Making Amends
A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS

A report by the Chief Medical Officer

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**Description**
A consultation document setting out proposals for reforming the approach to clinical negligence in the NHS

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Clinical Negligence – what are the issues and options for reform

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Modern health care is delivered in a highly complex, pressured environment often involving the care of vulnerable seriously ill patients. More than almost any other industry in which risks occur, health care is reliant on people, more often than machines, to make the decisions, exercise the judgement and execute the techniques which will determine the outcome for a patient.

In such circumstances things can and do go wrong. Sometimes unintentional harm comes to patients as a result of a clinical decision or a clinical procedure. Sometimes the consequences can be very serious for the patient, their family and carers.

The individual who has suffered harm as a result of the health care they have received must get an apology, a clear explanation of what went wrong, treatment and care, and where appropriate, financial compensation. The NHS must also ensure that such bad experiences of individuals are learned from so that future NHS patients throughout the country benefit from reduced risks and safer care. The primary aim must be to reduce the number of medical errors that occur.

Legal proceedings for medical injury frequently progress in an atmosphere of confrontation, acrimony, misunderstanding and bitterness. The emphasis is on revealing as little as possible about what went wrong, defending clinical decisions that were taken and only reluctantly releasing information. In the past, cases have taken too long to settle. In smaller value claims the legal costs have been disproportionate to the damages awarded. In larger value claims there can be lengthy and expensive disputes about the component parts of any lump sum payment and the anticipated life span of the victim.

This report describes the origins, strengths and weaknesses of the present system of medical litigation, analyses the issues and concerns which arise from the present arrangements and sets out proposals for reform.

The proposals for reform aim to ensure that: the emphasis of the NHS is directed at preventing harm, reducing risks and enhancing safety so that the level of medical error is reduced; there is a better co-ordinated response to harm and injury resulting from health care including investigation, support, remedial treatment and care where needed and fair recompense; the system
of redress is affordable and reasonably predictable in the way it operates; the system for providing redress acts as an incentive on health care organisations and their staff to improve quality of care and patient safety. While the system must be affordable and not distort priorities, the primary purpose of the proposals for reform is not to reduce the resources devoted to compensation where such compensation is due.

**Preventing harm: reducing risk, enhancing safety**

- Untoward harmful consequences of health care are more common than has previously been recognised:
  - 10% of hospital in-patient admissions may result in some kind of adverse event;
  - 5% of the general population report suffering some injury or other adverse effects of medical care; almost a third of those claim that the event had a permanent impact on their health;
  - 18% of patients reported being the victim of a medication error some time in the previous two years (though the figure is lower in the United Kingdom than other countries studied).

- Patients can experience avoidable adverse outcomes of care as a result of: a sudden catastrophic event (e.g. the injection of the wrong drug); being treated by a service performing sub-optimally (e.g. diabetes being inadequately controlled); suffering a recognised complication of care (e.g. a drug side effect or an infection after surgery); failing to gain access to a service using evidence-based best practice (e.g. not receiving ‘clot busting’ drugs quickly enough after a heart attack).

- Until recently, relatively little attention had been given in any country to trying to identify the sources of risk in health care and to finding ways to reduce it in a planned and organised way. A much higher level of error has been tolerated in health care than has been acceptable in other sectors. This is now changing and the NHS is one of the first health systems in the world to give high priority to enhancing patient safety by systematically learning from what goes wrong.

- In the long-term, learning effectively from mistakes, errors and incidents will make health care safer and will result in many fewer instances of serious harm as a complication of medical care.

- The relevance to medical litigation is obvious – if more of the healthcare risks that currently cause harm to patients are identified, anticipated and reduced, then the number of avoidable injuries to patients should be reduced. So too should their severity. This must be the primary aim.

- Action to improve communication and information sharing with patients as well as developing a more modern process of informed consent will also help reduce complaints and claims for litigation.
The nature of medical injury leading to claims

- The data available to describe the nature of medical injury leading to claims for negligence are not comprehensive but show that:
  - in NHS hospitals the largest two categories of claims for negligent care are death and unnecessary pain (accounting for over a fifth of such claims);
  - in primary care over half of claims are for failed or missed diagnosis and almost a quarter for medication error;
  - the hospital medical specialties attracting most claims were the various branches of surgery as well as obstetrics and gynaecology (almost two thirds of all claims between them);
  - birth-related brain damage (including cerebral palsy) alone accounted for just over 5% of cases of medical litigation in which damages were paid and 60% of all annual expenditure on medical litigation in 2002/2003.

The costs of clinical negligence

- Comprehensive information on the costs of claims and compensation paid for clinical negligence has not until recently been collected centrally by the NHS. Data from the NHS Litigation Authority (established in 1995), surveys of NHS Trust hospitals commissioned for this report and earlier ‘one off’ surveys and estimates show 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;
  - claimants’ legal costs outweigh defendants’ legal costs: for cases settled with an award in 2002/2003 they were 82% higher for older cases and 88% higher for more recent cases;
  - the National Audit Office 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 smaller claims.

- The primary purpose of this document is not to cut the resources available to recompense patients harmed in the course of health care. The reforms proposed are designed to ensure that those resources are better targeted to meeting the needs of the harmed patient.

Injury and harm from health care: the consequences

- The effects of a serious adverse and unexpected outcome of care go beyond the impact of the physical injury itself. The psychological and social impact can include anxiety, depression, fear of future treatment, disruption to work and family life.

- Patients and families who are faced with complex legal procedures with which they are unfamiliar feel disadvantaged and rarely consider that they have had a satisfactory response to their concerns. The response of the health service when there is a serious medical accident can make matters worse: no co-ordination of a plan for remedial care; different views being offered on
the likely health outcome; lack of sympathetic support in the event of a death and unclear explanations.

- The impact of a serious medical accident or negligence claim on the clinical team concerned must always be a secondary consideration to the trauma experienced by the injured patient and their family. However, the incidence of depression amongst doctors involved in such cases, the loss of self-confidence within a clinical team, the growth in manslaughter actions against doctors and loss of morale amongst the medical profession as a whole are significant features of the present climate.

**Medical negligence and tort law**

- It will never be possible to make health care free of all risk. So there will always be a need to consider the needs of those patients and their families who suffer harm. These needs may include further treatment, care and rehabilitation, day-to-day support, adapted accommodation and aids to daily living and making good the loss of employment prospects and future earnings.

- In this country, compensation for medical harm is largely dealt with through a legal process that begins with an allegation of medical negligence.

- This area of civil law is called ‘tort’ law. A tort is an act or omission that causes harm to an individual's property, reputation or interests. Negligence is the specific tort involved in medical litigation. The law of tort imposes a duty of care where one party could reasonably foresee that her or his conduct may cause harm to another. Under this law a patient who suffers harm must prove that the hospital (or other health organisation) that owes the duty of care has caused the injury or damage through care delivered in a negligent manner.

- In the United Kingdom the precedent for judging whether medical negligence has taken place was set out in a court judgment made in the mid-1950s. It is known as the ‘Bolam’ test and states that a doctor “is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical opinion”.

- This ‘test’ is a difficult hurdle in proving a case of negligence: the practitioner who treated a seriously injured patient could be an ‘outlier’ (compared to the majority of his or her peers) in the standard of care provided but not be held to be negligent. In the late 1990s another authoritative judgment modified the Bolam test and provides that if the medical opinion is not capable of withstanding logical analysis the judge is entitled to conclude that the opinion offered is unreasonable and the action is negligent.

- Many criticisms have been made of this traditional system of paying compensation based on tort law and these include:
  - the length of time the process takes from claim to compensation and the complexity of the system;
  - the high legal costs of litigation proceedings;
  - the relative absence of alternative ways to resolve disputes in medical injury cases;
– the climate of blame, acrimony and confrontation which it engenders;
– lack of support and advice to those wishing to claim;
– the encouragement to doctors to practise defensive medicine;
– damage to the morale of clinicians and clinical teams;
– undermining the doctor-patient relationship;
– lack of explanation and apologies to patients who suffer harm;
– discouragement from reporting errors, which is a prerequisite to learning from them.

● Some other countries including the United States of America, countries in Australasia, and others in the Commonwealth, inherited the tort-based system of law from the United Kingdom. Many have experienced similar problems in administering a system of compensation for medical injury within a framework of tort law.

● Problems have been at their most extreme in the United States of America where the problem has been described as ‘out of control’ with a highly adversarial climate, escalating costs of settlement, doctors’ insurance premiums becoming unaffordable, and a high degree of ‘defensive medicine’ being practised (estimated to cost $25 billion). Medical litigation is estimated to cost 0.2% of the entire Gross Domestic Product (GDP) of the USA compared with 0.04% in the UK.

Handling claims: the NHS Litigation Authority

● The NHS Litigation Authority administers two schemes for pooling the risks from litigation against NHS bodies: one relating to older claims for care received before April 1995 and one for claims arising from care received after that date. The contributions that NHS Trusts make towards the costs of clinical negligence are determined by the NHS Litigation Authority based on its assessment of the risk management standards in place in each NHS Trust.

● The NHS Litigation Authority is responsible for handling clinical negligence claims to ensure a fair outcome for the patient and for the NHS. It retains a panel of expert clinical negligence solicitors firms to run and provide advice on individual cases. Originally the NHS Litigation Authority handled cases above individual NHS Trusts’ ‘excess’ levels. However, since April 2002 it is managing all claims, irrespective of value.

● The NHS Litigation Authority dealt with nearly 7,000 claims for clinical negligence in 2002/2003, just under 7% relating to episodes of care that took place prior to 1995.

The NHS Litigation Authority experience is that:

– 60 to 70% of claims do not proceed beyond initial contact with a solicitor or disclosure of medical records;
– 30% of claims formally pursued are abandoned by the claimant;
– 95% of settlements are reached ‘out of court’.
Primary Care is different: claims for negligence against general practitioners are defended and settled by the medical defence organisations which are not part of the NHS Litigation Authority processes.

The NHS Litigation Authority has improved the efficiency of claims handling. In particular:
- it has achieved better quality handling of clinical negligence claims through the use of specialised in-house claims handlers and solicitors from its expert panel;
- it has encouraged earlier admission of liability where appropriate, leading to speedier resolution of claims;
- it has encouraged NHS Trusts to provide explanations and apologies;
- it is working to promote the greater use of mediation;
- it is participated in a pilot scheme to fast-track small claims;
- it has reduced the costs of defending claims against the NHS by capping fees for defence lawyers.

Reforms to the operation of tort law

Reforms have also been introduced or proposed to personal injury legislation within the existing tort system, most significantly those proposed by Lord Woolf in his "Access to Justice" report in 1996. These include:
- the introduction of Pre-Action Protocols to provide a clear sequence of action for both parties to follow, with timescales;
- enabling claimants as well as defendants to make offers to settle (known as Part 36 offers);
- increased use of single joint experts;
- encouragement of Alternative Dispute Resolution;

Other reforms more recently considered include:
- the move from lump sum compensation to periodical payments – on which legislation has recently been introduced – where an agreed amount is paid each year;
- a pilot scheme, known as Resolve, to speed up the handling of claims valued at under £15,000 through the use of single joint experts.

Some reforms are still being implemented and whilst it is too early to assess the benefits of all the recent reforms in full, the impact so far seems to be:
- greater emphasis on admitting liability where justified and less on defending claims at all costs;
- speedier, more expert claims handling;
- earlier settlement of cases, and in particular, fewer settlements at the door of the court;
- containment of defence costs.
However, other changes have served to increase the size of the clinical negligence compensation bill:
- the reduction of the ‘discount rate’ (i.e. the assumed rate of interest which an investment will attract) which is used in calculating lump sum awards;
- the Working Time Directive which means more carers may have to be employed where 24-hour care is needed, with associated employer liability and National Insurance costs;
- the willingness of the courts to include a wider range of care needs and therapies within the damages awarded;
- a court judgment which raised the level of payments for the pain and suffering element of any damages;
- conditional fee arrangements, which are used in a small minority of clinical negligence claims, may have had some effect but the evidence is inconclusive.

The case for reform: key issues

I have considered whether recent reforms and those currently in train are sufficient to improve the response to clinical negligence cases, as some commentators have argued. However even with these reforms, the present system warrants further action because:
- it is complex;
- it is unfair – apparently similar cases may reach different outcomes;
- it is slow – cases can take up to four years from the time of claim to settlement – though timescales have decreased in recent years;
- it is costly in legal fees; diversion of clinical staff time from clinical care; staff morale; and public confidence;
- patients are dissatisfied with the lack of explanations and apologies or reassurance that action has been taken to prevent repetition;
- it encourages defensiveness and secrecy and stands in the way of learning and improvement in the health service.

A vision for a successful alternative to the present system

Any new system should create a climate where:
- risks of care are reduced and patient safety improves because medical errors and near misses are readily reported, successfully analysed and effective corrective action takes place and is sustained;
- remedial treatment, care and rehabilitation are available to redress harm and injuries arising from healthcare;
- any financial compensation is provided fairly and efficiently;
- payments of compensation act as financial incentives on healthcare organisations and their staff to improve quality and patient safety;
- the process of compensation does not undermine the strength of the relationship between patient and healthcare professional;
- different entry points to expressing complaints and concerns about standards of care are well co-ordinated and well understood by the public and healthcare professionals;
- the system of compensation is affordable and reasonably predictable in the way it operates.
No fault compensation

- There have been many advocates for introducing a system of ‘no fault’ compensation as a replacement for the current tort based system for awarding compensation for medical injury, including the Report of the Bristol Royal Infirmary Inquiry (Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995, July 2001).

- No fault schemes for medical injury have been introduced in:
  - Sweden: The Patient Insurance scheme provides compensation for injury caused by treatment or examination where the injury could have been avoided by a different action which would have satisfied the need for treatment in a less hazardous way. A second scheme provides compensation if a patient can show on the balance of probability that they have suffered an injury caused by a drug;
  - Finland, Denmark and Norway have schemes similar to the one in Sweden;
  - New Zealand: Compensation is payable for personal injury caused by medical error (where there is a negligence test) or mishap (where the consequence is a rare outcome of treatment);
  - Virginia and Florida, USA: which provide no-fault compensation for babies with birth-related neurological injuries.

Funding for these schemes is provided through insurance or a levy on healthcare providers. Claimants are not prevented from pursuing action through the courts except in New Zealand and the two birth-related schemes in the USA.

- No fault compensation schemes currently in operation in the UK include:
  - the Industrial Injuries scheme which may provide benefits for employed earners injured in the course of their work;
  - the Criminal Injury Compensation scheme which provides lump sum awards to those who have suffered injury or the families of those who have died as a result of violent crime;
  - the Vaccine Damage Payment Scheme which provides a tax-free lump sum of £100,000 where serious mental or physical damage has been caused by the administration of specified vaccines.

The case for no fault compensation

- The main arguments in favour of ‘no fault’ compensation are:
  - fairness;
  - speedier resolution of cases;
  - lower administrative and legal costs than court action;
  - increased certainty for claimants on the circumstances in which compensation is payable and increased consistency between claimants;
  - reduced tension between clinicians and claimants;
  - greater willingness by clinicians to report errors and adverse events.
The case against no fault compensation

- Critics of no fault compensation schemes argue that:
  - overall costs will be higher than under a tort system;
  - it will open the floodgates to compensation payments and fuel a compensation culture;
  - disputes about causation remain, even if ‘fault’ is removed;
  - disputes about the amount of damages remain, unless there is a tariff-based approach;
  - it is difficult to distinguish injury from the natural progression of the disease in some cases;
  - explanations and apologies are not necessarily provided in a system which focuses on financial recompense alone;
  - a no fault scheme, in itself, does not improve accountability or ensure learning from adverse events.

- The review specifically considered the option of a comprehensive no-fault compensation system. This was rejected because:
  - a true ‘no-fault’ scheme would lead to a potentially huge increase in claims and overall costs would be far higher than under the present tort system. Initial estimates suggest the annual bill could reach £4 billion.
  - to be affordable, compensation would need to be set at substantially lower level than current tort awards and would not necessarily meet the needs of the harmed patient;
  - it would be difficult to distinguish harm to a patient from the natural progression of a disease;
  - no-fault schemes, of themselves, do not improve processes for learning from error or reduction of harm to patients.

Alternative approaches

- the possibility of a tribunal system to compensate those injured through clinical negligence on the basis of a tariff of prescribed amounts for each injury was considered, similar to the systems for compensating industrial injuries or those injured in the course of a crime. The idea of a tariff-based system was rejected as being too blunt an instrument to reflect the range of potential healthcare injuries and their impact on an individual. It would also not have provided a focus on remedial treatment and care for those injured. A tribunal system was rejected, as to meet Human Rights requirements it would be likely to end up as a replica of the courts.

Proposals for reform

- The 19 recommendations in this report propose reform of the existing system of dealing with claims for medical negligence. All of the recommendations will be the subject of detailed consultation and, in particular, consideration of their potential impact on policies on a range of benefits and the way they are delivered.
New NHS-based system of redress

- The establishment of a new system of providing redress for patients who have been harmed as a result of seriously substandard NHS hospital care is proposed (The NHS Redress Scheme). The new arrangements would have four main elements:
  - an investigation of the incident which is alleged to have caused harm and of the harm that has resulted;
  - provision of an explanation to the patient and of the action proposed to prevent repetition;
  - development and delivery of a package of care providing remedial treatment, therapy and arrangements for continuing care where needed;
  - payments for pain and suffering, out of pocket expenses and care or treatment which the NHS could not provide.

- Patients would be eligible for payment for serious shortcomings in NHS care if the harm could have been avoided and if the adverse outcome was not the result of the natural progression of the illness. Payment would be made:
  - by a local NHS Trust for reimbursement of the cost of the care leading to harm (or similar amount)
  - by a national body for amounts up to £30,000.

- Families of neurologically impaired babies would also be eligible for the new NHS Redress Scheme if:
  - the birth was under NHS care;
  - the impairment was birth-related;
  - severe neurological impairment (including cerebral palsy) was evident at birth or within eight years. Genetic or congenital abnormality would be excluded.

- A package of compensation would be provided in cash or kind according to the severity of the impairment, judged according to the ability to perform the tasks of daily living, and would comprise:
  - a managed care package;
  - a monthly payment for the costs of care (at home or in a residential setting) which cannot be provided through a care package (in the most severe cases this could be up to £100,000 per annum);
  - one-off lump sum payments for home adaptations and equipment at intervals throughout the child's life (in the most severe cases, this could be up to £50,000);
  - an initial payment in compensation for pain, suffering and loss of amenity capped at £50,000.

- The recommendations in this area apply to England only, as does the whole of this Report. However, I recognise that any proposed changes to arrangements in England for care and compensation for severely neurologically impaired babies could have implications for the rest of the United Kingdom. These issues are currently being discussed with the devolved administrations.
Extension of the scheme

- The new NHS Redress Scheme would be centred on the needs of NHS patients, initially those treated in hospital and community health settings. Further consideration will be given to redress for patients treated under NHS funding arrangements but by independent or voluntary sector providers in the United Kingdom or abroad.

- After a suitable period of operation and evaluation, consideration would be given to extending the scheme to provide higher financial compensation and to encompass NHS primary care services.

Administration of the new schemes

- A national body building on the work of the NHS Litigation Authority would operate the new procedures. In the case of the element of the scheme relating to neurologically impaired babies, a national expert panel would be responsible for determining whether the impairment was birth-related, reviewing the severity of impairment and other factors and reporting to the national body.

Handling of cases which still go to law

- The new NHS Redress Scheme would not take away a person’s right to sue through the Courts but:
  - except for cases of children with cerebral palsy, there would be a presumption that they had first applied to the NHS Redress Scheme;
  - those accepting packages of care and compensation under the NHS Redress Scheme would be required to waive their right to go to court on the same case.

- For cases that do not fall within the criteria of the scheme:
  - there would be an expectation that mediation would be used as a first step and pre-action protocols would require mediation to be attempted in specified types of cases. Acceptance of a mediation package would be binding;
  - there would be strong encouragement of the use of periodical payments in larger value cases including ‘out of court’ settlements;
  - the costs of future care would no longer reflect the cost of private treatment;
  - specialist training would be provided to judges handling clinical negligence cases.
Relationship to other complaints and incident procedures

- The new NHS Redress Scheme would be closely aligned to the new NHS complaints procedure. Making a claim for compensation would no longer be a disqualification from pursuing a complaint.

- A new standard would be introduced for after-event and after-complaint management by the NHS so that there is a full investigation of each case, a clear explanation is provided to victims and any necessary remedial action taken. Staff training should be undertaken to achieve a higher quality response to complaints and incidents.

- An individual at NHS Trust Board level would be required to take overall responsibility to ensure that the organisation rigorously investigates and learns effectively from complaints, adverse events and claims, ending the present fragmentation of these processes. Investigation of complaints and incidents should be co-ordinated under a single senior manager.

- The administering national body would monitor the local and national compensation payments and publish annual listings by NHS providers to act as an incentive for risk reduction and patient safety at local level.

Duty of candour and legal privilege in adverse event reporting

- Statutory provisions would be introduced to encourage openness in the reporting of adverse events. This would encompass:
  - a duty of candour requiring clinicians and health service managers to inform patients about actions which have resulted in harm;
  - exemption from disciplinary action for those reporting adverse events or medical errors (except where there is a criminal offence or where it would not be safe for the professional to continue to treat patients);
  - legal privilege would be provided for reports and information identifying adverse events except where the information was not recorded in the medical record.

Care and support for victims

- The NHS in conjunction with other agencies would be required to develop effective rehabilitation services. The provision of rehabilitation services also features in the cross-Departmental review of Employers’ Liability Insurance and will form an important part of the next stage of that review.

- The NHS, together with other agencies, would be required to explore the scope for developing a greater range of high quality facilities and services for severely disabled children.
Questions for consultation

Views and ideas are invited on any of the issues raised by this report as well as on the specific proposals. I would be particularly interested in responses to the following questions:

The NHS Redress Scheme

- What should be the qualifying criteria: the ‘Bolam’ test currently used in assessing clinical negligence or a broader definition of sub-standard care?
- If the latter, what would be the preferred formulation?
- Should there be a minimum qualifying level in terms of the extent of the disability, e.g. in terms of days off work or in hospital or in terms of the levels of disability?
- Should there be an upper financial limit to the cases to be dealt with under the scheme? If so, is £30,000 the right starting point?
- Should the financial limit for the scheme apply to the whole package of care and cash or the cash element only?
- Should consideration be given to including primary care from the outset?
- Should patients/claimants be entitled to funding for legal advice to assess the fairness of the Redress Package? If so, what limit should be set on the amount of funding available?
- Will making it easier to obtain a package of care and support plus modest financial compensation reduce or increase the number of people making applications to the scheme? Why? Could this be mitigated?

The NHS Redress Scheme for babies who are severely neurologically impaired. What should be the qualifying criteria: is “birth-related severe neurological impairment” a reasonable test?

- Should a qualifying birth be restricted to one in an NHS Trust?
- Should patients/claimants be entitled to funding for legal advice to assess the fairness of the Redress Package? If so, what limit should be set on the amount of funding available?
- Should patients be able to go straight to court and not use the scheme if they believe they can prove negligence?
- Should courts have access to the deliberations of the expert panel if a compensation package is rejected and the case subsequently goes to court. What might be the impact on numbers claiming compensation?
- Should the right to go to court be removed in favour of a new, speedier, more responsive Tribunal system for all cases of severe neurological impairment?

NHS Litigation Authority

It is proposed that the new body established to oversee the NHS Redress Scheme should be modelled on or developed from the existing NHS Litigation Authority. What mechanisms would be needed to ensure that a body with this structure would not have a conflict of interest in administering the NHS Redress Scheme and retaining responsibility for assessing claims or
recommendations for NHS compensation payments? Should this body be a Special Health Authority? A non-Departmental Public Body?

Repeal of Section 2(4) of the Law Reform (Personal Injury) Act 1948

If an NHS cost basis is used to calculate damages for future care costs, should the NHS be required to provide guarantees for this treatment? How might it do this? Would a system of independent case managers be required?

Mediation

Are there additional ways of encouraging greater use of mediation and other alternative dispute resolution procedures?

Legal costs

Are there any further steps that could be taken to control legal costs in clinical cases?
It has been estimated that 50 million clinical decisions are taken for every million of the population every year in the NHS.

These decisions involve all aspects of the care of patients – initial diagnosis, treatment options, care, after care, follow-up and rehabilitation. They are taken by a wide range of healthcare professionals. Some of these clinical decisions involve matters of life and death – for example whether to visit a child whose mother calls the doctor in the early hours of the morning to express concern that her little boy’s fever may be the early signs of meningitis. Some will determine a person’s future life course: for example, the decision to intervene in labour when the unborn baby is showing signs of fetal distress. Some will influence an individual’s quality of life: for example, how intensively to treat a large leg ulcer in an elderly diabetic woman whose mobility is seriously affected as a consequence. Other clinical decisions will be more mundane but still important to the patient: for example, when to remove the stitches after a minor operation, thereby allowing a return to work.

All clinical decisions require judgements to be made based on the skill and experience of the doctor or other health professional supported by best practice evidence and the availability of clinical information. Increasingly, these decisions are made in consultation and partnership with the patient. Diagnosis, treatment and care will often involve a technical procedure or the use of drugs. In many situations today, decisions and clinical procedures are undertaken by clinical teams as well as by individual clinicians.

Modern healthcare is a highly complex process. It is delivered in pressured and fast-moving environments in which there are many seriously ill patients. Things can and do go wrong. Sometimes unintentional harm comes to the patient as a result of a clinical decision or a clinical procedure. Errors can occur in the process of care resulting in injury. Sometimes they are serious and occasionally patients die as a result. Unforeseen complications of diagnosis or treatment can arise and again can cause unintended harm to the patient. Almost all procedures and treatments have recognised complications, which
can be minimised but cannot be eliminated completely. Some patients will be unfortunate enough to suffer such reactions or complications of treatment.

**Adverse outcomes of care**

5. Patients can experience adverse outcomes of care, which are potentially avoidable, in one of four main ways.

<table>
<thead>
<tr>
<th>Exposure to an Avoidable Adverse Outcome of Medical Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients may:</td>
</tr>
<tr>
<td>- be subjected to a sudden catastrophic event;</td>
</tr>
<tr>
<td>- be treated by a service performing sub-optimally over a period of time;</td>
</tr>
<tr>
<td>- experience a recognised complication or side-effect of treatment;</td>
</tr>
<tr>
<td>- fail to gain access to the best that modern medical care can offer.</td>
</tr>
</tbody>
</table>

6. Firstly, they could be the victims of a sudden catastrophic event for example becoming paralysed as a result of the wrong drug being injected by mistake.

<table>
<thead>
<tr>
<th>Example of sudden catastrophic event: intrathecal injection error</th>
</tr>
</thead>
<tbody>
<tr>
<td>On 4 January 2001, a teenager attended as a day case patient for chemotherapy as part of his medical maintenance programme, following successful treatment of leukaemia.</td>
</tr>
<tr>
<td>The treatment consisted of:</td>
</tr>
<tr>
<td>Vincristine – to be given intravenously (into a vein);</td>
</tr>
<tr>
<td>Cytosine – to be given intrathecally (into the spine);</td>
</tr>
<tr>
<td>Other drugs – to be taken orally (by mouth).</td>
</tr>
<tr>
<td>The Vincristine was wrongly given intrathecally and tragically the young man died.</td>
</tr>
<tr>
<td>At least 23 incidents have been reported worldwide of Vincristine being injected into the spine by mistake. Almost all have proved fatal. The most recent report was in a medical journal in 2002, giving details of a patient who died in Spain.</td>
</tr>
</tbody>
</table>

*Sources: Toft, B. External Inquiry into the adverse incident that occurred at Queen’s Medical Centre, Nottingham, 4th January 2001. Department of Health, April 2001; Capsticks Solicitors.*
7. Secondly, patients might be being treated by a service that is delivering poorer standards of care than comparable services elsewhere in the country. It is well recognised that services in all countries can vary greatly in the outcomes they achieve for patients with similar conditions. For example, a service caring for diabetic patients which performs sub-optimally may lead to a faster rate of progression of the diabetes than would occur with high quality care. The consequences for patients could be poor metabolic control of their disease, leg ulcers, blindness and even premature death.

8. Thirdly, a patient may suffer a recognised complication of care. No procedure or treatment in medicine is entirely risk-free and complications for many treatments are well documented. Bleeding after surgery necessitating a return to theatre will sometimes occur, although it is uncommon. A wound infection after an operation is more common. It is important that patients have a clear explanation of such risks before they undergo investigation or treatment, and share in the decision about the treatment options. However, what will matter most to the patient, accepting that some medical complications are inevitable, is to know in their own case whether the risk has been reduced to the lowest possible level. There is also considerable variation in this respect, with some services being very good at containing the risk of complications whilst others are much less effective, even amongst patients whose severity of disease is very similar.
Some hospitals are much better at reducing the risk of infection after surgery

Source: Surveillance of Surgical Site Infection (SSI) – in English Hospitals 1997-2000. PHLS Nosocomial Infection Surveillance Service. Available at www.phls.co.uk

Note: Each point in the above figure represents the incidence of surgical site infection for a participating hospital. Boxes placed on the sets of points for each category give the estimates of the 25th, 50th and 75th percentiles of the incidence of SSI and the ends of the vertical lines the 10th and 90th percentiles. The percentiles are only shown where at least 10 hospitals contributed sufficient data.

9. Fourthly, a patient may experience an outcome of care which is less satisfactory than it could have been had they been treated by a service that was using the most up-to-date clinical management of their condition. Increasingly, NHS patients will have much more information to help them to choose their care and will wish to use services where evidence-based best practice is the norm and the best outcomes of treatment are consistently achieved.
Proportion of heart attack patients receiving thrombolysis (‘clot busting’ drugs) within 30 minutes of arrival in hospital

Source: Royal College of Physicians Myocardial Infarction National Audit Project

Example: Harm affecting a group of patients due to departure from normal practice.

An eye surgeon changed from the normal method of injecting an antibiotic used during eye surgery. Instead of injecting the drug subconjunctivally (under the white of the eye), he injected it into the anterior (front) chamber of the eye. This was done in the belief that it would give a better chance of reducing complications in higher risk patients. It was then discovered that the antibiotic concerned was not licensed for intraocular use. A review was undertaken of patients who had been treated in this way and seven were found to have poor vision as a result.

Outcome: claims settled for around £12,000 each.

A new emphasis on patient safety

10. Until relatively recently, little attention had been given in any country to trying to understand why medical errors and accidents occur. As a result, healthcare internationally was many years behind some other industries which serve the public in learning from accidents and reducing future risks. This is now changing. There is worldwide interest in how to identify and reduce the risks of healthcare and thereby enhance patient safety. The NHS is 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.
Clinical negligence and its costs

11. It is in this general context – the complexity of modern healthcare, the diverse nature of unintended harm to patients or complications of care, the imperative to reduce risks by learning from experience – that the question of how to compensate patients for the harm they suffer must be addressed.

12. Traditionally, at the heart of this is an adversarial process directed towards the courts, which begins with an allegation or complaint made by a patient or family. It turns on the concept of clinical or medical negligence and how it is investigated and proved.

13. Over the years, the costs of compensating injured patients through this legally based system have steadily grown. Between the 1970s and the early 1980s, allowing for inflation, the cost of settling claims increased by just over 400 per cent. Over the past decade costs have risen by over 750 per cent from £53 million in 1990 to approximately £450 million in 2001/2002.

14. One way of viewing such a figure is that although it appears a large sum of money in absolute terms, it represents slightly less than 1% of the annual expenditure of the NHS.

Growing concern about the clinical negligence process

15. Increasingly, however, there has been concern about containing the costs of litigation for clinical negligence. There has been a growing feeling that though there may not necessarily be savings by doing things differently, there could be different ways of using the money to benefit patients. With the mounting size of the clinical negligence bill for the NHS has also come concern from observing the position on the other side of the Atlantic.

16. In the United States of America the healthcare liability system has been described frequently as ‘out of control’. The healthcare system in the USA is very different to the NHS. There are also important differences in the legal system. Attitudes in society also differ. Nevertheless, it is estimated to cost US$22 billion a year, representing 0.2% of the Gross Domestic Product (GDP) of the USA compared with 0.04% of GDP in the UK.
17. As a result, amongst the main concerns expressed in the United Kingdom are:

- a growing awareness that the climate of blame and retribution, which is so prominent in the current adversarial system, is incompatible with the open recognition and reporting of mistakes and errors as a prelude to learning from them;
- 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;
- the lack of advice and support for those making a claim;
- the damage to morale of individual clinicians and clinical teams who can remain under a cloud of litigation proceedings, sometimes for years on end;
- the encouragement to doctors to practise defensive medicine for fear of litigation;
- the disparate and fragmented routes through which concerns or complaints about standards of care must be pursued;
- the disproportionate legal costs of litigation proceedings, particularly when claims are for smaller amounts;
- the relative absence of alternative ways to resolve disputes where compensation for medical injury is being sought;
- a lack of explanations and apologies to patients and their families when things go wrong, and no provision of evidence of steps taken to prevent a recurrence of similar incidents in the future;

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Features of the medical liability system in the USA

- Tort system of legislation inherited from Britain.
- Medical litigation costs as a percentage of Gross Domestic Product (GDP) are 0.2%: the highest in the world.
- Lawyers take high contingency fees.
- Large jury awards in medical malpractice cases: median award $1 million in 2000 (compared to $500,000 in 1995).
- High rate of defensive medicine incurring an estimated US$25 billion additional healthcare costs.
- Very high malpractice premiums for some doctors.
- Rates of claims high in some specialities: obstetricians on average are sued three times in their careers.
- Reduced access to medical care in more litigious States as doctors go elsewhere to practise.

* this estimate relates to 1991
Doing things differently

18. In July 2001, the Government announced that I would undertake a wide-ranging review of possible reforms to the way cases of clinical negligence are handled and to make proposals for improvement. In particular, I was asked to look at no fault compensation schemes; whether the medical treatment and care costs element of any compensation should continue to be based on the costs of private, rather than NHS treatment; the use of structured settlements rather than lump sum payments; and greater use of mediation or other ways of resolving disputes.

Expert opinion, public consultation and research

19. In compiling this report, which results from the remit I was given, I have:

- undertaken a public consultation through a ‘Call for Ideas’ paper published in August 2001 (www.doh.gov.uk/clinicalnegligencereform);
- held a series of meetings with an advisory group of experts from the legal and medical professions, patient groups, the NHS and medical defence organisations (full membership at www.doh.gov.uk/clinicalnegligenceform);
- met with a range of individuals and groups representing different stakeholder views;
- commissioned research projects into:
  - the numbers and costs of claims;
  - what claimants and complainants said they wanted when they made a claim or a complaint;
  - patient views on compensation levels;
  - how compensation awarded in cerebral palsy cases was used.
- reviewed a range of documentation including information on the operation of no fault compensation schemes in other countries; reports on the operation of the clinical negligence system in this country and evidence on how recent reforms to the civil justice system have affected the way clinical negligence claims are handled;
- received written representations from a wide range of individuals and interested parties.
Other relevant initiatives

20. During preparation of the report a number of important and relevant pieces of work were being undertaken in parallel and these have been taken into account. These included:

- a review of the NHS complaints procedure;

- an evaluation by the Lord Chancellor’s Department of the reforms introduced following Lord Woolf’s review of civil litigation processes (*Access to Justice 1996*, www.lcd.gov.uk/civil/final/);

- a consultation by the Lord Chancellor’s Department on whether periodical payment should be imposed (*Damages for Future Loss: Giving the Courts the power to order Periodical Payments for future Loss and Care costs in personal injury cases*, Lord Chancellor’s Department 2002, www.lcd.gov.uk/consult/general/periodpay.htm);

- initiatives to speed up claims handling in the NHS, including bringing all claims (regardless of value) within the NHS Litigation Authority’s procedures and a pilot study on ‘fast tracking’ small value claims;

- implementation of a new patient safety programme within the NHS, based on comprehensive reports of adverse events and near misses, learning from them and taking action to reduce risks (*An Organisation with a Memory*, Department of Health, June 2000, www.doh.gov.uk/orgmemreport/ and *Building a Safer NHS for Patients*, Department of Health, April 2001 www.doh.gov.uk/buildsafenhs);

- initiatives to improve clinical governance in the NHS (www.cgsupport.org), including the work of the National Clinical Assessment Authority (www.ncaa.org), the National Institute for Clinical Excellence (www.nice.org.uk) and the Commission for Health Improvement (www.chi.nhs.uk);

- the requirement on NHS bodies since the 2001/02 financial year to conduct a review of their risk management systems and provide a statement on the effectiveness of their Internal Control as part of their annual financial statements (www.doh.gov.uk/riskman.htm).
A vision for a new approach

21. In addressing my remit, I found it helpful to formulate at the outset a vision for what an improved system might seek to achieve.

A vision for a successful alternative to the present system of medical litigation for clinical negligence

- risks of care are steadily reduced and patient safety improves because medical errors and near misses are readily reported, successfully analysed and effective corrective action takes place and is sustained;
- harm and injuries arising from healthcare are fairly and efficiently compensated;
- payment of compensation acts as an incentive on healthcare organisations and their staff to improve quality and patient safety;
- the process of compensation does not undermine the strength of the relationship between patient and healthcare professional;
- different entry points to expressing complaints and concerns about standards of care are well co-ordinated and well understood by the public and healthcare professionals;
- the system of compensation is affordable and reasonably predictable in the way it operates.

The aim of this report

22. As a result this report aims to:

- describe the origins, development, strengths and weaknesses of the present system of litigation for clinical negligence;
- analyse the issues and concerns which arise from the present arrangements;
- make the case for change;
- set out a package of ideas and proposals for reform and improvement of the present system which would meet the vision for a new approach.
1. The celebrated maxim ‘primum non nocere’ (‘first do no harm’), widely quoted as part of the Hippocratic Oath, does not actually appear in exactly that form in the original versions of the Oath. Although scholars differ in their opinion as to the true historical origin of the phrase, it was used by Florence Nightingale. Establishing as a primary duty doing no harm resonates strongly with the ethos of a modern health service. Delivering high quality health care must start by protecting patients from harm, and ensuring that their care is as safe as possible.

2. The high standard of education and training of health professionals, their codes of ethics and the conscientious way in which the vast majority carry out their work with patients has meant that until recently ‘doing no harm’ was not an explicit goal of health services around the world.

3. Avoidable harm, it was assumed, was kept to a minimum and when it did occur was seen within a conceptual framework of litigation which was fought, won, lost and settled according to the merits of the case, the opinion of expert witnesses, the skill of the lawyers involved and the wisdom of the courts.

Risks of healthcare and their reduction

4. The last five years has seen a sea-change in attitudes towards avoidable harm in healthcare. This has come about for three main reasons:

- research has shown that avoidable adverse events are much more common in healthcare than previously recognised;
- the tolerance of error in healthcare is relatively high compared to other fields;
- policy-makers in healthcare have realised that their sector is well behind other industries in implementing successful strategies for reduction of risk for consumers and in enhancing safety.

5. This is reflected in the growth of research interest in the whole subject. Until the late 1990s there was relatively little attention given to the question of medical error, its causation and to patient safety in the healthcare literature.
Today there is much greater coverage of these issues in professional and scientific journals.

6. Research in the United States of America, Australia and the United Kingdom, using broadly similar methodologies, has suggested levels of adverse events amongst hospital in-patients ranging from 3.7% to 16.6%. This would be broadly equivalent (using the United Kingdom figure) to 850,000 adverse events occurring to hospital in-patients each year.

<table>
<thead>
<tr>
<th>Results of a United Kingdom Pilot Study of Adverse Events in Hospitalised Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of inpatient episodes leading to harmful adverse events</td>
</tr>
<tr>
<td>10% (around half preventable)</td>
</tr>
<tr>
<td>Direct cost of additional days in hospital as a consequence of adverse events</td>
</tr>
<tr>
<td>£250,000 for 1011 admissions</td>
</tr>
<tr>
<td>Broad extrapolation to the NHS in England based on 8.5 million inpatient episodes a year</td>
</tr>
<tr>
<td>850,000 admissions lead to adverse events</td>
</tr>
<tr>
<td>Up to £2 billion direct cost of additional bed-days</td>
</tr>
</tbody>
</table>

Source: An organisation with a memory, Department of Health, 2000
7. Most research concerned with describing the problem has concentrated on counting the adverse events which have actually occurred in hospitals. Very few studies have sought to gather information directly from the general population about their adverse experiences of medical care. Research carried out for this report asked a community-based sample of people about injuries or harm that they believed had occurred during medical care.

8. Of the 8,000 people interviewed, approximately 400 (just under 5%) considered that they had suffered injury or other adverse effects as a direct result of their medical care. Just over half of these related to treatment in a NHS hospital and just over a quarter to treatment by a general medical practitioner. Although over half of the respondents said that the impact on their health or work was insignificant or only temporary, 28% reported a temporary or permanent major disability and almost 30% reported that the event had had a permanent impact on their health.

<table>
<thead>
<tr>
<th>Public experience of medical injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>A sample of the general public was interviewed:</td>
</tr>
<tr>
<td>nearly 5% reported illness, injury or impairment they believed was caused by medical care;</td>
</tr>
<tr>
<td>of this group, 30% claimed that the event had had a permanent impact on their health;</td>
</tr>
<tr>
<td>55% of these adverse events happened in NHS hospitals and 25% in primary care.</td>
</tr>
<tr>
<td>Source: MORI Survey commissioned for this report, 2002</td>
</tr>
</tbody>
</table>

9. An authoritative international study examined patients’ experience of medication error in the United Kingdom and four other countries. This study surveyed people who had existing ill-health or were patients. It found that a substantial proportion reported experiencing medication error, with the proportion for the United Kingdom being slightly lower than the other countries. However, the majority, in all countries, said that the error had had serious consequences.
10. Research into the frequency and pattern of serious incidents in healthcare and
detailed analysis of catastrophic events experienced by patients has improved
the understanding of the true causation of such harm. The similarities between
the sources of risk in the environments in which healthcare is provided and the
position in other sectors (such as the airline industry) are today much more
widely acknowledged.

11. In the past health services have unwittingly tolerated much higher levels of
error and risk than would be acceptable in other sectors in which the public is
being served. For example, in a seminal and widely quoted study from the
United States of America, the level of error ‘tolerated’ in health care equates to
quite staggering levels of risk in other industries. For example, accepting the current level of mis-prescribing of antibiotics for respiratory infection would equate to a 1000-fold increased risk of dying in an air crash, if the level of error in healthcare were applied to air travel.

<table>
<thead>
<tr>
<th>Defects per million opportunities</th>
<th>Selected healthcare examples</th>
<th>Selected industrial examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4</td>
<td>–</td>
<td>Allied-Signal: 3 model factories</td>
</tr>
<tr>
<td></td>
<td>–</td>
<td>Publishing: one misspelled word in all the books in a small library</td>
</tr>
<tr>
<td>5.4</td>
<td>Deaths caused by anaesthesia during surgery</td>
<td>–</td>
</tr>
<tr>
<td>10–16</td>
<td>–</td>
<td>US domestic airline fatalities</td>
</tr>
<tr>
<td>230</td>
<td>–</td>
<td>Airline baggage handling Restaurant billing</td>
</tr>
<tr>
<td>6,210</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>10,000</td>
<td>1% of hospitalised patients injured by negligence</td>
<td>–</td>
</tr>
<tr>
<td>66,800</td>
<td>–</td>
<td>Publishing: 7.6 misspelled words per page in a book</td>
</tr>
<tr>
<td>210,000</td>
<td>21% of ambulatory antibiotics for colds</td>
<td>Banks deposit 36 million cheques in wrong account daily</td>
</tr>
<tr>
<td></td>
<td>–</td>
<td>Airplane deaths increased 1000 fold</td>
</tr>
<tr>
<td>308,000</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>580,000</td>
<td>58% of patients with depression not detected or treated adequately</td>
<td>–</td>
</tr>
<tr>
<td>690,000</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>790,000</td>
<td>79% of eligible heart attack survivors fail to receive beta blockers</td>
<td>–</td>
</tr>
</tbody>
</table>


More recently a new approach to combating risk in healthcare has emerged. This recognises that patient safety should be a core priority within the quality assurance and quality improvement programmes of the health service. It also recognises that human error is inevitable in the operation of any service. This is particularly so in healthcare which is delivered in a complex, high technology environment requiring many different human judgements, interventions and decisions.
13. Human error in healthcare can never be completely eliminated but the opportunities for it to occur can be reduced and when error does happen its impact can be minimised. However, this can only take place if there is an awareness amongst health policy makers, institutional managers and, most particularly, front line clinical staff that designing safe systems and safe products will mean fewer incidents in which patients experience harm, fewer catastrophes in which they suffer serious injury and even death, and fewer claims for compensation for negligent acts.

14. Air travel has become safer because the airline industry has given a priority to safety. Staff are encouraged to report errors, incidents and near misses so that they can be learned from. In that way when something does go wrong, action can be taken where possible to avoid it happening again.

15. This approach is very applicable to healthcare. The National Patient Safety Agency (NPSA) was established in July 2001 to spearhead a national patient safety programme and provide a clear focus on patient safety issues.

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### Making patient care safer: a major programme in the NHS

**The National Patient Safety Agency will:**

- Collect and analyse information
- Assimilate other safety-related information from a variety of existing reporting systems
- Learn lessons and ensure they are fed back
- Where risks are identified, produce solutions and establish mechanisms to track progress
16. Key priorities of the NPSA are to set up a national reporting and learning system for adverse events; to provide practical solutions to improve patient safety and to promote their adoption; and to develop an open and fair culture within the NHS where patient safety has a high priority. The patient safety programme currently being implemented within the NHS will be successful if:

- there is much greater safety consciousness amongst all NHS staff;
- the culture within the NHS generally and individual healthcare organisations encourages the reporting of mistakes and adverse events as a source of learning, not of blame and retribution;
- good information systems capture data on adverse events and near misses and analyse them so that opportunities for risk reduction action are obvious;
- methods are developed so that the redesign of healthcare systems, processes and products is rapidly adopted to bring about and sustain safety improvements.

17. The relevance to clinical negligence litigation should be obvious. If more of the healthcare risks which currently produce harm to patients are identified, anticipated and reduced then the number of avoidable injuries to patients should also be reduced. So too should their severity.

The nature of medical injury leading to claims

18. There are very few data available to provide a clear picture of the kinds of medical injuries which occur, or whether the pattern in litigation reflects the pattern of medical injury generally.

19. The basis of claims made for clinical negligence which were handled by the NHS Litigation Authority (because they exceeded the ‘excess’ limit for NHS Trusts to deal with) is quite diverse. The largest two categories in the six years after 1995 were death and unnecessary pain, (together accounting for nearly 22% of such claims).
When hospital medical negligence claims are examined by clinical specialty, two disciplines stand out: obstetrics and the various surgical specialties. Between them they account for nearly two thirds of all claims.

The largest clinical negligence payment made by the NHS

Until the autumn of 2002, the largest damages payment for negligence made by the NHS was £4.9 million in summer 2001 (plus claimant costs of £400,000 and defence costs of £200,000) for a cerebral palsy case.

A court ruling on 15 October 2002 exceeded this with an award of £7 million plus a structured settlement of £250,000 per annum to a woman who was brain damaged during the birth of her child. This was an approval of an agreed settlement reached at an earlier mediation between the parties.

The incident is an example of where safety measures introduced to reduce one sort of risk had created a different risk. Essentially, when the woman had a fit which led to a cardiac arrest, the hospital ‘crash’ team could not get into the labour suite because they did not know the code to the combination security lock. The security lock was introduced as a protection against baby snatching incidents of the kind that have occurred rarely in some parts of the country. The NHS Litigation Authority conceded breach of duty and causation at an early stage.
21. Particular categories of harm can be analysed in more detail. Harm resulting from medication is a major category. The claims data for hospital patients bringing clinical negligence actions on this basis show that ten drugs in particular are implicated in such claims.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Percentage of claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-epileptics</td>
<td>5.6</td>
</tr>
<tr>
<td>Warfarin</td>
<td>4.9</td>
</tr>
<tr>
<td>Steroids</td>
<td>4.2</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>3.8</td>
</tr>
<tr>
<td>Opiates</td>
<td>3.8</td>
</tr>
<tr>
<td>Penicillin</td>
<td>3.0</td>
</tr>
<tr>
<td>Diazepam</td>
<td>3.0</td>
</tr>
<tr>
<td>Heparin</td>
<td>2.6</td>
</tr>
<tr>
<td>Non-steroid anti-inflammatory</td>
<td>2.6</td>
</tr>
<tr>
<td>Intravenous Drugs (various)</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Source: NHS Litigation Authority survey of claims database 2000/01

† Excludes Group Actions
22. These drugs are amongst those on which work is also focussed by the NPSA and the Department of Health in the context of understanding the harm caused by inappropriate prescribing, dispensing or administration of medicines and what action might be taken to reduce it. A report by the Department of Health’s Chief Pharmaceutical Officer reviewing the whole field of medication error and setting out an approach to reducing it is due to be published later this year.

![Example of harm from medication error: severe allergic reaction to penicillin](Image)

A 36 year-old patient was admitted to hospital for drainage of an abscess on her leg. Her allergy to penicillin was documented in her notes and her general practitioner wrote to the hospital to warn them of the allergy when he referred the patient. Because of the severity of the allergy the patient wore a medical alert bracelet to warn healthcare providers. Despite these warning she was prescribed and administered an intravenous dose of Magnapen®, a combination of penicillin to which she had a severe anaphylactic reaction and cardiac arrest, resulting in a persistent coma. The nursing staff were unaware that Magnapen® contained penicillin.

23. Claims made by patients treated in primary care followed a different pattern, with failed or missed diagnosis accounting for half of all such claims and medication error almost a quarter.

![General Practice: Main causes of claims](Table)

<table>
<thead>
<tr>
<th>General Practice: Main causes of claims</th>
<th>Percentage of claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failed or delayed diagnosis</td>
<td>57</td>
</tr>
<tr>
<td>Medication error</td>
<td>22</td>
</tr>
<tr>
<td>Minor surgical procedure</td>
<td>6</td>
</tr>
<tr>
<td>Failed or delayed referral</td>
<td>5</td>
</tr>
<tr>
<td>Other</td>
<td>10</td>
</tr>
</tbody>
</table>

Source: Combined figures from the Medical Defence Union database 1990-2002 and a Medical Protection Society Survey of 1,000 claims in 2001
24. Within the category of delayed diagnosis, approximately half related to surgical conditions, about a third to medical conditions and a fifth to obstetric or gynaecological problems.

**Example: Misdiagnosis in primary care**

A young child became unwell overnight and started to vomit. The following morning there was some improvement but she later became sleepy and developed a high fever. Her mother called the surgery and was put through to a general practitioner who advised her to continue with oral fluids and liquid paracetamol. The doctor said he was unable to visit as the surgery was very busy, but advised the mother to bring the child to surgery the following morning if she was no better.

The following day another general practitioner from the surgery made a home visit because the child was no better. No rash was present but a diagnosis of chest infection was made. Oral antibiotics were prescribed. The parents were concerned about meningitis, as there had been a recent case locally, but the general practitioner reassured them.

The child was found dead the following morning. Post-mortem examination confirmed the cause of death to be haemophilus influenza meningitis and a claim for negligence was made. The medical expert’s report said that the child should have been admitted to hospital as the symptoms of meningitis are non-specific. The general drowsiness and the inability of the child to keep down fluids should have alerted the general practitioner to the need for urgent hospital treatment.

**Outcome:** settled for the claimant with a payment of £18,000.
The human consequences

25. The effects of a serious adverse and unexpected outcome of treatment go beyond the impact of the physical injury itself. Patients and their families almost always feel let down by the health service in general and the doctor in particular. Claims analysis shows unnecessary pain, unnecessary or additional operations, infections and fractures are the harm for which compensation is most frequently sought. Because patients expect the health services to make them better, they will usually be totally unprepared for such adverse outcomes, even where some of the risks have been explained.

26. The response of the health service when there is a serious medical accident can make matters worse. Patients or their families often find that there is no co-ordination of a plan for remedial treatment and care where needed; confused communications with different practitioners offering different views on the likely health outcome of the event; lack of sympathetic support in the event of a death in particular and a lack of explanations. Overall too many families are left with the impression that the NHS closes ranks when something goes wrong, to exclude the victim.

27. Trying to get an explanation through the complaints systems or making a claim for compensation currently adds to the frustration and trauma for patients and their families. Where compensation is awarded, claimants are often dissatisfied with the claims process. This is confirmed by the Department of Health's own research: even where claimants received compensation, they still wanted an explanation and an apology. Feelings of anger and bitterness will often persist and can become a life-long pre-occupation.

28. The trauma of the process is exacerbated by the length of time it takes to reach a conclusion, satisfactory or otherwise. And there is perception amongst patients of a lack of independence on the part of those enquiring into the complaints and concerns they raise.

Psychological impact of medical injury

- Extreme shock
- Anxiety
- Emotional numbing
- Depression
- Uncertainty about recovery
- Fear of future treatment
- Disruption to work and family life

29. Causing a serious medical accident or being the subject of a clinical negligence claim is also traumatic for the doctor and other members of the clinical team involved. It has been estimated that 38% of doctors who are the subject of a clinical negligence claim suffer clinical depression as a result of the process. The length of time cases take to come to court means these problems may be drawn out. Whether there is a finding of negligence or not, at the conclusion of the proceedings there is damage to a doctor’s reputation, morale, self-esteem and professional confidence. Although this consideration must always be secondary to the trauma experienced by the injured patient and their family, it is nevertheless doubtful whether the destruction of the self-confidence and morale of clinical teams around the country is an additional price that should have to be paid in circumstances where the harm resulted from an honest mistake.

30. Many have expressed concern about the extent to which retribution may be playing too great a part in the current response to injury of NHS patients. The rise in cases of manslaughter brought against doctors involved in patient deaths after medical error is very striking. The fuelling of a climate of hostility between patients and the healthcare professionals treating them is another worrying development.

### Growth in actions for manslaughter brought against doctors involved in medical error related deaths

<table>
<thead>
<tr>
<th>Decade</th>
<th>Number of manslaughter cases against doctors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970s</td>
<td>2</td>
</tr>
<tr>
<td>1980s</td>
<td>2</td>
</tr>
<tr>
<td>1990s</td>
<td>17</td>
</tr>
</tbody>
</table>

*Source: BMJ November 15th, 2000 – R E Ferner: Medication errors that have led to manslaughter charges – BMJ 2000; 321: 1212-1216*
31. The events which led to the failure in standards of care in the children’s heart surgery service in Bristol during the 1990s, the removal and retention (for research and teaching purposes) of children’s organs after post-mortem examination in Bristol, Liverpool and other centres, all epitomised the gap which had opened up between the perception of the public and that of the medical profession in what was acceptable or unacceptable freedom in clinical decision-making.

Messages from the Bristol Royal Infirmary Inquiry

- the service in Bristol was based on a paternalistic approach to families and to the care and support they needed;
- the culture in Bristol was not one which encouraged openness and honesty in the exchange of information between and amongst healthcare professionals and between them and families;
- the absence of a culture of safety and a culture of openness meant that concerns and incidents were not routinely or systematically discussed and addressed.


32. The media furore in the aftermath of these events was wounding to medicine’s image of itself as a caring, well-motivated profession. The repercussions to the morale and motivation of health professionals have been significant as is shown, for example, in surveys of doctors’ attitudes and job satisfaction. These events can be seen as a turning point in the development of a new culture and new relationship between practitioner and patient based on partnership, communication and provision of information.

Findings of a regular survey of junior doctors’ attitudes and job satisfaction – doctors surveyed in their pre-registration year

<table>
<thead>
<tr>
<th>Year of qualification</th>
<th>Number citing media vilification of doctors as a reason for job dissatisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993 or 1996</td>
<td>3</td>
</tr>
<tr>
<td>1999 or 2000</td>
<td>63</td>
</tr>
</tbody>
</table>

Source: UK Medical Careers Research Group, University of Oxford
The importance of consent and information for patients

33. It is a well-established principle that valid consent must be obtained from a patient before providing a clinical examination or treatment. For consent to be valid the patient must be informed of the nature and purpose of a clinical procedure. Failure to obtain consent or to provide sufficient or suitable information to a patient may lead to a charge of assault. A number of successful medical litigation actions each year will be as a result of failure to obtain proper consent from the patient before a procedure is carried out. There have been cases in which doctors have been disciplined or struck off by the General Medical Council for not obtaining consent.

34. Views on what constitutes “sufficient or suitable information” have developed over the years. For example, a House of Lords judgment in 1985 indicated that the amount of information to be given was essentially a matter of medical opinion although the Law Lords suggested that the patient should be informed of substantial risks of grave adverse consequences and be put in a position to make a balanced judgement about the treatment offered. More recently the Court of Appeal has suggested that a doctor should normally inform a patient of “significant risk which would affect the judgement of a reasonable patient”.

35. There is little research evidence to show that better provision of information or patient involvement in the decision-making process reduces the potential for litigation. However, it seems logical that better understanding of the potential risks of a proposed course of treatment or of the expected progression of a disease should help to reduce claims based on misunderstandings or unrealistic expectations of the proposed treatment. That is not to say that providing a long litany of every potential risk of treatment, however small, is either desirable or a means by which clinicians absolve themselves of the duty of care. Action to improve communication, information sharing and the consent process are an important part of putting patient at the centre of their care. It is important too in establishing a partnership between patients and practitioners as the predominant model of care, and moving away from the old relationship characterised by the professional decision-maker and a passive recipient of care.

36. The Department of Health’s Reference Guide to Consent for Examination or Treatment published in 2001 says that patients must:

- be provided with suitable information in a form they can understand;
- have the opportunity to ask questions;
- be able to give explicit consent to a particular procedure or course of action;
- give consent voluntarily, without pressure or undue influence.
37. Patients these days should have a much better idea than they might in the past about:

- what an operation or other procedure involves;
- what could go wrong, even with the application of the best clinical skills;
- an understanding of how the clinician personally views the treatment and his or her broader assessment of the case.

38. This places important responsibilities on the patient by providing the opportunity to contribute more directly to the decision making process. In this way the consent process offers a route to improved understanding by patients of both the potential and limitations of the available treatment options and modern medicine more generally.

The case of cerebral palsy

39. Cerebral palsy is caused by damage to the nervous system. The term ‘cerebral palsy’ is used to describe the disabilities associated with the underlying brain injury. Estimates of its incidence in the population vary between different epidemiological studies but a figure of around two or three cases of cerebral palsy per 1000 live births is most often quoted.

40. Of all the cases of illness and disability which are involved with medical litigation, cerebral palsy, perhaps, arouses the strongest emotions. Although cerebral palsy can be very mild and almost unnoticeable in some cases, the scale of the disability and the care needs of the child and future adult in severe cases means that the occurrence of cerebral palsy can be a tragedy for the child and family concerned.

41. Cerebral palsy is an umbrella term for a group of disorders characterised by difficulty in movement, described clinically according to various classifications. These classifications are not mutually exclusive. One describes the type of motor impairment and the other describes the limbs involved. One classification divides cerebral palsy into one or more of four types of movement disorders resulting from nervous system damage: spastic, athetoid, dystonic and rigid. Another classification describes the limbs involved: quadriplegia (all four limbs), diplegia (legs affected more than the arms) and hemiplegia (one side of the body affected with upper part worse). A proportion of children will also have a learning disability (formerly called mental handicap).

42. The individual with cerebral palsy can have many other disabilities including physical, sensory and behavioural impairment as well as epilepsy. Their and their families’ need for care can be diverse and include: surgery and a range of therapies to assist with mobility, aids to daily living, home adaptations and equipment, special educational support, transport, nursing care (which may be needed round the clock) and replacement of lost earnings.
43. Neurological impairment in infancy (of which cerebral palsy is the largest category) accounts for the majority of the large payments made in clinical negligence litigation. In the financial year 2002/2003, birth-related brain damage (including cerebral palsy) in the NHS accounted for:

- just over 5% of all cases of medical litigation in which damages were paid
- 60% of all expenditure on medical litigation.

44. The determination of causation and negligence in cases of cerebral palsy is often particularly difficult. Particularly contentious is establishing whether birth asphyxia (deprivation of oxygen during labour or immediately after birth) was the cause of the impairment of the nervous system suffered by the infant.

45. For most of the 20th Century it was believed that cerebral palsy was commonly caused by birth asphyxia. Awards for damages often turned on whether the care in labour, during birth or immediately after birth was below the standard expected. Legal analysis of causation would focus on potentially avoidable factors such as whether foetal monitoring was properly applied and acted upon and whether a Caesarean section should have been carried out.

46. Research evidence of the cause of severe neurological impairment in infancy has moved modern medical thinking away from a model of causation focussed purely on birth asphyxia.

47. The cause of cerebral palsy is not fully understood. However, a wide range of factors have been implicated including genetic predisposition and infections whilst the baby is in utero. Authoritative medical opinion, drawing on research studies, suggests that between 3% and 20% of cerebral palsy may be related to birth asphyxia (with a lower figure being more likely). One of the major international figures in cerebral palsy research, Dr Karin Nelson (of the National Institute of Neurological Disorders and Stroke in Bethesda, Maryland) wrote recently that “most cerebral palsy is not due to birth asphyxia”.

48. However, it is too early to speak of a consensus amongst world experts on the causation of cerebral palsy. Other recent studies have concluded that there was a very low rate of established brain injury acquired before birth. This continuing disagreement amongst experts has implications for decisions on negligence in cerebral palsy cases and is a factor pointing away from tort litigation as the best way of compensating for the disorder.
Over the last three or four decades there have been significant developments in maternity and neonatal care. Rates of survival of small and premature babies have improved dramatically. Caesarean section rates have increased.

Despite these developments, cerebral palsy rates have not fallen as might have been predicted had the causation mainly been birth asphyxia. Indeed, the rate of cerebral palsy has increased because it is commoner amongst low birth weight babies, and because of improvement in standards of care there are many more surviving small babies. Reliable data showing these trends in cerebral palsy are not available nationally, and must be derived from parts of the country which have maintained special registers or carried out surveys. A long-running survey in the North East of England confirms the trend in the occurrence of cerebral palsy which is also shown in research studies in this country and abroad. It is too early to say whether the reduced incidence in cerebral palsy amongst low birth weight babies over the last few years will be sustained.

### Cerebral Palsy

Cerebral palsy does not have a clear-cut single cause. It can be caused by injury to the brain before, during or after birth. Examples of factors linked to its causation are:

- Infections during pregnancy (for example rubella).
- Jaundice in the infant.
- Rhesus blood group incompatibility (which leads to jaundice).
- Birth asphyxia – (severe blood or oxygen shortage in the brain or trauma to the foetus during labour and delivery).

**Risk factors associated with cerebral palsy:**
- low birthweight;
- premature birth;
- being small for gestational age (intra-uterine growth retardation);
- the foetus being male;
- multiple births;
- poverty/deprivation.
51. Given its known birth prevalence, cerebral palsy can be assumed to result in over 1,300 affected births each year in England and Wales. Each year from 1998 to 2001 the NHS Litigation Authority (NHSLA) received between 400 and 500 claims relating to cerebral palsy, although many of these will relate to births in a number of previous years. Therefore it is clear that only a minority of parents who have a child with cerebral palsy bring claims for medical negligence.
Of the birth related cerebral palsy claims concluded by the NHS Litigation to the end of September 2002, only around one third received damages. These averaged £670,000 for claims relating to incidents since 1995 and £1,225,000 for the older cases. The highest payment in a cerebral palsy case to date is £5.5 million, paid in February 2003. Less than 4% of cases went before a court. Of those which did, damages were received by 82% of the claimants. Those that do go before the court are usually where there is a dispute about the level of settlement rather than causation or breach of the duty of care. In addition, in cerebral palsy cases, the court is often required to approve any settlement.

### Cerebral Palsy Claims 1995-2002: status of claim

<table>
<thead>
<tr>
<th>Status</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Withdrawn or discontinued</td>
<td>944</td>
<td>43</td>
</tr>
<tr>
<td>Settled out of court</td>
<td>640</td>
<td>29</td>
</tr>
<tr>
<td>Won by the claimant in court</td>
<td>60</td>
<td>&lt;3</td>
</tr>
<tr>
<td>Lost by the claimant in court</td>
<td>13</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Yet to be settled</td>
<td>518</td>
<td>24</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,175</td>
<td>100</td>
</tr>
</tbody>
</table>

*Source: NHS Litigation Authority*

Mrs A’s daughter was born in 1991. Her daughter was effectively born dead and one minute after birth there were still no signs of life. Cerebral palsy was diagnosed and her mother attributed this to the events surrounding her labour and delivery.

The case was referred to a solicitor in 1993. Subsequent midwifery and obstetric reports highlighted the sub-standard care that Mrs A had received during her labour and delivery. As the little girl grew, it was clear that her disabilities included spastic quadriplegia and severe seizure disorders. At one stage she was having up to 80 fits a day. Although it was clear that the care during delivery was sub-standard, it was argued on behalf of the hospital that the injury was caused by some earlier event and the damage was not caused at birth. The child’s experts held the view that a forceps delivery should have been carried out an hour or more earlier and brain damage had been caused by asphyxia. The defendants admitted causation and liability in October 2000 but a settlement of £3,150,000 was not reached until January 2002, a week before trial.

*Source: Association for the Victims of Medical Accidents*
Medical negligence, commonly referred to now as clinical negligence, is broadly comparable to many other forms of legal action based upon fault in which someone seeks compensation for a personal injury that they have suffered.

The concept of medical negligence

Essentially the individual bringing the medical negligence action has to prove four elements of their claim:

- the existence of a duty of care;
- a breach of that duty of care (i.e. negligence);
- that the injury or damage was caused by the breach of the duty of care or the breach was a material contribution to the injury;
- the extent of the injury or damage resulting from the breach of the duty of care.

A healthcare organisation such as an NHS Trust has a primary liability to select competent, qualified staff, to provide proper equipment and facilities and a safe system of care. It also has a secondary liability, sometimes called ‘vicarious liability’, for the actions or omissions of its employees in relation to patients.

In practice, within the NHS, the existence of a duty of care is seldom challenged and so the individual who has been harmed and is bringing a claim has to prove the other three components: negligence, causation and injury.

This area of civil law is called ‘tort’ law. A tort is an act or omission which causes harm to an individual property, reputation or interests. The specific tort involved in medical litigation is negligence. It is a civil rather than a criminal wrong. The law of tort imposes a duty where one person can reasonably foresee that her or his conduct may cause harm to another. This area of law therefore deals with disputes about torts and who should pay damages to put them right. The aim is, so far as is possible, to put the defendant back in the position she or he would have been had the tort not occurred. Tort based law systems are in
place in the United Kingdom, the United States of America, India, Australia and Canada as well as in a number of other Commonwealth countries.

6. The potential benefits which the tort system can provide in the medical context are:
   - to provide compensation for the victims of medical harm;
   - to act as a deterrent to other practitioners;
   - to create a mechanism of accountability.

7. In order for a claim for negligence to be successful, the harm that resulted from the medical care must be proven to have resulted from care (or lack of care) delivered in a negligent manner.

8. In the United Kingdom the precedent for judging whether medical negligence has taken place was set out in a court judgment made in the mid-1950s. Mr Justice McNair presiding in the case of Bolam v Friern Barnet Hospital Management Committee in 1957 ruled that a doctor “is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical opinion”.

9. This judgment dominated legal and medical attitudes to medical negligence for more than thirty years but it did not stop the concept of negligence being contentious when looked at from the public or patient perspective. Basing it on conformity to a ‘school of medical opinion’ rather than consistency with normative or expected practice essentially meant that the practitioner treating a seriously injured patient could be an ‘outlier’ (compared to his or her peers) in the standard of care provided, but still not be held to be negligent.

10. The ‘Bolam test’ was widely regarded as reinforcing the philosophy that the standard of medical practice required of a doctor is determined by medical opinion.

11. In the late 1990s, another authoritative judgment on the concept of medical negligence modified the ‘Bolam test’. This judgment delivered in 1998 in the case of Bolitho v City and Hackney Health Authority, provides that, in applying the ‘Bolam test’, if it can be shown that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion offered is not reasonable or responsible and hence the action is negligent. In summary, the standard of care which is sought is that which can be supported by a responsible body of medical opinion provided that this can withstand logical challenge. This was seen as giving power back to the judges to challenge medical opinion.

12. One of the reasons that clinical negligence litigation is different from legal claims made for other forms of personal injury is that in the latter the person injured was usually previously healthy. In healthcare the ‘injured’ person is
usually suffering from a pre-existing disease process. This is why causation in
clinical negligence litigation is often quite difficult because it means that the
claimant (i.e. the patient or their family) must prove that it was the clinician's
negligent action or omission that caused the adverse outcome rather than
progression of the disease process itself.

Handling clinical negligence litigation in the NHS

13. Before the establishment of the NHS, all relationships were contractually based
and here the law was well established. Little thought was given, when the NHS
began (and doctors became employees of the new State-run service), as to who
would be sued in a case of medical negligence.

14. When doctors joined the NHS in 1948, they took with them the tradition
of autonomous clinical practice whose standard was governed by professional
self-regulation. They were sued in their own right, although the hospitals in
which they worked could also be enjoined in the action.

15. In the United Kingdom, there are three main defence organisations for doctors
and dentists. All were founded more than 100 years ago. The Medical Defence
Union (MDU), the Medical Protection Society (MPS) and the Medical and
Dental Defence Union of Scotland (MDDUS) are not-for-profit, membership
organisations, owned by the members. Doctors and dentists who are members
pay an annual subscription. For many years this stayed at a flat rate but in the
late 1980s differential subscriptions were introduced. Hospital doctors began to
pay more than general practitioners and those in high-risk specialties such as
obstetrics and gynaecology paid even higher rates.

16. In the 1950s, two NHS circulars were issued that required all doctors (whether
working in hospitals, general practice or the community) to subscribe to
medical defence organisations. Each year, they had to show proof that they had
paid and were reimbursed for the cost of the subscription. Successful medical
negligence claims were settled by a medical defence organisation on behalf of
the doctor although Health Authorities could also be required to make
payments depending on their share of liability.

17. The position for hospital doctors changed in 1990 with the introduction
of NHS Indemnity. This came against a background of steeply rising
subscriptions and claims. Regional (and district teaching) Health Authorities,
as employers of hospital doctors, became responsible for all new and past
claims for negligence against their doctors from 1990. As NHS Trusts became
established and were then the employers of hospital doctors, they took on
this liability.

18. From 1990 (i.e. after NHS Indemnity was introduced), the role of medical
defence organisations in clinical negligence claims has been mainly to cover
general practitioners and hospital doctors in private practice against negligence
claims not covered by NHS Indemnity. Today defence subscription rates for
private work vary by medical specialty, risk bands and the amount of private work done. The Medical Defence Organisations also continue to provide wider advice and assistance to their members, for example, on General Medical Council (GMC) proceedings, boards of inquiry and risk management.

Medical Defence Union (MDU) Subscription rates (for all members prior to 1990 and illustrating levels for obstetricians after that)

Source: MDU subscriptions database 2002
Note: 1980–1989 every member paid the same amount, from 1989 rates were paid depending on the specialty

Medical Defence Union (MDU) Subscription rates for general practitioners from 1990

Source: MDU subscription database 2002
Note: 1980–1989 every member paid the same amount, from 1989 rates were paid depending on the specialty, in this case a typical general practitioner.
By the early 1990s there were 98 different firms of solicitors acting for NHS Trusts and health authorities in England. In addition, very few NHS Trusts at that time employed experienced claims managers.

The system for handling claims for clinical negligence within the NHS at that time was not very well co-ordinated or managed. As a result:

- the way in which claims were dealt with disadvantaged both plaintiffs and the NHS;
- there was a lack of informed and pro-active management of claims resulting in great delays and a generalised lack of urgency;
- the NHS as a whole did not seem to attach much importance to the subject and there was little high level management involvement;
- there were inadequate controls on lawyers and the NHS on the whole did not have the skills to manage the legal system as a properly informed and interested client;
- the NHS and its constituent bodies were not consistent in their treatment of the accounting issues arising from clinical negligence cases;
- there were no effective mechanisms or incentives for reducing clinical risk and improving patient safety.

In a highly significant development, in November 1995, the NHS Litigation Authority (NHSLA) was created. The new Authority’s functions were:

- to administer two schemes established by the Secretary of State for pooling the risks from litigation against NHS bodies (the two schemes were for incidents occurring on or after 1 April 1995, and for old claims relating to NHS care received before 1 April 1995);
- to determine standards of risk management and claims handling and to encourage the adoption of these standards throughout the NHS;
- to determine contributions from its members towards the costs of clinical negligence;
- to handle clinical negligence claims where appropriate to ensure a fair outcome in the interests of the NHS and patients generally;
- to determine applications from NHS Trusts under either of the two schemes for financial support to help meet the cost of clinical negligence settlements;
- to run systems to ensure the correct payment of financial support under the two schemes.

The Clinical Negligence Scheme for Trusts (CNST) was established in 1995 as a means for NHS Trusts to fund the costs of clinical negligence litigation through an annual contribution and a pooling of funds which meant that a high value claim against any one NHS Trust would not threaten the viability of the scheme.
23. It originally operated with a defined ‘excess level’ (much like on car and home insurance policies). Below a certain level of claim, the local NHS organisation dealt with it entirely. Above the ‘excess’ the NHSLA took over claims handling. Excess levels in the past ranged from £10,000 to £500,000 depending on the type of NHS Trust and the risk management measures it had in place. Contribution levels required of a NHS Trust reflect the clinical governance and risk management measures it has in place as assessed by the NHSLA. For cases above the excess level the costs were split with the NHSLA, usually on a 20% (from the NHS Trust) – 80% (from the NHSLA) basis. From April 2002 the excess level approach was abolished and the NHSLA now deals with all claims, irrespective of their value.

24. The Existing Liabilities Scheme (ELS) was also introduced in 1995, but it deals with older claims. It covers NHS Trust liabilities for incidents arising from treatments given before April 1995. Originally this was for cases where the estimated settlement costs were above £10,000. From April 2001, the NHSLA handled these older cases of all values. The Existing Liabilities Scheme is funded entirely by the Department of Health and does not require an annual premium to be paid by the NHS Trusts (as does the Clinical Negligence Scheme for Trusts).

25. In addition the NHSLA runs a third scheme to meet the costs of claims relating to incidents occurring prior to April 1995 where there is no longer a Health Authority or other ‘body’ to meet the claim (for example, as a result of mergers or the closure of healthcare facilities). This is known as the ex-Regional Health Authorities (ex-RHA) scheme.

26. The NHSLA employs specialist claims advisers, who manage claims against NHS Trusts. It also retains a panel of expert clinical negligence solicitor firms across England to provide advice to NHS Trusts on claims they receive and to run individual cases if necessary. The previous 98 solicitors firms engaged in defending clinical negligence cases against NHS Trusts and Health Authorities have therefore been reduced to a panel of 14.

### Risk management standards set by the Clinical Negligence Scheme for Trusts (CNST):

- Information is used pro-actively to improve clinical care;
- A policy for the rapid follow-up of major clinical incidents;
- Appropriate information for patients on the risks and benefits of proposed treatment before consent is sought;
- A comprehensive system for the management of medical records;
- Systems to ensure the competence and training of all clinical staff;
- A clinical risk management system;
- Clear procedures for the management of general clinical care.
In summary, since the NHSLA was established, a very different approach to handling clinical negligence claims in the NHS has been established. In particular:

- an expert panel of clinical negligence solicitor firms has been established, reducing variable standards in claims handling;
- cases are actively managed by skilled claims managers employed by the NHSLA: the previous more passive relationship between individual NHS bodies and (often) local firms of solicitors has gone;
- the emphasis has been placed on settlement where there is liability;
- the considerable bargaining power of the NHS has been used so that costs paid to defence solicitors have been controlled;
- incentives have been created to enhance patient safety and reduce risk;
- training for local claims managers has been introduced;
- NHS Trusts have been encouraged to offer apologies and provide explanations (see below);
- schemes to fast track claims and develop the use of mediation have been piloted.

### Apologies and Explanations

“The NHS Litigation Authority will not decline indemnity or take any point against a member on the basis of an apology, explanation or expression of sympathy made in good faith.

**Apologies**

It seems to us that it is both natural and desirable for those involved in treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient’s relatives and to express sorrow or regret at the outcome. Such expressions of regret would not normally constitute an admission of liability, either in part or in full, and it is not our policy to prohibit them, nor to dispute any payment, under any scheme, solely on the grounds of such an expression of regret.

**Explanations**

Patients and their relatives increasingly ask for detailed explanations of what led to adverse outcomes. In this respect they are no different from their equivalents in any other field. Closely linked to this desire for information is the frequently expressed view that they will feel some consolation if lessons have been learned for the future.”

_NHS Litigation Authority Circular 02/2002_
Historic picture of clinical negligence claims: numbers and costs

28. To obtain a comprehensive picture of the trends in claims and compensation paid for clinical negligence, even over the past two decades, has not proved possible. Comprehensive information on the number of claims and their costs has not historically been collected centrally by the NHS. Prior to the introduction of NHS Indemnity, cases were handled and costs met by the Medical Defence Organisations. Subsequently, cases were handled at the local NHS Trust level (for hospital cases) and by the Medical Defence Organisations (for primary care). The best available information relates to claims arising from incidents since 1995 and handled by the NHSLA.

29. To supplement this and inform this report, research was commissioned to seek further information for all NHS Trusts. Whilst the aim was to take stock of all claims received in each year since 1995, together with information on settled claims, it became apparent that in many NHS Trusts basic information on claims was not kept in a readily accessible or consistent format. Data analysed in this section therefore provide only a partial picture. More comprehensive information will, in due course, be available on claims from April 2002 onwards when the NHSLA took over the handling of all claims.

30. In the late 1970s it was estimated that there were around 700 claims against doctors, dentists and pharmacists each year (representing 0.2% of all personal injury claims). Information published by the Medical Protection Society and Medical Defence Union in the late 1980s suggested that claims doubled in the period 1983 to 1987 (from 1,000 to 2,000) and that the average value of damages also more than doubled.

31. Data on the claims handled by the NHSLA show a nearly fifteen-fold increase in the number of claims for medical injury arising after 1 April 1995, from 392 in 1996/97 to 5,765 in 2002/03. These figures do not include older claims handled under the Existing Liabilities Scheme nor claims handled solely by NHS Trusts (i.e. below their ‘excess’ level).

32. As an indication of the current volume of claims, the NHSLA received a total of 6,797 claims under both the Existing Liabilities Scheme and the Clinical Negligence Scheme for Trusts in 2002/2003. There appear to have been slight reductions in 2001/02 and 2002/2003 but it is too soon to say whether this is the start of a downward trend. This is in line with recent reductions in the number of cases approved for Legal Aid as reported by the Legal Services Commission (LSC).
33. Medical negligence represents a small proportion of all the personal injury claims reported to the Compensation Recovery Unit, at less than 1.5% in 2001/02. This compares with an estimated 0.2% at the end of the 1970s. While the number of claims remain small, proportionate to the number of patients treated each year and the overall number of personal injury claims, each claim represents a harmed and dissatisfied patient and the cost to the NHS is significant.
34. Recent information from the NHSLA suggests that 60 to 70% of claims do not proceed beyond initial contact with a solicitor or perhaps disclosure of medical records. Of those that do proceed, 95% of the claims settled by the NHSLA to September 2002 were settled out of court. Of those that went to court, the claimant received damages in 78% of cases, though these cases include many which only related to the size of the award (the ‘quantum’) – ie the claimant was bound to be awarded something.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abandoned by claimant</td>
<td>7,527</td>
<td>28</td>
</tr>
<tr>
<td>Settled out of court</td>
<td>12,469</td>
<td>47</td>
</tr>
<tr>
<td>Fought in court and won by claimant</td>
<td>489</td>
<td>2</td>
</tr>
<tr>
<td>Fought in court and won by NHS</td>
<td>138</td>
<td>1</td>
</tr>
<tr>
<td>Yet to settle</td>
<td>5,751</td>
<td>22</td>
</tr>
<tr>
<td><strong>Total (‘files opened’)</strong></td>
<td>26,374</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: NHSLA database 1995 to 2002

Note: These data are for actual claims reported under all schemes, above excess levels. The analysis does not include cases investigated but not proceeded with as a claim.

35. Figures for total NHS expenditure on clinical negligence (including compensation costs and defence costs) are not generally available prior to 1996/97. The estimated annual value of compensation in 1974/75 was £1 million, whilst a special survey undertaken by the Department of Health provided a figure of £53.2 million for expenditure specifically on clinical negligence at the beginning of the 1990s. By the beginning of the 21st Century this had increased to approximately £400 million.

<table>
<thead>
<tr>
<th>Year</th>
<th>Expenditure (Cash)</th>
<th>2002 prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>1974/75</td>
<td>£1m</td>
<td>£6.33m</td>
</tr>
<tr>
<td>1990/01</td>
<td>£53.2m</td>
<td>£74.5m</td>
</tr>
<tr>
<td>1996/97</td>
<td>£235m</td>
<td>£273m</td>
</tr>
<tr>
<td>1997/98</td>
<td>£144m</td>
<td>£162m</td>
</tr>
<tr>
<td>1998/99</td>
<td>£221m</td>
<td>£242m</td>
</tr>
<tr>
<td>1999/2000</td>
<td>£373m</td>
<td>£399m</td>
</tr>
<tr>
<td>2000/01</td>
<td>£415m</td>
<td>£434m</td>
</tr>
<tr>
<td>2001/02</td>
<td>£446m</td>
<td>£446m</td>
</tr>
</tbody>
</table>

The growth in group actions

36. Increasingly, claims against the NHS which affect large numbers of patients are being co-ordinated by claimants’ representatives through Group Litigation Orders. Group Litigation Orders can be made wherever there are a number of claims which raise common or related issues of law or fact. The question at issue can then be addressed once by the courts and should produce economies for both claimants and defence. However, the process can sometimes be used by lawyers orchestrating group claims to bring publicity to their cases before the scale of any harm or wrongdoing has been assessed objectively.

37. The cost of group actions can be high. Many of the group actions raise novel or complicated questions of law or fact and this may lead the courts to award higher remuneration per hour than usual to the solicitors involved. Group litigation may involve costs which appear disproportionate to the damages available to any one claimant within the group.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Approximate number of potential claimants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retention of Organs and Tissues following Post-Mortem Examination</td>
<td>2,900</td>
</tr>
<tr>
<td>Bristol children’s heart surgery service failure</td>
<td>225</td>
</tr>
<tr>
<td>Use of unsterilised instruments</td>
<td>214</td>
</tr>
<tr>
<td>Early failure of replacement hips</td>
<td>190</td>
</tr>
<tr>
<td>Mis-diagnosis of Down’s syndrome</td>
<td>154</td>
</tr>
<tr>
<td>Use of LSD for therapy</td>
<td>133</td>
</tr>
<tr>
<td>Under-dosage of radiotherapy for cancer treatments</td>
<td>132</td>
</tr>
<tr>
<td>Delay in diagnosis of invasive cervical cancer</td>
<td>121</td>
</tr>
<tr>
<td>Indecent assault against female patients</td>
<td>50–100</td>
</tr>
<tr>
<td>Misinterpreted breast screening results</td>
<td>79</td>
</tr>
<tr>
<td>Prescription of anti-convulsant drugs to epileptic women in pregnancy</td>
<td>72</td>
</tr>
<tr>
<td>Wrong diagnoses of epilepsy</td>
<td>70</td>
</tr>
</tbody>
</table>

*Source: NHS Litigation Authority*
38. Group actions can generate significant fees for the solicitors and barristers involved. The earning potential for claimants’ lawyers is significant at limited risk to themselves as even if they lose they are guaranteed Legal Aid rate fees. A number of legal firms now specialise in this type of litigation and regularly advertise their services over a wide area. However, it may be that fewer group actions will be funded in the future as the LSC now has the power to fund an individual case to test an issue of general principle and refuse funding for all other cases until the issue is resolved.

Primary care

39. Data on clinical negligence litigation in primary care and the private sector are not routinely published. Data available from one of the indemnifiers, the Medical Protection Society, suggest a relatively low number of claims which proceed against general practitioners: between 400 and 500 per year for the past five years.
40. The indemnity costs have shown a similar rise over the past decade to that in NHS hospital claims from under £2 million in 1992 to £15 million in 2001.

![Payments made of claims against general practitioners](image)

*Source: Medical Protection Society*

41. The largest general practice settlement reported by the Medical Protection Society (£2.9 million) was to a diabetic mother whose premature labour resulted in a brain damaged baby. The second and third highest (each approximately £2.3 million) resulted from failures of diagnosis in cases of meningitis leading to irreversible brain damage, reflecting the fact that delayed or misdiagnosis is the largest cause of claims in primary care.

![Medical Defence Union Claims](image)

*Source: Medical Defence Union*
The private medical sector

42. Comprehensive data on the nature of claims in private practice is not available. However, the number of claims by specialty can be expected to show a similar distribution to NHS hospital practice, for example in that obstetrics is a high-risk field. This is reflected in the rates of subscriptions to the medical defence organisations. However, information on the size of awards in the private sector for settlements out of court are not available.

43. Published analyses of litigation in private practice give some insight into the nature and risk of the injuries sustained. For example, in orthopaedic surgery (which slightly exceeded obstetrics in claims settled) the Medical Defence Union paid out £16.6 million in compensation over a 10-year period on 192 claims.

44. The largest settlement (£1.3 million) was paid to a man in his thirties who suffered permanent damage to the nervous system after an operation for a slipped disc. A substantial proportion of settlements were for wrong-site surgery. Such cases often arose through incorrect marking of the operation site, because of poor communication within the clinical team.

Anatomical distribution of settled claims relating to orthopaedics
(in private health care)


45. One published study has combined NHS claims data with that of the private sector to focus on vascular surgery. The majority involved the treatment of varicose veins. Indeed, this category exceeded any other in general and vascular surgical practice. The authors concluded that the likely cause of most claims was failure to advise patients about potential risks and expected benefits of the treatment concerned.
The size of clinical negligence awards is increasing

46. Not only are more people now making claims but the size of awards is also increasing, although the last two years has seen the number fall. The average monetary value of settlements and the maximum paid out in any year have both risen.

### Claims relating to the treatment of varicose veins in the NHS and private hospital sector

<table>
<thead>
<tr>
<th>Cause</th>
<th>Number of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nerve damage</td>
<td>76</td>
<td>31.2</td>
</tr>
<tr>
<td>Incorrect or unsatisfactory surgery</td>
<td>36</td>
<td>14.8</td>
</tr>
<tr>
<td>Discoloration and scarring</td>
<td>21</td>
<td>8.6</td>
</tr>
<tr>
<td>Femoral vein damage</td>
<td>16</td>
<td>6.6</td>
</tr>
<tr>
<td>Infection</td>
<td>15</td>
<td>6.1</td>
</tr>
<tr>
<td>Femoral artery damage</td>
<td>13</td>
<td>5.3</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>11</td>
<td>4.5</td>
</tr>
<tr>
<td>Tourniquet damage</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>51</td>
<td>20.9</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>244</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>


### Trends in value of awards

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Average Award £</th>
<th>Maximum Award £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid 1970s</td>
<td>1,454</td>
<td>16,500</td>
</tr>
<tr>
<td>Mid 1980s</td>
<td>10,827</td>
<td>475,000</td>
</tr>
<tr>
<td>Mid 1990s</td>
<td>111,595*</td>
<td>2,347,115</td>
</tr>
<tr>
<td>2002</td>
<td>259,038*</td>
<td>12,000,000</td>
</tr>
</tbody>
</table>

1990s and 2002 – NHS Litigation Authority
*figures exclude claims with zero damages
Further developments have or will lead to further increases in the size of compensation awards:

- **Reductions in the discount rate**

  Large awards for future care costs are subject to an adjustment (the ‘discount’) to take account of the income a claimant can earn when the lump sum awarded is invested. Until 1998, the discount rate was 4.5% (i.e. it was assumed that this was the average interest over time that the claimant could expect to earn on the invested lump sum). In 1998 the discount rate was reduced to 3% following a House of Lords judgment in the case of Wells v Wells. The Lord Chancellor then used his powers under the Damages Act 1996 to set a new discount rate of 2.5% in June 2001. This was needed to ensure the value of payments to victims, in some cases for many years ahead. However, this lower discount rate had an instant effect on the NHS of increasing the size of any lump sum awarded as it assumes the claimant will earn a lower return on his or her investment.

<p>| Impact of changes to the discount rate imposed on lump sum payments for clinical negligence |</p>
<table>
<thead>
<tr>
<th>Discount Rate</th>
<th>Time Period</th>
<th>Effect on a test case (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5%</td>
<td>Before 1998</td>
<td>902,800</td>
</tr>
<tr>
<td>3.0%</td>
<td>After 1998 (House of Lords Ruling)</td>
<td>1,036,700</td>
</tr>
<tr>
<td>2.5%</td>
<td>After 2001 (Lord Chancellor’s decision)</td>
<td>1,086,900</td>
</tr>
</tbody>
</table>

Increased costs to the NHS as a result of the change in the discount rate are estimated at £20 million in 2001/02 and £500 million for future liabilities.

- **Compensation for pain and suffering**

  The majority of larger value claims include an element of compensation for pain and suffering and loss of amenity. A Law Commission report, *Damages for Personal Injury* (published in December 1998), looked at whether awards of damages for non-pecuniary loss in personal injury cases – i.e. the pain and suffering element – were being made at satisfactory levels. The conclusion was that awards were too low in cases of serious personal injury and should be increased by between 50 and 100 percent. In November 1999 the Government announced that this was an area of law which was for the courts to determine and where the Government had no plans to legislate. Subsequently, in 2000, in the case of Heil v Rankin, the Court of Appeal looked at a number of personal injury cases awaiting appeal, including clinical negligence cases, in order to set new rates of compensation for non-pecuniary loss. The effect of this judgment was to increase the highest levels of award for pain and suffering by one third from £150,000 previously to an expected £200,000 now. Awards for pain and suffering below £10,000
were not increased but there would be a tapered increase for injuries falling between £10,000 and the highest awards. The impact of this judgment in costs to the NHS is estimated as £74 million in future liabilities.

- **Increasing costs of carers**

  The Working Time Directive restricts the working week to 48 hours. More carers will therefore now be needed to provide care, sometimes for 24 hours a day, seven days a week. Increases in employers’ National Insurance contributions and employers’ liability insurance will also increase the costs of long term care.

**Cost to the public purse of clinical negligence**

48. Clinical negligence claims are the only major area of personal injury law for which Legal Aid is still available. In all, nearly 90% of clinical negligence cases receive Legal Aid. To qualify for Legal Aid, the claimant must meet financial eligibility criteria and in some circumstances agree to contribute to the legal costs. Although full funding is only available for those on Income Support, just under half the population are eligible on income grounds for some Legal Aid. In addition, the Legal Services Commission (LSC) must satisfy itself that the merits of the case justify the grant of public funding. Broadly speaking, the test is designed to measure whether, taking all the circumstances into account, a privately paying client of moderate means would be prepared to spend his or her own money on taking the case. The Commission must consider the prospects of success and also the possible benefits of litigation and where possible compare them to the likely costs. Specifically:

- if the prospects of success are very good (80% or more), likely damages must exceed costs;
- if the prospects of success are good (60 to 80%) likely damages must exceed likely costs by a ratio of at least 1.5:1;
- if the prospects of success are moderate (50% to 60%), likely damages must exceed likely costs by a ratio of at least 2:1.

49. Under the current arrangements the aim is to achieve a balance between refusing funding where there is little or no hope of success, and over-cautiously depriving litigants who may have cases from pursuing them.

50. In cases valued at less than £10,000, assistance with investigation may be refused if the LSC believes that it is more appropriate for the claimant to pursue the NHS complaints procedure.
51. Of the clinical negligence cases which concluded in 2001/2002, 53% of cases were not funded beyond initial investigation. Of those that proceeded to litigation 57% were successful. Success rates have improved in comparison with earlier years, although, because many cases take several years to conclude, most of these cases were started before the LSC introduced major reforms in funding in 1999. The full impact of these reforms has yet to work through in concluded cases.

<table>
<thead>
<tr>
<th>Year</th>
<th>Cases proceeding beyond investigative stage (%)</th>
<th>Success rate in litigation of those proceeding beyond investigation (%)</th>
<th>Success rate of all cases granted Legal Aid (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996/97</td>
<td>49</td>
<td>46</td>
<td>23</td>
</tr>
<tr>
<td>1999/00</td>
<td>40</td>
<td>61</td>
<td>24</td>
</tr>
<tr>
<td>2000/01</td>
<td>41</td>
<td>57</td>
<td>24</td>
</tr>
<tr>
<td>2001/02</td>
<td>47</td>
<td>57</td>
<td>27</td>
</tr>
</tbody>
</table>

Source: Legal Services Commission

52. While the total cost to the NHS in 2001/02 of clinical negligence litigation was £446m, the total cost to the public purse, taking into account Legal Aid paid to patients and families, was £477.9 million.

<table>
<thead>
<tr>
<th>Annual costs of compensating medical injury from public funds</th>
<th>Cost (£ million)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal Aid for patients and families</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>Clinical Negligence Scheme for Trusts (post April 95 cases)</td>
<td>83</td>
<td>17.4</td>
</tr>
<tr>
<td>Ex-Regional Health Authorities</td>
<td>4</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Existing Liabilities Scheme</td>
<td>343</td>
<td>71.7</td>
</tr>
<tr>
<td>NHS Trust payments</td>
<td>16</td>
<td>3.4</td>
</tr>
<tr>
<td>NHS Litigation Authority costs</td>
<td>7.9</td>
<td>1.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>477.9</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

Source: NHS audited accounts 2001/02, NHSLA Annual Report 2001/02, Legal Services Commission Survey of Legal Aid
The relationship between claimant and defence costs

53. The costs in a clinical negligence case will include the fees of the solicitor and the barrister dealing with the case, and any expert(s) advising on issues of negligence, causation and the level of damages needed to meet the claim for loss and future care (‘quantum’). Costs are usually awarded against the losing party. However, although there is provision for the NHS, if successful against a legally aided claimant, to recover its costs, either from the loser or from the Legal Aid Fund, the circumstances in which a court may make such an order are limited and in practice it is very rare. Therefore even in cases which the NHS successfully defends, it will find it very difficult to recover its costs, where the claimant’s case has been publicly funded.

54. Overall, claimants’ costs outweigh defence costs. For the newer claims (i.e. arising from post-1995 injuries) claimants’ costs were nearly 85% higher than the defendants’ costs. The NHSLA has capped the fees payable to the defence lawyers at a level considerably below claimant lawyers’ costs, which the NHSLA reports may average £300 per hour. This will have had some impact. However claimants’ costs, particularly for the older cases, will always be likely to exceed defendants’ costs as they have to commission and chase medical reports and have to prove their case. It must also be remembered that in unsuccessful cases claimant lawyers will be limited to the rates paid by the Legal Services Commission (LSC) which may be fixed by regulation or contract to as little as £70 per hour.

| Relative size of claimants’ and defendants’ legal costs in medical litigation cases |
|---------------------------------|-----------------|-----------------|-----------------|
|                                 | Claimant costs (£m) | Defendants’ costs (£m) | % by which claimants’ costs were higher |
| Pre-1995 injuries              | 10.1             | 5.8              | 74.1            |
| Post-1995 injuries             | 9.6              | 5.2              | 84.6            |

Source: NHS Litigation Authority. Data relate to financial year 2002/2003 and claims closed with an award.

55. The legal and administrative costs of settling claims exceeded the money actually paid to the claimant in the majority of claims under £45,000 and took up an even higher proportion of the total amount paid out in the smaller claims. This underpins the fact that many clinical negligence cases are complex, time consuming and involve a core minimum of work to reach the same stage in a claim. Inevitably the proportion of costs to damages falls as the level of damages rises. Reforms introduced by the then Lord Chancellor’s Department and LSC to limit clinical negligence contracts to specialist panels of lawyers will help ensure the effective management of cases and this is expected to bring a reduction in costs in the longer term.
The potential costs of a case influence the ability of patients or families to bring a claim for clinical negligence. The highest proportion of people pursuing a claim is in relatively low- or high-income households. Claimants on a low to moderate income may be eligible for Legal Aid. Those with high incomes may be able to support their own case. Those with middle incomes may have less access to justice as they are unable or unwilling to risk their own money in pursuing a case, even where partial funding is available through Legal Aid. 'Before the event' legal expenses insurance may be available relatively cheaply, for example as an adjunct to a home insurance policy. However, relatively few people are aware of the availability of this insurance and that it often includes cover for legal costs in clinical negligence claims up to a typical indemnity of £25,000 to £50,000.

<table>
<thead>
<tr>
<th>Value range of claim</th>
<th>Percentage costing more to settle than the size of the award</th>
</tr>
</thead>
<tbody>
<tr>
<td>10,000 – 15,000</td>
<td>78</td>
</tr>
<tr>
<td>15,000 – 20,000</td>
<td>76</td>
</tr>
<tr>
<td>20,000 – 25,000</td>
<td>74</td>
</tr>
<tr>
<td>25,000 – 30,000</td>
<td>66</td>
</tr>
<tr>
<td>30,000 – 35,000</td>
<td>57</td>
</tr>
<tr>
<td>35,000 – 40,000</td>
<td>48</td>
</tr>
<tr>
<td>40,000 – 45,000</td>
<td>61</td>
</tr>
<tr>
<td>45,000 – 50,000</td>
<td>39</td>
</tr>
<tr>
<td>Over £50,000</td>
<td>18</td>
</tr>
</tbody>
</table>

57. A large number of personal injury claims other than clinical negligence are funded by conditional fee arrangements (CFA) – usually referred to as ‘no win, no fee’. These are often backed up by ‘after the event’ insurance policies to cover the costs of the other party if the case is lost. After the event insurance is also available that covers both sides’ costs where there is no CFA. However, there has so far been little take up of CFAs and insurance-backed products in the field of clinical negligence. This is partly because the availability of such insurance is in practice limited. It is also very expensive – reflecting the high degree of uncertainty and complexity in clinical negligence cases and the fact that Legal Aid is still available in clinical negligence cases. To encourage lawyers to use conditional fee arrangements and to make justice more accessible to middle income claimants, the Lord Chancellor’s Department made it possible for claimants’ solicitors’ to charge up to 100 per cent uplift on their basic fees if they win and to make ‘success fees’ and after the event insurance premiums recoverable from the losing side. Defendants as well as claimants can use conditional fee arrangements and they are therefore available to the NHSLA’s solicitors as a means of running those cases it believes have a serious defence.
Future NHS liability for clinical negligence

58. A patient or family usually has three years from when they discover they have suffered harm from treatment to bring a claim, although this period can be extended at the discretion of the court. For children, the three years begins once they are aged 18 years. Unless the disability ends, claimants with a mental disability effectively have an unlimited time in which to bring the claim (or have it brought on their behalf). It can therefore be some time between the date of an incident and a claim being received, particularly in the case of cerebral palsy where it may be some years before the full extent of a child’s injuries or care needs are known.

59. It is important for the NHS to understand what the potential backlog of claims might be both numerically and in value. The National Audit Office (NAO) estimated on the basis of a sample of 71 NHS Trusts that there were some 23,000 claims outstanding at the end of March 2000. Its estimate of the value of these claims, where there was a greater than 50% likelihood of the claim succeeding, was £4.4 billion. Estimates from research conducted for this report, based on a larger sample of 136 NHS Trusts, gave a broadly similar result. That reported just under 22,000 outstanding claims at April 2001, with an estimated value of nearly £5.6 billion. This liability would be incurred over a number of years if all the claims succeeded. At the end of 2001/02, the NAO reported that the NHS now expects to pay out for £5.25 billion in respect of known or expected claims.

<table>
<thead>
<tr>
<th>Incident year</th>
<th>Number of outstanding claims</th>
<th>Expected value (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 1990</td>
<td>2,673</td>
<td>1,713</td>
</tr>
<tr>
<td>1991</td>
<td>519</td>
<td>282</td>
</tr>
<tr>
<td>1992</td>
<td>655</td>
<td>304</td>
</tr>
<tr>
<td>1993</td>
<td>798</td>
<td>349</td>
</tr>
<tr>
<td>1994</td>
<td>984</td>
<td>378</td>
</tr>
<tr>
<td>1995</td>
<td>1,393</td>
<td>478</td>
</tr>
<tr>
<td>1996</td>
<td>1,323</td>
<td>432</td>
</tr>
<tr>
<td>1997</td>
<td>1,665</td>
<td>381</td>
</tr>
<tr>
<td>1998</td>
<td>2,545</td>
<td>445</td>
</tr>
<tr>
<td>1999</td>
<td>3,575</td>
<td>362</td>
</tr>
<tr>
<td>2000</td>
<td>3,378</td>
<td>315</td>
</tr>
<tr>
<td>2001</td>
<td>2,415</td>
<td>153</td>
</tr>
<tr>
<td>TOTAL</td>
<td>21,923</td>
<td>5,592</td>
</tr>
</tbody>
</table>

*Source: Survey of NHS Trusts commissioned for this report.*
Basis for financial compensation

60. The principles which are adopted in determining compensation for medical negligence are that the person should be compensated for:

- pain and suffering;
- past loss of earnings and costs of care;
- future loss of earnings and costs of care.

61. Medical negligence is more complicated than many other areas of personal injury because unlike those other areas, most people have had a prior health problem for which they were being treated as patients.

62. Thus, for a patient who suffers a catastrophic injury – say a young mother rendered paraplegic during neck surgery – the number of headings under which compensation is calculated is likely to be large and encompass for example:

- pain, suffering and loss of quality of life;
- costs of ‘round the clock’ domiciliary care;
- costs of physiotherapy and rehabilitation programmes;
- costs of domestic help;
- childcare costs;
- ongoing medical treatment costs;
- costs of future care;
- adaptation to accommodation;
- assistance technologies;
- loss of earnings;
- interest on the damages.

| Illustrative breakdown of lump sum payments for catastrophic injury based on a £3.5m claim |
|---------------------------------|--------|--------|
| Breakdown of award                | Cost (£) | Percentage |
| Pain, suffering, loss of amenity  | 185,000 | 5       |
| Loss of the ability to earn a living | 350,000 | 10      |
| Past and future care             | 2,965,000 | 85     |

63. The largest percentage of such awards reflects the past and future care costs. Common law precedent lays down the process for calculating these costs. Essentially, this involves a range of experts on each side assessing the different elements of care required and their costs, and life expectancy, to arrive at a total figure for the compensation required. In some more complex cases each side
may engage up to eight or nine experts to present views on the condition and prognosis, life expectancy, costs of care, speech therapy, occupational therapy, communication, housing and adaptation needs. It can lead to the distasteful spectacle of experts arguing about the expected life span of the victim in front of the person concerned and their family.

64. Compensation for clinical negligence is usually paid as a ‘once and for all’ lump sum. In large value cases this often has to be invested to cover the costs of care for the rest of the victim’s life or for the ongoing needs of their dependants. It is worth noting that funds in a trust established from a lump sum award and the capital value of annuities resulting from structured settlements annuities are not generally taken into account when assessing entitlement to future Social Security benefits. Income from the trust or annuity that is not intended and used for normal living expenses is also disregarded. This is to protect damages for care costs and other special needs. Although there are cases where a family inherits a large sum if the victim dies earlier than anticipated, our research has demonstrated that the main concern in cases of severe disability is that the money will run out.

65. The practice of making lump sum payments has long been contentious and has aroused critical comments in this country and abroad over many years.

“When it is determined that compensation is to be made, it is highly irrational to be tied to a lump-sum system and a once-and-for-all award. The lump sum award presents problems of the greatest importance. It is subject to inflation, it is subject to fluctuation of investment, income from it is subject to tax – yet our law of damages knows nothing of periodic payment.”

Justice Dickson, Supreme Court of Canada (1978)

66. The alternative to the lump sum is a structured settlement now becoming known as periodical payments. Structured settlements can be either “top-down” or “bottom-up” settlements. In a “top-down” settlement the claimant’s future losses, including costs of care and treatment, are quantified on the basis of an estimate of future need (as in a lump sum payment). Part of the lump sum is then used to purchase an annuity to provide payments each year to meet future losses. “Bottom-up” structured settlements enable the defendant to pay for future losses by periodical payments. This avoids argument about life expectancy and the uncertainties that involves. In the case of the NHS meeting the cost of settlements out of current expenditure, a payment is made each year for the agreed annual monetary value.

67. At present, periodical payments can only be ordered by the court with the agreement of both parties to the action. However legislation currently in passage through Parliament will enable the courts to order periodical payments without the consent of the parties.
CHAPTER 4

Perceptions of the Current System

1. Many commentators over the years have criticised the system of handling claims for clinical negligence.

Public attitudes and concerns

2. The community-based survey commissioned for this report asked those injured by their treatment what remedies they considered most appropriate. Nearly 60% of respondents wanted an apology, explanation or inquiry into the cause of the incident. Only 11% said that financial compensation was the most appropriate remedy. In the more serious events the proportion who simply wanted an apology or explanation fell to 15%, while the proportion looking for support in dealing with the consequences rose from 5% to 35%. The proportion who said financial compensation was the most appropriate remedy increased with the severity of the incident but did not rise above 15% in any severity category.

<table>
<thead>
<tr>
<th>Public’s Attitude to Medical Injury</th>
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<tbody>
<tr>
<td>A sample of the general public was interviewed. Of the nearly 5% who had been affected by medical injury, the main responses they wanted from the NHS were:</td>
</tr>
<tr>
<td>34% an apology or explanation</td>
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<tr>
<td>23% an enquiry into the causes</td>
</tr>
<tr>
<td>17% support in coping with the consequences</td>
</tr>
<tr>
<td>11% financial compensation</td>
</tr>
<tr>
<td>6% disciplinary action</td>
</tr>
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Source: MORI survey commissioned for this report, 2002

3. The respondents who reported having suffered injury after treatment were also asked about the amount of compensation which would have satisfied them. Nearly 70% said they were not seeking financial compensation. Of those suggesting a figure only 5% thought that compensation in excess of £50,000 would have been appropriate for their injury. Although these findings are
interesting it is important to extrapolate with care to any system in which compensation might be easier to obtain as nearly 20% of the sample said they had not sought compensation because they had not thought of it.

4. Criticisms and concerns raised by patients’ groups in response to the Department of Health’s *Call for Ideas* document (published in 2001, see Chapter 1) were primarily:

- the lack of explanations and apologies to patients or their families when things go wrong: even those who had received compensation were often no wiser about what had happened or why;
- the lack of reassurance or evidence that steps were being taken to prevent the same thing happening to someone else;
- the fact that the complaints process was halted if a claim was made;
- the adversarial nature of the process which contributed to the trauma for the patient or relatives;
- the perceived lack of independence in the process;
- the imbalance of knowledge between the patient and the defending NHS Trust and doctor;
- lack of advice and support to claimants;
- delay.

**Concerns of clinicians**

5. A great deal has been written and said by clinicians who have commented on the present system of clinical litigation in this country. Concerns expressed by the clinical (mainly medical) community fall into the following broad areas:

- adversarial procedures as in the tort system, which destroy the relationship between doctors and patients;
- the length of time to settle cases, meaning that the litigation was hanging over them and affecting their performance for some time;
- the damage to their professional reputation, whether they were found to be negligent or not: the fact of the case was sufficient for the damage to reputation and morale;
- the encouragement given by the current system to concealment and lack of frankness;
- the encouragement given by the current system to practise defensive medicine as seen in the USA.
Concerns of lawyers

6. During the course of this work, concerns raised by the legal profession, representing both claimant and defendant lawyers, were:
   - delay in the system acting as a barrier to resolving complaints and claims;
   - defensiveness of NHS staff and a culture of silence – often perceived as cover up;
   - the Human Rights Act enshrines the right of access to the courts and there must not be a ‘special law’ for NHS patients;
   - if the NHS introduced a system of no fault compensation denying patients the right to seek a remedy through tort, the compensation floodgates would be opened;
   - the adversarial nature of the process;
   - the lack of explanation or apology to the victim;
   - poor support for claimants and the barrier between complaints and claims;
   - the lack of systematic learning from adverse incidents;
   - lack of an adequate rehabilitation system which could make long-term care more effective and affordable.

Concerns about the NHS complaints system

7. A major subject of concern raised through the Call for Ideas responses and in the individual meetings I held with stakeholders was the NHS complaints procedure.

8. The current NHS complaints procedure is in transition. A formal complaints procedure has operated in the NHS since 1966 and this has been subject to a number of reviews over the years. Prior to 1996 there were three separate NHS complaints procedures in operation – one for complaints about primary care practitioners, one for clinical complaints and one for non-clinical complaints. There was major dissatisfaction with this fragmentation, as well as about the way the individual procedures operated. A major review was therefore undertaken in the mid-1990s. The conclusion of this process led by the Wilson Committee was that there should be a single NHS wide complaints procedure.

9. As a result, a new procedure was introduced to the NHS from 1996 and it is still in place. The key features of the procedure were:
   - a strong emphasis on local resolution of complaints;
   - when local resolution failed, investigation by an Independent Review Panel made up of NHS staff intended to take an independent view of the complaint;
   - referral to the Health Service Commissioner (Ombudsman) if the complainant remains dissatisfied.
10. Within this two-stage structure the process for dealing with complaints about primary care practitioners and hospital and community health services varies slightly. Practitioners deal with the first stage themselves, with complaints which are not resolved passing on to Primary Care Trusts to deal with the second stage.

11. At the time the 1996 system was implemented there was a commitment to an evaluation, once the procedure had bedded down, to see how well it had met its objectives. The evaluation took place in 1999/2000 and a report was submitted in March 2001. Following this, a listening exercise on reforming complaints ran alongside the Call for Ideas. Both exercises raised similar concerns about complaints.

12. The main issues raised by those with concerns about the complaints procedure were:

- as viewed by patients and their representatives, it lacks transparency, is insufficiently independent and too frequently fails to yield an apology or explanation for what went wrong;

- the Independent Review Panel was regarded by complainants as unsatisfactory. It was perceived as taking too long; lacking thoroughness in investigation and feedback; and being biased and unfair;

- the possibility of the complainant bringing a legal claim means that the complaints procedure must be halted with the result that some patients will never receive an apology or explanation;

- there is anecdotal evidence that many complainants resort to making legal claims as a result of their frustration with the complaints system. However, the fact that the complaints process is halted when a claim is made adds to complainants’ dissatisfaction;

- there is little systematic learning from complaints by the NHS either at local or national level;

- views were polarised on the pros and cons of merging the complaints and claims processes (which are currently entirely separate): some feel that it is a sensible, patient-friendly integration of two similar processes, others predict that the ‘conversion rate’ of complaints into claims would rocket.

13. The Government is committed to reforming the complaints procedure to make it more independent and responsive to patients’ needs. The Budget statement in April 2002 indicated that there would be independent scrutiny of complaints. It is proposed that the new Commission for Healthcare Audit and Inspection (CHAI), which will be independent of the NHS and Department of Health, will have independent scrutiny of complaints as one of its functions. It has also since been agreed that subject to legislation, CHAI will carry out the second stage of the procedure – an objective assessment of the complaint and how it should be resolved. This may include the Commission investigating complaints which have not been resolved at local level, or referring them
directly to the Ombudsman for consideration. This will bring the true independence which is lacking in the present ‘second stage’ of the NHS complaints procedure.

14. In the financial year 2000/1 there were nearly 33,000 written complaints relating to clinical treatment in NHS hospitals. Most of these were resolved at local level. In the same year there were 312 independent reviews of care given in a hospital or community care setting, though these will include some reviews of complaints not relating to clinical matters.

15. In the same year, there were 44,442 complaints made by patients treated in primary care, 35,000 of which were against general practitioners. There is little routinely available analysis of the detail of these complaints. However, the two main medical defence organisations have analysed data on the proportion of complaints that they became involved in, supporting their members.

16. This analysis by the medical defence organisations also provides a valuable insight into the number of complaints against general practitioners which result in claims for negligence. This ‘conversion rate’ is relatively small and has been between two and six percent over the last decade.

Reason for complaints made in primary care services where the complaint had led to medical defence organisation involvement

Source: Data are combined from Medical Defence Union and Medical Protection Society and relate to 1998
17. Those who argue in favour of combining the complaints and claims procedures point out that patients should have one point of entry when they have concerns about the standard of care received, and not be disadvantaged by having to find their way through the system. This would enable quicker and more local resolution of disputes without the need to go to court. It would also remove duplication in the investigation of complaints and claims. They also point out that what patients or their families want from either system is similar: a thorough investigation leading to explanations, apologies and assurances that action has been taken by the health service to prevent repetition. They also want the means to rectify the harm, either through further treatment or care or financial recompense. Those who disapprove of the integration of the two systems worry that it might encourage the seeking of compensation by those who would otherwise have been satisfied by the complaints procedure.

18. The survey of public attitudes undertaken for this report does confirm that on the whole people are seeking an explanation, an apology and a reassurance that the incident will not harm a future patient. However, there is a growth in the number of group actions assisted by specialist firms of lawyers and it is possible that this could increase the proportion of people who seek compensation.
Concerns about payment of compensation

Periodical Payments

19. At present the majority of compensation is paid by way of a lump sum. However concerns have been raised that this will almost inevitably over or under compensate claimants. For example, assessments of life expectancy on which the award is based are likely to be inaccurate and the claimant has to manage the investment of the lump sum to make it last for his or her lifetime. If the claimant lives longer than expected this can result in the money running out too soon; alternatively the claimant may die earlier than expected, from whatever cause, leaving a windfall for the family to inherit.

20. In reply to the Department of Health’s Call for Ideas the concept of periodical payments received widespread support (over 65% of respondents).

21. The advantages of periodical payments would be:

- that the claimant would be reassured that they could spend their income to meet their needs without worrying that they may run out of money at some future date;
- there would be no need for lawyers and clinicians to argue over life expectancy, which can be a cause of distress to claimants and their relatives;
- compensation will accurately meet needs, as there will be no requirement to guess life expectancy or future needs;
- the need for financial advice and the risk of investment will fall on the negligent party;
- for the NHS, budgeting would be more accurate for regular payments than single lump sums;
- cases could be settled more quickly as there would be no need to wait until the full care needs of the patient had been assessed before an agreement is reached (at present some cerebral palsy cases wait many years before they are assessed).
22. However, some concern was expressed that payments of this type might not be suitable in every case. Reasons for this were that they:

- can still require an ongoing relationship between the claimant and the organisation that has caused the injury;
- can be inflexible for claimants who wish to use their award for other purposes (the example given was of a claimant who wished to set up in business);
- require administration (so are not efficient for small amounts of compensation);
- can be problematic for claimants who wish to emigrate.

23. Concerns were also raised about the concept of reviewability in periodical payments. Some respondents felt that it could lead to ‘snooping’, that reviews could be both traumatic and costly and that they might introduce uncertainty into the system for the claimant or would be used as weapon by either side to harass the other.

24. Periodical payments apply only to future loss and care costs. A large proportion of clinical negligence cases are unlikely to include future care costs. However, future care costs form a large proportion of compensation payments where they are awarded – up to 85% of the largest claims. Typically these will be cerebral palsy cases and other major brain or physical injuries.

25. The then Lord Chancellor’s Department consulted on a new approach to payments for the costs of future loss and care costs in the consultation paper *Damages for Future Loss* (March 2002). Following on from an earlier consultation on the discount rate and the principle of structured settlements, *Damages for Future Loss* proposed that the courts should be given the power to order periodical payments for future loss and care costs in personal injury cases without the consent of the parties (at present, periodical payments or structured settlements can only be ordered by the court with the agreement of both parties to the action). It also sought views on various issues including whether there should be a presumption that periodical payments would be used in larger value cases, and whether periodical payments should be reviewable and if so, in what circumstances.

26. In large value clinical negligence cases settled by way of periodical payments, a guaranteed income stream would provide the future element of the award for losses and care costs. Past losses and the pain and suffering element of the award would still be paid as a lump sum.

27. The then Lord Chancellor’s Department published the post-consultation report on 7 November 2002, which indicated majority support for the courts having the power to order periodical payments and for the concept of review. On 28 November 2002, the Government introduced legislation in the House of Lords to implement the proposal to give the courts the power to impose periodical
payments orders for future loss and care costs in personal injury cases. Any courts awarding damages for future pecuniary loss in respect of personal injuries will be required to consider whether to make an order for periodical payments. Periodical payments could not be imposed in settlements negotiated by the NHSLA (93% of clinical negligence cases), although many obstetric claims where claimants are unable to handle their own affairs will require court approval, at which point the judge could intervene.

28. There are significant advantages to periodical payments. For claimants, there is the certainty that the payments will be made throughout their life at a guaranteed level. For the NHS there is the scope for more accurate budgeting for future payments. The expectation is that the courts will set the lead in imposing periodical payments in the majority of appropriate clinical negligence cases, and that claimants’ payments made as part of a settlement negotiated by the NHSLA will follow suit.

Concerns about payments to meet the cost of private health care

29. At present the care costs in all personal injury cases reflect the costs of private care. This dates from the inception of the NHS.

30. It has been suggested that claimants receiving an award often make use of NHS services to provide their care despite the award reflecting the cost of private treatment. If this is so, the NHS effectively pays twice for cases of clinical negligence. Research was undertaken on anonymised records of the Court of Protection to evaluate how awards in 40 cerebral palsy cases had been used. No evidence was found of the money not being spent on the range of care, therapy and other assistance identified as necessary at the time of the award. In addition most beneficiaries used the award sparingly to provide the care needed. To ensure that the money did not run out, many relied on interest from the lump sum to provide the care needed rather than the lump sum itself.

31. In the Call for Ideas, we asked for views on the possibility of removing the requirement to meet the costs of private care on the grounds that the NHS and Social Services provide many of the types of care and treatment those injured during treatment might need.

32. Concerns were expressed by claimant and patient groups that:

- it would be inequitable to remove the private care costs only from those suffering a medical injury;
- there is insufficient capacity in the NHS to provide care for everyone who might need care if the provision for private care costs was removed for all personal injury cases;
- they would not be able to access the range of treatments and care needed through the NHS;
they would not wish to have an ongoing relationship with the organisation which had injured them;

- rehabilitation services available to the NHS were inadequate to meet the need for either rapid and intensive or long term support.

33. So whilst there was considerable opposition to any move to change the basis of compensation within the current system, for those injured by NHS treatment it can be argued that the NHS itself should be under an obligation to put right the damage caused. Although money is now the traditional response, a comprehensive care package (i.e. ‘non-financial compensation’), promptly provided and efficiently delivered, is an obvious alternative. The NHS would often need to put together such a package of care from a variety of private sources. However, the obligation to organise high quality care, rather than simply pay the money, could lead to a better understanding of, and a sense of responsibility for, the long-term effects of an a medical injury on patients. This in turn could provide an incentive to initiating measures to prevent recurrences of the problem.

34. The possibility of the NHS putting together care packages for harmed patients sits well with the Government’s commitment to provide care from a number of sources for NHS patients. The same argument does not however apply to the bulk of personal injury cases. There is the potential for the NHS to be overwhelmed if it has to provide care for all personal injuries (e.g. road traffic accidents), however caused. And it can be argued that the insurance premiums through which most other compensation is funded are set at a level to cover the costs of private care for those harmed.

**Concerns about Compensation Recovery**

35. Before a claimant can receive compensation in a personal injury case, the Compensation Recovery Unit (CRU) of the Department for Work and Pensions must assess the amount of recoverable state benefits that the claimant may have received. This is so that a person who receives compensation in respect of an injury is not compensated twice, once by way of an award of damages and once by way of the State benefits system. However, the process for assessing the amount to be deducted from the compensation payment has been criticised as being slow and costly.

36. By law, the compensator – the person or organisation making a compensation award – must notify the CRU when a claim for compensation is made. The compensator must request a ‘certificate of recoverable benefits’ from the CRU before settling the claim. (Recoverable benefits are those benefits which have been claimed and paid as a consequence of the injury for which compensation is being awarded.) The CRU is required to issue the certificate of recoverable benefits within 28 days but the certificate may have to be updated a number of times in long-running cases. The compensator is required to pay the full amounts of the recoverable benefit to the CRU. He may offset some or all of the amount paid to the CRU against specified aspects of damages in the overall compensation award and pay the balance to the injured person.
37. The system has been criticised firstly, because it militates against settling low value claims quickly and secondly, particularly in the context of NHS medical negligence litigation, because it represents the movement of funds from one Government Department to another. However, to exempt cases where the compensator is a Government Department would mean accepting that double compensation would occur.

**Concerns about the absence of adequate rehabilitation services**

38. Research has shown that effective rehabilitation services for those who have suffered an injury can lead to shorter overall hospitalisations, hasten recovery and help prevent future disability. This is especially so where rehabilitation is provided at an early stage. This brings personal benefits to the injured party and also wider benefits to society. It is a concept that is used widely in other countries. For example, in New Zealand the medical accident/misadventure compensation system places obligations on the State to provide rehabilitation and on the patient to follow an agreed rehabilitation programme. The focus is on the return to health and work of the injured party.

39. In the context of clinical negligence cases, rehabilitation as an initial response to an adverse incident or as part of a package of remedies to a complaint or claim could hasten the recovery of the patient from the harm or injuries caused, or improve the long-term prognosis. The patient's quality of life can sometimes be improved immediately by speedy provision of adaptations, aids or treatment. Provision of rehabilitation could therefore potentially reduce the need for, or intensity of, long-term care and so the financial costs of the claim to the NHS. It might even remove the need for a claim in some cases.

40. Rehabilitation services are not new to the NHS, but dedicated rehabilitation capacity is not widely available. Rehabilitation services could play a more significant part in the response to adverse events in the NHS. However, the capacity will need to be developed. The Department of Health, with the NHSLA, is currently exploring the scope for a new approach to the immediate aftermath of adverse events which could give rise to a claim for negligence. An NHSLA pilot scheme in a small number of NHS Trusts will fund dedicated rehabilitation services to be provided immediately for major injuries arising from adverse events. The pilot has not yet started but its impact will merit close attention for its wider applicability. In addition, the development of rehabilitation services for a wider population is under consideration as part of the NHS Long Term Conditions National Service Framework.

**Previous reviews of the Negligence System**

41. Recurring concerns about the system of compensation for personal injury in general and clinical negligence in particular has triggered a number of reviews of aspects of the litigation process.
Pearson Commission

42. The Royal Commission on Civil Liability and Compensation for Personal Injury, sitting in the mid-1970s, resulted in the Pearson report in 1978. The Pearson Commission undertook a wide-ranging review of the arrangements for providing compensation for injuries in a number of fields including medical negligence, employment and transport. It particularly examined the case for no fault compensation. The Commission considered that social security benefits and services such as those provided by the NHS were the most important source of compensation. It concluded that compensation paid through tort should continue as a supplement to the social security system, but that social security benefits should be offset against tort awards (as in the system now operated by the Compensation Recovery Unit). No fault compensation schemes were not generally recommended in the report.


43. In 1994 Lord Woolf, Master of the Rolls was asked by the Lord Chancellor to undertake a review of the civil justice system. He considered the current system:

- too expensive – with costs often exceeding the value of the claim;
- too slow in bringing cases to a conclusion;
- too unequal with an imbalance between a powerful wealthy litigant and an under-resourced one;
- too uncertain both about potential costs and the length of time a case will take leading to fear of the unknown for claimants;
- incomprehensible to many litigants;
- too fragmented in that there was no-one with the clear overall responsibility for the administration of civil justice;
- too adversarial, with the rules of the court being ignored by the parties.

44. In Access to Justice 1996, the report arising from Lord Woolf’s Inquiry, particular attention was drawn to problems in the area of medical negligence:

- disproportionate costs in comparison with damages, especially in lower value cases;
- the general delay seen in resolving all cases was regarded as even more unacceptable in this area;
- cases without merit were often pursued and clear-cut claims defended for too long;
- the success rate was lower than in other areas of personal injury litigation;
- the suspicion between parties was more intense and the lack of co-operation greater than in many other areas of litigation.
45. Lord Woolf also drew attention to the difficulty for claimants other than those receiving Legal Aid to pursue claims because of the costs of medical litigation. The problem of proving both causation and negligence was seen as accounting for much of the excessive cost but the mutual suspicion and defensiveness in this area of litigation was identified as the root of the problem.

**National Audit Office Study**

46. In 2001, The National Audit Office (NAO) published its Report “Handling Clinical Negligence claims in England”, concentrating on claims arising from incidents prior to 1995. The NAO study had been prompted by concerns, including those expressed by Lord Woolf (and by the Public Accounts Committee in its 5th Report (session 1999-2000)), about the lack of publicly available information on claims and whether the system for dealing with clinical negligence was as cost effective, quick, efficient and humane as it should be. The Report examined the number of claims, the potential costs of settling them and the time taken to settle. It also provided some insight into patients’ access to remedies other than money; and the processes involved in managing and settling claims. The NAO study concentrated on Existing Liabilities Scheme cases, which are by definition the older and often more complex cases. The report highlighted:

- the lack of publicly available information on claims;
- concerns about the scale of the current and likely future costs of settling clinical negligence claims;
- the disproportionate costs of low value claims;
- poor handling of claims in the past, leading to delays and additional costs;
- the additional distress, both to patients or relatives making claims and to clinicians accused of negligence, when there is delay in resolving claims;
- the exclusion from access to the legal process for people who do not either qualify for Legal Aid or have significant personal resources;
- the lack of a package of measures to meet claimants’ needs.

47. The NAO made a number of recommendations, which were accepted by the Department of Health and the then Lord Chancellor's Department. The recommendations included that:

- the NHSLA should draw up an action plan to address claims that have been open more than five years;
- the LSC should monitor the progress of cases over five years old and take steps to bring them to a timely conclusion;
- the NHSLA and LSC should hold regular meetings to consider general concerns in concluding cases;
● the Department of Health should give clear guidance to NHS Trusts on what information they may give to patients who have suffered adverse incidents, including those who have suffered negligent harm;

● the Department of Health, the then Lord Chancellor’s Department and the LSC should further investigate ways of satisfactorily resolving small and medium sized claims;

● in considering any reorganisation of claims handling by NHS Trusts, the Department of Health should take into account not just cost, but also how to provide NHS Trusts with financial and other incentives to reduce incidents that lead to claims and how best to deliver those functions that need to be carried out locally;

● the NHSLA and LSC should each develop quantified measures of performance for the solicitors they instruct or fund and incorporate these into selection procedures, contracts and monitoring arrangements.

48. The action taken in response to those recommendations is set out in Chapter 5.
Recent Reforms and Changes

1. The system of litigation for clinical negligence is not static. Reforms to improve the legal system have been introduced, others have been proposed or are being planned. The NHSLA as the central agency responsible for handling claims against NHS hospitals has introduced a range of improvements to claims handling since it was established in 1995. There are other factors which have had a bearing on the handling of clinical negligence claims and the resulting payments made.

2. The implications of these reforms and changes are reviewed in this chapter.

Civil Justice Reforms

3. The aim of Lord Woolf’s proposals (described in detail in the previous chapter) was to: put greater emphasis on settlement of claims and make litigation less adversarial; to make litigation costs more predictable and proportionate to the value and complexity of the case; and to provide shorter, more certain timescales for litigation. One whole chapter of Lord Woolf’s report specifically focussed on medical negligence litigation and was highly critical of the status quo. His wider recommendations applicable to all civil litigation included:

- the introduction of Pre-Action Protocols to set down rules about how the early stages of a dispute should be run before it came to court and sanctions if the rules were not met;
- enabling claimants as well as defendants to make offers to settle (known as ‘Part 36’ offers);
- increased use of single joint experts (i.e. one expert appointed to advise both ‘sides’);
- an increased role for the courts in managing cases so that cases would be allocated to one of three tracks: small claims (eventually set at up to £5,000); Fast Track (up to £15,000, trial of one day or less within 20-30 weeks) and Multi-track for larger and more complex cases. The aim was for the court process more accurately to reflect the relative value and complexity of the case (the limit for personal injury claims in the small claims track is £1,000).
Clinical negligence claims are usually excluded from the Fast Track as they are regarded as too complex;

- encouragement of Alternative Dispute Resolution (ADR) – such as mediation – so that disputes are resolved wherever possible without recourse to the courts.

Reforms to Personal Injury Civil Litigation proposed by Lord Woolf

- Pre-action protocols
- Part 36 offers (to enable claimants to make offers to settle)
- Use of single joint experts
- Case management allocating cases to:
  - small claims track (up to £5,000)
  - fast track (up to £15,000)
  - multi-track (over £15,000 or complex)
- Alternative Dispute Resolution


4. His specific recommendations relating to clinical negligence were:

- training for health professionals in the legal context of their work;
- the General Medical Council and other regulatory bodies should clarify the responsibility of healthcare professionals to their patients when they discover possible negligence in their care and treatment;
- hospital record systems should be improved to help trace former hospital staff;
- a pre-litigation protocol for medical negligence cases should be developed;
- ADR should be encouraged in medical negligence, especially for smaller claims;
- medical negligence cases should be handled by specialist judges or in specially designated court centres;
- there should be special training in medical issues for judges;
- standard tables for calculating damages should be used wherever possible to reduce the cost of quantifying complex medical negligence (and other personal injury) claims;
- the Court Service should facilitate a pilot study of the various options for dealing with medical negligence claims below £10,000.
Implementation of Access to Justice

5. Lord Woolf sought to create reforms to the civil justice system so that it is fair to litigants, just in the result it delivers, understandable to those who use it, and has procedures and costs proportionate to the issues involved. Implementation of the reforms commenced in April 1999. The then Lord Chancellor’s Department’s evaluation of the Civil Justice Reforms showed evidence of fewer claims being settled at the door of the court and more being settled before the day of hearing. Generally 90% of personal injury claims do not now reach court. The figure for clinical negligence is even higher. Research and evaluation to date have found that protocols and Part 36 arrangements are working well and having the desired effect. All this supports the view that the improvements Lord Woolf proposed are speeding up the handling of claims by the legal system.

6. There is other evidence too, that the Woolf reforms are making an impact, for example:

- the clinical disputes Pre-Action Protocol came into force on 26 April 1999. A survey of members of the Association of Personal Injury Lawyers (APIL) showed that 48% felt that earlier settlement had been reached and 33% of cases avoided litigation as a result;
- anecdotal evidence suggests that clinical negligence claimant solicitors have welcomed Part 36 offers (introduced in 1999) and use them regularly;
- slightly fewer cases now involve an expert instructed by only one party: 25% in 1997, 22% in 2000 (Lord Chancellor’s Department Report Emerging Findings 2001).

7. As far as implementation of the recommendations made specifically in the area of clinical negligence is concerned:

- there are still relatively few cases using ADR in the clinical negligence area as in other types of cases. However, the numbers are increasing – for example, in the first year of the NHSLA’s mediation initiative there were only nine mediations, in the second year 34 mediations took place;
- the GMC publication *Good Medical Practice* requires that when a patient has suffered serious harm, the doctor should explain what has happened and act to put matters right where possible;
- work is in hand within the Department of Health to ensure that the NHS is more readily able to trace and identify relevant staff when claims arise many years after incidents have occurred;
- a Pre-Action Protocol was developed and issued by the Clinical Disputes Forum in 1998 setting out how the new arrangements for case handling should operate for clinical negligence disputes (this was one of the first areas in which pre-action protocols were introduced and pre-dated their formal introduction);
the Judicial Studies Board Guidelines provide more standardised valuations for many injuries to help ensure more consistency in award levels.

**Action by the NHS Litigation Authority to improve claims handling**

8. When the NHS Litigation Authority (NHSLA) came into being in 1995 it did so with a remit to improve the way in which claims were handled in the NHS at the time. Concern was particularly focused on delay, disproportionate legal costs, variable standards of handling claims at local level, and the acrimonious and confrontational climate in which the process of medical litigation took place. These issues were discussed in the previous chapter.

9. The fact that the NHS placed its overall management of clinical negligence litigation in the hands of a national agency created a significant opportunity for improvement.

10. The development of the role of the NHSLA has taken place alongside the Woolf reforms. The NHSLA has tried to work to promote Lord Woolf’s proposals where it has the scope directly to do so.

11. The key strategies that the NHSLA has introduced to bring about improvement are:

- more expert handling of claims using in-house specialised claims handlers and solicitors from its expert panel of solicitors: as a result, a realistic assessment of the strength of the case is made at an early stage;

- liability admitted earlier where this is appropriate and only those claims that are truly defensible are fought; as a result cases are settled more quickly. New (CNST) cases now take on average 1.19 years from claim to settlement. Older higher value (ELS) cases now take less than four years to settle compared with five and a half years in 1999/2000;

- capping legal costs by setting fixed rates for defence lawyers fees; as a result defence costs have fallen from 13% of damages in 1995 to 10% in 2002/2003;

- encouraging NHS Trusts to provide apologies and explanations. As a result, in almost all cases where liability is admitted an apology is given by the NHS Trust; however, anecdotal evidence is that full explanations are still rarely given;

- from April 2002, handling all clinical negligence claims regardless of value. This will improve claims handling for the lower value claims and free up resources within NHS Trusts to concentrate on offering remedial support, resolving complaints and addressing the causes of medical errors;

- sharing information on old cases which appear to be supported from public funds with the LSC, to expedite or close them;
designing a further pilot scheme to assess the feasibility and impact on compensation costs of offering a rehabilitation package to medical negligence claimants with the aim of reducing long-term suffering and compensation costs.

Action by other stakeholders

12. A pilot scheme, known as Resolve, was launched in December 2001. This scheme was established by Resolve (a private company) with the support of the Department of Health, the NHSLA and Action for Victims of Medical Accidents (AVMA) to speed up the handling of claims valued at less than £15,000 and to improve access to justice for patients. Under the scheme a claimant lawyer from a pre-agreed panel and medical experts agree to turn around reports and paper work within strict time-scales and within an overall fee of £3,250. Claimants’ lawyer’s fees are capped. Resolve takes a fee for administering the case. Jointly instructed medical experts provide a medical report within 21 days and the claimant lawyer has 14 days in which to assess the report. The NHSLA then settle cases on the basis of the reports provided within the scheme rather than seeking further opinions under the scheme. If the claim is successful the NHSLA meets the claimant’s solicitor’s fixed costs. If it is unsuccessful the claimant’s solicitor and Resolve meet their own costs. There is therefore no financial risk to the claimant and it allows those on moderate incomes who do not qualify for Legal Aid to pursue a claim.

13. An evaluation of the first 100 cases accepted into the scheme was published on 1 November 2002. The pilot demonstrated that it is feasible to construct a scheme to handle a large number of small claims quickly. However, while 75% of claimants whose cases were successful felt that the Resolve process was “very good” only 30% of claimants who did not succeed agreed.

Resolve: the first 100 cases

- the typical time from referral to closure was 18.4 weeks;
- less than half the claims accepted into the scheme were judged to have a valid claim;
- the average settlement was £7,200.

Source: Evaluation of the Resolve Pilot Scheme: Oct 2002

14. The Clinical Disputes Forum was formed in January 1996. It consists of representatives of every group involved in clinical negligence: client groups, patient and consumer representatives, NHS managers, doctors and dentists as well as solicitors on both sides, barristers, experts, the NHSLA and the Legal Aid Board. The former Lord Chancellor’s Department, the Department of Health, the General Medical Council, the Law Society and the Nursing and Midwifery Council (which regulates the nursing professions) are also involved. The formation of the Forum was stimulated by a speech by Lord Woolf in July 1995 calling for the foundation of an “umbrella” organisation of people who
would not normally talk to each other but who could work together for the benefit of patients and health professionals alike.

15. As well as providing the opportunity for the discussion of common issues, the Clinical Disputes Forum was instrumental in developing the Pre-Action Protocol for clinical negligence claims, setting out how the early pre-court stages of such a claim should be handled. This was the first Pre-Action Protocol to be introduced and has made a significant contribution to the improvement in handling of clinical negligence claims. The Forum has also worked on:

- the interface between complaints and claims;
- the use and conduct of experts' meetings;
- the use of lump sum damages;
- mediation;
- appeals from regulatory bodies; and
- regulation of private medicine.

Action by the Legal Services Commission

16. On the claimants’ side the Legal Services Commission (LSC) has also taken steps to improve claims handling through:

- introducing contracting, franchising and Quality Mark systems. Only quality assured practitioners are funded to provide legal services under the Community Legal Service (CLS). Funding for Legal Representation is restricted to specialist quality assured firms with solicitors with membership of the specialist panels of the Law Society or AVMA.
- stricter merit tests for clinical negligence cases which require clinical negligence cases to satisfy minimum thresholds on prospects of success and cost benefit;
- encouraging the referral of claims of less than £10,000 to the NHS Complaints System rather than proceeding directly to litigation, helping to exclude the smaller and weaker claims from expensive legal action;
- the establishment of a Special Cases Unit to manage all cases where costs are likely to exceed £25,000, including clinical negligence cases. This includes more detailed scrutiny of cases; additional restrictions on the solicitors who can handle clinical negligence cases; case plans and the fixing of solicitors' costs against those plans;
- providing information to the public, including information on the law relating to medical accidents; lists of lawyers and advice centres which meet community legal services quality standards; and information in the financial tests for qualifying for publicly funded legal services;
17. Under the stricter controls on Legal Aid funding introduced in 1999 the number of public funding certificates issued for clinical negligence cases has stabilised and remained static for the last three years.

**Alternative Dispute Resolution**

18. Lord Woolf placed significant emphasis on Alternative Dispute Resolution (ADR) as a means by which medical negligence claims might be resolved without legislation. The Courts have now placed an obligation on lawyers to consider its use, with an increasing onus on them to do so rather than to litigate.

19. Mediation, or facilitated negotiation, is the most common form of ADR. In this process the mediator, who may or may not be legally trained, brings together both parties (either physically or by bringing together their views to identify what is important to each party). The outcome may be a package of measures, including but not limited to financial compensation.

20. Since May 2000, the NHSLA has been requiring solicitors representing NHS bodies to consider every case for mediation; to offer mediation in appropriate circumstances and to report on those considered unsuitable. The LSC also requires mediation or other forms of ADR to be considered at key stages of litigation and requires reasons to be given if ADR is not pursued. The LSC also requires any offers of ADR from a defendant to be notified to the Commission so that, if appropriate, further funding can be limited to support of ADR.

21. In the first year of the NHSLA’s mediation initiative, take up was low but the second and third years have seen a significant rise in the number of cases being mediated.

<table>
<thead>
<tr>
<th></th>
<th>Mediations offered</th>
<th>Mediations which have taken place</th>
<th>Settlements</th>
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<tbody>
<tr>
<td><strong>Year 1</strong></td>
<td>106</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td><strong>Year 2</strong></td>
<td>152</td>
<td>34</td>
<td>25</td>
</tr>
<tr>
<td><strong>Year 3 (10 months)</strong></td>
<td>337</td>
<td>47</td>
<td>31</td>
</tr>
</tbody>
</table>

*Source: NHS Litigation Authority*

22. The majority of claims that were mediated were valued at over £100,000. Only three claims settled at mediation for under £20,000. The average value of cases settled as a direct result of mediation was £123,881, with a range of £3,500 to £1.1m, though this excludes two very high settlements that would otherwise skew the average. Mediation is not a cheap alternative to litigation. The most expensive fee to date incurred by the NHSLA was in excess of £5,000 for one day’s mediation and to this must be added solicitor’s fees, and sometimes Counsel’s fees and experts’ fees. However, mediation can help both parties to
focus on the strengths and weaknesses of a case and what outcome the parties wish to achieve. The NHSLA’s experience suggests that the process may be particularly successful where there is a representative from the defendant NHS Trust present at the mediation, who is able to provide a face to face explanation and apology even where there is no admission of legal liability. It has also suggested that claims may subsequently be settled as a direct result of mediation, even where they have not been settled on the day of the mediation.

23. One suggested reason for the low take-up of mediation is the lack of trained mediators who are available quickly. The NHSLA, AVMA and the Centre for Effective Dispute Resolution (CEDR) are currently involved in a study funded by the Legal Services Commission to assess the feasibility of national training and accreditation for a panel of expert clinical negligence mediators.

24. The first phase of this study has recently been completed and demonstrated strong support for developing specialist knowledge and skills for mediators in clinical negligence disputes. There was also support for providing specialist training in mediation for the lawyers involved in clinical negligence to help widen their role and skills to become experts in dispute resolution. The study has also demonstrated support for a preliminary process review where the parties to a dispute and their lawyers could explore the suitability and timing of mediation or other forms of dispute resolution in a neutral non-binding forum to find the most suitable way forward for a particular case. The intention is to pilot this approach in the next phase of the study.

**NHS Litigation Authority Mediation Initiative: evaluation**

- Approximately 65% of offers of mediation refused by claimants
- Nearly 75% of cases mediated reached settlement after mediation in the second year of the initiative
- Many lawyers initially less comfortable with mediation than traditional settlement meeting
- Average value of cases settled at mediation is £123,881
- Highest settlement at mediation more than £7 million, lowest £11,000
- Mediations mainly took place after legal proceedings had been issued
- Number of trained/experienced mediators still small and few are women

*Source: NHS Litigation Authority*
1. No fault compensation schemes provide an alternative to tort litigation as a way of providing financial compensation for injuries. They generally remove the need to prove negligence as a criterion for making payments, although most schemes retain a test of causation and many also have tests of avoidability. Advocates of no-fault compensation argue that it provides compensation for harm suffered during medical care faster and more fairly than tort litigation and helps greater numbers of victims. Under no-fault compensation schemes, it is suggested, there is scope for proper investigation of what went wrong and why without the defensiveness inevitable in an adversarial system of litigation. Others, however, argue that medical accountability may be reduced in a no-fault system.

In Learning from Bristol, Professor Sir Ian Kennedy said:

“The system [of clinical negligence litigation] is now out of alignment with other policy initiatives on quality and safety: in fact it serves to undermine those policies and inhibits the safety of care received by patients... We believe that the way forward lies in the abolition of clinical negligence litigation, taking clinical error out of the courts and the tort system.”


2. A number of countries and jurisdictions have introduced no fault compensation schemes for medical injuries. They differ in their scope and in the eligibility criteria used. These existing schemes are reviewed in this section.

General No Fault Compensation Schemes

New Zealand

3. A no-fault compensation scheme was originally introduced in New Zealand in 1972. It has undergone some amendment (to eligibility criteria in particular) over the intervening years.
Eligibility Criteria

4. Compensation is payable for “personal injury by accident”. Personal injury caused by medical mishap or medical error is included within the definition of personal injury. A “medical mishap” is defined as when the patient was provided with the correct treatment, properly given, but the patient had a complication which was both rare and severe. A medical mishap is rare if it would not occur in more than 1% of cases in which the treatment is given. It is not rare if the patient knows the risks before treatment started. A medical mishap is severe if the patient was in hospital for at least 14 days or was significantly disabled for at least 14 days or the patient died.

5. A “medical error” is defined as “the failure of a registered health professional to observe a standard of care and skill reasonably expected in the circumstances”, (similar to the Bolam test used in the English negligence cases). Causation must be demonstrated. The claim must be made within 12 months of the injury.

Administration

6. The Accident Compensation Corporation administers claims. Simple claims may be finalised within eight to 12 weeks from the date of claim. In March 2001 a review of the scheme found that it took 15 weeks on average to finalise medical mishap cases but up to 41 weeks for medical error.

Basis of Payment

7. Payments are made for medical treatment, loss of earnings (80% of pre-injury earnings up to a certain limit), transport and accommodation costs and death benefits. For injuries prior to April 2002 a weekly independence allowance (NZ $64.99) was payable where the injury had a serious long-term effect. For injuries occurring after April 2002 a lump sum of a maximum of NZ $100,000 is payable.

Funding

8. The cost of claims is met by a combination of general taxation, premiums charged to medical practitioners and levies on employers. Administration costs account for approximately 7% of the overall budget.

The size of the scheme

9. Four hundred and twenty-three claims were made in 2000/01 at a cost of NZ $22 million.

Special features

10. A key feature of the New Zealand scheme is that claimants are prevented from seeking common law damages.
Sweden

11. The Swedish system of no-fault compensation was originally based on a voluntary system of collective insurance. It was put on a statutory footing by the Patient Injury Act 1996, which came into effect on 1 January 1997.

Eligibility criteria

12. Claimants are compensated for injury caused by treatment or examination where the injury could have been avoided by a different action which would have satisfied the need for treatment in a less risky manner.

13. Compensation is also paid for injuries caused by defective equipment, the misuse of equipment, incorrect diagnosis when there were signs of the disease which were missed and for injury caused by infection transmitted during health care. Compensation is not available for claims based on the lack of informed consent, unavoidable complications or where treatment or diagnostic procedures were undertaken for all illnesses that would be life threatening or cause severe disability if left untreated. To qualify the patient must have been incapacitated for at least 30 days, hospitalised for 10 days, have suffered permanent disability or have died. The patient is required to prove causation on the balance of probabilities. Claims must be made within three years of the date of injury.

Administration

14. The Patient Insurance Association administers the scheme. Appeals may be made to the Patient’s Claims Panel. Claims take six months to process on average.

Basis of Payment

15. Compensation is provided for loss of earnings, future loss of income, medical treatment, rehabilitation costs and financial costs and for pain and suffering.

Funding

16. The Swedish County Councils fund the scheme. They have responsibility for the provision of health care.

Size of the scheme

17. Approximately 6,500 to 7,000 claims are made each year. Just under half receive compensation averaging €6,912.

18. A second insurance scheme covers injuries from drug treatment. The scheme is financed by the pharmaceutical industry.
Finland

19. Finland introduced a pharmaceutical injury insurance scheme in 1984 and a treatment injury insurance scheme in 1987 under the Patient's Injury Act, both modelled on the Swedish System. The aim was to withdraw from fault liability as a prerequisite for compensation.

Eligibility criteria

20. Compensation is payable for injuries that have been caused by medical examination or treatment, an accident associated with treatment, ambulance transportation or defective medical equipment. Compensation is also payable for injury caused by infection arising from treatment. Unavoidable risks and minor injuries are excluded. Only injuries valued at over €168 and requiring more than two weeks in hospital generally receive compensation. Claims must be made within three years of the date of injury.

Administration

21. The Patient Insurance Centre administers the scheme. Claims take on average nine months (from the date of claim) to be processed. Appeals may be made to an Appeals Board where about 10% of appeals are rejected.

Basis of payment

22. Compensation is awarded for pain and suffering and for financial loss, over and above state benefits received. A claim for care would not be permitted as this is provided by the state. Payments are usually made in monthly or yearly instalments, rather than as a lump sum. There is no maximum limit to the compensation payable.

Funding

23. Healthcare providers take out insurance to cover any claims.

Size of the Scheme

24. In the first year, the scheme rejected 62% of claims made and settled 482 cases. More recently the number of claims has been fairly constant at about 7,000 per year. About one-third of claimants receive compensation. Payments are on average about one-third of what would be awarded in the UK. In 2001 the scheme paid out just under €17.2 million.

Special Features

25. Claimants retain the right to go to court, where they must prove negligence and causation, but few do in practice.
Denmark and Norway

26. Denmark and Norway also both have no-fault compensation schemes for medical injury which are similar to those operating in Sweden and Finland.

France

27. A different approach is adopted in France. Until recently all claims against the state for medical negligence were handled under administrative law, but compensation was not automatic for all hospital mistakes. Fault did not have to be proved in certain circumstances such as injections (including vaccinations), medicines causing damage and contaminated blood transfusions. In other cases fault had to be proved before the Administrative Court. The judge directed the procedures and decided the case, largely on the basis of written evidence.

28. The position in France changed in October 2002 with the establishment of the National Office of Medical Accident Compensation (ONIAM). It has a budget of €70 million for each of its first two years of operation. There will be four Regional Commissions of Conciliation and Compensation, each headed by a magistrate which will have panels of experts (from a national list) to investigate cases. Compensation will be payable for:

- medical accidents;
- problems resulting from an intervention by a medical practitioner;
- infection occurring during the course of treatment.

29. It will not be necessary to establish fault but:

- the harm must be directly linked to the treatment;
- it must have a detrimental effect on the patients health;
- there must be a minimum 25% reduction in capacity.

30. Acceptance of an offer of compensation prevents a claim being made through the courts. If the Compensation Commission finds that there has been fault then the claimant will be entitled to compensation from the practitioner’s insurance (insurance is compulsory for medical practitioners). Liability may be apportioned between the insurer and the compensation fund if some elements of the case attract fault but others do not.

No-Fault Compensation for Birth-Related Neurological Injuries

31. More targeted schemes of no fault compensation for birth-related neurological injuries operate in the states of Virginia and Florida in the USA. Both were introduced as a response to the rising cost of compensation in birth injury cases and the rising insurance premiums for obstetricians which resulted.
A scheme was introduced first in Virginia in 1988. Florida followed in 1989 but has had the larger numbers of claims.

**Virginia**

*Eligibility Criteria*

32. Claims may be made where there has been “injury to the brain or spinal cord of an infant caused by the deprivation of oxygen or mechanical injury occurring during the course of labour, delivery or resuscitation in the immediate post-delivery period in a hospital, which renders the infant permanently non-ambulatory, aphasic, incontinent and in need of assistance in all phases of daily living”.

33. The scheme only covers babies born alive. Claimants have 10 years in which to lodge their claim.

**Administration**

34. The State Workers Compensation Commission administers claims. Proceedings range from a telephone conference call to a full hearing of three doctor panels. Such hearings are only held in disputed cases. The aim is to process a case in 120 days but research in 1997 showed an average of 148 days.

**Basis of Payment**

35. Compensation is for ‘net-economic loss’ only, including medical and rehabilitation expenses, residential and custodial care, equipment, travel and loss of earnings. There is no compensation for pain and suffering nor may expenses covered by insurance be claimed.

**Funding**

36. Claims are met by subscriptions levied on healthcare providers and hospitals contribute on the basis of a fee per baby born in the previous year. The scheme currently has a forecast shortfall of some US$80 million resulting from a rise in claims. Subscription currently stand at US$5,000 per obstetrician and US$250 per physician and US$50 per live birth for hospitals. One quarter of one per cent of insurance premiums in the state also help fund the scheme.

**Size of the Scheme**

37. The scheme receives approximately 10-15 new claims each year, and is growing. There are 72 children receiving payments from the scheme at present.

**Special features**

38. A claim under the scheme extinguishes the right to sue unless gross or wilful negligence is shown. Lawyers are involved in putting together the application to the scheme for which they are paid ‘reasonable expenses’ (up to US$50,000).
Florida

Eligibility Criteria

39. The Florida scheme defines a birth-related neurological injury as an 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 occurring during labour, delivery or resuscitation in the immediate post-delivery period, which leaves the infant permanently and substantially mentally and physically impaired. A key difference from the Virginia scheme is the inclusion of a minimum birth weight (thereby excluding premature deliveries, which the Virginia scheme would cover). However the degree of disability required to qualify is lower than in Virginia as the infant does not need to be in permanent need of assistance in all the activities of daily living. Generally the Florida criteria are seen as less restrictive than Virginia’s. Disability or death caused by genetic or congenital abnormality are excluded, as are temporary or minor birth-related injuries.

Administration

40. The Florida Neurological Injury Compensation Association administers the scheme. Legal and other claims associated costs dropped over the first three years of the scheme from an average of US$30,000 per case to US$3,000 per case as procedures and precedents were developed. The average time for dealing with a case once a claim was made was 110 days for paid cases, 303 days for rejected cases. The use of lawyers by claimants is high.

Basis of payment

41. Compensation is awarded for medical and rehabilitation costs, residential and custodial care, medicine and drugs, special equipment and facilities and for related travel and a parental allowance of up to US $100,000 per case. Expenses covered by benefits or insurance are excluded. Payments are made as expenses are incurred.

Funding

42. Funding is through levies on healthcare providers similar to the Virginia scheme.

Size of the scheme

43. Though larger than the Virginia Scheme, only 282 cases have been through the scheme since it was established. In 2001, 26 cases were heard, of which 13 were accepted, 10 were rejected and in three cases parents were seeking to have their case ruled out of the scheme so that they could sue in tort.

Special Features

44. Entry into the scheme precludes litigation in the courts. However, a study in 1997 found that of 101 cases which would have qualified under the scheme, 50 claimed and 51 chose to litigate in the courts. It also appears that court judgments are accepting more cases as within their jurisdiction.
No-Fault Compensation in the Broader Context

45. A number of schemes operating in the United Kingdom operate on a no-fault basis. These include the Industrial Injuries Scheme, the Criminal Injuries Compensation Scheme and the Vaccine Damage Payment Scheme.

46. The Industrial Injuries Scheme may provide compensation to an employed earner injured at work. If the percentage disablement is assessed above a certain level, benefit is payable. The amount of benefit is dependent on the percentage disablement level. The Department for Work and Pensions administers the scheme, which has approximately 60,000–72,000 new claims each year and approximately 350,000 ongoing live cases. It is estimated that around 39% of claims are successful.

47. The Criminal Injuries Compensation scheme provides compensation if the claimant has suffered injury or death as a result of violent crime in the last two years, subject to certain eligibility tests. An award is made on a set tariff depending on the degree of injury ranging up to £250,000 for someone suffering quadriplegia. In the financial year 2000/2001, there were 79,000 applicants of whom 37,000 received compensation at a cost of £228 million. The Criminal Injury Compensation Authority administers the scheme at a cost of approximately £300 per case in 2000/01. There was however a backlog of nearly 94,000 cases in March 2001. Claimants under the scheme remain free to litigate in tort but any compensation received through the scheme is offset against the damages awarded through litigation (if they are higher).

48. The Vaccine Damage Payment Scheme was introduced in 1979 to ease the present and future burdens on those suffering from vaccine damage and their families. It provides for a tax-free lump sum, currently £100,000, where the Secretary of State for Work and Pensions is satisfied that on the balance of probabilities serious mental or physical disablement has been caused by the administration of specified vaccines. Claims must be made within six years of the date of vaccination or the child reaching age 21 years, whichever is the later. Since the scheme began, approximately 5,000 claims have been received and 910 awards made to June 2003.

Analysis – Key Features of No-Fault Compensation

49. The possibility of introducing a no-fault scheme to settle personal injury cases and clinical negligence has been considered a number of times over the years. In 1978 it was the subject of a Royal Commission Review, led by Lord Pearson. This review rejected the use of no-fault compensation for medical negligence cases on the grounds that:

- it would still be necessary, and difficult, to establish causation;

- it would be difficult to decide between injury caused by negligence and the natural progression of the disease or the foreseeable side effects of the treatment;
• if the focus of the scheme was on negligent injury, it would be no clearer who should receive compensation;

• the use of adjudication procedures would continue to place burdens on the medical manpower available;

• if no-fault compensation were introduced in medical negligence, there would be a knock-on effect to other areas of personal injury.

50. However, the Pearson Commission recognised that the case for no-fault compensation for medical injury was strong enough to make it likely that the issue would need to be reviewed again in time.

51. The no-fault schemes for medical injury around the world reviewed here have a number of features in common:

• all have tests of causation or avoidability. New Zealand and Sweden includes a test of negligence akin to the Bolam test used in tort in the UK;

• a patient must suffer a minimum level of severity of injury to qualify for compensation (this is often set with reference to days of disability or days in hospital);

• there are limits on the types of compensation which can be awarded, for example compensation may not be available for pain and suffering and the levels of compensation may be capped;

• the primary source of compensation is insurance payments, benefits or state funded care – the ‘no-fault’ scheme acts as a ‘top-up’;

• in Scandinavia and New Zealand there are high levels of claims relative to the UK;

• compensation payments are lower than those typically awarded by courts in the UK;

• the New Zealand scheme and to some extent the Virginia and Florida Scheme restrict access to the courts.

52. The more comprehensive system of social welfare and social insurance support available in New Zealand and the Scandinavian countries may affect the acceptability of the schemes in those countries. In Scandinavia, in particular, the compensation awards are low relative to UK tort awards because they are topping up already generous social insurance payments for income replacement.
England has fewer clinical negligence claims per 100,000 population, and the proportion of successful claims is lower. However, the average compensation award in England is far higher than the average in the New Zealand and Sweden schemes.

The advantages of no-fault compensation schemes appear to be:

- speedier resolution of cases by removing the need to dispute negligence in court;
- lower administrative and legal costs per case;
- increased certainty for claimants of the circumstances when they will receive compensation;
- reduced conflict between clinicians and claimants;
- greater willingness by clinicians to report adverse events.

The following disadvantages have also been suggested:

- overall costs would be higher than under a tort system because of the increased numbers likely to claim; or there would be an unacceptable reduction in the level of compensation awarded to keep costs within affordable levels (and if under-compensated, individuals would fall back on the state);
- disputes about causation would continue even if negligence were removed;
- it would be difficult to distinguish the natural progression of a disease from an error in treatment;

| England claims experience compared with two countries using no fault based compensation schemes |
|------------------------------------------|--------|--------|
|                                          | Sweden | NZ     | England |
| Claims per annum                         | 7,775  | 1,743  | 10,517† |
| Paid claims per annum                    | 3,654  | 1,046  | 4,207   |
| Population                               | 8,910,910 | 3,737,277 | 50,225,000 |
| Claims per annum per 100,000 population  | 87     | 47     | 21      |
| Paid claims per annum per 100,000 population | 41     | 28     | 8       |
| Average payment (GBP 1996)               | 63,000 SEK | 7,419 NZD | 57,447 GBP |
| Average payment                          | 6,107  | 3,115  | 45,957  |

†Figure calculated from estimates given by NHS Trusts in response to a survey

Source: Evaluating policy alternatives for patient compensation: Fenn, Gray, Rickman, Diacon, Carrie, Young. 2002 commissioned for this report
a tariff-based system of compensation may not be sufficiently responsive to individuals’ needs;

● a lack of medical accountability for standards of care;

● a no-fault scheme does not of itself guarantee that claimants receive an explanation or apology.

56. In addition concerns have been expressed about the implications under the Human Rights Act 1998, if restricted access to the courts was a feature of the introduction of a no fault compensation scheme.

57. Much of the argument about no fault schemes centres on the assumption that all harm of whatever severity would automatically be compensated.

58. Given the estimated level of adverse events within the healthcare system and the number of complaints relating to clinical treatment, such a comprehensive no-fault scheme, where payment was automatically available for injury resulting from treatment or missed diagnosis would open up the potential for tens of thousands of claims per year. The no fault schemes in Sweden and New Zealand receive between two and four times more claims than the tort system in England and make payments between three-and-a-half and five times more often. However, in the New Zealand scheme it appears that only about one in 20 potential claims are actually made, 60% of them being successful. A relatively low proportion relate to medical error which raises the question of whether the scheme provides an incentive to prevention.

59. Even with a tariff system limiting the amount of compensation there is the potential for a greatly increased compensation bill. Average payments at 1996 levels were approximately £6,000 per claim in Sweden, £3,000 in New Zealand and £46,000 in Great Britain. For a comprehensive no fault system to be affordable, awards would have to be significantly reduced from current levels. For the more serious injuries and higher levels of awards this is unlikely to be acceptable. The alternative of limiting eligibility according to the degree of disability suffered appears fairer as it is based on need. However, in the schemes examined the thresholds of disability are set quite high – either at a percentage of reduced capacity or length of hospitalisation. If the threshold is set too high few claimants are likely to benefit leading to concerns about a two-tier system and denial of redress to many harmed patients. Many schemes also cap compensation for pain and suffering and for loss of earnings.

60. As the schemes examined have shown, it is possible to construct a scheme which compensates patients for long-term harm suffered as a result of sub-standard care, through an administrative process. Such a process enables claimants to have faster access to compensation, with more certainty about the level of payment they are likely to receive. It also allows the money to be directed to patients rather than the legal process. Minimising adversarial proceedings also avoids diverting the time and efforts of clinicians away from providing patient care. Simpler compensation schemes for straightforward,
relatively low value claims would take many claimants out of the tort system. The alternative of faster, more certain, but possibly lower compensation might prove attractive to many people. And while no fault schemes are often criticised for failing to provide the explanations and apologies which claimants seek there is no reason why these cannot be built into a compensation system.

61. While concerns have been raised that the tort system gives rise to defensive medicine, the alternative concern has been raised that no fault schemes reduce clinical accountability and reduce incentives for health professionals to pay attention to the quality of care they provide. Research carried out for this report did suggest some evidence of these incentive effects, as has previous research in America and elsewhere. However it is hard to quantify these effects, and clearly the majority of health professionals strive to offer high quality care, not because of the impending threat of litigation but because of their professionalism and training. However, as we have seen errors do occur. The tort system appears to have provided little incentive for prevention of errors or for putting right the mistakes that are made.

62. The potential of a less adversarial system to help the NHS develop a more open approach to the reporting of error has been described by Sir Ian Kennedy in his *Learning from Bristol* report. In addition, instituting a more direct link between harm and compensation through an administrative system could provide an added incentive to invest in the prevention of adverse events – something which the remote and lengthy litigation process does not currently deliver.
1. Earlier chapters have set out the options for reform and their advantages and disadvantages as identified through responses to the Call for Ideas, discussion in the advisory group, research commissioned for the review and meetings held with stakeholders. Chapter 1 sets out the ideal features of a system for addressing injury when things do go wrong. In considering the extent to which it was possible to achieve the ideal, four main options were identified. These were classed by reference to the basis on which a response is offered and the structure through which that response is provided:

- **continue tort reform** i.e. allow the Woolf reforms to bed in, continue to use the court based tort process involving lawyers, with a focus on blame and responding only to patient led concerns (for example formal NHS complaints and clinical negligence claims);

- an all encompassing ‘no-fault’ scheme, as established in other countries, most notably Sweden and New Zealand;

- a **tariff based national tribunal** for compensation such as that used in compensating personal injury arising as a result of crime; and,

- a composite option drawing on the best points of the first three.

**Continue tort reforms**

2. There have been a variety of reforms of the tort system in recent years, most significantly those following on from proposals made by Lord Woolf in 1996. These have been set out in more detail in the preceding Chapters. In summary, they were designed to improve access to justice, speed up the judicial process and to reduce the number and cost of experts involved in a case. They were also designed to encourage alternatives to court action to resolve disputes and facilitate agreement on compensation. Many of those commenting to the review suggested that these and other initiatives currently in the pipeline, for example, the legislation to allow courts to order periodical payments to settle claims rather than a lump sum, would in themselves be sufficient to address problems and concerns relating to the legal process for resolving medical disputes.
3. There is no doubt that recent reforms, in particular the work of the NHSLA and that undertaken by the Clinical Disputes Forum have improved the speed and expertise of claims handling and have helped contain some costs. This is most notable in the defendant sector where costs as a percentage of damages have reduced from 13% to 10% over recent years. Work by the Law Society and Civil Justice Council further suggests that the Woolf reforms have been well received, particularly Part 36 offers and the Pre-action protocol. However, there are still many areas where progress has been slower and more difficult to achieve: the use of medical experts; the adversarial nature of the system; poor case management at the court stage; and the availability of experienced judges are amongst the most important of these.

4. Similarly, evidence given in response to the Call for Ideas by those with experience as claimants, as well as in forthcoming research by the LSC on claimants’ experiences, suggests that claimants remain dissatisfied with the tort based system and what it can offer.

5. I have therefore rejected the option solely based on continuing tort reform because:

   - it remains a lottery who can and who cannot prove ‘negligence’ – not least in cerebral palsy cases;
   - it does little to support patients making complaints and claims;
   - the current legal system provides little or no incentive to report, learn from and reduce errors;
   - the adversarial system undermines the relationship between the patient and healthcare profession, reduces trust in the NHS as a whole and diverts staff from clinical care;
   - if a litigation culture takes hold, as in the USA, costs will spiral out of control and the practice of defensive medicine will increase; and
   - an independent evaluation of a small claims pilot supported by the Department of Health and NHSLA found that even patients who receive compensation often remain dissatisfied if they do not also receive the explanations or apologies they seek or reassurance about the action taken to prevent repetition.

6. Even a modified court based process can not address these issues.

No-fault based compensation

7. Chapter 6 sets out in detail the types of no-fault based schemes established in other countries, the best known of which are those which operate in Sweden and in New Zealand.
8. In summary, the advantages of a comprehensive no fault compensation system are said to be that:

- claims are settled more quickly (months rather than years for many no-fault schemes);
- administrative and legal costs per claim are lower (for example, tort costs in Florida can account for up to 40% of the award, yet the no-fault scheme spends less than 5% of its expenditure on legal advice);
- patients are clearer about the circumstances when they will receive compensation;
- there is reduced conflict between clinicians and claimants;
- because of the removal of ‘blame’, clinicians are more willing to report adverse events and repetition can be avoided.

9. However, there are also potential disadvantages:

- overall costs are far higher than under equivalent tort systems because of a lower threshold for claiming (i.e. no need to prove negligence) and increased numbers of claims;
- for a no-fault scheme to be affordable compensation would need to be at substantially lower levels than tort awards currently, which would not necessarily meet the needs of the harmed patient (for example, average tort payments in the UK (1996 prices) were £45,957 whilst those in Sweden and New Zealand were only £6,107 and £3,115 respectively (1996 prices));
- on a technical level, it would be difficult to distinguish harm from the natural progression of a disease.

Overall costs of no-fault based schemes.

10. Although not the sole factor, the costs of any no-fault based scheme are important for the NHS. Every penny spent on compensation is money that could otherwise be spent providing health care. Costs are also a concern for the no-fault schemes already established and it is informative to see how the schemes have responded to this. Each scheme includes tests to limit access to compensation or caps on the compensation that can be awarded. For example, the scheme in New Zealand incorporates tests of ‘medical mishap’ and ‘medical error’; these re-introduce concepts similar to Bolam around ‘reasonable standard of care and skill’ as well as a rarity test.

11. Research was commissioned to assess the cost of a comprehensive no-fault based compensation scheme in the NHS. Two types of scheme were tested. First a scheme based on causation alone, which would be most like ‘true’ no-fault, as to obtain compensation the injured patient would only have to demonstrate that their treatment caused the injury leading to their claim. Second, a scheme similar to that in Sweden was modelled, based on the concept of ‘preventability’. Compensation would be paid only where the injury
might have been prevented (whilst still providing treatment). Administration costs were estimated using a range of values reflecting the costs of different levels of investigation (range £350 per case to £4,100 per case).

12. The percentage of cases to be compensated was estimated using information from the Swedish scheme. The number of likely applicants was estimated from information from the MORI survey of those who believed that they had been injured as a result of medical treatment in recent years (which gave an estimate of just over 800,000 preventable adverse events per year). Finally, the level of compensation awarded was estimated using the present level of damages (it was assumed that the same type of injuries would occur under a no-fault scheme as occur under tort). Assumed damages payments were reduced by 25% and 50% from present levels to reflect the restrictions in other no-fault schemes which result in compensation at levels much lower than English tort claims. The table shows the range of the resulting estimates of potential costs for an NHS scheme.

<table>
<thead>
<tr>
<th>Policy Option</th>
<th>Eligibility</th>
<th>% eligible cases applying</th>
<th>Level of Damages in £ million</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>50% reduction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Awards Costs</td>
</tr>
<tr>
<td>Option 1</td>
<td>Causation</td>
<td>28</td>
<td>1,836 262</td>
</tr>
<tr>
<td></td>
<td>Causation</td>
<td>19</td>
<td>1,259 180</td>
</tr>
<tr>
<td>Option 2</td>
<td>Preventability</td>
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<td>1,469 210</td>
</tr>
<tr>
<td></td>
<td>Preventability</td>
<td>19</td>
<td>1,008 144</td>
</tr>
</tbody>
</table>


13. I have concluded that in addition to the disadvantages set out above, a comprehensive no-fault scheme was unaffordable for the NHS. Estimates suggest that even with a 25% reduction in the current level of compensation the cost of a true no-fault scheme would vary between £1.6bn per year (if 19% of eligible claimants claimed) to almost £4bn (if 28% of eligible claimants claimed). This compares with the £400 million spent on clinical negligence in 2000/01.

14. I also considered the implications of the Human Rights Act 1998 if the quid pro quo for introducing a no-fault compensation scheme was removal of the right to go to the court, as had happened in New Zealand. Any no-fault arrangements would need to comply with Article 6 of the European Convention on Human Rights: the right to a fair hearing. In practice, this would potentially mean making provision for a public hearing, with equal rights for each side to present their case. In ensuring that each side could be heard it is likely that the NHS would have to fund the provision of legal advice. In effect this would mean the NHS running and funding a hearing mechanism similar to the courts, but in parallel with the courts.
15. Given the disadvantages set out at paragraph 9, the potentially large costs and the practical difficulties in framing an efficient comprehensive no-fault based scheme, not least to conform with the Human Rights requirements, I have rejected a wide ranging no-fault scheme for all types of injury.

A National Tariff And Tribunal

16. I considered the option of establishing a national tribunal backed by a tariff setting out fixed rates of compensation for cases of clinical negligence. A scheme along these lines presently provides compensation to those injured as a result of crime (through the Criminal Injury Compensation Authority (CICA)) with a similar system also in place for those in dispute with their employers (employment tribunals).

### Criminal Injuries Compensation

#### Key features
- Paid to those who have suffered an injury as a result of crime;
- No limitation on the right to sue the assailant in the courts;
- Process – initial investigation and assessment by the Criminal Injuries Compensation Authority (CICA) – reassessment by CICA on appeal – final appeal to an expert panel.

#### Awards
- Tariff-based, assessed on the basis of a medical report from the applicant's doctor and a police report;
- Paid as lump sums;
- Tariff provides for 400 possible injuries ranging from Level 1 £1,000 (e.g. broken finger) to Level 25 £25,000 (quadriplegia);
- Compensation for loss of earnings and future care costs available for injuries lasting more than 28 weeks.

#### Size of scheme (2000/02)
- 78,630 applications received;
- 74,859 applications resolved;
- More than 60% of awards between £1,000 and £2,000;
- 13,000 people received awards below £25,000;
- 19 payments between £30,000 and £250,000 (the maximum);
- three payments of £250,000;
- £207.8 million spent in compensation with operating costs of £20 million;
- backlog at 1 April 2001 93,579.
17. Both the criminal injuries and the employment tribunals systems appear to have:

- relatively low levels of awards by comparison with clinical negligence cases (60% of CICA awards were between £1,000 and £2,000);
- relatively low costs per case (£300 for each Criminal Injuries Compensation case resolved without appeal);
- high volume of claimants when compared to clinical negligence claims;
- large backlogs of cases;
- low satisfaction levels from claimants.

18. In addition, there remains a significant amount of legal representation in the employment tribunal process.

19. Establishing a national tribunal backed by a tariff scheme would potentially lead to replicating the courts within the NHS because an administrative tariff based system would also need to comply with the Human Rights legislation, particularly if the right to go to court was to be removed. It appears that a tariff-based tribunal system is only likely to be effective if the right to go to court were removed. This is because of:

- the lack of flexibility in award levels to reflect the circumstances of the injured patient;
- the low extent to which clinical negligence cases lend themselves to the type of examination provided by the tariff schemes currently in place; and,
- the generally lower levels of compensation awarded.

20. Many of those who commented on this option were particularly concerned that tariffs leave little scope for flexibility in terms of the compensation paid to take account of the range of circumstances and need of those who make applications. If the aim of any damages awarded is to put the patient back in the position in which they would have been had the injury not occurred then this is obviously often closely related to the individual circumstances and impact of the injury upon the patient. Therefore, in considering this option thought was given to whether the response of the NHS to such injury should continue to be on the basis that the goal would be to put the patient (as far as is possible) back in the position they would have been in. I have concluded that it should be so.Whilst there is already effectively a tariff in personal injury cases for general damages (pain and suffering) through the Judicial Studies Board Guidelines, this only gives a range of damages and excludes the special damages related to the specifics of an individual case. At best therefore, I concluded that a tariff-based approach could only contribute to part of the development of the NHS response to clinical negligence.
21. A further consideration was that the complexities of some higher value clinical negligence cases would not readily lend themselves to the quick investigation and tariff approach adopted, for example, by the CICA. Seriously injured patients may have complex and varied needs as a result of the harm they have suffered, which might not be readily evident without detailed investigation and assessment. In such circumstances a quick and straightforward assessment, followed by a one-off payment – for example – such as the maximum £250,000 which CICA can pay to a person who has quadriplegia as a result of a crime might not reflect the needs of the injured party. Additionally, such a scheme does not readily provide the basis for the detailed explanation and apology many patients tell us they seek. For these reasons a national tribunal system and tariff for all injuries has not been pursued.

22. The remaining option forms the basis of our proposals for reform. In developing this package of measures I have drawn on the best elements of the above options. Central to the proposals is a new way of responding if things go wrong. It involves a process of providing redress for patients harmed as a result of seriously substandard NHS hospital care, building on the best elements of the options above to tackle the deficiencies of the present system. For example, it draws on the quicker assessments for straightforward cases provided by a tribunals process, while ensuring that the response includes an explanation and apology. This new process would be based on the concept that the patient should be returned to the condition they would have been in had the injury not occurred. It would also include:

- an investigation of the incident leading to the alleged harm and the resulting harm;
- provision of an explanation to the patient of what happened and action proposed to prevent repetition;
- development and delivery of a package of care including remedial treatment or continuing care as necessary;
- payments for pain and suffering, and the costs of care or treatment which the NHS could not provide.

23. The main elements of the reform package are supported by proposals designed to improve prevention and handling of adverse events at local level; to provide rehabilitation and remedial treatment to reduce the long term impact of the harm caused; and to reduce the need to fund private care for those harmed.

24. I believe that the overall package would be more responsive to the needs of patients. It would also be beneficial to doctors, the vast majority of whom would have the cloud of clinical negligence litigation removed but who would be free to learn from and improve their practice in a positive way. It would also provide the basis for handling a wider range of injuries if successful. The next chapter sets out the details of these proposals.
CHAPTER 8

Proposals for Reform

1. Legal proceedings for medical injury progress in an atmosphere of confrontation, acrimony, misunderstanding and bitterness. The process is anathema to the spirit of openness, trust, and partnership which should characterise the modern relationship between doctor and patient. Moreover, the whole nature of a legal dispute between two parties works against the wider interests of patients. The emphasis is on revealing as little as possible about what went wrong, defending clinical decisions that were taken and only reluctantly releasing information. The tort system of medical litigation looks towards blame, retribution and deterrent as its weapons. In contrast, a modern health service aiming to improve safety year-on-year should use the bad experience of one patient as a source of rapid and systematic learning so that perhaps thousands of future patients do not suffer in the same way.

2. Few neutral observers would try to argue that quality and safety of health care are improving because health care professionals are behaving more conscientiously clinically as a result of having watched their colleagues being sued. Ironically, this potential deterrent effect of tort litigation in medicine is considerably weakened by the fact that the majority of cases are now settled out of court anyway. No information or publicity draws the circumstances to wider attention. So, the learning from the incident is restricted to the few people within the hospital or clinical team who saw or heard about it.

3. In contrast, there is a world-wide impetus now behind the emphasis on creating an open system in which errors are recognised as most often being due to systems weaknesses in which the individual who made the mistake is at the end-point of a chain of events rather than its instigator. This perspective sees safer, higher quality care being driven by investigation and learning in a climate largely free from blame and fear. The National Patient Safety Agency (NPSA) is leading this work in England and Wales.

4. The ideal must be to ensure that the individual who has suffered harm or a poor standard of care receives an apology, an explanation, treatment, care and where appropriate financial compensation whilst the NHS as a whole learns the lessons. Creating reforms which are fair both to individual patients and
meet their needs as well as making care safer for all NHS patients is the overall goal of the reforms proposed in this report.

5. Patients who are faced with complex legal procedures with which they are unfamiliar feel disadvantaged and rarely consider that they have had a satisfactory response to their concerns. This is so even if they eventually receive compensation. In the past, cases have taken too long to settle. In smaller value claims in particular, the legal costs have been disproportionate to the damages awarded. In larger value claims, there can be lengthy (and expensive) disputes about the component parts of any lump sum award and the anticipated life span of the victim. At the end of the day some people who are severely damaged as a result of inadequate healthcare will receive large damages, while others with apparently similar disabilities receive not a penny. Nor are rehabilitation services and facilities for special care and education for children with more extensive mental and physical disabilities routinely available through public provision.

6. The reforms to the civil justice system introduced since Lord Woolf’s *Access to Justice* Report and the establishment and work of the NHS Litigation Authority have produced significant improvements since 1995. Claims are now dealt with more quickly. The quality of claims handling more generally has been improved. Settlements are encouraged to take place at an earlier stage where there is liability. Further initiatives, for example, to provide mediation as an alternative method of dispute resolution and to fast track lower value cases are showing promise.

7. As discussed in the previous chapter, many legal commentators have argued that the tort system is still the best framework for dealing with medical injury. They argue that recent changes and proposals for reform to the operation of this field of personal injury law should be allowed to bed down and enabled to fulfil their early promise. They point out that it is a fundamental human right that a victim or their family should have recourse to law. They warn that any form of no-fault compensation would usher in a compensation culture amongst NHS patients and be far more expensive for the NHS as a whole.

8. These are valid arguments but it is impossible to escape from the fact that tort sits so uncomfortably in an NHS with an ethos of equity and a wish to bring the greatest good to the greatest numbers.

9. Even a reformed tort system is unfair in compensating only the select few. It offers no dynamic for higher quality and safer care for the large number of patients treated by the NHS every day, every week, every year. It creates few incentives for providers of health care to reduce risk. It offers no solution to the rising tide of defensive medicine – a massive cost to the US health system – where potentially hazardous and costly investigations are carried out not for the benefit of the patient but for the sole purpose of fending off a successful lawsuit. The doctor who is looking over her shoulder is not the patient’s best ally when difficult clinical decisions need to be taken.
10. For all these reasons, the recommendations that follow are aimed at fundamental reform. They do not propose removing the patient’s right to sue an NHS doctor or provider of care, but they move the role of tort from its current central position to the outer perimeter of the NHS. All of the recommendations will be the subject of detailed consultation and in particular, consideration of their potential impact on policies on a range of benefits and the way in which these are delivered. The recommendations apply to England only.

- **Recommendation 1: An NHS Redress Scheme should be introduced to provide investigations when things go wrong; remedial treatment, rehabilitation and care where needed; explanations and apologies; and financial compensation in certain circumstances.**

Harm to a patient may come to light as the result of an adverse event, a complaint, or a claim from a solicitor. In all cases, the response should be:
- an investigation of the incident which is alleged to have caused harm and of the harm that has resulted;
- provision of an explanation to the patient of what has happened and why and the action proposed to prevent repetition;
- the development and delivery of a package of care, providing remedial treatment, therapy and arrangements for continuing care where needed.

The proposed NHS Redress Scheme would provide a mechanism for organising this response and in suitable cases considering whether payment for pain and suffering, for out of pocket expenses and for care or treatment which the NHS could not provide should be made. The requirement would be to reach a decision on the case within six months from the initial approach from the patient.

The new NHS Redress Scheme is centred on the needs of NHS patients, initially those treated in hospital and community health settings. Further consideration will be given to redress for patients treated under NHS funding arrangements but by independent or voluntary sector providers in the United Kingdom or abroad.

**Routes of access to the Scheme**

Access to the Scheme and to the package of care and possible financial compensation for an adverse outcome of NHS care would be:
- following a local investigation of the adverse event or of a complaint;
- following an independent review of a complaint by the Commission for Healthcare Audit and Inspection (this body is a new health inspectorate which it is proposed, subject to Parliamentary approval, will inspect the quality of local NHS services as well as investigate NHS complaints not resolved at local level);
- following a recommendation by the Health Services Commissioner (who will investigate complaints not resolved by the Commission for Healthcare Audit and Inspection);
- following investigation of a claim made directly by a patient or relatives to the NHSLA.
Criteria for payment

The criteria for receiving payment would be that:
– there were serious shortcomings in the standards of care;
– the harm could have been avoided;
– the adverse outcome was not the result of the natural progression of the illness.

Elements of compensation package

In the short-term, the capacity of the NHS to provide packages of care may be limited and financial recompense may be offered as an alternative. However, the Scheme should encourage the development of this capacity over time. It is envisaged that case managers would be needed under the auspices of the successor body to the NHSLA, to develop care packages and monitor their implementation.

The financial element of the compensation would be limited to:
– the notional cost of the episode of care or other amount as appropriate, at the discretion of the local NHS Trust;
– up to £30,000 where authorised by the national body managing the new scheme (i.e. a successor to the NHSLA – see recommendation 3).

The advantages of the proposed scheme over the current arrangements are that there would be a full investigation of the complaint or claim; development of a package of the remedial care and rehabilitation where required; faster resolution and an offer of compensation where due; and reduction in legal costs as it would not be necessary for lawyers routinely to be involved.

The scheme should be piloted within the scope of existing legislation to help with framing the detail of new primary legislation. This will build on earlier ‘fast-track’ scheme pilots and allow the logistics and acceptability of the scheme to be assessed. Under current legislation the pilot will need to be based on a ‘Bolam’ test of clinical negligence. However, the pool of cases submitted in the pilot will also be assessed against alternative tests by a medico-legal panel. This will both inform the exact phrasing of the test and also help gauge in more detail the potential impact on the likely number of successful claims and their costs of using a lower qualifying threshold of ‘sub-standard care’.

● Recommendation 2: The NHS Redress Scheme should encompass care and compensation for severely neurologically impaired babies, including those with severe cerebral palsy.

Cerebral palsy and birth-related neurological injury are amongst the most complex claims currently handled by the NHSLA and receive some of the largest compensation payments. However, because of the difficulty in proving both causation and negligence, one small group receives compensation while another larger cohort does not. Boundaries are always difficult to draw, as some hard cases will fall the wrong side of the line.
However, it is proposed that the remit of the new NHS Redress Scheme should better meet the needs of more of these severely neurologically impaired children and their families.

**Eligibility criteria**

The following eligibility criteria to qualify for inclusion in the Scheme would apply:
- birth under NHS care;
- severe neurological impairment (including cerebral palsy) related to or resulting from the birth;
- a claim made to the Scheme within eight years of the birth;
- the care package and compensation would be based on a severity index judged according to the ability to perform the activities of daily living;
- genetic or chromosomal abnormality would be excluded.

**The package of compensation**

Redress would be provided in cash and in kind, according to the needs of the child for assistance with the tasks of daily living resulting from the severity of impairment and would comprise:
- a managed care package;
- a monthly payment for the costs of care which cannot be provided through a care package (in the most severe cases this could be up to £100,000 per annum);
- lump sum payments for home adaptations and equipment at intervals throughout the child’s life (in the most severe cases this could be up to £50,000);
- an initial payment in compensation for pain, suffering and loss of amenity capped at £50,000.

**Assessment under the Scheme**

The scheme would be administered by a national body building on the work of the NHSLA, on application from the parents. A national panel of experts would review the severity of impairment and causation (i.e. whether the impairment related to or resulted from the birth). The advantages of such a scheme would be to make compensation and support available to a wider range of severely disabled babies and children without the need to establish negligence or fault. It would also control costs to the NHS by meeting the actual care needs as they arose. During the consultation period the Department of Health will be working with families with children suffering from severe neurological impairment and their representatives and with expert clinicians and care workers in this field to develop the basis of the severity index for assessing the care package.
Issues for Devolved Administrations

The recommendations in this area apply to England only, as does the whole of this Report. However, I recognise that any proposed changes to arrangements in England and in particular, for care and compensation for severely neurologically impaired babies could have implications for the rest of the United Kingdom. These issues are currently being discussed with the devolved administrations.

Recommendation 3: A national body building on the work of the NHS Litigation Authority should oversee the NHS Redress Scheme and manage the financial compensation element at national level.

The role of the NHSLA since it was established in 1995 has been impressive. It is proposed that a national authority be established with a widened remit to manage the new scheme. The name of the Authority should be changed to reflect the new emphasis of the scheme.

The role of the national body should encompass eight main functions:
- assessing claims or recommendations for NHS compensation payments from patients or families, NHS service providers, the Commission for Healthcare Audit and Inspection, and the Health Service Commissioner;
- allocating compensation payments based on the merits of the claim or recommendation up to a maximum of £30,000 (except for neurologically impaired babies);
- assessing claims and developing packages of care and compensation under the scheme for severely neurologically impaired babies;
- levying ‘insurance’ payments from NHS service providers to fund the new schemes;
- monitoring the provision of care and rehabilitation packages under the scheme at local level;
- monitoring the local and national compensation payments made and publishing annual listings by NHS providers to act as an incentive to reduce risk and improve patient safety at local level;
- assessing and managing claims for care (other than neurologically impaired babies) where damages of greater than £30,000 are progressing under the tort system;
- continuing to manage older medical negligence claims for care given prior to the date of introduction of the new scheme.

Recommendation 4: Subject to evaluation after a reasonable period consideration should be given to extending the scheme to a higher monetary threshold and to primary care settings.

Bringing claims against general practitioners and other primary care professionals within the scheme would extend the benefits of a faster, less litigious process to general practitioners’ patients. It would also ensure that provision of care and levels of compensation were equitable between hospital and primary care patients.
Recommendation 5: The right to pursue litigation would not be removed for patients or families who chose not to apply for packages of care and payment under the NHS Redress Scheme. However, patients accepting a package under the Scheme would not subsequently be able to litigate for the same injury through the courts.

Patients or families would retain the right to pursue litigation for clinical negligence under the tort system instead of applying to the NHS Redress Scheme and for claims above the limit of the scheme. However, where a patient enters into the NHS Redress Scheme and accepts a Redress package, they should not subsequently be able to litigate on the same case. The faster decision, care and compensation package together with an explanation and apology should offer a fairer alternative to those harmed than an uncertain litigation process. It is envisaged that before accepting an offer under the NHS Redress Scheme, a small amount of money would be made available to patients to allow them to seek independent advice on the fairness of the offer.

Recommendation 6: A new standard of care should be set for after-event/after-complaint management by local NHS providers.

Despite NHSLA guidance to NHS Trusts (most recently in 2002) to encourage apologies being offered at a senior level, claimants and patient groups are still not receiving what they regard as genuine apologies or full explanations in all cases.

Each adverse event or complaint should have a full and objective investigation of the facts of the case, commensurate with the severity of the harm, so that patients or their families are provided with a full explanation of what has happened, an apology where something has gone wrong, and a specification of the action (local and national) being taken to reduce the risk of a similar event happening to future patients.

The explanation should be written in simple non-technical terms and should be given to the patient or family with an offer for follow-up discussion if they wish it. Where a service improvement is being implemented, the patient or family should be invited back to the hospital to see or hear about it when implementation is complete.

In addition, under the proposed NHS Redress Scheme, NHS Trusts should take early action to offer any remedial treatment or rehabilitation measures that may be indicated to counteract the harm suffered. A senior level member of staff should take responsibility for co-ordinating the immediate response, communicating with the patient or family and liaising with case managers for the development of more complex packages of care and rehabilitation. The benefits of such an approach will be improved ‘after care’ of those receiving a very bad outcome of care. The provision of remedial treatment at an early stage should reduce suffering and the long-term effects of any harm, with obvious benefits to the patient and savings to the NHS.

Each NHS Trust would be required to publish information annually on the payments made under the new scheme.
A new standard should be set covering these areas and the new Commission for Healthcare Audit and Inspection should assess compliance with it in inspections.

- **Recommendation 7:** Within each NHS Trust, an individual at Board level should be identified to take overall responsibility for the investigation of and learning from adverse events, complaints and claims.

  The techniques of root cause analysis, for which training is being developed by the NPSA in the context of adverse events, are equally applicable to complaints. In essence, the aim is to look for the reasons why an event happened, along a causal chain, rather than seek to allocate blame to a single individual. A full investigation of this kind not only allows for a full explanation to be given to the patient but can also identify the action necessary to prevent repetition. Patients should be told what that action is, and where possible and appropriate provided with evidence of the changes made. Bringing together the investigation of problems in service delivery, however identified, at a senior level will facilitate learning and remedial action.

- **Recommendation 8:** The rule in the current NHS Complaints Procedures requiring a complaint to be halted pending resolution of a claim should be removed as part of the reform of the complaints procedure.

  An investigation should automatically take place as part of the initial local response to a complaint. This may reveal a situation where development of a package of care or treatment and consideration of financial recompense under the NHS Redress Scheme may be appropriate. However, even in the larger value cases, if patients subsequently decide to pursue the litigation route, the complaints process should continue to provide the explanations which patients and families seek. The anticipated benefit is that this may reduce rather than increase the number of people who pursue a formal litigation process and may reduce the dissatisfaction complainants and claimants currently feel at the end of the process.

- **Recommendation 9:** Training should be provided for NHS staff in communication in the context of complaints, from the initial response to the complaint through to conciliation and providing explanations to patients and families.

  While it is easy to say that complaints should be welcomed as a means of improving services, it is a very human response to feel undermined and personally criticised. In addition, many patients and families will be distressed and angry when they or a loved one have been harmed. Training for staff at all levels will help overcome the defensive reaction which most claimants and complainants feel is the current automatic response to their concerns. The introduction of the Patient Advice and Liaison Services are the first stage in this process but it is vital that communications throughout each NHS Trust are focussed on the needs of patients and their families.
Recommendation 10: Effective rehabilitation services for personal injury, including that caused by medical accidents, should be developed.

Dedicated rehabilitation services are not widely available for those injured as a result of treatment or otherwise. Some other countries place far greater emphasis on the state to provide rehabilitation services and on the patient to follow an agreed rehabilitation programme.

Research demonstrates that effective rehabilitation can lead to shorter periods of hospitalisation, hasten recovery and help prevent long term disability. In the short-term, the current NHSLA pilot scheme to offer early rehabilitation in suitable clinical negligence cases should proceed and be subject to independent evaluation. In the longer term, the development of rehabilitation packages should form part of the NHS Redress Scheme. In addition, attention should be given to the development of rehabilitation services as part of the Long Term Conditions National Service Framework.

There is an ongoing cross-Departmental review of Employers’ Liability Insurance. Given the prominence in that review of discussions on rehabilitation, work to support the development of rehabilitation services should be mindful of the outcomes of the review.

Recommendation 11: The Department of Health together with other relevant agencies should consider the scope for providing more accessible high quality but lower cost facilities for severely neurologically impaired and physically disabled children, regardless of cause.

Special care and education facilities for severely brain damaged and physically disabled children are currently provided in the private sector, at high cost. There are a limited number of such facilities and the lack of geographic spread often contributes to the need for families to establish their own facilities at home. The potential for developing a network of high quality but lower cost facilities should be explored with SCOPE and other patient and carer groups.

Recommendation 12: A duty of candour should be introduced together with exemption from disciplinary action when reporting incidents with a view to improving patient safety.

In 1987, Sir John Donaldson, then Master of the Rolls said “I personally think that in professional negligence cases, and in particular in medical negligence cases, there is a duty of candour resting on the professional man”. There has however been no binding decision of the courts on whether such a duty exists. The Law Society’s code of professional conduct for solicitors requires them to notify their clients if they become aware of a possible negligent act or omission. Such a duty, which would give statutory force to the General Medical Council’s Code of Good Medical Practice for doctors, should be introduced in legislation to require all healthcare professionals and managers to inform patients where they become aware of a possible negligent act or omission. The concomitant of the duty of candour should be provisions providing for exemption from disciplinary action by employers.
or professional regulatory bodies for those reporting adverse events except where the healthcare professional has committed a criminal offence or it would not be safe for the professional to continue to treat patients.

**Recommendation 13: Documents and information collected for identifying adverse events should be protected from disclosure in court.**

A statutory provision should be introduced to provide legal protection for adverse event reports provided locally or to national such as the NPSA. This would ensure that such documents could not be compelled to be produced in a court and would reduce the disincentive to the reporting of errors. Such a provision would seek to balance competing public interest in encouraging healthcare professionals to report adverse events and the public or individual interest in access to information about those incidents. The protection would only apply to reports of adverse events where full information on the event is also included in the medical record. Information for a court action would have to be gathered afresh, from the medical record and other sources. Such protection for adverse events reports would follow the practice in Canada, some US States and Australia.

**Recommendation 14: Where a claimant was seeking Legal Aid to pursue a claim for clinical negligence, the Legal Services Commission should take into account whether or not the case had already been pursued through the NHS Redress Scheme.**

The results of the investigation undertaken to inform decisions on eligibility and level of award under the NHS Redress Scheme would provide valuable information to the LSC in deciding whether or not to support an application for Legal Aid to someone pursuing a claim for clinical negligence where they had not accepted a package of care and compensation under the scheme. For the claims eligible for the NHS Redress Scheme, the expectation would be that they would have been pursued through that route, to protect the public purse from the unnecessary expenditure on Legal Aid in lower value cases (this would not apply to cerebral palsy cases). Existing powers should be sufficient to enable the LSC to act on this recommendation but in the longer term the approach should be built into the Commission’s Funding Code criteria.

**Recommendation 15: Mediation should be seriously considered before litigation for the majority of claims which do not fall within the proposed NHS Redress Scheme.**

The successor body to the NHSLA should require their panel solicitor firms to consider every case for mediation and to offer mediation where appropriate. Mediation is not a cheap alternative to litigation. However, it can offer claimants the package of measures they say they seek: apologies, explanations, an opportunity to discuss the issues with the healthcare providers face to face and to explore issues other than financial compensation. It can also be followed by an out-of-court settlement of a large claim.
To encourage increased take-up of mediation, improved information is required for NHS staff, for Patient Advice and Liaison Services and for Independent Complaints Advocacy Services on what mediation entails and the cases for which it may be suitable. The Department of Health and the NHSLA should develop work to provide this.

In addition a larger pool of trained and accredited mediators is necessary to ensure that appropriate expertise is readily available. The Department of Health, the Department for Constitutional Affairs, and the LSC should build on the initial feasibility study work supported by the LSC, NHSLA, AVMA and CEDR to support the establishment of an advanced clinical negligence mediation training and accreditation programme and to test and evaluate a preliminary process review to explore the suitability of mediation or other forms of dispute resolution in particular cases.

Recommendation 16: The expectation in paying damages for future care costs and losses in clinical negligence cases not covered by the new NHS Redress Scheme should be that periodical payments will be used.

The Courts Bill, includes provision to give the courts power to make an order for periodical payments without the consent of the parties. Such payments can provide certainty for claimants that future care needs will be met and avoid distressing arguments about the life expectancy of the victim. It will also allow the NHS to spread its expenditure in large value cases. The Government has indicated during passage of the Bill that the circumstances in which periodical payments can be varied will be tightly drawn to avoid frequent return to the courts for reassessment. However, the legislation will only impact directly on cases decided in the courts, which is less than 1% of clinical negligence claims.

Although the NHSLA has no power to impose periodical payments in cases where settlements are negotiated outside the NHS Redress Scheme, the new legislation should help promote the widespread use of periodical payments by the courts so that the expectation in clinical negligence cases will become that these will apply. This will provide the lead for those negotiating settlements and in time lead to acceptance of periodical payments in negotiated cases.

Recommendation 17: The costs of future care included in any award for clinical negligence made by the courts should no longer reflect the cost of private treatment.

Section 2(4) of the Law Reform (Personal Injury) Act 1948 provides for the care costs component of an award for damages to be based on the costs of private rather than NHS treatment. This applies to all personal injury claims.
It is recommended that the law should be changed to exempt clinical negligence cases arising from NHS treatment from this provision. Instead, as part of any settlement, the NHS defendant should undertake to fund a specified package of care or treatment to defined timescales. It is envisaged that case managers under the auspices of the national body administering the NHS Redress Scheme would develop care packages and monitor their delivery to avoid patients having to deal with the NHS Trust where they had suffered harm. Initially at least, the costs may be similar to providing a sum of money to purchase private care as the NHS would have to fund elements of the care package privately and from a variety of sources. However, this recommendation fits well with the vision for the future of the NHS which offers and responds to patients’ choices by sourcing the necessary care and treatment from a range of providers.

- **Recommendation 18: Special training should be provided for Judges hearing clinical negligence cases.**

  The clinical negligence cases that reach court can be highly complex. They are also infrequent, meaning that any one judge will see clinical negligence cases only rarely. If the introduction of the NHS Redress Scheme is successful, this problem will be exacerbated in the future. Although the nature of these cases is such that a diet consisting only of clinical negligence cases is likely to be unpalatable, the provision of specialist training in medical issues as recommended by Lord Woolf would be beneficial.

- **Recommendation 19: The Department for Constitutional Affairs (DCA) and the Legal Services Commission should consider further ways to control claimants’ costs in clinical negligence cases which are publicly funded and the DCA and the Civil Justice Council should consider what further initiative could be taken to control legal costs generally.**

  In cases which are successful and costs are paid by the NHS, claimants’ costs consistently exceed defence costs by a wide margin. Because of the burden of proof and investigation falling on claimant lawyers there will always be some imbalance in costs. There are also advantages, in order to discourage lawyers from pursuing poor cases, in lawyers getting paid more in successful cases than in unsuccessful ones. Effective action has been taken by the NHSLA to control defence costs which makes the contrast with claimants’ costs starker. The day to day awarding of costs is a matter for the Courts, which are required to assess the proportionality and reasonableness of the costs incurred and the overall amount. These tests of proportionality and reasonableness should be rigorously applied. The Civil Justice Council may also wish to consider the issue of claimants’ costs in its work over the coming year. In addition, within the pre-action protocol currently being revised by the Clinical Disputes Forum, the requirement on claimant solicitors to keep the NHSLA and LSC informed about the progress and status of long-running cases should be strengthened. The NHSLA’s successor and LSC should work together to appoint single joint experts wherever possible as a further means of containing costs.
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