1

General introduction

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1 Introduction

Medical liability is one of the core issues analysed in the European Legal Development project undertaken by the University of Cambridge. This chapter explores some of the developments in medical liability and the backgrounds thereof, which are further analysed in the national reports. The legal systems which have been selected for this purpose are Austria, England and Wales, France, the Netherlands, Scotland and Spain. Occasionally references to other jurisdictions will be provided. This will particularly be the case with regard to Finland, which is one of the Nordic countries having introduced a patient insurance scheme. Another jurisdiction[1] which will in some instances be referred to is that of the United States, where medical negligence law has developed earlier than in Europe as a distinct legal category.

Many liability questions are solved the same way all over Europe. But there are also differences. These differences are perhaps of a temporary nature. The law with regard to medical services has been developing fast; what in one jurisdiction has just been settled may soon become the law in other legal systems. Yet there are differences, and in this introduction to the book, some of the main differences will be set out. These relate to the question how medical malpractice should be dealt with: by public or private law (Section 2), in contract or tort (Section 3), what role codes of conduct play (Section 4), the history of liability in private law (Section 5), the role of patients' rights (Section 6), the standard of care (Section 7), proof and causation (Section 8), who is liable (Section 9), damages (Section 10), exemption clauses (Section 11) and patient insurance systems (Section 12). An intriguing question is the extent to which harmonisation of medical negligence law is to be expected at the

[1] Or to be more precise: a number of jurisdictions, each state having its own law.

European level (Section 13). Finally, some general conclusions will be reached (Section 14).

This chapter relies principally on the national reports published in this volume. Useful information could also be extracted from two projects with aims which are similar to those of the European Legal Development project: the Project on Medical Liability in Pennsylvania[2] and the Netherlands-based 'Shifts in Compensation project'.[3] The latter project, like the European Legal Development project, is looking for events which caused the regime to change. The Shifts in Compensation project distinguishes between major and minor shifts. Major shifts are considered to be those changes to the law that involve a significant reform of the compensation system, where the rules on entitlement, the claims procedure and compensation methods are significantly changed,[4] such as the introduction of the patient insurance scheme in the Nordic nations, the *loi* of 4 March 2002 in France and the case of *Chester v. Afshar*[5] in England. Minor changes introduce limited changes to the entitlement criteria, the claims procedure or the compensation method.[6]

The Shifts in Compensation project includes mass medical catastrophes, such as those involving Thalidomide and HIV. The present study has a smaller scope: it only covers the individual liability of hospitals and health care providers. The latter may include nurses and other personnel, but in fact the law focuses almost exclusively on medical doctors. Like the Shifts in Compensation project, this project focuses on the medical adverse event, which according to the Harvard Medical Practice Study consists of an injury caused by medical management rather than the underlying condition of the patient.[7]

Two other publications which will be referred to occasionally are two comparative casebooks, compiled by Faure and Koziol,[8] viz. by Winiger, Koziol, Koch and Zimmermann.[9]

[2] See William M. Sage and Rogan Kersh (eds.), *Medical Malpractice and the U.S. Health Care System* (Cambridge: Cambridge University Press, 2006). A useful overview of the American situation is also given in '2006 Medical Malpractice Symposium' (2006) 59 *Vanderbilt Law Review* 1015–381, 1457–98.

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[4] Rui Cascao and Ruud Hendrickx, 'Shifts in the Compensation of Medical Adverse Events', unpublished paper for the Shifts in Compensation conference, Rotterdam, 2006.

[5] [2004] UKHL 41. See also the Dutch and Spanish annotations in (2007) 15 *European Review of Private Law* 433–50.

[6] Cascao and Hendrickx, above n. 4.

[7] *Ibid*., para. 1.2.

[8] Michael Faure and Helmut Koziol (eds.), *Cases on Medical Malpractice in a Comparative Perspective* (Vienna: Springer, 2001).

[9] B. Winiger, H. Koziol, B. A. Koch and R. Zimmermann (eds.), *Digest of European Tort Law, Vol. 1: Essential Cases on Natural Causation* (Vienna: Springer, 2007).

