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EUROPEAN COMMITTEE ON LEGAL CO-OPERATION
(CDCJ)

REPORT
ON MEDICAL LIABILITY IN COUNCIL OF EUROPE MEMBER STATES

A comparative study of the legal and factual situation in Member states
of the Council of Europe

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References

- CALLENS, S., “Medical Civil Liability in Belgium. Four Selected Cases”, *European Journal of Health Law*, Volume 10, No. 2, June 2003, 115-133.
- COUSY, H. and DE GRAEVE, M., “Belgium”, in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 84-101.
- DAHLMAN, C. and WENDEL, L., “Sweden”, in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 188-200.
- DUTE, J., “Medical Malpractice Liability: No Easy Solutions”, *European Journal of Health Law*, Volume 10, No. 2, June 2003, 85-90.
- GALAND-CARVAL, S., “France” in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 102-122.
- GIESEN, D., *Arzthaftungsrecht: Die zivilrechtliche Haftung aus medizinischer Behandlung in der Bundesrepublik Deutschland, in Österreich und der Schweiz*, Tübingen, Mohr, 1995, 467p.
- GODDEVRIENDT, F. en CALLENS, S., “De impact van zorgrichtlijnen op de medische aansprakelijkheid”, in X, *Recht in beweging*, Antwerpen, Maklu, 2004, 315-340.
- GRUBB, A., “Special Forms of Negligence: Problems of Medical law” in MARKESINIS, B.S. en DEAKIN, S.F., *Tort Law*, Oxford, Clarendon Press, 4th edition, 1999, 816 p.
- JONES, M., *Medical Negligence*, London, Sweet & Maxwell, 2003, 966p.
- MCHALE, J.V., “Medical malpractice in England: Current Trends”, *European Journal of Health Law*, Volume 10, No. 2, June 2003, 135-151.
- MEMETEAU, G., “France”, in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, The Hague, Kluwer Law International, 1998, 160p.
- NESTEROWICZ M., BAGINSKA, E. and DEN EXTER, A., “Poland”, in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, The Hague, Kluwer Law International, 2002, 116p.
- NYS, H., “Belgium”, in H. NYS (ed.) and R. BLANPAIN (general ed.), *International Encyclopaedia of Laws. Medical Law*, The Hague, Kluwer Law International, 1997, 150p.
- PETRY, F.M., “Medical Practitioner’s Liability in German Law”, in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 34-55.
- PRICE, D., “United Kingdom”, in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, The Hague, Kluwer Law International, 2002, 314p.
- SANDOR, J., “Hungary” in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, The Hague, Kluwer Law International, 2003, 148p.
- VANSWEEVELT, T., *De Civielrechtelijke Aansprakelijkheid van de Geneesheer en het Ziekenhuis*, Antwerpen, Maklu, 1992, 947p.
- WESTERHÄLL, L., “Sweden”, in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, The Hague, Kluwer Law International, 1998, 128p.

Introduction

During the debates at the plenary meeting in May 2004, the European Committee on Legal Co-operation (CDCJ) took account of the concerns expressed by some delegations, that is to say the increasing importance of medical liability in some Member States and the trend towards defensive medicine. An expert study was instigated aimed at providing the CDCJ with preliminary information and assessment concerning the probability of adopting a new instrument in the area of medical liability of physicians.

The study will focus on two aspects. In the first part of the study a comparative analysis of the legal and factual situation concerning medical liability in some Member States of the Council of Europe will be carried out. On the one hand, the study will analyse the liability of a physician for his own behaviour towards the patient which means that product liability and vicarious liability will not be included. When considering the physician's liability, a distinction will be made between liability for technical errors such as a wrong diagnosis or treatment (not respecting the standard of care) and liability for not respecting individual patients' rights (informed consent). On the other hand, attention will be paid to the 'medical malpractice crisis'. In this respect, the study will deal with topics such as number of complaints, damages awarded, defensive medicine, etc.

