Chapter 4
European Legislative and Juridical Overview

Paola Frati and Matteo Gulino

Abstract The first part of this chapter gives an introduction to what is a comparative overview of medical liability in Europe, while the second part focuses on medical liability in Western Europe in both Civil and Common Law systems, concentrating on Fault, Contractual and Extra-Contractual Responsibility, Standard of Care, and Burden of Proof. The third part of the chapter examines the key role of mediation in Medical Responsibility in Court Systems and Administrative Systems. The following sections discuss, respectively, the models in place in the Scandinavian countries, the French experience of medical liability, and the "Loi Kouchner", including the English experience of the NHS Authority Litigation and the key role of mediation. Finally, medical responsibility in Eastern Europe is discussed, focussing on Bulgaria, the Czech Republic, Slovakia, Russia, and Lithuania, while the chapter concludes with a discussion of the present and future perspectives with regard to the issue of medical liability in Europe.

Contents

4.1 Introduction 70
4.2 Medical Liability in Western Europe Between Civil Law and Common Law 72
4.2.1 Fault 74
4.2.2 Contractual and Extra-Contractual Responsibility 74
4.2.3 Standard of Care 76

P. Frati (✉) · M. Gulino
Department of Anatomical, Histological, Forensic and Orthopaedic Sciences, "Sapienza" University of Rome, Viale Regina Elena 336, 00185 Rome, Italy
e-mail: paola.frati@fastwebnet.it

M. Gulino
e-mail: matteo.gulino@uniroma1.it

S. D. Ferrara et al. (eds.), *Malpractice and Medical Liability*,
DOI: 10.1007/978-3-642-35831-9_4,

4.2.4 Burden of Proof 77
4.3 The Key Role of Mediation in Medical Responsibility 78
4.3.1 Court Systems 79
4.3.2 Administrative Systems 79
4.4 Scandinavian Countries: Models 80
4.5 The French Experience and the "Loi Kouchner": The *Aléa Thérapeutique* 82
4.6 The English Experience of the NHS Authority Litigation and the Key Role of Mediation 86
4.7 Medical Responsibility in Eastern Europe: Bulgaria, Czech Republic, Slovakia, Russia, and Lithuania 87
4.8 Conclusion 88
References 91

4.1 Introduction

The exponential increase in cases of both medical malpractice and cross-border mobility of health professionals and patients represents a suitable reason to explore the field of medical responsibility, using a comparative approach, also at the international level.

The consolidation of a Judiciary system oriented towards preferential respect of patients' needs and the recognition of compensatory damages—sometimes presuming the existence of a causal relationship and thus without a real fault investigation—suggests to the majority of health professionals the need for a reconsideration of the adequacy of National Compensation Systems.

The comparative analysis of medical malpractice cases allows us to consider that the health systems of many countries are moving toward a no-fault (or no-blame) compensation of the physicians' and/or hospitals' responsibility. That is why a future affirmation of the obligation of result is foreseeable. Indeed, the peculiar system of burden of proof, which is more and more pressing for the physician, leads to a kind of bond issue for which, when the patient does not recover, the health professional can be accused of malpractice and obligated to provide fault compensation. In other words the presumption of responsibility of the health professional can be overcome only by the determination of the unforeseeable event which directly prevents the expected result.

At present, society is oriented towards a substantial process of legislative globalization and harmonization. Clearly, this is also true in the field of medical liability. The quality of the physicians' performance and the patient figure, perceived as an autonomous center of rights, has progressively involved public opinion and media attention.

There are several reasons which have combined to raise the number of judicial proceedings, including the increase of patients' awareness of their rights.[1]

[1] In this regard, we have to recall the 2006 Euro barometer report, which shows that 78 % of EU citizens believe that the issue of medical mistakes is relevant and that 73 % of them learned about mistakes committed by the health system from newspapers and mass media.

Indeed, differently from the past, a high quality medical care paradoxically determines the consequence that, in the case where the expected result is not achieved, the physician is automatically responsible until proved otherwise.

Evidently, the main concern regarding this approach is represented by the establishment of a regulation excessively inspired by a welfare perspective aimed at guaranteeing, as much as possible, compensation for damages through suitable insurance coverage. The existence of an obligatory health insurance (i.e. a financial guarantee) may imply a less rigorous assessment of responsibility, thus determining a higher liability to allow for the fault compensation. On the other hand, the health professional, financially guaranteed by insurance, would feel relieved of his own responsibilities in case of possible negligence. In other words, the concern is focused on the illogical and distorted situation in which the purpose seems to warrant a higher number of compensations, neutralizing in this way the healthcare protection. Indeed, the increased fault compensations may permit the erosion of the principle of fault personalization and favor standard fault compensations, possibly inappropriate to the circumstances of a specific case. Consistently, the European trend is towards the guarantee of the highest number of claiming patients rather than the individual quantification of the damage (Ponzanelli 2003); in France, for instance, through the introduction of the juridical institute of aleatory therapeutics, some typologies of medical error are considered as a social risk that must be shared among the community members on the basis of a central state logic.

However, France (Act 303/2002) and Scandinavian countries consider insurance essential in order to guarantee suitable health-risk coverage. Notably, a situation in which a higher number of compensations would be guaranteed could result in a sort of worrying over-deterrence of health professionals, hospitals, and insurance companies. In other words, an extremely prudent medical approach (defensive medicine) would be likely to take shape, which could limit the freedom of the physician and the health of the patient.

Moreover, the transfer of compensatory damages from the single physician to the health structure, which is pushed to be insured, could lead the physician to develop a reduced perception of his own personal responsibility. Indeed, the physician would act with the awareness that possible fault compensation would be covered by the hospital (or the health institution). Furthermore, the insurance instrument could facilitate the patient's access to compensatory damages and would determine as well the consequence of a minor quantum, being the amount of compensation established "ex ante", before the establishment of the legal question, with the purpose of favoring an agreement between the parties.

As better explained below, the reasons behind the increase in medical malpractice cases (including the related management cost) can be identified in both the legislative lack (absence of specific legislation regarding health responsibility), and the inadequacy of the national compensation systems. In most European countries, we observe a juridical tendency to shift the burden of proof from the patient to the health structure/physician, through principles that only ostensibly belong to different juridical systems: i.e., the *res ipsa loquitur*, typical of the Common Law system and the burden of proof, which is typical of the Civil Law

system. Indeed, these different juridical aspects both derive from the common principle that failure to attain the expected result determines a fault of the professional *in re ipsa*, which is well explained by the statement: "the evidence (failure to attain expected result) which creates a deduction of negligence". Actually, the lack of an expected result, which would correspond to the "normal" result following a correct medical act, automatically places the physician in a fault status, who will then have to prove the contrary data in relation to the presumptive wrong act. Together, these observations open the way to the introduction of the hypothesis of truly objective responsibility, which is now perceived both in Italy and also in France, Spain, Germany, and many other European countries characterized by either Common or Civil Law systems.

Notably, if on one side the impact of the media could really affect the evolution of health cases, it is also true that potential damage compensation is the primary goal of each juridical system facing the issue of health injury.

However, such compensation is related to different elements, such as the nature of the medical-health obligation, the burden of proof law system and, above all, the potential availability of instruments established by the legislator to promote extra-judicial conciliation. In this regard, it is essential to underline that the conflict is often characterized by a lack of communication and discussion between the contending parties. Therefore, it would also be necessary to emphasize the fundamental role played by the extra-judicial phase in the clinical cases.

The necessary involvement of the patient is underlined by the European trend, which considers correct information crucial to obtaining the effective participation of the patient in the decisions which involve his own body and health, and not only with the purpose of relieving the physician of responsibility. In cases in which such a correct patient/physician dialogue was lacking and damage compensation has been requested, an extra-judicial resolution may help, though ex-post.

After all, the idea of the physician as an unfailing subject is nowadays rather anachronistic and is not compatible with the present conception of relative truth, which is intimately connected to the state of current knowledge and technological development. For this reason, regardless of the specific issues of the socio-cultural environment of each juridical system, it would be desirable to adopt international rules shared by several countries according to a perspective of legislative integration.

4.2 Medical Liability in Western Europe Between Civil Law and Common Law

The outlining of a common structure of the European legislative systems with regard to the issue of medical responsibility is not an easy task. In fact we can note that these juridical systems are very different and they do not always adopt the same approach. However, the most complicated issue is deciphering the variety of historic and socio-cultural environments that characterize the different countries,

as well as the political and institutional changes incurred in some geographical areas of Eastern Europe (Birmontiene 1996).

Indeed, every effort aimed at drawing comparisons, similarities, and contrasts in the strict sense would appear inadequate and, above all, irrelevant for the resolution of the discrepancy.

Consequently, the purpose will be not to catalogue in a static way, but to analyze the matter in a constructive and functional way. In other words, it will be necessary to analyze the similarities existing among the different legal orders in-depth, regardless of the typical distinction between Civil and Common Law, in order to trace a common central thread.

As we will subsequently understand, judicial conflict in the field of medical responsibility often represents an ideal area for the infringement of general principles and the adjustment of juridical institutes—usually created for abstract cases—towards the concrete needs of the patient. The first problem is certainly represented by the identification of those criteria in the categorization of the different European legislative systems, in order to find a possible common asset.

We could start by distinguishing between the Roman Law system, the Civil Law system (characteristic of the majority of continental European countries), and the Anglo-Saxon Common Law system (typical of England and former British Empire colonies such as Ireland). Secondly, we could analyze the impact of the different levels of Judges' decision-making autonomy on the rules that govern medical responsibility. English law is an example of the Common Law system, where there is a reduced utilization of the regulatory instrument. The practical training of the Common Law jurist, as opposed to the more theoretic approach typical of the Civil Law system, determines the validity of the *stare decisis* compulsoriness. Unlike the Roman system, in fact, Common Law is defined as a system principally based on the analysis of case law.

The application of such an approach to the medical liability field would determine the prevalence of the judges' interpretative analysis of the clinical cases, though assisted by experts in Law Medicine, at the expense of the written law and the underlying ratio.

However, the comparative analysis based merely on the distinction between Civil Law and Common Law, does not allow us to achieve our purpose, due to the lack of an ad hoc legislation in the majority of European countries, regardless of their Civil or Common Law based juridical system (Grossen and Guillod 1983). In some countries such as Italy, this situation determines the Judges' tendency to exceed their role in applying existing law, often becoming real interpreters or law creators rather than applicators. This concept is well expressed by the Italian Supreme Court in verdict n. 9471/2004, which defines medical liability as a responsibility in action resulting in the identification of standards of conduct, on the basis of which the theories of fault, causal relationship, and damage are subjected to continuous changes with regard to the traditional schemes, under both a substantial and probationary profile.

Certainly, the lack of specific rules in this field represents a common finding about which we must reason according to perspective criteria, also taking into

account that in the last decade the regulation trend has progressively increased (for instance, the matter of damages arising from medical assisted reproduction in Spain) (Act 14/2006).

The analysis of European juridical systems underlines the fact that damages arising from medical malpractice could have consequences under penal, civil, and administrative codes, depending upon specific circumstances. In some countries (France, Spain, The Netherlands) medical liability is regulated by both Private and Administrative Law, according to whether the damage is caused by a physician within a private or public hospital (Serra and Carrara 2005).

At this point, the best approach for a comparative analysis of juridical systems is to reason about the assumption that in every European country the fault represents the fundamental criteria in the establishment of medical responsibility.

First of all, it would be important to identify on what basis the fault is established. Pragmatically, medical liability is linked to the presence of two main elements: (1) the recognized standard of care and the boundaries of the Fault notion (when the physician's conduct is negligent according to a generally accepted standard of care) and (2) the burden of proof regulation, including the related contents.

4.2.1 Fault

Generally, the right of the patient to obtain compensatory damages arises only in the case where the physician has committed a fault. The conduct of the physician could be an act or an omission. In most cases, Medical Liability Law based on fault considers conduct wrongful and guilty when it is negligent and relatively avoidable. Therefore, the fault represents the starting point for the patient's claim either in contract or in tort. In the first case, the fault can be considered as deviating from the standard of care (relating to the hypothetical physician's prudence and diligence, like a sort of rule of best practise) and, in the latter case, as the violation of the patient's right (as, for example, the lack of correct information, i.e., of an informed consent). With reference to the standard of care, the physician has to fulfill his/her duties appropriately, with diligence, and in accordance with the current state of medical art. On the contrary, with reference to the violation of the patient's right, the physician has to inform the patient correctly and precisely regarding the treatment.

4.2.2 Contractual and Extra-Contractual Responsibility

The comparative analysis of the European juridical systems demonstrates that sometimes the distinction between contract and tort, non-fulfillment and tort, as well as contractual responsibility and extra-contractual responsibility, assumes relevance in the issue of medical liability. In fact, there are juridical systems that regulate medical liability on the basis of tort law and others on contract law. In

some juridical systems (e.g. Italy) the case law evolution has been limited to the field of the contractual regulation, while in others, such as Austria, Germany, and England, medical liability falls under both contractual and extra-contractual law (Bernhard and Koch 2003; De cruz 2001; Stauch 2008).

The difference between the institute of contractual and extra-contractual responsibility assumes relevance under several aspects, such as, for example, in the different punishment or compensation purpose (*ratio*) in the statute of limitation, in the damage quantification procedures, and in the burden of proof regulations. Indeed, while extra-contractual responsibility has a punitive purpose (to prevent unlawful acts), the contractual responsibility has the purpose of reestablishing the parties' interests, according to the contract rules. For example, with regard to the burden of proof, while the institute of contractual responsibility facilitates the patient's position, the institute of extra-contractual responsibility instead facilitates the physician's position on the basis of the general principle which establishes that people who go to court must demonstrate the facts relating to their compensation claim. Furthermore, contractual responsibility usually provides for a greater prescription compared to that of the extra-contractual responsibility.

The two frameworks are also different under the profile of fault. In contractual responsibility, the fault presumes the violation of a contractual provision or, more generally, the occurrence of a breach/wrong execution. In extra-contractual responsibility, however, the fault is based on the violation of the general cohabitation principle of *neminem laedere*, which establishes that everyone is obliged to respect the generic duty of not harming the others' juridical sphere. In other words, such a principle provides that any person who causes unfair detriment to another, through willful or negligent conduct, must compensate the victim for any resulting damage suffered.

As mentioned above, in the field of medical responsibility the application of one institute rather than the other one determines relevant consequences, which can facilitate or not the patient's position. However, in the authors' opinion, it is not useful to categorize juridical systems on the basis of contractual or extra-contractual responsibility, due to the actions of the Magistrate, which contribute to the mixture of elements from both categories. In fact, today we are facing the progressive affirmation of a less strict adoption of the typical characteristics of the contractual and extra-contractual responsibility frameworks.

On the other hand, in all European countries the rules of medical liability are mainly of juridical origin. While this consideration is predictable, due to the extra-contractual (i.e. regulated by *Lex Aquilia*) responsibility regulated by a reduced number of rules, the same is not true for contractual responsibility, which now requires the establishment of a Health contract (Italy, Spain, France, Germany, etc.), the content of which is entrusted in full to the juridical verdicts.

On the other hand, the agreement between the hospital/physician and the patient is based on verbal relationships and thus lacks a social contract, including common provisions. Indeed, also in countries characterized by the Civil Law system, the Courts establish—in cases where a contract exists—the contractual parties, the respective provisions and requirements, and the responsibility and proof rules. General rules, although noted, are reinterpreted by judges. Doctrine states that the

contractual obligations of the physician mirror those typical of extra-contractual accuracy (Atiyah 1986).

Over recent years a progressive affirmation of an approach designed to guarantee to the patient (considered a weak person) a privileged position has taken place in most European juridical systems.

In fact, the analysis of the evolution of Case Law in several countries allows us to show how contractual systems restrict the patient's chance of obtaining compensation by the use of the category of obligations of means, while extra-contractual systems open the way to the patient's claim through principles like *res ipsa loquitur*. Although in some countries the general rule is that the burden of proof is upon the patient—according to the scheme of extra-contractual responsibility—it is possible to point out that the trend of making use of the principle of Fault presumption permits an easier acknowledgement of compensatory damages.

As previously underlined, the European experiences have in common a particular attention to the protection of the patient's rights, though in different stages. In fact, while in some countries the patient's rights are protected during the pre-trial phase through specific laws which determine the techniques of distribution of health risks, in other countries this kind of protection is activated directly during the trial phase thanks to the action of the Judges in ordering that the patient be released from the burden of proof.

For example, in France, the first solution has been privileged with the introduction of a specific check of health risks, which is the mandatory insurance for every hospital. Instead, in other European experiences, the purpose of patient rights protection is pursued with the adoption of a probationary system favorable to the patient.

This trend started at the European level, with the introduction of the principles of the inversion of the burden of proof by the provider of a defective service in "market services" of specific fields. To such a provider, the various European Courts compare the health professionals (proposed Directive, G.U.C.E. January 18, 1991 n. C-12). This trend has been further supported by the principle of the right to an impartial trial, which is supported at the European level and aims to warrant all parties the opportunity to present their arguments, avoiding disadvantages with respect to the opposite party.

4.2.3 Standard of Care

In order to ascertain the fault of the physician it is necessary to analyze and evaluate his/her conduct in the execution of a specific treatment. Except for the cases where the physician does not respect operative protocols, the physician's conduct is guilty when he/she did not execute the treatment according to the required standard of care.

The physician must have the knowledge and competence in order to guarantee a good level of care in the treatment of the patient. In this way, the physician has to fulfill his/her duties by observing a professional standard of care, based on the

standard of experienced physicians in their specific medical field. Sometimes the appropriate knowledge and competence can be identified through specific guidelines.

With regard to standard of care, while certain juridical systems make reference to the *bonus pater familias* (good family father), such as in Italy, France, and Spain, others, like UK and Scandinavian countries, use the reasonable physician standard with respect to the accepted medical knowledge (*ars medica*). Obviously, the accepted medical knowledge is established at the moment the treatment is carried out, the discovery of alternative or new therapies set up at a later time with respect to patient care being irrelevant.

Moreover, with regard to the purpose of this work, it is important to highlight some peculiarities introduced in several juridical systems that further complicate comparative analysis. It is sufficient, for instance, to recall the legislation of Germany, Austria, and the German speaking Switzerland, where the patient's right to obtain compensation is balanced with the physician's right-duty to act always on the basis of science and conscience (Bauer and Pollak 2007).

In other words, this means that the physician has the right not to be obliged to apply specific prescriptions issued by other doctors: a legislation that emphasizes the physician's self-responsibility and independence (Hurwitz 1995). Notably, these kinds of legislative choices are based on the principle that a fair medical activity is, by its nature, as free as any other scientific activity.

A different case is represented, for example, by UK, where more importance seems to be assigned to the role of guidelines in the fault investigation.

4.2.4 Burden of Proof

In the case of extra-contractual responsibility, the patient has to demonstrate the physician's fault, the causal connection, and the damage received. However, the European legislative overview provides several interesting examples of jurisprudential creations and juridical constructions often designed to compensate for the differences between the physician's and the patient's position. That is why the patient is in the weaker position, because of the difficulties he/she faces in proving damage. The analysis of the single legislative experiences demonstrates the spread of mechanisms that derogate from general principles of contractual responsibility through praxis introduced by jurisprudential evolution, such as the reversal of burden of proof or the *res ipsa loquitur* institute.

With reference to the burden of proof the causal relationship, which can be defined as the existing relationship between medical malpractice and the damages/death that occurred, is assumed to be of special relevance. The comparative analysis of the European Juridical systems demonstrates that the investigation of the causal relationship follows different procedures, depending on whether the investigation is executed within a civil trial or penal trial.

While in the latter field a rigorous verification is favored, as much as possible supported by scientific laws with respect to the rule of *in dubio pro reo*, in the Civil field we observe a depreciation of the nexus, increasingly founded on the rule, now shared by countries based on both Common or Civil Law systems, of "more probable than not", with increasing openness towards the recognition of the damage following loss or lowering of chance (of recovery).

Therefore, we can generally assume that the injured subjects are willing to choose the civil course rather than the penal one, with regard to complex and important cases as well.

Generally, the civil law adopts probabilistic theories aimed at answering the question of whether there is fault or not on the basis of the "more yes than no" formula and therefore there exists a lower grade of certainty. On the contrary, in penal law the positive answer must be formulated "beyond any reasonable doubt" and then with a major grade of certainty. In other words, while in civil law the causal relationship is ascertained through a probability greater than 50 %, in penal law this certainty has to reach a percentage very close to 100 %.

This differential commitment assumes a critical importance, especially in the medical field, where damages can often also be traced back to other causes that are outside the physician's control (as for example genetic predisposition, inadequate lifestyle, etc.).

4.3 The Key Role of Mediation in Medical Responsibility

The interest within the European juridical systems towards alternative ways of settling medical malpractice claims has increased in the last decade.

Such an interest arises from the excellent outcomes and trends observed in European systems where settlement of medical responsibility claims is delegated to alternative organisms, different from the judicial authority (i.e. the Swedish model).

There has also been a significant interest within the European Union in an alternative way of resolving disputes, where the Directive 2008/52/EC of 21 May 2008 was issued by the European Parliament and Council concerning certain aspects in matters of civil and commercial mediation.

Although not specifically falling into the field of medical liability, the directive mentioned above does underline the importance of access to justice and promotes the employment of extra-judicial procedures (Directive 2008/52/EC).

Within the international literature it is possible to find a new way of categorizing the European juridical system, which is surely useful for thinking about the current situation of medical liability issue.

Two main different systems have been delineated: the court systems and the administrative systems (Essinger 2008).

4.3.1 Court Systems

A court system is defined as a juridical system when patients' claims are mainly settled by courts. The majority of the European juridical systems can be categorized as court systems: Italy, Spain, Portugal, Germany, France (except for the ONIAM field and considering the role of CRIC), Lithuania, Slovak Republic, etc. The main characteristic of these countries is represented by the lack of administrative procedures, as occurs in Sweden. Indeed, in these countries a high number of judicial cases are observed. Ordinarily, the patient claims are settled by Judges who are assisted by experts in Law and Medicine. Patients often discover a lot of barriers before obtaining damage compensation, because they cannot use easy damages compensation procedures. Indeed, when the fault compensation is finally established by the sentence of the Judge, the patient must face, beyond the legal expenses and the judicial taxes, the stress linked to trial duration.

4.3.2 Administrative Systems

An administrative system is defined as a juridical system where patient claims are mainly settled by administrative procedures. In Europe, typical examples of administrative systems-based countries are Sweden, with the Patient Insurance Scheme, England with the NHS Litigation Authority, and France, with ONIAM.

As stated in the Doctrine, among overseas countries typical examples of administrative systems are located in Australia and in New Zealand (Woodhouse 1967–New Zealand); (Bismark and Paterson 2006; Colleen 1999; Bismark et al. 2006; Sappideen 1993). Another interesting example is represented by Germany where the Regional Chambers of physicians established panels to investigate and settle patients' claims. Such panels are regulated by their own statutes. The only difference with respect to the court systems is that the involvement of the court is not required.

The mode of adjustment varies. In most of the cases the damage compensation is subjected to the demonstration of the causal link between the damage and the physician's performance. In other circumstances, a finding of avoidance determined under the "experienced specialist" role is required. In any case the evaluation of the eligibility of the patient to be compensated for the damage is established extra-judicially, without the involvement of the Court.

Often, however, in the international literature, welfare compensation systems (in which the indemnity is guaranteed, e.g., in Scandinavian countries) are considered as No-Fault (Hubbard 2000).

In fact, the only difference that can be identified between these models and the models based on fault is the existence of an easier burden of proof regulation for the patient and the absence of difficulties in accessing compensation procedures (Adelman 2004).

Administrative systems do not have punitive purposes. They focus their attention especially on the compensation for the damage suffered by the patient. Therefore, it is more correct to define them as no-blame systems, such as occurs in Sweden (Pukk-Harenstam et al. 2008).

Furthermore, it is important to underline that these kinds of indemnity systems often operate according to a different logic, which is the grant of compensation according to standards (without a personalization of the injury).

4.4 Scandinavian Countries: Models

The compensation damage models of Scandinavian legislation represent a good example of a system of social security indemnity that, unlike the traditional approach characteristic of the Common Law systems, does not take into account the evaluation of the fault, providing a verification of the predictability and avoidance of the damage as an essential assumption. These systems are in force specifically in Sweden, Finland, Norway, and Denmark.

The availability of statistical data in Sweden suggests a better evaluation of the Swedish model according to a comparative approach.

The Swedish compensation system was implemented for the very first time in 1975, though as a voluntary scheme. Indeed, the introduction of a mandatory system was formalized only in 1997, when the Patient Injury Act (PIA) (*Patientforsakringen*) was enacted. The enacted Law provides for a mandatory insurance for all the hospitals operating in the Swedish territory and it regulates how and when the patient has the right to obtain compensation for the injury arising from medical malpractice. With this Act a burden of proof lower than that necessary under the general Torts Act of 1992 in Sweden was put in place.

Under the PIA the injured patient has to show the relationship between hazards/death due to the physician's misconduct and the avoidable nature of the adverse event. Such a relationship has to result according to a preponderant probability higher than 50 %, recognized as *reasonable certainty*.

The existence of avoidability is ascertained by evaluating the correctness of the physician's performance and by verifying the existence of possible less risky procedures for the treatment of the patient's disease.

It is important to recall that the Swedish Legislator's choice aims to identify six categories of damages entitled to compensation: (1) incorrect health treatment (with the presumption that the injury could have been avoided if the choice had been different), (2) defects in the medico-technical products or hospital equipment used in the physician's performance, (3) absent/incorrect diagnosis, (4) transfer of a contagious substance entailing infection in connection with treatment,

(5) accidents, (6) prescription or provision of pharmaceuticals in contravention of regulations or instructions.[2]

For our purposes, another important aspect is the part of the PIA related to the regulation of the administrative procedures. Such administrative procedures have the aim of guaranteeing to the patient access to the compensation system even without the need to take legal action. The claim is paid directly by the insurance company of the hospital after a medical expert investigation.

The relationship between the injured and insurer is governed by transparency and information. Article 17 regulates the Patient Claims Panel, which was established to promote a correct application of the PIA and issues opinions at the request of a patient, care provider, insurer, or court. The Panel is composed of various members, including medical experts and representatives of the patients' interest.

Although the panel's decision is not mandatory, generally insurers comply with it.

Statistical data show the benefits of the Sweden reform, especially with respect to the excellent outcomes gained in the reduction of the amount of work by the judiciary system. It has been calculated that every year an average of 45 % of the compensation requests are received (and then compensated).[3] Only 10 % of these requests end up in the courtroom. The percentage of the extra-judicial claims settled in the Scandinavian countries amounts to 99 % (Swedish Patient Insurance Association) (Essinger 2008).

[2] Article 6 provides "[…] (1) an examination, care, treatment, or similar measure provided that the injury could have been avoided either through a different performance of the chosen procedure or through the choice of another available procedure which according to an assessments made retroactively from a medical point of view would have satisfied the need for treatment in a less hazardous manner; (2) defects in the medico-technical products or hospital equipment used in the performance of an examination, care, treatment or similar measure, or improper use of the same; (3) an incorrect diagnosis; (4) transfer of a contagious substance leading to infection in connection with an examination, care treatment, or similar measure; (5) accidents in connection with an examination, care, treatment or similar measure, or during a patient transport or in connection with a fire or other damages to health care premises or equipment, or; (6) prescription or provision of pharmaceuticals in contravention of regulations or instructions […]". The English translation has been kindly provided by Carl Espersson, Legal Adviser at The Swedish Patient Insurance Association/Patientförsäkringsföreningen.

[3] Article 18 provides for "the insurers affiliated to the Patient Insurance Association shall together maintain and finance a patient claims panel. The Panel shall include representatives of the patients' interest. Further regulations concerning the Panel's composition will be issued by the Government, which shall also approve the rules of procedure of the Panel. The Panel shall at the request of a patient or other person suffering loss, a health care provider, an insurer or a court pronounce its opinion in compensation cases." The English translation has been kindly provided by Carl Espersson, Legal Adviser at The Swedish Patient Insurance Association/Patientförsäkringsföreningen.

4.5 The French Experience and the "Loi Kouchner": The *Aléa Thérapeutique*

Although in a less incisive way with respect to the Swedish experience, France has to be mentioned among those European countries which have introduced a specific law in the medical liability field with the aim of making the damage compensation system more adequate to patient's needs. Of course, we have to state that the French juridical system represents one of the more complex contexts in which to face the matter of legislative reform in the medical malpractice field. This is due to the coexistence of Administrative Law and Private Law in this field. In fact the French law provides different rules depending on the public or private nature of hospitals. If the hospital is public the procedural rules of the Administrative Law will be enforced; while, if the hospital is private the procedural rules of the Private Law will be enforced. In the first case the hospitals have the right to act against the employee physician.

During the last 50 years, the French doctrinal overview distinguished itself for the extreme variety of submitted legislative reforms, some of them oriented towards the creation of a guarantee fund, while others focused on the conservation of the general rules of civil responsibility through the obligation of result provision. Ordinarily, in the French juridical system, with some exceptions, medical liability is regulated within the civil responsibility institute and is subordinated to the evidence of the physician's misconduct.

However, nowadays it is assumed that medical liability falls within the area of contractual responsibility and that the obligation of the physician must be defined as an obligation of means. The obligation of means is defined when its subject is a performance characterized by diligence, thus independent of the attainment of a specific result. Therefore, in the health field, to fulfill such an obligation the physician will have to carry out his performance correctly, regardless of the useful result expected by the patient. Moreover, at the same time, such an obligation became harsher because of several creations by judges (*obligation renforée, obligation de resultat atténuée, etc.*).

In the French juridical scenario one of the most controversial points is represented by the notion of *aléa thérapeutique*, on the basis of which several debates arose among judges. The resolution of such debates is also made more complicated by the coexistence of different jurisdictions and the risk of final judgement multiplications. For this reason, it is possible to recall several judgements by the Conseil d'Etat and of the Supreme Cour de Cassation.

The Conseil d'Etad defined the *aléa thérapeutique* as that risk which is known but of which the realization is exceptional and there is no reason to believe that the patient is exposed to it in a particular way (Arret Bianchi) (Concil of Europe 2008). However, this definition has not been shared by the Supreme Cour de Cassation, because it is considered to be in contrast to the inspiring principles of civil responsibility. Indeed, according to the Court it would not be appropriate to talk about damage compensation, considering that the *aléa thérapeutique* requires

the existence of an accidental risk related to the physician's performance (which cannot be controlled) (Conseil d'Etat 1993).

The diversity of opinion between the Supreme Cour de Cassation and the Conseil d'Etad has offered to many authors an interesting point to consider. On one hand, some of them have been worried about a possible hardening of the physician–patient conflict, while others have considered it an important issue, because of the spreading and the affirmation of the theory in which the physician's performance is considered as an obligation of results. Lastly, others called attention to the provocative consequences of the *aléa thérapeutique* definition, questioning its interpretative limits.

The French Legislator implemented Act n. 303 on 4 March 2002, named *Loi Kouchner*, with the aim of resolving all the debates about the exact definition of *aléa thérapeutique*, providing a new specific Medical Liability Law. Several innovations were introduced by the *Loi Kouchner*: the consolidation of Fault Responsibility, the introduction of a new Solidarity National Fund, the *aléa thérapeutique*, the introduction of mandatory insurance for all hospitals operating in French territory, and the Regional Conciliation Committees. In this way, some aspects of the Public Health Code (*Code de Santé Publique*) were profoundly modified.

Among the innovations mentioned above, it is important to point out the provision of a pure No-Fault compensation system operating both when there is no fault in the physician's conduct (cases fall under the definition of *aléa thérapeutique*) and when the injury is caused by a nosocomial infection. In fact, in these cases the damage compensation is only subject to the demonstration of a direct link between the treatment therapy and the damage, the fault assessment not being required.

The Loi Kouchner reaffirmed the centrality of the Fault-Based system, giving back to the *aléa thérapeutique* its own exceptional element out of the physician's control (Cassation Civil 2000).

Indeed, Article 1142, paragraph 1, of the French Public Health Code, as modified by Article 98 of Act n. 303/2002, provides a duty of physicians and hospitals to respond to the negative consequences arising from Health Care treatments (prevention, care, and diagnosis) only when fault is declared (Cacace 2003). The second paragraph provides for an indemnity, in terms of national solidarity, operating in No-Fault cases and when the resulting invalidity is higher than 25 % (*aléa thérapeutique*).

The claims regarding injuries due to *aléa thérapeutique* are handled by ONIAM (*Office Nationale d'Indemnisation des Accidents, Médicaux, des affections iatrogènes et infections nosocomiales*), created ad hoc for the Public Fund management. Another important innovation is the provision of a mandatory insurance

for all public and private hospitals and physicians, as stated by Article 1142, second paragraph.[4]

Although the distinction between damages arising from physician fault and damages including the so-called *aléa thérapeutique,* is still valid, the law, in Article 1142, 14th paragraph, and in the following articles, provides for a preventive conciliation procedure, with the aim of filtering out patient claims, thus avoiding their transformation into juridical disputes.

For this purpose, the "*Commissions régionales de conciliation et d'indemnisation*" (Art. 1142, fifth paragraph) have been established[5] and damage

[4] Article 1142, second paragraph, provides for sans préjudice des dispositions du septième alinéa de l'article L. 1142-17, ouvrent droit à réparation au titre de la solidarité nationale: Les dommages résultant d'infections nosocomiales dans les établissements, services ou organismes mentionnés au premier alinéa du I de l'article L. 1142-1 correspondant à un taux d'incapacité permanente supérieur à 25 % déterminé par référence au barème mentionné au II du même article, ainsi que les décès provoqués par ces infections nosocomiales; Les dommages résultant de l'intervention, en cas de circonstances exceptionnelles, d'un professionnel, d'un établissement, service ou organisme en dehors du champ de son activité de prévention, de diagnostic ou de soins.''

26 Article 1142, second paragraph, provided for les professionnels de santé exerçant à titre libéral, les établissements de santé, services de santé et organismes mentionnés à l'article L. 1142-1, et toute autre personne morale, autre quel État, exerçant des activités de prévention, de diagnostic ou de soins ainsi que les producteurs, exploitants et fournisseurs de produits de santé, à l'état de produits finis, mentionnés à l'article L. 5311-1 à l'exclusion du 5", sous réserve des dispositions de l'article L. 1222-9, et des 11", 14" et 15", utilisés à l'occasion de ces activités, sont tenus de souscrire une assurance destinée à les garantir pour leur responsabilité civile ou administrative susceptible d'être engagée en raison de dommages subis par des tiers et résultant d'atteintes à la personne, survenant dans le cadre de l'ensemble de cette activité''.

[5] Article 1142, 14th paragraph, provides for lorsque la commission régionale de conciliation et d'indemnisation des accidents médicaux, des affections iatrogènes et des infections nosocomiales estime qu'un dommage relevant du premier alinéa de l'article L. 1142-8 engage la responsabilité d'un professionnel de santé, d'un établissement de santé, d'un service de santé ou d'un organisme mentionné à l'article L. 1142-1 ou d'un producteur d'un produit de santé mentionné à l'article L. 1142-2, l'assureur qui garantit la responsabilité civile ou administrative de la personne considérée comme responsable par la commission adresse à la victime ou à ses ayants droit, dans un délai de quatre mois suivant la réception de l'avis, une offre d'indemnisation visant à la réparation intégrale des préjudices subis dans la limite des plafonds de garantie des contrats d'assurance.

Cette offre in di quel évaluation retenue, le cas échéant à titre provisionnel, pour chaque chef de préjudice a in si que le montant des indemnités qui reviennent à la victime, ou à ses ayants droit, déduction faite des prestations énumérées à l'article 29 de la loi n" 85-677 du 5 juillet 1985 tendant à l'amélioration de la situation des victimes d'accidents de la circulation et à l'accélération des procédures d'indemnisation, et plus généralement des indemnités de toute nature reçue sou à recevoir d'autres débiteurs du chef du même préjudice. Les prestations et indemnités qui font l'objet d'une déduction du montant de l'offre sont remboursées directement par l'assureur du responsable du dommage aux débiteurs concernés.

Lors quel'offre prévoit le versement d'un e rente à la victime, cette rente est revalorisée dans les conditions prévues à l'article L. 351-11 du code de la sécurité sociale

L'offre a un caractère provisionnel si l'assureur n'a pas été informé de la consolidation de l'état de la victime. L'offre définitive doit être faite dans un délai de deux mois à compter de la date à la quelle l'assureur a été informé de cette consolidation.

L'assureur qui fait une offre à la victime est tenu de rembourser à l'office les frais d'expertise que celui ci a supportés.

compensation procedures have also been unified, regardless of the nature of the alleged health structure (both private and public).

These "commissions" are in charge of starting the compensation file and verifying, through an internal procedure, the patient's legitimate claim to the damage compensation. They could also submit an economic proposal to the insurance company (and/or to the ONIAM in case of lack of fault), that will be verified by the insurer within the mandatory deadline of four months (Art. 1142, 14th paragraph). The commission has to make an important decision: (1) if physician/hospital liability exists (where usually the indemnification is paid by the insurance company), or (2) if that indemnification is due in the name of 'national solidarity' (indemnification by a national organism called ONIAM), or (3) if it is a case where no damages occurred.

Generally, the procedure applies only to care provided since 5 September 2001 (Manaouil et al. 2006).

In the case where conciliation fails, the patient has the right to defend his/her own credit through the Court. The damage liquidation is gained after an internal procedure with the aim of verifying on the one hand the presence of a sustainable risk and on the other hand the prejudicial effectiveness of the event.

The innovations brought about by the Loi Kouchner contributed to endowing the French juridical system with originality, because of the introduction of a hybrid model in which typical elements of the traditional model (exclusively based on fault) coexist with aspects of the No-Fault system (exclusively based on causal relationship).

In conclusion, with regard to types of damage, the establishment of the legitimization of damage compensation (together with the validity of the claim itself) occurs through different juridical paths, depending on whether it arises from the

(Footnote 5 continued)

L'acceptation de l'offre de l'assureur vaut transaction au sens de l'article 2044 du code civil.

Le paiement doit intervenir dans un délai d'un mois à compter de la réception par l'assureur de l'acceptation de son offre par la victime, que cette offre ait un caractère provisionnel ou définitif. Dans le cas contraire, les sommes non versé es produisent de plein droit intérêt au double du taux légal à compter de l'expiration de ce délai et jusqu'au jour du paiement effectif ou, le casé chéant, du jugement devenu définitif.

Si l'assureur qui a transigé avec la victime estime que le dommage n'engage pas la responsabilité de la personne qu'il assure, il dispose d'une action subrogatoire soit contre le tiers responsable, soit contre l'Office national d'indemnisation si les dispositions du II de l'article L. 1142-1 trouvent à s'appliquer.

Si le juge compétent, saisi par la victime qui refuse l'offre de l'assureur, estime que cette offre é tait manifestement insuffisante, il condamne l'assureur à verser à l'office une somme au plus égale à 15 % de l'indemnité qu'il alloue, sans préjudice des dommages et intérêts dus de ce fait à la victime.

Dans le cas où les plafonds de garantie des contrats d'assurance de la personne considérée comme responsable par la commission seraient atteints, l'assureur avise sans délai cette personne ainsi quel'office institué à l'article L. 1142-22.

Pour l'application du présent article, l'Etat, au titre des activités de prévention, de diagnostic ou de soins qu'il exerce, est soumis aux obligations incombant à l'assureur''.

so-called *aléa thérapeutique* or from physician fault. In fact, in the case of damage (more than 25 % of invalidity) arising from the *aléa thérapeutique*, damage adjustment only occurs after the demonstration of the causal relationship between the claimed damage and the preventive and healthcare performance, regardless of physician fault. From a pragmatic point of view, the Legislator in 2002 accepted that some medical mistakes cannot be ascribed to the responsibility of the single physician, due to the great danger of a number of medical performances and the particular technicality of the medical science.

4.6 The English Experience of the NHS Authority Litigation and the Key Role of Mediation

England—a Common Law system—in which physician liability is inspired by strict principles of fault investigation—assumes importance among European countries for the key role that mediation, alternative dispute resolution (ADR), has in claims between patients and hospitals.

In fact, even though it has been introduced with the aim of simplifying and facilitating damage compensation procedures, medical liability continues to be regulated within the system based on Fault.

In 1995 the National Health Service Litigation Authority (NHSLA) was established, which is responsible for the National Health Service financial fund. The NHSLA is the body in charge of the management of public cases in the field of health responsibility (NHSCC Act 1990). The main purpose of the NHSLA is to promote the interaction between the injured patient and the health structure, with the aim of facilitating possible damage compensation. This body carries out its mediation functions through a centralized network of health specialists.

Nowadays, in contrast to Sweden, a mandatory insurance for the health structure does not exist in the UK, even though—factually—they joined the Clinical Negligence Scheme program, which was created in 1995.

This system is entirely managed by the NHSLA and allows health structures to obtain insurance against damages arising from clinical risks, determined by events that occurred after 1995, on payment of an insurance premium (usually established every year on the basis of the maximum expenses estimated for the following year).

Similar to the Swedish system, the damage compensation procedure is left to the administrative competences and the claims are handled by a Panel of specialists. This Panel carries out an evaluation, with the help of medico-legal experts, in order to establish the *an* and the *quantum* of the patient's claims.

However, differently from Scandinavian countries, the verification follows a different procedure, in which the injured party has a greater burden when demonstrating the physician's negligence, the causal relationship, and the damage suffered. The verification of the fault is determined on the basis of an analysis of the physician's performance with respect to the requirement of an acceptable

professional standard in the case of health performance. Consequently, the patient has the burden to demonstrate that the damage suffered is linked to the physician's fault by a causal relationship and that a different medical treatment, if correctly performed, would have caused no harmful consequences or, at least, consequences of minor medical-legal relevance.

Although the UK system does not formally adopt damage compensation principles based on mere causal demonstration, it is inspired by them when it saves money in the cost-management of claims through the utilization of alternative instruments, with respect to the judicial case. Indeed, the choice of centralizing—even in a non-mandatory way—damages compensation procedures in one body (NHSLA), resulting in the simplification of the UK compensation system and in a relevant reduction of the waiting period to obtain relief.

The statistical data underlines the importance the mediation activity provided by the NHSLA has assumed in the last years within the medical responsibility field, especially in terms of the reduction of the number of judicial cases and the relative time for the obtainment of damage compensation.

In this regard, it has been estimated that 96 % of compensation requests have been defined in an extra-judicial manner, without the judge's intervention (Essinger 2008).

4.7 Medical Responsibility in Eastern Europe: Bulgaria, Czech Republic, Slovakia, Russia, and Lithuania

Medical malpractice is now assuming remarkable importance, even within juridical systems belonging to Eastern Europe. The increase in patient claims makes the present situation as critical as that of Western Europe.

Unlike the experience of other European countries, the juridical system of Lithuania oversees the medical liability field through an ad hoc regulation (Birmontiene 1996; Ducinskiene et al. 2006). In fact, alongside general principles provided in the Constitution of the Republic, in Lithuania the rules of the Civil Code and Penal Code enforce the law on the rights of patients and compensation for damage to their health. Here the patient is considered the weak party who has several fundamental rights, the first being the right to health. Furthermore, the patient has the right to access the Health system and the right to expect an informed health treatment complying with the accepted knowledge of medical science.

In Lithuania a Fault-based system is enforced, where the damage compensation is granted after the positive ascertainment of the causal relationship between the physician's conduct and the hazards/death suffered by the patient. In this country administrative procedures for damages compensation do not exist, as in the Swedish system. Patient claims are handled by the Judges, though extra-judicial negotiations could even be carried out earlier. In Lithuania the role of the "Compensation Commission" is very important.

Differently from Lithuania, in the juridical systems of Bulgaria, the Czech Republic, Slovakia, and Russia, a specific regulation with regard to the medical liability does not exist. Consequently, the responsibility of the physician finds its regulation principally in the Civil Code and in the Penal Code. Hospitals are responsible for damages caused by the physician's conduct, because of the principle of employer responsibility for damages caused by the physician employee to third parties.

The juridical systems of these countries can be categorized as Fault-based models, where the compensation is granted after the evidence of the physician's fault, the damage suffered by the injured party and the causal relationship between the medical mistake and the damage. In these countries, no particular damage compensation procedures can be identified as administrative ones. Patient claims are specifically handled by the Courts, even though the Judges have the opportunity to promote the use of conciliation or alternative dispute resolutions, such as arbitration, between the parties (Essinger 2008).

4.8 Conclusion

A comparative overview of the European juridical systems demonstrates that in the majority of countries a specific legislation concerning the issue of medical responsibility does not exist.

The physician's misconduct/mistake is regulated on the basis of the general principles of the civil, penal, and in some cases administrative responsibilities. However, it is also clear that every system has understood the difficulties faced by the patient concerning the burden of proof, resulting in some cases in the jurisprudential context even deviating from general principles in certain situations, and in others with the introduction of administrative procedures for damage compensation.

From the analysis of the European juridical scenario we can outline two different kinds of damage compensation models in the field of medical liability: (1) those systems anchored to a classic model of fault verification (with a burden of proof that seems to be always heavier for the physician) and (2) those systems that may be inspired by the spreading concept of enterprise risk in the health field and that use models established on the idea of damage avoidability, with less focus on the fault concept. Those two systems are also respectively defined at the international level by the terms Fault-based system and No-Fault system.

However, we have to take into consideration that in practice the contraposition between the two models could actually be less clear-cut, since in Europe, apart from the French example (with respect to damages covered by the national solidarity fund), it is difficult to find a pure No-Fault system.

Most of the European juridical systems belong to the first category. However, we cannot underestimate the fact that the legislative reforms adopted by some countries, such as France and the Scandinavian countries, will give rise to great interest at the international level. Systems of damage compensation, based on the

Fault model, are located at the center of Europe, in some North European countries, and in Eastern Europe. While for example, in Sweden, Denmark, Finland, and France (for the aléa thérapeutique damages) there are alternative institutes which cannot be strictly considered as No-Fault compensations.

The main features of the No-Fault systems are the reduction of complications in the ascertainment of the physician's fault (simplifying the burden of proof) and the generalization of the clinical risk, through a healthcare vision. Indeed, these systems only require the direct relationship between the health care and the damage suffered. Therefore, the patient will not have to demonstrate the physician's fault, but only the proof that the damage derives from the physician's performance.

Another purpose is the reduction of the judicial management expenses by administrative compensation procedures of damage compensation. The No-Fault systems are usually joined with insurance coverage, aimed at indemnification in order to avoid lawsuits.

The adoption of one system rather than the other depends on a strategic and financial choice of how we want to face the issue of medical malpractice.

In fact, the institution of a No-Fault compensation system requires adequate financial resources.

Healthcare activities, as well as enterprise activities, constantly involve a margin of error, which exposes the hospitals to the risk that accidents may occur. Risk can be defined as the probability of those adverse events occurring. On average, the No-Fault systems avoid focusing specifically on human errors.

The clinical error is a consequence of the Health system (Reason 1990). Indeed, in this kind of a system, the error is not identified in a single health professional, but in the whole system. The spread of the collectivization of clinical risk shows that Public Health belongs to everybody and that the negative consequence arising from a physician's performance must be ascribed to the whole community itself. On the basis of this consideration there is the logical presumption that it is unacceptable not to compensate the injured patient regardless of whether the physician is guilty of misconduct or not. The whole community must be in charge of compensating the patient's damage, since health care represents one of the main priorities for modern States.

Obviously, a similar consideration can be made in Europe only with regard to the French experience (and exclusively with regard to damages arising from the aléa thérapeutique). In fact, other systems such as the Scandinavian one are hybrids and cannot be considered as an actual part of that policy. No-Fault based models would surely be desirable since they would contribute to the preservation of quality within the Health Service. Indeed, we should not underestimate the psychological damage connected to the trial suffered by the physician both in the mid and long-term period. As a matter of fact, the No-Fault-based systems provide for an approach inspired by the systemic nature of the medical error, without pursuing punishment. In other words, No-Fault-based models approach medical fault by focusing on the misconduct of single health professionals rather than on single human errors. On the other hand, as stated by James Reason, besides overt mistakes made by health professionals, every healthcare system includes latent

errors. Latent errors, though near-misses, can contribute to causing a damaging accident when associated with triggering events.

The No-Fault-based models also contribute to decreasing the risk of the affirmation of a defensive medicine approach, which surely appears as an inadequate remedy to protect patient care and health.

Indeed, defensive medicine consists of diagnostic and therapeutic treatments focused on avoiding the future possibility of malpractice effects, representing a guarantee for the physician's performance rather than for the patient's health. However, it is necessary to underline that provisions such as the obligation of insurance, national solidarity funds, and administrative compensation procedures related to insurances policies could also result in a counter-productive outcome. Indeed, the existence of an insurance coverage could on the one hand decrease the deterrent efficacy of the responsibility rules, and on the other hand represent a practical risk of duplication in the number of compensations. In other words, there is a relevant risk that from a situation of under-compensation (where the compensation to patient damages was marginally due to the scarce sensibility toward the issue of medical malpractice) we will witness a movement toward a situation of over-compensation, meaning an increase in the number of damage compensations (Cacace 2003).

Lastly, it is important to underline that the mediation role (as well as the role of administrative compensation procedures) would greatly facilitate the global situation due to the possibility of creating a more constructive dialogue between the parties. Therefore, for this reason we have to appreciate the efforts undertaken by the English NHSLA which, even though introduced within a Tort-based system, represent a concrete investment in the role of mediation. To conclude, in the European juridical scenario, even though several types of approaches to the medical liability matter coexist, we can highlight the emergence of a common and founded concern of an increasing objectification of the clinical risk especially when considering the judge's attitude, which is not very conciliatory.

Once we are aware of the inherent dangers involved in the physician's performance and the related risk of error (even accidental) within hospitals, we should ask ourselves whether it is more convenient, in the issue of medical responsibility, to play the card of the No-Fault or Fault-based models. Surely, an increased and wide use of administrative procedures would be desirable, with the aim of decreasing the expenses relating to the management of judicial cases and favoring a dialogue between physicians and patients.

In conclusion, it appears reasonable to consider that the consequences linked to the increase in claims in the health field can also be alleviated through an improvement of the informed relationship between the physician and the patient, which is often difficult due to the lack of understanding of medical-scientific notions. The hope is for a framework in which the physician and the patient cooperate in the search for a pacific solution, which should not be a utopian goal, but the result of deep reflection on the different needs of the medical world and the whole community.

References

Act 14/2006 of 26 May 2006 n. 14, relating on "sobreTécnicas de reproducciónhumanaasistida"
Act 303/2002 of 4th March 2002 n. 303, relating on "Drots des malades et à la qualité du système de sante"
Adelman HS (2004) The swedish patient compensation system: a viable alternative to the U.S tort system? bull am collsurg 89 (1):25–30
Atiyah PS (1986) Medical malpractice and the contract/tort boundary. Law and cont prob287
Bauer G, Pollak S (2007) MedizinischrelevanteRechtsvorschriften in Österreich. In: Madea B (ed) Praxis Rechtsmedizin, 2nd edn. Springer, New York, pp 637–656
Birmontiene T (1996) Patients' right legislation in Lithuania.Eur J Health Law 3(1):85–94
Bismark B, Paterson P (2006) No-fault compensation in New Zealand: harmonizing injury compensation, provider accountability, and patient safety. Health Aff (Millwood) 25(1):278–283
Bismark MM, Troyen Brennan A, Peter BD, Stuffert DM (2006) Claiming behaviour in a no-fault system of medical injury: a descriptive analysis of claimants and non claimants. Med J Aust 185:203–207
Cacace S (2003) Loi Kouchner: problemi di underdeterence e undercompensation. Danno e Responsabilità 4:435–441
Cassation civil, 1ere, 8 Novembre 2000
Colleen MF (1999) New Zealand's no-fault accident compensation scheme: paradise or panacea? Health Law Rev 8(3):3–10
Conseil d'état, 9 aprile (1993) (Arret Bianchi) in JCP, 1993, II, 22061 with note of MoreauJ
Council of Europe CONF-ML (2008) 03E, April the 15th 2008
De cruz P (2001) Comparative healthcare law. Cavendish, London
Directive 2008/52/EC of the European parliament and of the council of 21 May 2008 on certain aspects of mediation in civil and commercial matters
Ducinskiene D, Vladickiene J, Kalediene R, Haapala I (2006) Awareness and practice of patient's rights law in Lithuania. BMC Int Health Hum Rights 6:10. doi:10.1186/1472-698X-6-10
Essinger K (2008) Medical liability alternative ways to court procedures. In: European conference the ever-growing challenge of medical liability: national and European responses
Grossen JM, Guillod O (1983) Medical malpractice law: American influence in Europe? Boston Coll Int Comp Law Rev 6(1):1–27
Hubbard C (2000) Culpability and compensation in canadian health care: much ado about no-fault? faculty of law. University of Western Ontario, London
Hurwitz B (1995) Clinical guidelines and the law: advice, guidance or regulation? J EvalClinPract 1(1):49–60
Koch BA (2003) Austrian cases on medical liability. Eur J Health Law 1:91–114
Manaouil C, Rahal-Löfskog D, Montpellier D, Jardé O (2006) Fonctionnementpratique des commissions régionales de conciliation etd'indemnisation. Presse Med 35(11–2):1707–1715
NHSCC-national health service and community care act 1990
Ponzanelli G (2003) La responsabilità medica ad un bivio: assicurazione obbligatoria, no-fault o risk-management? Danno e Responsabilità 4:428–430
Pukk-Härenstam K, Ask J, Brommels M, Thor J, Penaloza RV, Gaffney FA (2008) Analysis of 23 364 patient-generated, physician-reviewed malpractice claims from a non-tort, blame-free, national patient insurance system: lessons learned from Sweden. QualSaf Health Care 17(4):259–263. doi:10.1136/pgmj.2008.070326
Reason J (1990) Human error. Cambridge University Press, Singapore

Sappideen C (1993) No fault compensation for medical misadventure, australian expression of interest. J Contemp Health Law Policy 9:311

Serra GB, Carrara C (2005) Paralisi cerebrale nel neonato: il problema della responsabilità professionale medica e la crisi delle assicurazioni: proposta di ordinamento in Italia. Riv It Ost Gin 7:362–367

Stauch M (2008) The law of medical negligence in England and Germany: a comparative analysis. Hart Pub, Oxford

woodhouse report (1967) Compensation for personal injury in Ne Zealand: report of the Royal Commission of injury. Government Printer, Wellington