This chapter does not present an overall picture of relevant data. In some of the reviewed jurisdictions, data are collected by national agencies, such as the National Health Service Litigation Office (NHSLO) in England and Wales and the *Office National d'indemnisation des accidents médicaux, des affections iathrogènes et des infections nosocomiaux* (ONIAM) in France. The Shifts in Compensation project tries to compare the available data for the jurisdictions covered. Although the researchers do admit that such comparison is difficult because the data collected do not always present all medical negligence claims. Taking this into account, they found the following claim rate per 10,000 hospital discharges:[10]

Sweden 63
Finland 55
Denmark 40
Germany 24
England 5
France 2

In assessing these data one must be cautious. Thus, under the Nordic patient insurance schemes, claims may not only be filed where liability arises, as in the other European jurisdictions, but also in case of other adverse medical developments. Second, the data are about claims and a claim is not always well founded. Moreover, even where it is well founded, financial compensation may also be quite variable. Thus, under the Nordic insurance schemes, non-material loss is not compensated and material losses, because of the well-developed social insurance, are often compensated to a much lower amount than in other European jurisdictions.

In the following paragraphs, the order in which the national reports will be presented will not be the same everywhere. Rather, those jurisdictions will be presented first which either are an example of the mainstream or rather of the most radical departure thereof.

2 Health care system: public or private law

The structure of the health care system has an impact on the branch of law which intervenes with liability issues. An analysis of medical liability in a jurisdiction should therefore start with a brief sketch of this jurisdiction's health system. This may be wholly private, wholly public, or somewhere in between. In the early nineteenth century, there was private medicine for those who could pay (or who belonged to a mutual insurance that

[10] Cascao and Hendrickx, above n. 4, para. 6.

could pay), or there was charitable medicine for the poor and a limited amount of publicly funded medical treatment. In more recent times, the state has become a major provider of health care, and this has had an impact on the importance of private law as the mechanism for providing compensation.[11]

At one extreme, the United Kingdom now basically has a public system, the National Health Service, which in 1948 replaced a mixed system of private, voluntary (charitable) and municipal hospitals.[12] Everyone is entitled to free treatment or has to pay a small charge under the NHS cover, though many people do have private health insurance. In Austria, a large majority of 79% of all hospitals are operated by legal persons under public law; only 21% of the hospitals are privately operated.[13] Austria has a long tradition of social security; at present 97.6% of all Austrians are covered by social security.[14] In Spain, 40% of the hospitals are public and 60% private; the public hospitals are larger however, and provide more health care than the private hospitals.[15] France likewise has a mixed system with a public and a private sector, where 78% of secondary care is provided by the public health service.[16] The Netherlands have recently changed their system of financing health care from a predominantly social health insurance to a private one. Dutch citizens outside the upper-income bracket no longer are automatically insured, but all citizens now have to take out private insurance themselves.[17] Everyone now can freely choose an insurance company and the kind of cover one wishes. The drawback of the system is that some 240,000 citizens have failed to acquire insurance.

To the extent that a health care system is public, the question arises whether or not this means that any liability lies in administrative law or in private law. In France, there traditionally exists a dichotomy.[18] Relations of patients with private hospitals are considered to be contractual – or occasionally delictual – and conflicts with such hospitals are dealt with by the ordinary courts. Relations with state hospitals are considered as administrative law and conflicts with the 'users' (*usagers*) are solved by

[11] See Nils Jansen and Ralf Michaels, 'Private Law and the State/Comparative Perceptions and Historical Observations' (2007) 71 *RabelsZ* 345–97; Ralf Michaels and Nils Jansen, 'Private Law Beyond the State? Europeanization, Globalization, Privatization' (2006) 54 *American Journal of Comparative Law* 843–90.

[12] See English (Chapter 2) and Scottish (Chapter 3) reports.

[13] Chapter 5, p. 112. [14] Chapter 5, p. 111.

[15] Chapter 7, p. 168. [16] Chapter 4, p. 72.

[17] Henriette Roscam Abbing, 'Recent Developments in Health Law in the Netherlands' (2006) 13 *European Journal of Health Law* 133–42.