In the second part, the study will focus on the possibility of drafting an international legal instrument containing major common standards in the area of medical liability.¹ Again, a distinction will be drawn between medical liability as a consequence of violating the standard of care and liability for not respecting individual rights. In this respect, it is worth mentioning that with regard to individual patients' rights, the European Convention on Human Rights and Biomedicine already contains some common standards.

For the research, a number of interesting legal systems have been chosen. Given the limited scope of the project, it was not possible to address most of the European Countries in detail. Therefore, the authors have chosen countries from different regions: a German-oriented country (Germany), a southern country, namely France, a western country (Belgium) and two countries from Eastern Europe, Poland and Hungary. In addition, attention is also paid to the common law system (United Kingdom) and the Scandinavian model (Sweden).

Because of the limited scope of the project and due to the short period of time in which the study had to be completed, the authors relied extensively on the contributions in the *International Encyclopaedia of Laws: Medical Law* and on the contributions made in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 329p. For a few countries, some extra references are included.

¹ During the debates at the plenary meeting in May 2004, the CDCJ also asked whether a political consensus can be expected among the Member States on the adoption of such an international instrument. The study will not focus on this aspect since the answer will be considered by the CDCJ itself and further by the Committee of Ministers if the first two questions are answered positively.

Part I: Comparative study of the legal and factual situation in Member States in the Council of Europe

A. Legal situation

1. Medical malpractice liability of the physician: general remarks

In order for a patient to succeed in a medical malpractice claim, certain requirements have to be met. A first necessary condition to hold a doctor liable is that the doctor is at *fault*, that is to say that he failed to act according to the required standard of care (a wrong diagnosis or treatment) or that he failed to respect individual patients' rights (failure to inform the patient properly concerning the risks related to the particular treatment). Once fault is established, the patient also has to demonstrate the *damage* suffered. Damage can be material or immaterial/moral. In most countries, it is generally accepted that the burden of proof rests upon the patient. Furthermore, as a third essential requirement, the patient also has to establish the *causal link* between the doctor's breach of duty and the damage suffered.

This study will focus on medical malpractice liability in some Member States of the Council of Europe. Once the required standard of care is established, attention will be paid to the different aspects of medical liability as outlined above. In addition, the study will also take a closer look at no-fault compensation schemes which some countries have set up.

2. Belgium and France

Because of comparable developments of civil law in Belgium and France the authors have chosen to restrict themselves to a study of the situation in Belgium. However, there are also some significant differences which will be clarified in this paragraph.

2.1. Introduction

In Belgium medical liability is not regulated by specific legislation, resulting in a situation in which civil liability as well as criminal liability of a physician for damage or injury caused by improper conduct are governed by the general rules of civil and criminal law. Civil liability of a physician can arise when an obligation, originating from contract between the physician and his patient or from tort, is not fulfilled. The French law of torts distinguishes two sets of rules, on the one hand the general rules in the Civil Code which are applicable to the contractual as well as non-contractual liability of individuals and private bodies (civil courts). On the other hand, there is a set of specific rules which are applicable to the liability of public authorities, *le droit de la responsabilité administrative* (administrative courts). However, despite the differences, both systems are mainly fault-based.

In both systems, concurrence of contractual and non-contractual liability is excluded²; article 1382 Civil Code is inapplicable when the fault was committed in the execution of a contractual obligation. In case, the breach is also a criminal act, an action in tort remains possible. However, tort liability is only relevant in case of damages to a third party or where services are rendered to a patient who is not in the position to give consent to the treatment.

2.2. Standard of care

Following a decision of the French Court of Cassation (*Mercier case*), a *contract* between a physician and his patient results in an obligation *not to cure* the patient but to offer him medical help conscientiously and attentatively, in conformity with the data and advances of medical science³, in the sense that the current level of scientific progress should be taken into account. The Belgian Court of Cassation accepted this

² Court of Cassation, 7 December 1973, *Arr. Cass.* 1974, 395 cited in H. NYS, "Belgium", in H. NYS (ed.) and R. BLANPAIN (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 1997, 62-63.

