infirmary Inquiry (2001) which was critical of the existing clinical negligence system. For details of the Bristol Inquiry see Box 2.

Box 2

The Bristol Royal Infirmary Inquiry

The Bristol Royal Infirmary Inquiry was established in response to the high death rates of babies receiving heart surgery at the hospital during a 12 year period. The central issue was why the poor performance was not identified and dealt with much earlier. The report of the Inquiry was published in 2001 and included 200 wide ranging recommendations for change in the NHS.

A key finding was the need to change NHS culture. It saw the most important feature of a culture of safety as creating "an open and non-punitive environment in which it is safe for healthcare professionals to report adverse events" (Chapter 26, paragraph 17). This would help to overcome the non-reporting of error by removing "fear of exposure or blame, whether in the press or through litigation" (Chapter 26, paragraph 24).

In this context the report made two points against clinical negligence. Firstly, it argued that the tort system:

- "institutionalises the notion of blame" (Chapter 26, paragraph 28), thus creating a peverse incentive "to cover up and deny." (Chapter 26, paragraph 30);
- is a non-systematic and haphazard form of accountability as "few cases ever actually see the light of day in court." (Chapter 26, paragraph 28) Most are settled behind closed doors;
- does not lead to learning. "Many cases are handled locally and not widely known about. Of those that do reach the NHS Litigation Authority (NHSLA), many are settled without attention to any notion of learning the wider lessons." (Chapter 26, paragraph 29);
- hinders discussion of problems because of fear of legal "disclosure" (Chapter 26, paragraph 31).

It quotes the Organisation with a Memory's estimate that the NHSLA has details of some 14,000 claims that have not been analysed to suggest lessons for the future. Secondly, it argued that the financial incentives for improvement were diminished by the limited discounts obtained from the NHSLA on premiums for having good systems in place. Moreover "the bulk of payments for clinical negligence are still met directly by the NHSLA, thus insulating trusts from the full financial impact of error." These limited signals were unlikely to be relevant "to those healthcare professionals involved in the day-to-day care of patients." (Chapter 26, paragraph 11). We discuss the NHSLA scheme in section 12.

It recommended:

- abolishing the system of clinical negligence. The DH to set up an expert group to "consider alternatives.. including an alternative administrative system of compensating those who suffer harm arising from medical care." (Summary paragraph 86);
- immunity from disciplinary action for reporting adverse events or near misses. Confidential reporting to be possible. Failure to report to be a disciplinary offence.

Making Amends focuses on alternative methods of compensating patients to the tort process. Its proposals are summarised in Box 3. These do not remove the right to sue, but seek to "move the role of tort from its current central position to the outer perimeter of the NHS" (chapter 8 paragraph 10). It is important to understand the linkage between the two reports. The sentiment in both is that the tort process is a hindrance to improving patient safety. Hence the desire, set out in An Organisation with a Memory, to use alternative means such as the NPSA to tackle patient safety[4], and the proposals set out in Making Amends to use other methods of compensation for patients harmed by the NHS. Our concern is that these proposals decouple the issue of accountability for error and the issue of compensating patients for errors that cause harm. We now expand on our thinking.

[4] Making Amends states that the NHS was "one of the first health systems in the world to give a high priority to enhancing patient safety by systematically learning from what goes wrong." (Chapter 1 paragraph 10).

Box 3

The main reform proposals set out in "Making Amends"

An alternative to tort: The NHS Redress Scheme

Making Amends seeks to "move the role of tort from its current central position to the outer perimeter of the NHS." (Chapter 8 paragraph 10). To do this it proposes a two part NHS Redress Scheme:

- firstly, to offer an alternative to tort for small claims, by providing compensation equivalent to the notional cost of the episode of care or up to £30,000. The qualifying test is to be the existing "Bolam test" of clinical negligence (that is, a clinician's action is not negligent if the action is supported by a responsible body of similar professionals), but it could move to a lower qualifying threshold of "sub-standard care";
- secondly, to encompass care and compensation without limit of value for severely neurologically impaired babies. The qualifying criteria to be impairment "related to or resulting from the birth", i.e. there is no requirement to show negligent behaviour, merely to show that the injury occurred at birth.

A revised NHS Litigation Authority (NHSLA) is to oversee the NHS Redress Scheme. The Legal Services Commission (LSC) is to take into account use of NHS Redress Scheme in deciding whether or not to provide Legal Aid. Subject to a satisfactory evaluation of experience, two extensions of the Scheme are proposed. It should be expanded to primary care and have a higher ceiling than £30,000 on claims.

Changes to the Tort system

Patients will still have the right to go to court instead of using the Redress Scheme, or in addition if they do not accept the outcome of the Scheme. There will also be a category of claims not covered by the two elements of the Redress Scheme. Making Amends therefore proposes further reforms to the tort process. The main changes it proposes are as follows:

- a duty of candour with exemption from disciplinary action;
- adverse event reporting to be protected from disclosure in court;
- periodical payments to be used in non NHS Redress Scheme cases;
- costs of future care in tort awards in case of clinical negligence should not be based on the cost of private treatment, but on a commitment by the NHS defendant to fund a package of care to specified timescales;
- special training for Judges hearing clinical negligence cases;
- the Department for Constitutional Affairs and the LSC to look at further ways to control claimants' costs in cases that are publicly funded.

[5] In addition there are proposals to improve complaints management and to increase the potential for mediation and other alternative methods of dispute resolution.

5 OUR CONCERNS ABOUT THE PROPOSED APPROACH

We do not accept that the decoupling of accountability for error from mechanisms for compensating patients is a necessary or desirable component of reform. Administrative mechanisms for improving patient safety can, and should, be linked to those aimed at compensating patients who are harmed for two main reasons:

- patients seeking compensation for harm will report incidents from which the NHS can learn and information from patient compensation claims can be used to improve patient safety;
- there should be a clear financial link between a hospital's record in harming patients and the contribution that hospital has to make towards compensation paid to patients so it has a financial incentive to invest in avoiding errors.

Overall, the proposed changes in Making Amends have much merit. The broad objective of reducing the administrative and legal costs associated with claiming compensation is laudable. We can also see benefits in moving from a negligence or fault-based system to one based on preventability[6], i.e. where it is sufficient to demonstrate than an error has caused the injury, whether or not it was negligent. This is for two reasons. Firstly, more people harmed by the NHS will claim and receive compensation, and secondly, as a consequence of this more information will be generated about incidents that cause avoidable injury to patients. We think it is essential, however, in any systematic reform to link incident reporting mechanisms and patient compensation mechanisms, so avoiding the decoupling implied by An Organisation with a Memory and Making Amends. The NHS should be moving towards an administrative system that uses a test of liability based on preventability – in effect a no-fault approach – but that nevertheless maintains a clear link between error reporting and compensation and thus preserves the deterrent effects of compensation. We return to our proposed approach but first we set out alternative approaches to patient safety and compensation and comment on the international examples Making Amends refers to.

[6] Strictly the small claims element of the proposed Redress Scheme is not based on preventability but on fault and the birth related injuries element is based on causation whether or not preventable.

6 ALTERNATIVE APPROACHES TO PATIENT SAFETY AND COMPENSATION

The key issues are:

- how does the NHS ensure that adverse events are reduced to a cost-effective level? This is the issue of *accountability*. It is unlikely to make sense to seek to reduce error to zero even if it were possible, because the cost (in terms of additional training, use of more expensive technologies, or improved systems) would far outweigh the benefits of reduced health loss;
- how should we, if at all, compensate those who have suffered from a preventable error that causes harm? Should they receive payments which are not available to those who have suffered from non-preventable errors? This is the issue of *compensation*. An important element of this is equity. Are the right people compensated and do they get the right amount of compensation?
- how do we make sure systems designed to reduce error and compensate people have low administrative costs? These costs include legal fees, the uncompensated time and anxiety of both patients and clinicians and hospital administrative expense. This is the issue of *administrative efficiency*.

There are a number of mechanisms that can tackle the issues of accountability and compensation, with varying degrees of administrative efficiency (Danzon 2000). These include:

- *altruism, professional or ethical concerns*, which encourage doctors to act as better agents for patients. These only tackle accountability. We believe that they are insufficient, even to deliver accountability;
- *professional bodies including licensing bodies*. In the UK the General Medical Council is the disciplinary body for doctors. In addition the medical Royal Colleges also operate disciplinary procedures. Again, these only tackle accountability and can generally only be activated in the event of a serial pattern of misconduct. This means that they are not relevant to most patient safety issues;
- *informal market mechanisms, such as reputation and referral networks*. These are mechanisms of accountability, but again we believe these cannot be relied upon on their own to deliver improvements in patient safety;
- *liability for damages*. Different liability rules are discussed in Box 4. As discussed above, the existing system of liability in the UK is fault-based tort or negligence: compensation is paid only if it can be proved that the harm was the result of an inadequate standard of care. An alternative rule of professional liability is "strict liability" in which the clinician pays compensation for all injury arising from the treatment, whether it arose from negligence or not. This is in effect a pure "no fault" based approach, where the patient has to demonstrate causation (the intervention led to the injury) but not negligence on the part of the clinician. The US workers compensation system is a model of strict liability that may be relevant to the NHS and we discuss this in Box 5. However, unlike some no-fault schemes currently operated and discussed in section 7 below, strict liability requires that those who cause injury pay for it. Because of this link, liability addresses concerns of compensation and accountability simultaneously;

- *incident reporting and performance measurement of outcomes and processes*. These can look both at processes such as incident reporting methods and the use made of the information reported, and outcomes such as mortality and readmission rates, which may be good indicators of safety, if adjustments can be made for the underlying condition of the patient. These are potentially efficient methods of creating accountability, but do not provide compensation. A weakness of incidence reporting, however, is that the health care professional is the primary input source. It may be that complaints information can be fed into the system. However, patients will be more motivated to report adverse events if they can obtain compensation.

  Separating incident reporting from compensation risks reducing patient reporting of error – a key source of information;
- *compensation bodies*. These pay out compensation to patients based on specified eligibility criteria (such as proof of fault, preventability, or causation). Most administrative compensation bodies only tackle compensation and do not assist in providing accountability. This does not have to be the case, and we suggest there are ways of achieving a link between administrative systems aimed at accountability and those aimed at compensation, through the use of financial contributions towards the compensation scheme linked to the claims experience of hospitals;

Box 4
Tort based systems for tackling error and compensation

The negligence rule is based on the assumption that health care (and other professionals) owe a duty of care to their patients (or clients). As in most professional services there is an asymmetry of information. In the case of medicine, patients are usually imperfectly informed about the competence of specific providers and the risks and benefits of treatments. They also cannot usually monitor the quality of care delivered to them.

To obtain compensation, patients are required to show both that their injuries are a consequence of the treatment and that the clinician and the hospital were negligent in causing the injuries, i.e. that they failed to meet the due standard of care. This standard is defined by the courts in terms of good ("responsible") practice by fellow professionals (see Box 3).

In principle, such practice is that which would be adopted by comparing the costs of taking additional care relative to the expected benefits of doing so, i.e. cost-justified precautions. Indeed, the judgment given by the House of Lords in the recent case of Bolitho imposes a requirement that the standard proclaimed must be justified on a logical basis and must have considered the risks and benefits of competing options (Samanta and Samanta, 2003). In this sense the courts apply rules of cost-effectiveness. When negligence is proven, patients are compensated for economic loss, future health care costs, and for pain and suffering.

There are two other possible liability rules. Firstly, there could be *first party liability (caveat emptor)* whereby the patient is responsible for taking out insurance (or the state provides social insurance) which would compensate them if they experience an adverse outcome (whether caused by error or not). The price of the insurance premium will typically reflect age, sex and other risk factors for injury. There is no direct impact on the clinician from injuring patients although there may be an indirect effect through impact on reputation.

The other possible rule of professional liability is strict *third party liability* in which the clinician pays compensation for all injury arising from the treatment, whether it arose from negligence or not. This is in effect a "no fault" based approach, where the patient has to demonstrate causation (the intervention led to the injury) but not negligence on the part of the clinician. However, unlike some no-fault schemes in practice, strict liability requires that those who cause injury are required to pay for it.

In each case the groups compensated differ. In first party liability it is those who take out insurance and who are injured. In negligence based tort it is those who are harmed by negligent treatment. In the strict third party liability case it is all of those injured by the treatment.

- *complaints processes*. These are internal systems which investigate, and can help to deliver accountability, but, in the NHS, have no power to compensate.

Clearly it is possible to pursue compensation and accountability objectives using different instruments, and to minimise the administrative costs associated with these instruments. However, we maintain that the link between actions which cause harm and the financial consequences of that harm is an important principle which both encourages the reporting of adverse events and provides incentives to prevent them occurring. This principle can be retained through ensuring that hospitals are liable for their preventable errors by building the principle into the funding structure of an administrative compensation scheme such as the Redress Scheme proposed in Making Amends.

Box 5
Workers' compensation in the US: a strict liability system

A form of no-fault or strict liability injury compensation that has attracted considerable interest are workers' compensation schemes in the US. These schemes, requiring employers to pay the costs of medical care and wage replacement for work-related injuries and illnesses, originated in the 1910s, with the support of a coalition of workers, employers, and insurers who anticipated gains from replacing negligence liability.

Typically, State compensation schemes require employers to purchase and bear the full cost of state-regulated workers' compensation insurance for all medical and rehabilitative services and payment of lost wages to workers with work-related illness or injury caused by their work. Each State scheme defines what types of injuries are compensable, determines the type and amount of benefits payable under their workers' compensation insurance, and processes and adjudicates claims administratively rather than via litigation. Compensation benefits are capped as maximum weekly payments, typically covering medical care, disability benefits, rehabilitation services and death and funeral benefits. There are substantial variations between States in these benefits: for example, the maximum weekly payment for permanent total disability is 60% of state average weekly wages in Arizona, and 205% in Iowa.

During the 1970s and 1980s, increasing frequency of claims, expanded worker coverage and higher benefit payments resulted in a rapid increase in workers' compensation costs (to $62 billion in 1992) and doubled the employer costs of workers' compensation as a percentage of payroll. Since then, tightened eligibility criteria and frozen or reduced benefit levels have helped to contain rising costs, while risk rating has provided employers with incentives to invest in accident prevention programs.

Historically, within this strict liability system, with workers in good health the occurrence of a work-related injury has been easy to identify. However, now many work-related injuries remain uncompensated, primarily because causation is hard to prove: in particular, musculoskeletal disorders, cancers and nervous system diseases cannot easily be linked to specific work exposures. Danzon (2000) has pointed out that ease of demonstrating causation is the main reason why workers compensation schemes have hitherto been efficient. In medicine it is usually more difficult to demonstrate causation.

7 INTERNATIONAL EXPERIENCE OF ALTERNATIVES TO TORT

New Zealand

In 1972, New Zealand moved to a no-fault system of compensation for accidents (the Accident Compensation Scheme, ACS). This replaced the previous tort system. Despite lack of specific data on clinical injuries, concerns about the costs of ACS lead to reform in 1992. For our purposes, the key change was the redefinition of medical misadventure, from the general "personal injury by accident", including "physical and mental damage caused by medical, surgical, dental and first aid misadventure" to the

narrower "personal injury resulting from medical error or medical mishap". The former involves concepts not unlike negligence ("failure of a registered health professional to observed a standard of care and skill reasonably to be expected in the circumstances"), while the latter relates to adverse consequences of treatment that are both "rare" and "severe" (both of which receive precise, quantifiable, definitions). Apparently, cost control required a tight definition of eligibility under the scheme.

Interestingly, Davis *et al* (2001) suggest that take-up for medical misadventure has been relatively low (at 5 per cent of potential claims) under the scheme, an observation that counters the idea that no-fault (as redefined in 1992) necessarily opens 'claims floodgates'. Paterson (2001) describes the New Zealand system as combining no-fault with "rehabilitation rather than redress" for practitioners and also reports a perception of doctors "reluctant to blow the whistle on errant colleagues" (p 194). Hence it does not deliver accountability. He sees this as "missing the mark" (p 194). He does not advocate a return to a tort system of compensation or for a formal link between compensation and accountability (as we propose) but argues, perhaps somewhat optimistically, for renewed public responsibility and medical morality in the operation of the ACS.

Sweden

Sweden has operated a non-tort system (the Patient Compensation Insurance scheme, PCI) for compensating medical injuries since 1975 that is usually described as no-fault. Several authors, however, note the scheme's reliance on identifying some form of medical error before compensation is due. There is also a minimum injury period before compensation is payable. It would therefore appear that, as in New Zealand, the Swedish scheme is effectively aimed at compensating more serious injuries in circumstances where some notion of error can be identified. While the costs of the scheme appear low, it should be remembered that much compensation is achieved through a generous social security system. Even so, cost pressure in the 1990s led to compensation caps and deductibles being introduced.

An important factor to be borne in mind when assessing the Swedish scheme's costs is the potential hidden cost of diluting deterrence. Such dilution appears likely because "from the provider's perspective, the scheme is both no-fault and no-liability" (Danzon, 2000, p. 1391) . Claimants do not need to identify a provider when claiming and there is no financial consequence for the latter arising from successful claims. Patients must file (at their own cost) a separate complaint with the Medical Responsibility Board (MRB) if they wish physician conduct to be examined explicitly. The MRB and PCI are decoupled and do not share information so there is little link between the compensation and deterrence or accountability aspects of the scheme. This decoupling was key to getting doctor co-operation with the PCI scheme. Perhaps not surprisingly, Danzon (1994) found in the early 1990s there were only 6 MRB claims per 100 doctors, as compared to 21 PCI claims per 100 doctors. Only around 1 in 6 of the MRB claims led to some sanction whilst 40% of the PCI claims received compensation. This gives a ratio of 1 in 9 paid PCI claims leading to some MRB sanction, if we assume that these involve the same cases.

Florida and Virginia

The US States of Florida and Virginia have operated no-fault schemes for birth-related injuries since 1988. To gain a sense of the cases involved, the Florida's Neurological Injury Compensation Association (NICA) is aimed at "injury to the brain or spinal cord of a live infant weighing at least 2,500 grams at birth caused by oxygen deprivation or mechanical injury in the case of labor [or] delivery... which renders the infant permanently and substantially neonatally and physically impaired." Virginia's Birth Injury Fund (BIF) less restrictively excludes a weight threshold but more restrictively requires the infant to need permanent assistance in all aspects of daily living. There are caps on compensation: Florida places a cap of $100,000 on pain and suffering and does not compensate for future loss of earnings; Virginia does not compensate non-pecuniary loss but does accept claims for future wage loss.

Deterrence is, in principle, achieved by the reporting of claims to the relevant Medical and Health Departments who are responsible for State-wide quality and licensing. However, Bovbjerg and Sloan (1998) have some reservations about the effectiveness of this procedure, again based on the decoupling of compensation and deterrence: for example, the licensing Departments do not always receive the results of the NICA/BIF investigations into claims.

8 THE IMPACT OF LIABILITY ON PATIENT SAFETY: THE CASE FOR "PREVENTABLE ERROR"

In Figure 1, we identified the core of adverse events that are caused by negligence – some 30% of all adverse events. If we apply the current legal rules for determining negligence, these events are those which could have been avoided by taking cost-justified precautions (see Box 4) – precisely the events which should be avoided. One way of achieving this outcome is to encourage those who have been harmed to use the courts to establish whether they were harmed through negligence, and make those responsible pay for the consequences. This is the tort approach. As we noted in Box 4 it is necessary for the patient to prove both causation and fault. However, because of the expense and difficulty in proving fault, the numbers of eligible patients receiving compensation is relatively small. Moreover, the reliability with which the courts are able to determine whether clinical actions were cost-justified or not may not be high, and consequently "unnecessary" procedures may be encouraged in order to provide a legal defence ("defensive medicine"). For both these reasons, a widening of the basis of liability may be beneficial, along the lines of a strict liability scheme such as the US Workers' Compensation scheme (see Box 5). If hospitals are made to be responsible for the harm arising from all of their actions, they will in principle weigh up the extra costs of avoiding the adverse events, and take precautions when these costs are less than the reduction in compensation payable to injured patients. Strict (or "no-fault") liability can therefore in principle achieve the desired outcome: those adverse events which should be avoided will be avoided. At the same time patients who have suffered adverse events as the consequence of medical treatment will obtain compensation without having to demonstrate negligence. More patients will obtain compensation for two reasons. Firstly, the move to no-fault or strict liability will increase the likelihood of those patients who experience injury from negligent care making a claim, and secondly, it will enable patients injured from adverse events that were not negligent. These adverse events may have been due to non-negligent preventable errors (i.e. those which it was not cost-effective to invest in avoiding), or to a complication in a medical intervention which results in unavoidable harm to a proportion of the patients receiving it.

However, in relation to clinical practice, the separation of adverse events due to medical intervention from those due to the underlying condition is notoriously difficult. In principle the patient has to show in a tort action that the clinician's action led to his injuries "on the balance of probabilities" before going on to demonstrate that the action was negligent. In practice the courts may apply a principle of "all or nothing" when determining causation: if there is some possibility that the clinician's action caused the patient's harm, then compensation will be awarded. That is, it is likely that compensation would be awarded for injuries over and above the whole set of adverse events in Figure 1 – including those which were not caused by medical treatment. This would result in a very high cost scheme to the extent that it was paying compensation to those injured by chance, or who's underlying condition deteriorated, simply because the injury occurred in a hospital. It is for this reason that existing no-fault patient compensation schemes such as those in Sweden and New Zealand have adopted some test of "preventability" or "error", as well as insisting on the use of "substantial probability" as the basis for proving causation, rather than the "balance of probabilities" test used in tort. We suspect that equivalent restrictions will be needed as and when the Redress Scheme moves to a broader basis for liability than that currently in place.

9 "MAKING AMENDS" PROPOSALS FOR TORT REFORM

The tort process has been much criticised and we summarise in Appendix I the case made against it in Making Amends and the other reports and look briefly at the evidence. We should note, however, that Making Amends sees a continuing role for a reformed fault-based tort process in picking up cases not covered (at least initially) by the Redress Scheme. Patients will also have the right to opt for fault-based tort instead of using the Redress Scheme. We support these uses of fault-based tort. They will provide a safety check or backstop should the Redress Scheme fail to provide proper compensation for patients. Tort

and administrative processes are not mutually exclusive systems. They can run side by side.

Although the fault-based tort process has been improving, it can be further improved. The changes to the tort process proposed by Making Amends are generally welcome. We comment on two where we have concerns:

- A duty of candour on the part of clinicians is important but should not lead to exemption from disciplinary action. We favour the proposal in the Bristol Royal Infirmary Inquiry Report that confidential reporting be possible, but failure to report an incident should be a disciplinary offence;
- Protecting adverse event reporting from disclosure in court will reduce any likelihood of the tort process reducing incident reporting, but there is a risk that clinicians will use pre-emptive reporting of incidents where they were at fault to limit the ability of patients to get redress through the courts.

10 "MAKING AMENDS" PROPOSALS FOR A REDRESS SCHEME FOR SMALL CLAIMS

We welcome the small claims element of the proposed Redress Scheme, but there are some issues that should be considered.

It is certain to reduce administrative cost and delay for those who claim. However, the resulting packages seem likely to be less well tailored to the specific needs of claimants – they will tend to be more homogeneous as a result of the speed with which they are developed. In turn, this may produce less "equitable" settlements by comparison with the current system.

The European Convention on Human Rights guarantees individuals a right to a fair hearing when seeking redress. This may create an adverse selection problem for the Redress Scheme. Claimants could enter the scheme, see what it offered, take (free) legal advice, then only accept the scheme's offer if it was 'high'. The scheme may therefore incur administrative costs for claims that subsequently end up in the courts. However, the availability of this tort option will help to ensure that the Scheme pays reasonable levels of compensation.

Fenn et al. (2002) provide some estimates of the costs of running a small claims scheme for claims with value below £30,000 and with eligibility based on fault as at present. Assuming an 80% increase in claiming under this scheme, (this figure comes from the MORI study conducted by Fenn et al), they estimate that there would be 16,587 fast-track claimants per annum, of whom 6,635 (40%) would be paid compensation. In addition, there would be 3,764 tort claimants within the £30,000 threshold, of whom 1,506 would obtain payment. The total costs of the small claims scheme would be £116 million. When added to tort claims above £30,000, the total cost of compensating claims would be £517 million – a £70 million increase relative to the current tort arrangements. This increase is mainly held in check by the retention of the current fault-based criteria for eligibility. The extension of eligibility to cover claims where preventability alone is established would increase the numbers of claimants substantially, and therefore the overall cost of the scheme to the NHS. However, the social cost of a wider scheme may be justifiable to the extent that:

- more patients who are injured by adverse events that it was cost-justified for the NHS to invest in avoiding get compensated for their injuries;
- there are corresponding reductions in social and private insurance payouts to patients;
- most importantly, there are reductions in the overall numbers of errors as a result of improved deterrence effects combined with better information on incidents coming from the extra patient claims.

Overall, then, the small claims element of the Redress Scheme is likely to increase the number of claims and the amount of compensation paid to patients by the NHS, and at reduced administrative cost. These are positive developments, providing the NHS is able to learn from the errors that give rise to the claims and hospitals' contributions to the costs of the Redress Scheme reflect the harm they cause and the quality of their processes for identifying and preventing error. It will thus be essential to avoid the decoupling present in the schemes. We return to this in Section 12.

11 "MAKING AMENDS" PROPOSALS FOR A REDRESS SCHEME FOR BIRTH RELATED INJURIES

We welcome the proposals for birth related injuries. Again there are some issues.

The move to causation rather than fault as the basis for compensation will not eliminate the difficult issues of proof which have given rise to concerns about the arbitrariness of the fault-based tort process. This is because causation is often the issue giving rise to difficulty in these cases. The hospital may concede that care was at fault but argue that the birth related injury was not caused by that care. The difficulties in establishing causation based on a "balance of probabilities" may lead to denial of compensation in some cases; on the other hand, it may lead to the courts awarding compensation on the basis of relatively weak evidence on causation[8]. Hence our suggestion that some test of "preventability" or "error" may be necessary, as well as the use of "substantial probability" as the basis for proving causation.

Decoupling of accountability and compensation is a real risk. As we noted in Section 8, the US States of Florida and Virginia have operated no-fault schemes for birth-related injuries since 1988. Deterrence is, in principle, achieved by the reporting of claims to the relevant Medical and Health Departments who are responsible for State-wide quality and licensing. However, we have seen that some concerns have been raised about the methods by which NICA and BIF achieve accountability.

The figure of £517 million we quote in Section 10 above for the revised cost of clinical negligence including the small claims element of the Redress Scheme assumes that birth-related injuries remain *within* tort. It seems likely that a no-fault scheme for these injuries would, itself, raise costs. We have no evidential basis for an estimate as to how much, but we can note the figures quoted for Florida by Sloan et al. (1997) suggesting that 13 out of 51 cases originally filed for tort and failing in the courts eventually succeeded in the no-fault (NICA) scheme – implying an increase in successful claims (relative to tort) of 25%. To gain a (loose) sense of possible figures here, we can note that Making Amends suggests that 60% of current expenditure on clinical negligence is related to birth-related injuries (paragraph 43). With a current total cost of approximately £450 million (paragraph 13), this means an estimated £270 million relates to birth related injury cases. A simple increase of 25% on the £270 million would imply an increase of £67 million per annum. When added to the extra cost of the small claims element of the scheme this would increase total cost to £584 million.

As with the small claims element of the Redress Scheme, the birth related element of the Redress Scheme is likely to increase the number of claims and therefore the amount of compensation paid, albeit at reduced administrative cost. Again, these are positive developments, providing the NHS is able to learn from the errors that give rise to the claims and hospitals' contributions to the costs of the Redress Scheme reflect the harm they cause and thus provide them with clear incentives to invest to improve the quality of their processes for identifying and preventing error.

We now set out how the Redress Scheme needs to be managed in order to achieve this.

[8] This may happen because there are real issues of equity. Is it right that a baby born with severe disabilities that were not caused by the delivery should receive no compensation when their need for lifetime care is very high? How these babies will in practice be cared for will impact on any interpretation of causation.

12 CHANGING THE ROLE OF THE NHS LITIGATION AUTHORITY

The NHS Litigation Authority (NHSLA) was set up in 1995 to run a Clinical Negligence Scheme for Trusts (CNST). The CNST pools the costs of Trusts' liabilities for clinical negligence. The NHSLA administers other schemes to deal with pre-1995 claims (negligence claims have a long "tail" as it can take many years from an incident occurring to a resolution of a case in the courts). The CNST operates on a pay as you go basis, i.e. contributions collected each year are only

sufficient to cover claims paid out plus expenses. The main aim of the CNST is to "minimise the overall costs of clinical negligence to the NHS …defending unjustified actions robustly, settling justified claims efficiently, and creating incentives to reduce the number of negligent claims." (NHS Executive, 1996)

Existing trends

An increasingly centralised approach to pooling clinical negligence risks has been developing for some years, in contrast to the increasing financial autonomy devolved to health care providers in 1990. The responsibility for compensating injured patients has, almost unnoticed, shifted first from the individual clinician to the hospital trust, and now to the NHSLA as the central agency set up to pool litigation risks. As a culmination of this process the NHSLA has, from April 2002, taken financial responsibility for 100% of all claims against NHS hospitals. Prior to this date, under the terms of the CNST, hospitals had to retain part of the cost through choosing an "excess" level, below which they were responsible for the patient's claim.

We would argue that the combined effect of switching financial responsibility for negligence from individual clinicians to hospitals[9], and imposing a minimum excess level as a condition of pooling risks through the CNST, represented a coherent policy for the 1990s. Although hospitals could pass on the cost of their below-excess claims to health care commissioners, this in itself provided some kind of financial discipline.
It was subsequently argued, however, that this decentralisation of accounting responsibilities for small value claims placed an administrative burden on hospital management, and led to difficulties in producing consolidated estimates for the NHS accounts. These difficulties were behind the move to shift all financial responsibility for claims to the NHSLA. The latter is now therefore the dominant force in the administration of patient compensation – it is akin to a mutual risk-pooling organisation with (regulated) monopoly powers. This is a potential matter of concern as:

- the current subscription rates for the CNST do not reflect claims experience very well and so provide weak incentives for hospitals to invest in avoiding errors. This concern was identified in the Bristol Royal Infirmary Inquiry (2001) as we note in Box 2 above;
- the NHSLA has a poor track record to date in generating national information from the claims it processes that can be fed back into systems to reduce error.

The role of the NHSLA needs to evolve to underpin an efficient administrative Redress Scheme for the NHS.

Role of the NHSLA in the Redress Scheme

Making Amends suggests that a streamlined approach to assessing patient compensation can most efficiently be achieved by building on the existing NHSLA infrastructure. It is assumed that the financing of the scheme will continue to be met from contributions from trusts levied by the NHSLA. However, Making Amends is not specific about the way in which the finances of the Redress Scheme must be organised if strict liability deterrence effects are to be built in. Nor does it make clear about how the information on adverse events collected through the Redress Scheme is to be collated and fed back to hospitals. With deterrence, in terms of performance linked financial contributions, and information on adverse events, hospitals have the incentives and the tools to begin reducing the harm caused to NHS patients.

The NHSLA will have access to nationwide, pooled data on the frequency and severity of patient claims under the Redress Scheme, which should allow statistically reliable analyses of patterns of risk in various areas of clinical activity[10]. These can be used to improve patient safety and will complement the incidence reporting information on which the NPSA is focussing. The NHSLA will also be in a position to adjust the financial contributions made by individual hospital trusts to reflect their claims experience. In effect, the NHSLA will be in a position to put in place optimal risk-sharing contracts through a combination of excess and coinsurance rates as well as experience-related contributions.
Clearly, the NHSLA will have the *capability* to pursue these measures within its wider role. However, there are questions to be asked about its *motivation* to pursue them with vigour. Given its effective monopoly status, and the manifestly strong demand for risk pooling by hospital managers, what benefits are to be gained at the organisational level from improvements in risk-sharing between the NHSLA and hospitals? The NHSLA does not really have a strong incentive to reduce the number of claims it has to deal with either by putting in place optimal risk-sharing contracts or by making better information available to hospitals. It does have an incentive to be seen to be efficient in dealing with claims – and this is where it has put its effort.

Since the NHSLA reduced trust excess levels to zero, the remaining financial incentives for hospitals to pursue good risk management practices are through CNST subscription discounts. One such discount is given by the NHSLA to hospitals who achieve certain assessed risk management standards. While these standards are designed to include the presence of, *inter alia*, adequate incident reporting and complaints management systems, they are a reflection of processes, not outcomes. A second discount which does potentially give hospitals a financial stake in reducing the number and cost of claims is given by the NHSLA in relation to hospitals' claims experience. However, it is not particularly clear how claims experience is measured for this purpose. Newly opened claims may turn out to be unjustified, or have low settlement values. Claims closed with a known payment may reflect risk management decisions taken decades prior to the year of settlement. For some hospitals, small enough to experience low absolute numbers of claims, this information would in any case be thin, and sufficiently variable to mis-represent their relative risk in most years. In any case, unless these discounts are made more transparent, they may not succeed in providing the signals they are designed to send. We accept that there are issues in designing risk related contribution rates. However, much more could be done to establish a clear link between hospitals' contribution rates and their performance.

How then should the NHSLA's role be structured such that it is motivated to secure the accountability benefits we believe are essential? In the absence of a competitive market for liability insurance (something which may enter the debate alongside the creation of foundation hospitals) the problem is one of regulation. The Department of Health will have to put in place (and monitor) targets related to the performance of the organisation in pursuing both its compensatory and its accountability objectives. We note, in passing, that this is an area where economics can play an important role.

[9] This is the so-called "enterprise liability" rule. However, it remains necessary to identify and prove that an individual was negligent in carrying out his/her duties. Hospitals have agreed to meet vicarious liabilities on behalf of their employees.

[10] Data on claims should be coordinated with data on adverse events as reported to the National Patient Safety Agency (NPSA).

13 CONCLUSIONS

In addition to providing financial redress for injured patients, an NHS compensation system should ideally provide incentives to help clinicians and managers reduce the harm caused to patients where it is cost-effective to do so. Extending the scope of hospitals' liability towards patients, and making it easier and cheaper for patients to claim compensation, are both means of achieving this.

Overall, therefore, the Government's reforms set out in Making Amends are welcome. Both the small claims and birth injuries elements of the Redress Scheme are likely to increase the number of claims and the amount of compensation paid, at reduced administrative cost. These are positive developments, providing the NHS is able to learn from the errors that give rise to the claims, and hospitals' contributions to the costs of the Redress Scheme reflect the harm they cause and the quality of their processes for identifying and preventing error.

The NHSLA is currently charging contributions to hospitals that take account of their risk management processes but in addition hospitals' contributions need to reflect their record in harming patients. The NHSLA must also provide information on claims to enable the errors that give rise to them to be tackled. Failure to pursue these changes will limit the accountability benefits of wider access to compensation.

APPENDIX I
THE ISSUES AND EVIDENCE RELATING TO FAULT OR NEGLIGENCE BASED TORT

There is a widespread belief that the current link in the tort system between the reporting of adverse events and the payment of compensation yields no benefits and indeed may hinder the improvement in patient safety. This belief is fundamental to the thinking in Making Amends and to the earlier Bristol Royal Infirmary Inquiry Report. We consider the main points they make and summarise what is known about the efficiency of tort.

Hindering learning from mistakes

Making Amends argues that a negligence-based approach to medical injury is "…incompatible with the open recognition and reporting of mistakes and errors as a prelude to learning from them" (chapter 1 paragraph 17), and that it "…works against the wider interests of patients [as the] emphasis is on revealing as little as possible about what went wrong, defending clinical decisions …and only reluctantly releasing information…" (chapter 8 paragraph 1).

However, evidence on the question of hindering learning from mistakes is rather sparse. Limited anecdotal evidence from New Zealand suggests that changes to the tort-based litigation system had less impact on incident reporting than had been hoped for prior to the reforms. The Bristol Royal Infirmary Inquiry (2001) identified many other barriers to the openness required to fully learn from mistakes, such as lack of routine information concerning clinical performance, a culture of defensiveness created by the systematic under-funding of services, employees' fear of management responses to errors and mistakes, and concern about endangering future work prospects by criticising colleagues. It is also worth noting that two examples praised in the Bristol Report as encouraging openness and learning from mistakes – the reporting systems in place in the aviation industry and the reporting systems for coronary care mortality used in some US hospitals (Chassin 1996) operate in the continued presence of the tort system.

Deterrence effects

Making Amends states that the tort process "creates few incentives for providers of health care to reduce risk" (chapter 8 paragraph 9).

However, Fenn et al (2002) provide a summary of recent research by economists looking at deterrence effects in relation to fault-based liability. They suggest that whilst the evidence is mixed, a majority of papers present evidence consistent with a positive deterrence effect. Most of the studies relate to motor accident liability. The only study of deterrence in medical negligence (Weiler et al, 1993) found a negative relationship between the incidence of negligent injury and the deterrence measure, claims pre negligent injury. It suggested negligence liability led to a 29% reduction in the rate of negligent injuries per admission. The result was, however, not statistically significant. The evidence does not, however, sustain the Making Amends conclusions that tort has no deterrence effects. Danzon has estimated (Danzon, 1985) on conservative assumptions that the tort negligence liability system would pay for itself if it reduced negligent injury rates by 20% or more.

Defensive medicine

Making Amends states that tort has led to "the encouragement to doctors to practise defensive medicine for fear of litigation" (Chapter 1 paragraph 17).

Such evidence as exists here is, again, from outside the UK. However, three papers by Kessler and McClennan (1996; 2000a; 2000b) find evidence in US heart surgery that stricter tort regimes were associated with additional treatments that do not improve health outcomes. Ultimately, it is likely that clinicians and hospitals faced with sharp incentives under tort will want to supply "extra" care, but whether this should be interpreted as the impact of "deterrence" stopping them providing insufficient (quality of) care, or a "defensive" reaction to tort risk leading to oversupply remains an open empirical question. Incentives depend on the clarity of the expected standards of care. Removing the ambiguity in tort cases as to what it is reasonable to expect clinicians to do, for example by having national clinical practice guidelines, will remove the incentive to practice defensive medicine.

High transaction costs

Making Amends notes that there are "disproportionate legal costs of litigation proceedings, particularly when claims are for smaller amounts" (chapter 1 paragraph 17). It cites the National Audit Office study (NAO) which found that the legal and administrative costs of settling claims exceed the money actually paid to the victim in the majority of claims under £45,000 and take up an even higher proportion of the smaller claims. In addition, Making Amends notes that "in larger value claims, there can be lengthy (and expensive) disputes.." (chapter 8 paragraph 5). There is no doubt that tort has high transaction costs. This in part reflects the adversarial nature of the process, but also the liability rule, and the effort put into identifying the appropriate amount of compensation.

High overall expenditure

Making Amends cites evidence that annual NHS clinical negligence expenditure rose from £1 million in 1974/75 (£6.33 million at 2002 prices) to £446 million in 2001/02. However, this needs to be put in context. The annual cost of clinical negligence, while it has undoubtedly grown significantly since the 1970's, is still less than 1 per cent of the total NHS budget. The perception of a more significant cost burden stems from the frequent use in the media of accounting estimates relating to the (several billion) value of outstanding claims – a stock rather than a flow concept and therefore a misleading indicator of the impact on day-to-day resource needs. So whilst this cost in part reflects high transaction costs, it mainly reflects the need to compensate people the NHS has harmed. Compensation is well calibrated and is not excessive relative to the harm and loss claimants suffer. The real problem with the cost of tort is that it is not high enough. Few people harmed by the NHS actually seek and then succeed in obtaining compensation through tort – in the region of 4000-5000 patients annually, compared with our estimate of 450,000 adverse events.

Arbitrariness of who gets compensated

Making Amends notes "the difficulty and extensive delay experienced by patients and families who, on any reasonable assessment, deserve to be compensated for the harm that they have suffered" (chapter 1 paragraph 17) and "the lack of advice and support for those making a claim" (chapter 1 paragraph 17). The work by Fenn et al (2002) also finds survey evidence that potential claimants are put off by the complexity and potential cost of making a claim under tort.

Another dimension is which complainants get compensation? Making Amends argues that there is a 'lottery' effect as "the results can be arbitrary" because "some people who are severely disabled as a result of inadequate health care will receive large damages, while others with apparently similar disabilities receive not a penny" (chapter 8 paragraph 5). This may reflect problems around the burden of proof. However, the overall evidence is that there are limited numbers of type 1 (false positive, i.e. negligence is found in the court case but the error was not caused by negligent treatment) and type 2 errors (false negative, i.e. the injury was caused by negligence but the court did not award compensation.). The problem is the large number of harmed patients who never initiate a claim.

Conclusions

The evidence overall suggests that negligence based tort:

- could impact on disclosure and hence on learning from mistakes but there is little evidence of this;
- has deterrence effects;
- can lead to defensive medicine, but this can be managed by clarity on standards of care;
- is expensive in terms of transaction costs. This in part reflects the effort put into working out compensation, but primarily reflects the costs of an adversarial legal process;
- as a consequence of high cost and uncertain outcome leads to relatively few of those harmed by negligent behaviour pursuing claims;
- generates information but this maybe poorly used.

Overall as a system it is economically justified but could undoubtedly be further improved (the Woolf reforms speeded up the process and reduced costs) or replaced by more efficient administrative schemes using different liability rules such as those proposed in Making Amends. The important point is not the fact that negligence based tort has weaknesses, but the need to ensure that any proposals to replace it improve the situation. This requires a replacement system to increase the number of harmed patients who receive proper compensation, to reduce transaction costs, but above all to maintain and reinforce deterrence – the essential link between mechanisms for compensating patients who are harmed and mechanisms for improving patient safety to ensure that NHS providers have incentives to invest in avoiding harm and that the NHS learns from information from patient claims.