[18] Chapter 4, p. 70.

the administrative courts.[19] Spain now makes the same division as does France.[20] No such dichotomy exists in Austria[21] and the Netherlands,[22] where all conflicts between doctors and hospitals on the one side and their patients on the other are dealt with by the ordinary courts. This difference is not simply a matter of which court hears a case, but also affects the liability rules that are applied.[23]

Constitutional law may also play a role, for instance in the form of personality rights which are at the basis of patients' rights, especially in Germany.[24] In France, however, personality rights and self-determination are not referred to in judgments on medical liability,[25] and in the Netherlands this is also rare.[26]

Regardless of the organisation of a jurisdiction's health service, criminal prosecution is always possible against doctors who have infringed the law.[27] Civil liability and criminal liability do sometimes mix. In Spain and Germany, criminal law played a predominant role in the nineteenth century, and this continues in Spain, where the principle applies that everyone who is criminally liable is also civilly liable.[28] In terms of substantive law, criminal liability typically arises in the case of serious or gross fault (*faute lourde*). On the other hand, there may be procedural advantages to use criminal liability. In France, victims often join as *partie civile* in a criminal prosecution initiated by the *ministère public* or even oblige the *ministère* to start criminal proceedings.[29] A major advantage of this procedure is that the costs for the victim are minimal, since the public action will be responsible for obtaining the evidence; a disadvantage is that he depends upon the *ministère public*. Reforms to the Penal Code in 2000 have reduced the extent of criminal liability for negligence, and so the overlap between criminal and civil liability has been reduced.

[19] Chapter 4, p. 70, which mentions, however, that the Law of March 2002 on patients' rights and the quality of the health system now provides the same substantive system for administrative and contractual medical services.
[20] Chapter 7, p. 169. [21] Chapter 5, p. 112.
[22] Chapter 6, p. 137. [23] Chapters 4 and 7.
[24] See Olha Cherednychenko, *Fundamental Rights, Contract Law and the Protection of the Weaker Party/A Comparative Analysis of the Constitutionalisation of Contract Law, with Emphasis on Risky Financial Transactions*, PhD Utrecht (Munich: Sellier, 2007) and Chantal Mak, *Fundamental Rights in European Contract Law*, PhD Amsterdam (Alphen aan den Rijn: Kluwer, 2007).
[25] Chapter 4, p. 87. [26] Chapter 6, p. 140.
[27] Chapter 2 mentions a criminal case from the Mayor's Court of London from as early as 1321: see p. 70.
[28] Chapter 7, p. 170. [29] Chapter 4, p. 74.

3 Contract or tort

Where the law does create medical liability, this may be under the heading of either tort or contract. In the case of tort, the underlying idea is that an infringement of the patient's physical integrity entitles that person to protection by the law. In the case of contract, the idea rather is that there is a breach of the consensual relationship between doctor and patient. In the United Kingdom, contract law is of minimal importance (except in private medical treatment) because as the English report puts it,[30] there is no contract between NHS patients and the doctor or hospital. The one way then is to sue doctors and hospitals in negligence.[31] Only private patients can sue in contract. Likewise in Scotland negligence and not breach of contract is the ground for medical liability.[32] A jurisdiction where contract law was developed at an early stage is France, where the *Mercier* case in 1936 was pivotal in making medical liability a specific type of civil liability and recognised for the first time a contractual relationship between the patient and the doctor or hospital.[33] In some jurisdictions patients have a choice between contract and tort. In others, the whole dichotomy has lost some of its interest. This is especially the case in the Netherlands. In France, Geneviève Viney has observed a similar tendency.[34]

When required to choose between liability in contract or tort, the main argument in favour of the contract option is that it is based on self-determination, which is considered to be of fundamental importance in the relation between doctor and patient. But it has to be admitted that the contract model does have some disadvantages.[35] First, contract presupposes a capacity to consent, a capacity that is not necessarily present in, for example, psychiatric patients and even absent in comatose patients. Second, the contracting party and the patient are not always one and the same person. Children and persons required to undergo examination by a public official are two groups where the qualities are usually spread over different persons. Third, a contract usually embodies rights

[30] Below p. 35.
[31] Historically, other torts, such as trespass on the case, have also been used: below p. 36.
[32] Chapter 3, p. 57.
[33] Cass. civ. 20 May 1936, D. 1936.1.88, as reported in Chapter 4, p. 000. This case was important because it took medical activities such as surgery out of delictual strict liability for things (created in 1930) and maintained liability for fault, albeit now within contract, rather than within delict.
[34] Chapter 4, p. 71.
[35] See Pauline Allen, 'Contracts in the National Health Service Internal Market' (1995) 58 *Modern Law Review* 321–42.

and obligations for both parties. Instead, the medical services contract seems a very one-sided affair, with only two obligations on the side of the patient, one of which – the obligation to provide the physician with the necessary information and cooperation – can hardly qualify as an obligation, but rather as an 'Obliegenheit'.

The project, of which this volume is a part, is basically only concerned with the development of tort law. However, under the functional analysis of comparative law,[36] it is recognised that what in one jurisdiction, viz. that of England and Wales, may be qualified as tort, may well be deemed to be contract in other jurisdictions.[37] Therefore, relevant parts of contract law are included. In any case, the development of contract law does fit into the main research question of the European Legal Development project which is: 'How do Western legal systems develop?'

4 Codes of conduct, disciplinary boards

The conduct of medical doctors is not only governed by liability rules, but also by codes of conduct, codes of ethics, etc., which are established by the profession and where the maintenance of rules is left to disciplinary boards. An example is the *Ordre des médecins* (Organisation of medical doctors), which was set up in France in 1940 and in 1941 produced the first professional code of ethics. The 2002 Act now states that it is the task of the *Ordre* to ensure the competence of medical professionals and that the ethical principles of the medical profession are respected.[38] In other countries, professional bodies were created in the nineteenth century in order to certify medical competence and effectively create a profession. As in the French example, the existence of a profession helped to identify a standard of professionalism which could be applied to medical acts, whether they were conducted by recognised members of a profession or by 'quacks'. As experts appointed by the courts or, in the common law, as expert witnesses called by the parties, members of the professions would have an authoritative status in influencing the standards applied by the courts. As the national reports demonstrate, there is a relationship between decisions of disciplinary boards and medical liability.

[36] Konrad Zweigert and Hein Kötz, *Einführung in die Rechtsvergleichung auf dem Gebiete des Privatrechts* (3rd edn., Tübingen: Mohr, 1996), pp. 31–47 (also available in English translation).

[37] Chapters 6 and 4, p. 134 and p. 71. [38] Chapter 4, p. 75.

5 A history of liability in private law

Medical liability is a rather new phenomenon. Although not wholly unknown in the nineteenth century,[39] until fifty years ago it was rarely invoked in England and Wales.[40] There were, however, cases of liability which caused medical insurance to rise, e.g. in 1927 the jury's award of damages in *Harnett v. Fisher* was so far beyond the previous awards that the medical profession had to immediately raise its insurance cover substantially. Again, as the English reporter describes, the cost of compensation to the National Health System rose from £6.33 million in 1974/1975 to £446 million in 2001/2002. In other liberal professions, one finds similar developments.[41] In Austria, medical malpractice cases – although previously not unknown – only emerged as a hot topic in the last two decades of the twentieth century.[42] The same happened in Spain.[43] In France, the modern rise of medical liability cases had begun earlier, with the *Mercier* case of 1936 usually being taken as the starting point,[44] although liability cases do go back to 1835.[45] In recent years, the number of reported cases of medical liability has increased rapidly also in the Netherlands.[46] This has raised fears that soon liability will no longer be insurable[47] and that the costs of health care will grow beyond what society is willing to pay. On the other hand, it has also been pointed out that, until recently, the number of reported cases in the Netherlands has been consistently extremely low[48] and that even now many cases are not taken to court because this is too expensive or too cumbersome for the patients concerned.

Why did medical liability take off? Was this prompted by the American experience? The leading idea which is suggested in the various national

[39] Chapter 2 even mentions two cases decided in the fourteenth century: see p. 35.

[40] As the English reporter observes, as late as fifty years ago, an English author could remark that 'actions against medical men and hospitals [have] until recently been altogether unusual': see p. 28.

[41] Chapter 2, p. 29. [42] Chapter 5, p. 108. The same is true for Germany.

[43] Chapter 7, p. 164. [44] Chapter 4, p. 80. [45] Chapter 4, p. 78.

[46] A. T. Bolt and J. Spier, 'De Uitdijende Reikwijdte van de Aansprakelijkheid uit Onrechtmatige Daad' *Handelingen (Nederlandse Juristen-Vereniging*, 1996), pp. 19–22.

[47] The number of insurance companies willing to insure medical liability in the Netherlands has dropped from twenty to three within twelve years. The companies no longer take on the risk themselves, but rather serve as administrators for insurance mutuals – Bolt and Spier, n. 46. See also J. Spier and O. A. Haazen, *Aansprakelijkheidsverzekeringen op Claims Made-Grondslag* (Deventer: Kluwer, 1996). The same fears were expressed when the first medical liability cases were being brought in the US in the 1860s.

[48] In the first edition of *Beroepsfouten* (Zwolle: Tjeenk Willink, 1976), I. P. Michiels van Kessenich-Hoogendam refers to the fact that over the century preceding publication of her book only twenty medical liability cases have been reported.

reports is that the American experience has rather – perhaps undeservedly so – served as a disincentive. Two elements instead seem to have played a major role: the general development of tort – and contract – law in this area, including a growth of legal aid, and the movement towards patients' rights. The movement towards patients' rights will be dealt with in Section 6 below. Here the growth of tort law will briefly be described.

There is no doubt that tort law generally has increased in legal importance. As Jaap Spier recalls in one of the first volumes published by the Spier/Koziol group, when in 1853 Joel Bishop proposed to write a book on the law of torts, no publisher was interested in a work on such a subject.[49] Ever since, the scope of tort law has rapidly expanded, now covering seemingly every domain of society. The heads of damages to be recovered have also expanded. To an increasing extent, the question is now raised as to what instruments may be used to keep medical liability manageable.[50] One practical reason is that otherwise insurance may become too expensive or even unavailable. Two non-European areas have recently had insurance crises. In Australia, this, according to some authors, alleged[51] crisis has led to some new legislation and in the United States to proposals for new legislation.[52] In England, there has been an Act on compensation that aimed to reduce the amount of litigation in the field of medical liability.[53]

Although the development of medical liability looks spectacular, it should not be exaggerated. As the English reporter observes, the cost of compensation still amounts to only 1% of total NHS expenditures[54] and in relation to the number of medical errors, the number of complaints remains modest.[55] The large amounts of money recovered by some individuals should not blind us to the infrequency of medical claims relative to the number of medical procedures. People now expect to be cured by doctors, and medical services are more numerous and more sophisticated than in the past. As will be seen in Section 7, this change in the application and social importance of tort law should not necessarily be seen as a *change* in the actual rules.

[49] J. Spier (ed.), *The Limits of Liability/Keeping the Floodgates Shut* (The Hague: Kluwer Law International, 1996), p. v.
[50] See *ibid*.
[51] Peter Cane, *Atiyah's Accidents, Compensation and the Law* (7th edn., Cambridge: Cambridge University Press, 2006).
[52] '2006 Medical Malpractice Symposium' (2006) 59 *Vanderbilt Law Review* 1015–381, 1457–98.
[53] Chapter 2, p. 52, at n. 244. [54] Chapter 2, p. 29. [55] Chapter 2, p. 29.

Strange as it may seem, the aim of liability in tort or contract is not wholly without controversy. That the tort system serves to compensate victims is mostly beyond doubt, but whether it should also serve prevention and satisfaction is less certain. The preventative function may in some instances even clash with the compensation function, viz. when health care providers out of fear for liability claims 'cover up' rather than report accidents or near accidents. In the United States, several states have introduced schemes for safe reporting. The publication of the report 'To Err is Human: Building a Safer Health System' in 2000 led to the adoption in 2005 of the federal Patient Safety and Quality Improvement Act (2004), which aims at protecting the reporter of accidents. A similar statute in Europe is the Act on Patient Safety in the Danish Health Care System.[56] A non-statutory equivalent is the National Reporting and Learning System set up by the English National Patient Safety Agency.[57] A distinction can be drawn between the function of the law in providing compensation, and its function in setting standards or assigning risks, or simply in identifying how a harm (often fatal) happened to a patient. If standards are, by and large, benchmarked against those of the professions, and other mechanisms are developed to assign the responsibility for unsuccesful medical procedures, then that leaves tort/delict with the primary role of compensation and assigning risk, though it is not a major player for most patients in these areas.

6 The patients' rights movement

As in product liability, the growth of medical liability needs to be located in a change of social attitudes. At much the same time as consumers' associations were being established in the product area, in 1963 the charitable Patients' Association was founded in the United Kingdom. In 1982 it was joined by another pressure group.[58] These groups succesfully lobbied for government support. As the English reporter puts it: 'Modern politicians have been quick to recognise the political capital that can be gained by responding to patient concerns.'[59] In 2000, this led to the adoption in the government's five year plan for improving the NHS, and the recognition that the lack of concern for patients was at the heart of the NHS of today.[60] Following this, the NHS has been involved in issuing

[56] J. Legemaate *et al.*, *Melden van Incidenten in de Gezondheidszorg* (Utrecht: KNMG, 2006), p. 22. The authors propose a similar system for the Netherlands.
[57] Legemaate, *ibid.* [58] Chapter 2, p. 33.
[59] Chapter 2, p. 32. [60] Chapter 2, p. 52.