³ French Court of Cassation, 20 May 1936 (*Mercier*) cited in H. NYS, "Belgium", in H. NYS (ed.) and R. BLANPAIN (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 1997, 63 and VANSWEEVELT, T., *De Civielrechtelijke Aansprakelijkheid van de Geneesheer en het Ziekenhuis*, Antwerpen, Maklu, 1992, 49.

view. Consequently, a physician is under the obligation to use reasonable care and skills (effort) but he is not required to cure the patient or to achieve a specific result (result obligation) since the outcome of a treatment is uncertain and not only depends on the skilled exercise by the medical practitioner but also on the physical state and reactions of the patient. As a result a patient must show that he suffered harm because of the physician's fault which can consist of negligence, lack of skill, improper information, etc. However, exceptions are made by the courts in cases where a physician uses a known treatment of which the outcome is certain and which is under full control of the physician. In such situations, the courts can hold a physician liable for not achieving a specific result unless the physician can prove that the failure was not attributable to him (eg. Sterilisation);

The obligation to exercise reasonable care and skills according to the status of medical science refers to the professional standard that implies that care should not lie below the care that would be shown in similar circumstances by a reasonable, careful physician. When defining reasonable care, the conduct of a physician is compared with that of the *bonus medicus* or the standard of the prudent and competent physician with the typical qualities and skills and placed in the same circumstances as the defendant physician (objective standard of care).

2.3. Fault

Fault is the basis for a claim for malpractice either in contract or in tort. In the first place, we will consider the physician's liability for deviating from the standard of care and secondly, we will look at liability for not respecting patients' rights and other legal regulations.

2.3.1. Deviation of the standard of care

The main obligation of a physician is to act in a prudent and diligent manner. He is not obliged to achieve a specific result; rather he has to conduct himself with proper care and skill. Deviation from the professional standard will be considered a fault for which a physician can be held liable, even if he regards his action as reasonable.

2.3.2. Informed consent

A patient has the right to be informed by his physician. The right to receive information and the duty to obtain consent from the patient are laid down in specific legislation concerning patients' rights; article 7 and 8 in the Belgian law on patients rights⁴ and article L. 1111-2 and L. 1111-4 of the French law.⁵ In general, the information which needs to be given should include diagnosis, choice of treatment (in accordance with the theory of proportionality), risks, pain, alternatives, effects of (non-)treatment, etc. Furthermore, a physician needs to inform his patient in due time so that he is able to weigh all aspects of the treatment before consenting to it. With respect to the risks of a treatment, Belgian courts apply the theory of the normal and reasonable foreseeable risks. This means that the physician need not inform the patient about serious but exceptional risks or minor but frequent risks. However, in some cases it is decided that if the intervention is less necessary or urgent or if the intervention gives a poor result of improvement, the information must be more specific. On the other hand, it has also been argued that a physician needs to inform the patient about the risks that he believes are relevant for a normal person in the same circumstances whether or not to consent with the treatment (relevant-risk-theory). The latter opinion is supported by article 8 of the Belgian law on patient rights.

In France, the Cour de Cassation has recently altered the criterion of which risks the patient has to be informed.⁶ Prior to the judgement, courts also adhered to the theory of the normally foreseeable risks. Nowadays, they look at the seriousness of the risk which means that serious risks have to be communicated to the patient even if those risks are of exceptional occurrence. However, it has been

⁴ Wet betreffende de rechten van de patiënt van 22 augustus 2002.

⁵ Loi no 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé.

⁶ Cour de Cassation, 7 October 1998, *Bulletin Civil I*, n° 291 cited in GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 105.

established that a physician who has not given his patient all the information cannot be held liable for all the consequences of the realisation of the risk. Failure to warn has only deprived the victim of a chance to refuse. Recovery is therefore limited to a percentage of the loss suffered (loss of chance, see also §2.6.3.).⁷ The duty of the physician to inform may be limited. In case of emergency, a physician is not obliged to give all necessary information to the patient at the moment of treating him. In addition, when the physician has good reason to withhold information in the best interest of the patient (therapeutic exception), he may withhold information. Whether this was justified, has to be proven by the physician. Finally, a physician does not have to inform the patient if the patient does not want to know. However, if it would seriously harm the patient or third parties, exceptions will be made. Once a patient is properly informed, he has to consent to the treatment notwithstanding some exceptional situations such as an emergency. The need to obtain consent is based on self-determination and respect for physical integrity. Consent can be implied if the patient's will is certain. In order for a physician to start a treatment, consent of a patient needs to be real and given by a competent person and is only valid for the treatment consented to.

2.3.3. Administrative liability in France

In general, a public hospital is only liable for fault which means that the patient must show that harm was caused by a fault of an agent of the hospital or by a fault consisting of a defective organisation. In order to establish liability of a public hospital, it is sufficient for a patient to prove mere negligence.⁸ It follows that the patient carries the burden of proof but in some cases fault of the public hospital is presumed (e.g. iatrogenic infection). However, the presumption is rebuttable.

In addition, it has also been recognised that a public hospital can be held liable without the existence of a fault for so-called therapeutic risks. Two cases are important in this respect. In a one case, a hospital was held strictly liable for the unanticipated side-effects produced by a new medical technique.⁹ The second case concerned ordinary medical techniques. *In casu*, the court accepted strict liability for the exceptional risks and stated that

*“when a necessary medical test or treatment carries a known but exceptional risk, and when there is no reason to think that it is likely to occur in the circumstances, the public hospital is liable for all the direct damaging consequences of the test or treatment, providing that they are not related with the patient's initial state of health, nor to its foreseeable evolution, and providing that the loss suffered by the patient is extremely serious”.*¹⁰

Consequently, if the conditions are fulfilled and the causal link is established, a patient will be fully compensated for his loss without the need of establishing fault (strict liability).

2.3.4. Strict liability in France in private law

In general, French private law does not recognise strict liability. However, an exception is made in case of iatrogenic infections. It has been held by the Cour de Cassation that private doctors and hospitals are

⁷ Cour de Cassation, 7 February 1990, *Bulletin Civil I*, n° 75 cited in GALAND-CARVAL, S., “France” in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 105.

⁸ Conseil d’Etat, 10 April 1992, *Recueil Lebon*, 1992, 173 and Conseil d’Etat, 20 June 1997, *Recueil Lebon*, 1997, 254 cited in GALAND-CARVAL, S., “France” in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 104.

⁹ Cour administrative d’appel de Lyon, 21 December 1990, *JCP II*, 1991, 21698 (*Gomez*) cited in GALAND-CARVAL, S., “France” in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 104.

¹⁰ Conseil d’Etat, 9 April 1993, *Recueil Lebon*, 1993, 127 (*Bianchi*) cited in GALAND-CARVAL, S., “France” in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 104.

strictly liable for iatrogenic infections contracted by their patients.¹¹ Whether an iatrogenic infection occurred or not is not defined by the court. However, one can expect that the court will adopt a wide definition by accepting iatrogenic infections as those which had not yet developed when the patient was admitted to the hospital.¹² In case, no iatrogenic infection seems to have appeared, the patient must fulfil the conditions of a civil claim.

2.4. Causal link

The plaintiff must establish the causal link between the negligent behaviour of the physician and the damage suffered. Belgian case law adheres to the theory of equivalence of conditions meaning that any factor that has necessarily contributed to the existence of damage has to be considered as *a sine qua non* cause of the damage even if there was only an indirect link. In France, it is also up to the patient to establish that the physician's fault was a *sine qua non* for the loss and in addition, the causal relation needs to be established with certainty.

In cases where the physician had to achieve a specific result, liability will follow for not achieving the result unless he can prove the existence of an unknown cause such as force majeure, fault of a third party or fault of the patient.

2.5. Burden of proof

2.5.1. General

The burden of proof rests upon the injured patient who has to prove the facts of the case which constitute the physician's fault. Proving fault is not easy because it is not always clear whether the injury is a consequence of the fault. When it turns out to be impossible to prove fault, the patient must bear the risk of injury and damage. In addition, the patient must also prove damage and causality. It follows that the burden of proof resting upon the patient is heavy. Therefore, the courts have adopted in some cases the doctrine of *res ipsa loquitur*.

The burden of proof upon the patient differs according to the kind of obligation, that is to say the obligation to achieve a specific result and the obligation to act with reasonable care and skills. With regard to the former, the patient has to prove that the result was not achieved while in the latter case, he has to prove that the physician did not act as a normal and prudent physician placed in similar circumstances would have done.

2.5.2. The burden of proof with respect to informed consent

In case of injury a patient can sue the physician but he has to prove that the physician did not respect the right of the patient to be informed or improperly informed the patient and in addition, it has to be shown that, if he had been properly informed, he would not have consented to the treatment.¹³ Furthermore, it is also up to the patient to prove that the physician did not ask for his consent after he had received the information.

However, some courts in Belgium took account of recent case law in France and decided that the physician must prove that he fulfilled his duty to give information.¹⁴ In France, the Court of Cassation held that a physician must fulfil the information obligation towards a patient and he must prove that he

¹¹ Cour de Cassation, 29 June 1999, 1999, JCP II, 10138 cited in GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 113.

¹² GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 113.

¹³ See Court of Appeal Bergen, 11 January 1999, *T. Gez/Rev. Dr. Santé* 1999-2000, 278 cited in CALLENS, S., "Medical Civil Liability in Belgium. Four Selected Cases", *European Journal of Health Law*, Volume 10, No. 2, June 2003, 116.

¹⁴ Court of Appeal Liège, 30 April 1998, *T. Gez/rev. Dr. Santé*, 1998-1999, 139; Court of Appeal Antwerp, 22 June 1998, *T. Gez/ Rev. Dr. Santé*, 1998-1999, 144 cited in CALLENS, S., "Medical Civil Liability in Belgium. Four Selected Cases", *European Journal of Health Law*, Volume 10, No. 2, June 2003, 125.

provided the information.¹⁵ The Conseil d'Etat adopted this solution and decided that the burden of proof of the information is on the hospitals and not on the patients.¹⁶ This means that in case of doubt, the facts weigh against the physician.

The Court of Appeal of Liège decided that the burden of proof of informed consent is always on the physician. However, the Belgian Court of Cassation did not yet adopt that view.¹⁷ The court motivated its decision by referring to the principle of presumption of innocence in penal cases. Consequently, in a civil case whereby a patient starts a claim based on transgression, the patient must still prove that all the facts of transgression are present. If the physician refers to a ground for justification, the patient must also prove that this justification does not exist. In a very recent case the Court of Cassation has confirmed its position (December, 16th, 2004).

2.6. Damages

2.6.1. General

A patient can only recover damages in respect of negligent medical treatment if he has actually suffered damage. All damage has to be compensated, including moral damages for pain and suffering. Damages will be determined by comparing the current situation with the situation the patient would be in if the fault would not have occurred. Compensation for damages arising out of a breach of contract is limited to what was foreseeable whereas in tort liability, there is no limit of compensable damage. In order for damage to be recoverable, it has to be personal, certain and legitimate.

2.6.2. No-fault system

However recently, one claims a system of no-fault to be implemented which would apply to therapeutic accidents. According to a no-fault system, compensation can be granted irrespective of a mistake of the physician. In France, such a system is introduced with respect to public hospitals (§2.3.3.). In Belgium, however, no such system exists yet. With respect to France, no-fault is regulated in title 4 of the law on patients rights.¹⁸

2.6.3. Loss of chance

In Belgian and French law¹⁹ it is furthermore possible to claim damages for the loss of a chance to a better medical result. This was recognised by the Court of Cassation which confirmed the decision of the Court of Appeal holding a physician liable because of the loss of a chance of avoiding amputation or to have an amputation in a minor way.²⁰ In order for a claim for damages for loss of chance to succeed, it has to be established that the chance was ascertainable and not *de minimis*. The theory of loss of chance helps patients in establishing the causal link between fault and damage. It was also used to the issue of informed consent. In that case, the patient must only prove that, since he did not receive the required information, he lost the chance of giving consent based on all information.

¹⁵ Cass. Fr., 25 February 1997, *T. Gez/Rev. Dr. Santé* 1997-1998, 338 cited in CALLENS, S., "Medical Civil Liability in Belgium. Four Selected Cases", *European Journal of Health Law*, Volume 10, No. 2, June 2003, 125.

¹⁶ Conseil d'Etat, FR., 5 January 2000, *AJDA*, 20 February 2000, 137 cited in CALLENS, S., "Medical Civil Liability in Belgium. Four Selected Cases", *European Journal of Health Law*, Volume 10, No. 2, June 2003, 125.

¹⁷ Cour de Cassation, 14 December 2001, *T. Gez/Rev. Dr. Santé* 2000-2001, 239 cited in CALLENS, S., "Medical Civil Liability in Belgium. Four Selected Cases", *European Journal of Health Law*, Volume 10, No. 2, June 2003, 124..

¹⁸ Loi no 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé, Titre IV: "Réparations des conséquences des risques sanitaires".

¹⁹ Cour de Cassation, 8 July 1997, *Bulletin Civil*, n° 238; Cour de Cassation, 8 July 1997, *Bulletin Civil*, n° 239 cited in GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 115.

²⁰ Court of Cassation, 19 January 1984, *Arr. Cass.* 1984, 585 cited in H. NYS (ed.) and R. BLANPAIN (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 1997, 66.

3. United Kingdom

3.1. Introduction

In the United Kingdom, claims for medical malpractice can be based on contract (private patients), tort or equity. But in practice, most claims for damages are brought in the tort of negligence. The tort of negligence consists on the one hand of a legal duty to take reasonable care and on the other of a breach of that duty causing damage. The duty of care determines whether the injury or loss suffered by the patient can be actionable whereas breach of the duty refers to the standard of care with which a physician must comply in order to fulfil his duty of care towards the patient. Hence, it determines whether the physician acted negligent. In order for an action for negligence in common law to succeed, it has to be shown that the physician owed *a duty of care* to the patient, that there was a *breach* of that duty and that the breach *caused* the injury suffered by the patient.

3.2. Negligence

3.2.1. *Duty of care*

3.2.1.1. *The existence of a duty of care*

The duty of care arises from the tort of negligence which imposes on the physician a duty of care not to unreasonably injure the patient when diagnosing, giving advice and undertaking the treatment of the patient. However, it does not depend upon the doctor's status, qualifications or expertise. Rather it is imposed by law when the physician undertakes care for a patient.²¹

A duty of care does not arise out of the mere formal establishment of a physician-patient relationship nor does a formal ending of the physician-patient relationship necessarily end the duty of care owed by the physician since continuing care may be required until it is reasonable to end the treatment. In order for a duty of care to arise, the physician must be requested to provide medical services or become aware that such services are required. Generally, the duty will arise if the physician embarks on the care for the patient. This was also recognised by Lord Nathan who alleged that 'the medical man's duty of care ... is based simply upon the fact that the medical man undertakes the care and treatment of the patient'.²² This implies that who presents himself as possessing special skills and assumes responsibility, thereby undertakes a duty of care. However, even a person who does not possess the necessary qualifications or expertise comes under the same duty of care since by undertaking the treatment he presents himself as having these qualities.

In cases where no relationship exists between the patient and the physician, the general law on omissions applies meaning that there is no legal obligation upon a doctor to act as the Good Samaritan. However, a physician who chooses to do so will owe a duty of care to the patient. The duty then arises from the performance of the act. With respect to hospital doctors, the situation differs. As soon as a team of health care providers has undertaken care for a patient, all members of the team will owe a duty of care regardless of whether at that stage any treatment has been provided.

In some cases, the existence of a duty of care is considered controversial, that is to say in cases where it would not be just, fair and reasonable to impose a duty of care or where insufficient foreseeability or proximity exists.

3.2.1.2. *Scope of the duty of care*

The physician's duty of care towards his patient does not only involve the obligation not to cause harm but in some cases it also contains an obligation to exercise reasonable care, e.g. to prevent the patient from harming himself in case of psychiatric injury. As a result, a patient can bring an action for damages which

²¹ In *R. v Bateman*, the court ruled that 'if a person holds himself out as possessing special skill and knowledge and he is consulted, as possessing such skill and knowledge, by or on behalf of a patient, he owes a duty to the patient to use due caution in undertaking the treatment ... No contractual relation is necessary, nor is it necessary that the service be rendered for reward', [1925] 94, LJKB 791 at 794, cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 72.

²² Cited in A. GRUBB, "Special Forms of Negligence: Problems of Medical law" in MARKESINIS, B.S. en DEAKIN, S.F., *Tort Law*, Oxford, Clarendon Press, 4th edition, 1999, 273.

can include damages for physical injury and financial loss as well as damages for mental distress and suffering arising out of the injuries.

Cases in which a patient has suffered purely financial loss as a result of a negligent advice or information on which he relied, fall under the principles of *Hedley Byrne & Co Ltd v Heller & Partners Ltd*²³. Based on that judgement a physician can be held liable for economic loss relating to negligent misstatements if he advises a patient in circumstances in which he knows or ought to know that the patient will rely on it even where he was not consulted with a direct financial issue in mind (proximity). However, if the physician does not know that the patient intends to rely on his advice or if the patient relies upon it for an unexpected purpose, then it is likely that no duty of care will exist.

With regard to psychiatric injury a distinction can be made between psychiatric injury suffered as a result of physical injury and pure psychiatric injury. In the first case, the duty of care is not at stake but rather the issue of causation and remoteness because there was a pre-existing duty of care. Consequently, this kind of psychiatric injury can be actionable and non-pecuniary damages for pain and suffering can be claimed. With respect to pure psychiatric injury, the situation is much more complicated because no physical injury was sustained. In these cases, a distinction is made between primary victims who were directly or indirectly involved and thus within the range of foreseeable injury or believed they were within it. The other category, secondary victims, are victims who were an unwilling witness of injury caused to others. They can claim damages for psychiatric injury if, in addition to foreseeability, they can show that they had a close tie of love and affection with the person injured, that they were close to the incident or its immediate aftermath in time and space and that they directly perceived the incident.

3.2.2. Breach of the duty of care

Whether a physician has breached his duty of care in the tort of negligence will be determined by considering whether his conduct was reasonable in all the circumstances of the case. If he acted reasonable, liability will be excluded. But failure to exercise the standard of skills and care that a reasonable acting health care professional would do in similar circumstances constitutes a breach of the duty of care.

3.2.2.1. Standard of care

Whether a physician acted negligent or not, is to be determined according to the so-called *Bolam* test. In *Bolam v Friern Hospital Management Committee*²⁴ McNair J ruled that

‘... where you get a situation which involves the use of some special skill or competence, then the test whether there has been negligence or not is not the test of the man on the Clapham Omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that skill. A man need not possess the highest expert skill at the risk of being found negligent ... it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art.’²⁵

The ruling in *Bolam* implies that the standard of care with which a physician has to comply varies according to the type and degree of skill and care that the individual presents as having acquired. A physician is not to be judged according to the standards of the most experienced, most skilful, or most highly qualified member of the profession but by reference to the standards of the ordinary competent practitioner in that particular field.²⁶ Nor is a doctor to be judged by the standards of the least qualified or least experienced practitioner. