Introduction

Developments in modern medicine mean that healthcare services today offer effective treatment to many more patients than in the past. The greater ambition of medicine has led to a substantial increase in the number of medical acts[1] and in the complexity of techniques.[2] Healthcare expenditure has increased dramatically[3]. However, a negative consequence of medical progress is that, with the growth in the number and complexity of treatments comes a significant increase in iatrogenic harm.[4]

These changes have been accompanied by an evolution in the nature of the doctor–patient relationship. Whereas in the past that relationship was characterized by a mostly deferential attitude of the patient to his doctor, this deference has largely disappeared today,[5] a phenomenon no doubt linked to the development of consumerism and the patient rights movement.[6] Patients today desire a greater role in the decision-making

[1] For example, within the NHS, in 1951 there were 3.8 million 'finished consultant episodes' (the number of inpatients treated, calculated by the number of discharges and deaths), compared to 14.3 million FCEs in 2000–1, C. Newdick, *Who Should We Treat? Rights, Rationing and Resources in the NHS*, 2nd edn (Oxford University Press, 2005), 2.

[2] For a rapid review, see Newdick, *Who Should We Treat?*, 6–7.

[3] Expenditure on healthcare in the UK represented 6.6 per cent of GDP in 1997, and 9.4 per cent in 2011 (having fallen from a peak of 9.9 per cent in 2009), Office for National Statistics, *Expenditure on Healthcare in the UK: 2011*, 2013, 9.

[4] In 2000, it was estimated that there were around 850,000 adverse events in the English NHS, representing 10 per cent of admissions. Chief Medical Officer, *An Organisation with a Memory. Report of an Expert Group on Learning from Adverse Events in the NHS*, Department of Health (London: TSO, 2000).

[5] On this point, see, for example, W. Swain, 'The development of medical liability in England and Wales', in E. Hondius (ed.), *The Development of Medical Liability* (Cambridge University Press, 2010), 27; V. Harpwood, *Medicine, Malpractice and Misapprehensions* (Abingdon: Routledge-Cavendish, 2007), 67–71.

[6] Harpwood, *Medicine, Malpractice and Misapprehensions*, 63–7. H. Teff, *Reasonable Care* (Oxford University Press, 1994), 100–2; J. Harrington, 'Red in tooth and claw: the idea of progress in medicine and the common law', *Social and Legal Studies*, 11 (2002), 211–32;

process on treatment. What is more, society in general has become less risk-tolerant, which leads to a greater willingness by patients to sue when things go wrong.[7] Meanwhile, healthcare providers and governments have become much more conscious of the risks involved in treatment and of the extent of medical adverse events. As a consequence, healthcare safety has, over the last twenty years, become a central pillar in healthcare policy and governance.[8]

These developments in modern healthcare and in society invite us to question the appropriateness today of dealing with medical accident redress through civil liability when this, in England, is largely based on a corrective justice model.

For victims of iatrogenic harm, a fault-based civil liability system is ill-adapted to providing effective redress. The litigation process is often slow, stressful and expensive for claimants. It represents a very uncertain means of obtaining compensation due to the significant barriers to successful claims posed by the need to prove negligence and causation. By focusing on blame and financial compensation, the law fails to take sufficient account of a broader concept of redress which includes remedial treatment, rehabilitation and care, explanations and apologies.[9] Civil liability is also an inefficient way to ensure the recognition of patient rights and autonomy:[10] the law tends to focus on doctors' duties rather than on patient rights, and failure by a doctor to provide the patient with adequate information on the risks of his treatment will only be sanctioned where the patient can show a causal link between that failure and resulting personal injury. Meanwhile, from the perspective of healthcare service providers, the civil liability system engenders high liability costs. Its focus on blame is argued to encourage the practice of defensive

S. Halpern, 'Medical authority and the culture of rights', *Journal of Health Politics, Policy and Law*, 29 (2004), 835; S. Timmermans and H. Oh, 'The continued social transformation of the medical profession', *Journal of Health and Social Behaviour*, 51 (2010), 94.

[7] C. Ham, R. Dingwall, P. Fenn, D. Harris, *Medical Negligence, Compensation and Accountability*, King's Fund, 1988, cited in I. Kennedy and A. Grubb, *Medical Law*, 3rd edn (London: Butterworths, 2000), 541.

[8] See *infra*., Chapter 7, 150.

[9] As defined in S. McLean, *No Fault Compensation Review Group: Report and Recommendations*, 2011, vol. 1, 69.

[10] H. Teff, 'Consent to medical procedures: paternalism, self-determination or therapeutic alliance?' *Law Quarterly Review*, 101 (1985), 432; E. Jackson, 'Informed consent to medical treatment and the impotence of tort law' in S. McLean (ed.), *First Do No Harm: Law, Ethics and Healthcare* (Aldershot: Ashgate, 2006), 273.

medicine, while compromising improvement to safety by discouraging the reporting of adverse events.

In England, despite widespread dissatisfaction with clinical negligence law,[11] reforms to date have largely been limited to procedural adjustments to the clinical negligence litigation process. A push for more ambitious reform in the first decade of this century culminated in the NHS Redress Act 2006, which, despite its modest nature, has never been implemented in England, although an administrative complaints and redress scheme has been operating in Wales since 2011.[12] The period of economic recession and policy of austerity which we have seen since then has meant that significant reform of the clinical negligence system has disappeared from the political agenda. However, this does not mean that the need for reform has been removed, nor that reflection should not continue to be pursued on the nature of any future reform.

It is true that reform of the law on medical liability and redress is particularly challenging due to the need to reconcile conflicting objectives. The aim of facilitating victim compensation is likely to run counter to that of limiting the cost of liability; a need to ensure that the doctor–patient relationship is conducive to learning from medical error sits awkwardly with a desire to ensure that doctors remain accountable for their negligence. Such concerns are clearly not exclusive to clinical negligence law, yet they are particularly pronounced in the medical field due to the central importance to any society of maintaining a high level of healthcare. Also, unlike in other areas, imposing the burden of the risk of accidents on medical services cannot be justified by the profit motive of the defendant. Medical accident liability and redress also stands out due to the particular importance of ensuring a relationship of confidence between doctor and patient which is vital to high-quality care.

[11] See notably the criticisms voiced by the Chief Medical Officer, *Making Amends: a Consultation Paper Setting out Proposals for Reforming the Approach to Clinical Negligence in the NHS*, Department of Health, June 2003; House of Commons Select Committee on Health, *Sixth Report*, *Patient Safety*, 2009, para. 85; I Kennedy (chair), *Learning From Bristol: the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–95,* Cm 5207 (1), 2001; National Audit Office, *Handling Clinical Negligence Claims in England*, HC 403 (London: TSO, 2001). For academic criticism of the current system, see, for example E. Cave, 'Redress in the NHS', *Journal of Professional Negligence*, 27 (2011), 138; McLean, *No Fault Compensation Review Group: Report and Recommendations*,.

[12] NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (SI 2011 no. 704, W.108).

The challenges posed have not deterred certain countries from being more ambitious than England in their reform agenda and adopting administrative compensation schemes for medical accidents. New Zealand and Scandinavian countries are often cited as examples of alternative systems of redress for medical accidents. However, relatively little attention has been paid to French law,[13] where an innovative out-of-court compensation scheme for medical accidents was introduced in 2002. The French scheme guarantees full compensation for the victims of the most serious medical accidents without the need to prove fault. It provides cheap, simple and relatively fast compensation for over a thousand victims annually whilst ensuring the financial sustainability of redress. In many ways, the scheme offers a more realistic model for England than those operating in New Zealand and northern Europe, given that it is more restricted in scope, and retains fault as the principal basis of liability.

The aim of this book is to compare the law on medical accident liability and redress in England and France, to consider how both legal systems meet the various challenges posed in this area of law, and to reflect on the lessons that can be drawn from the French experience. Whilst this study naturally involves an analysis of the substantive law in England and France, it also looks at how the legal rules have been shaped by national legal traditions and cultures. Much of its focus is on the actual or possible effects of the legal rules on access to redress for victims, on the financial cost of that redress, on the coherence, complexity and fairness of the law, on the doctor–patient relationship and on patient safety.

In this way, this study is intended to contribute to the debate on reform of medical accident liability and redress law in England, and also in other legal systems which are considering change in this area. It also has broader resonance as a study in comparative tort law, and thus hopefully will be seen as contributing to the growing body of work in this field. To the extent that it underlines the significant differences in access to compensation for victims of medical accidents in the two legal

[13] Although see S. Taylor, 'Clinical negligence reform: lessons from France?', *International and Comparative Law Quarterly*, 52 (2003), 737; S. Taylor, 'Providing redress for medical accidents in France: conflicting aims, effective solutions?' *Journal of European Tort Law*, 57 (2011), 2. National reports on French law are contained in K. Oliphant and R. W. Wright (eds.), *Medical Malpractice and Compensation in Global Perspective* (Berlin: De Gruyter, 2013), 1093, and in B. Koch (ed.), *Medical Liability in Europe. A Comparison of Selected Jurisdictions* (Berlin: De Gruyter, 2011), 207.

systems, it also has relevance in the European context. Greater cross-border movement of patients is seen as an element in market integration, and the European Court of Justice case law on cross-border access to treatment[14] has recently been codified in the Patient Rights Directive 2011,[15] yet divergence in national laws on liability and redress means that when things go wrong, access to compensation for patients will vary depending on where they were treated. This is arguably undesirable from a consumer protection perspective and could potentially have a detrimental effect on the confidence of patients in seeking treatment abroad.

In Chapter 1 I consider the current state of the English law on medical accident liability and redress. I highlight the criticisms of clinical negligence law in England, before tracing the development of the domestic reform debate and considering the limited substantive and procedural changes that have been introduced. I then turn to look at the possibility of more ambitious reform. I examine the framework established by the NHS Redress Act and the scheme which has been running in Wales since 2011, before briefly describing the examples of alternative redress schemes provided by New Zealand and Sweden and the Scottish debate on reform.

Chapter 2 then examines the French law on medical accident liability and redress and compares this with the English rules. The French out-of-court settlement scheme co-exists with traditional liability principles. I therefore start by considering the liability rules that have been developed by the French courts. The comparison with English law will demonstrate how French law has placed greater emphasis on facilitating the compensation of victims, principally through introducing exceptions to fault liability for certain categories of claimant, and by a creative interpretation of causation principles. Greater weight in French law is also placed on criminal liability. I then turn to describe the French out-of-court settlement scheme. I explain how the scheme achieves its dual aim of facilitating access to compensation for victims and of limiting the liability burden on medical professionals and liability insurers. I provide an introduction to the operation of the scheme, an analysis which will be developed further in later chapters.

[14] Case C-158/96, *Kohll* v. *Union des Caisses de Maladie* [1998] ECR 1-01931; Case C-157/99 *Geraets-Smits* v. *Stichting Ziekenfonds, VGZ and Peerbooms* v. *Stichting CZ Groep Zorgverzekeringen* [2001] ECR 1-05473; Case C-372/04 *Watts* v. *Bedford Primary Care Trust* [2006] ECR 1-04325.

[15] Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, OJ 2011 no. L88, 4 April 2011, 45.

The comparison of French and English law undertaken in Chapter 2 underlines the significant disparities between the approaches of the two legal systems towards medical accident liability and redress. In Chapter 3, I consider the degree to which contrasts in legal and, more specifically, tort traditions and cultures can provide explanations for the differences in approach of the two systems. Whilst the contrasts in legal culture which I observe may well affect the extent to which the French approach will be transposable in England, there are a number of significant lessons that can be learnt from the French model, which I will present in the succeeding chapters.

Clearly a vital issue which is raised in any debate on reform of clinical negligence law is the financial sustainability of such measures. This has certainly represented a major argument against significant reform of the English system. In Chapter 4, I will consider the cost of medical accident liability and redress in France and the financial impact of the compensation scheme. Given the pro-victim orientation of French law, it might be supposed that the financial burden of liability on the state, medical service providers and liability insurers would be greater than in England. A study of the available statistics indicates that this is not the case. The introduction of the out-of-court settlement scheme has not led to an unsustainable financial burden on defendants and the state, and medical accident liability and redress in fact appears to cost much less in France than in England. This leads me to examine why the cost of liability in France is substantially lower than in England. I suggest explanations based on lower claims rates, and on the different levels of personal injury damages and legal costs. I draw conclusions on the extent to which the French experience can be used to counter fears in England that the adoption of an out-of-court settlement scheme would lead to unsustainable cost and to a flood of compensation claims.

French law succeeds in facilitating access to compensation for certain medical accident victims whilst ensuring that the regime is financially sustainable because the more generous rules established by the courts and the legislature only apply to restricted categories of victim. This categorization creates problems for French law which I consider in Chapter 5. The law becomes extremely complex, uncertainty is caused by the difficulties engendered by the need to interpret new concepts such as 'medical accident', and rather arbitrary distinctions are created between those who do and do not have access to compensation. I also consider whether the accident compensation scheme actually treats victims fairly. Again,

I examine what lessons for legal change in England can be drawn from the French experience.

In Chapter 6 I turn to reflect on the effect that liability and redress rules have on the doctor–patient relationship in England and France. The 'therapeutic alliance' between medical professional and patient is of central importance to the treatment process. Civil liability and redress rules will clearly affect this relationship in various ways. I consider to what extent liability rules in England and France contribute to the recognition of patient autonomy and a right to information on treatment. I consider whether the specific legislative duty of candour which is imposed in French law provides any support for the introduction of a similar obligation on doctors in English law. I also look at the extent to which the French out-of-court settlement scheme may help in reducing the blame and acrimony caused by the litigation process, and thus contribute to an improved doctor–patient relationship.

Chapter 7 is concerned with a central issue of modern healthcare, namely that of patient safety. I examine to what extent civil liability and redress rules in England and France can be argued to contribute to the promotion of patient safety. Although what civil liability rules can achieve here is clearly secondary compared to other modes of healthcare governance, civil liability law can be argued to have a role in promoting patient safety to the extent that it acts as a deterrent to negligent practice. Liability rules will only be successful in this role where they channel the cost of accidents to those best placed to avoid adverse events. I compare the effectiveness of French and English law in this respect. In other ways, liability rules can be argued to be detrimental to the promotion of patient safety since the threat of liability will tend to deter medical professionals from reporting mistakes and adverse events. However, where liability law focuses on systems errors rather than on establishing individual blame, this can contribute to improved openness. I compare English and French liability rules to see to what extent the two legal systems have embraced a systems-error approach to civil liability. I then consider whether the French out-of-court settlement scheme can contribute to patient safety by encouraging reporting and by facilitating the collection of data on adverse events.

1

The state of medical accident liability and redress in England

When the Chief Medical Officer for England published his report *Making Amends* in 2003 recommending reform of the law on clinical negligence, he described what were seen as the weaknesses of the current system.[1] The litigation process was slow, potentially costly and emotionally taxing for victims, and it was difficult for claimants to establish negligence and causation.[2] The report also argued that tort law did nothing to promote what it suggested was often most desired by victims of medical accidents, namely an explanation and an apology from the medical staff or organization, and information on what was being done to prevent similar accidents happening in the future.[3] The law was also unsatisfactory from the perspective of medical professionals. They resented the damage to their reputation caused by claims, the acrimonious nature of legal proceedings, the damage wrought by litigation on the doctor–patient relationship, and the temptation that the threat of liability exerted to practice defensive medicine. The tort system was also detrimental to patient safety, since it discouraged medical professionals from reporting errors.[4] It was moreover very costly. The financial burden to the NHS of clinical negligence claims was rising dramatically,[5] and legal and administrative costs exceeded the amount paid to victims in compensation in the majority of claims under £45,000.[6]

[1] Chief Medical Officer, *Making Amends: A Consultation Paper Setting Out Proposals for Reforming the Approach to Clinical Negligence in the NHS*, Department of Health, June 2003, esp. 75–85.
[2] Chief Medical Officer, *Making Amends*, 53 and 110.
[3] Ibid., 11 and 75.
[4] Ibid., 11 and 76.
[5] In 1974–5, annual NHS expenditure on clinical negligence litigation was £1 million (£6.33 million at 2002 prices), but had risen to £446 million by 2001/02. Ibid., 9.
[6] Ibid.

Medical accident liability and redress in England today

These criticisms voiced over ten years ago still have considerable resonance today.[7] Very much the same obstacles still face the claimant in a clinical negligence action. The compensation of medical accident victims remains reliant on traditional liability principles which render access to redress difficult. The application of the *Bolam* test[8] to clinical negligence claims makes it hard for the claimant to prove fault since the defendant can avoid liability if he can show that he acted in accordance with a practice accepted as reasonable by a responsible body of medical opinion.[9] Even if the House of Lords in *Bolitho* v. *City and Hackney Health Authority* has established that it is open to the judge to reject the expert opinion relied on by the defendant if it is not capable of withstanding logical analysis,[10] it is clear that such situations will be rare in practice. Proving causation also continues to pose particular problems in the clinical negligence context since it is often difficult to show that the damage was due to the defendant's negligence rather than to the patient's pre-existing medical condition.

By its reliance on traditional liability principles, the law thus still embraces a corrective justice model of civil liability which can be argued to be out of touch with contemporary perceptions of redress, which recognize the importance placed by patients on receiving an apology and an explanation for the causes of his harm. Despite efforts to develop a culture of openness,[11] the introduction of an obligation on medical services to report incidents[12] and a continuing discussion on how to develop candour,[13] clinical negligence law will tend to work against

[7] For an analysis of developments since *Making Amends*, see E. Cave, 'Redress in the NHS', *Journal of Professional Negligence*, 27 (2011), 138.

[8] *Bolam* v. *Friern Hospital Management Committee* [1957] 1 WLR 582.

[9] Per McNair J, 587.

[10] [1998] AC 232 at 243, per Lord Browne-Wilkinson.

[11] S. 2 of the Compensation Act 2006 states that 'an apology, offer of treatment or other redress shall not of itself amount to an admission of negligence or breach of statutory duty'. The same message has been conveyed by the National Patient Safety Agency, which also emphasizes that a patient has a right to openness: NPSA, *Being Open: Communicating Patient Safety Incidents with Patients, their Families and Carers*, Department of Health, 2009, 6; see also, for example, Care Quality Commission, *A Quality Service, a Quality Experience*, 2009; NHSLA, *Apologies and Explanations: Letter to Chief Executives and Finance Directors*, 2009. See Cave, 'Redress in the NHS', 145.

[12] Regulation 18, Care Quality Commission (Registration) Regulations 2009 (SI 2009 no. 3112).

[13] See Chapter 6, 137–41.

greater openness, and there would still seem to be significant resistance to reporting and candour within the healthcare system.[14]

Meanwhile, the cost of clinical negligence liability for the NHS has risen significantly. According to the NHS Litigation Authority, £1,244 million was paid in respect of negligence claims against the NHS in 2013–14,[15] slightly less than in 2012–13,[16] but up from £863,398,000 in 2010–11, and from £579,391,000 in 2006–7. As at 31 March 2014, the NHS estimated that it faced potential liabilities of £25.7 billion in clinical negligence claims.[17] Legal costs still represent a significant part of the financial burden. In 2013–14, the NHS paid £285 million in legal costs for claims closed in that year, which included over £233 million in claimant costs.[18] The number of claims against the NHS appears to be rising at a significant rate. In 2013–14, the NHS Litigation Authority received 11,945 claims for clinical negligence, compared to 10,129 in the previous year,[19] and to 6,088 in 2008–9.[20]

Reforming medical accident liability and redress law in England

Despite the criticisms made of the current liability and redress system, reforms have largely focused on procedural rather than substantive change. Lord Woolf's comprehensive review of the civil justice system and Final Report issued in 1996[21] led to the introduction of a pre-action protocol for the resolution of clinical disputes. The aim was to promote early settlement of claims, thus reducing recourse to litigation, and to encourage a greater climate of openness, although doubts have been

[14] As evidenced by the recently published report on the appalling standards of care at the Mid Staffordshire NHS Foundation Trust Hospital, *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*, HC 898, February 2013. The House of Commons Select Committee on Health, Sixth Report of Session 2008–9 (London: TSO, 2009), paras. 102–12, observed that there was still evidence of significant under-reporting of adverse events within the NHS. Also see Department of Health, *Safety First: A Report for Patients, Clinicians and Healthcare Managers*, 2006, 21, where it was noted that progress was still needed with respect to the operation of reporting mechanisms.

[15] NHSLA, *Factsheet 2, Financial information*, 2014, 2.

[16] £1,309 million paid in that year, Ibid., 3.

[17] This represents the estimated value of all known claims, together with an actuarial estimate for those claims with have occurred but have not yet been reported. Ibid., 2.

[18] Ibid., 3.

[19] NHSLA, *Factsheet 3, Information on Claims 2013–14*, 2.

[20] NHSLA, *Annual Report and Accounts 2012–13*, 14.

[21] *Access to Justice: Final Report to the Lord Chancellor on the Civil Justice System in England and Wales*, HMSO, 1996.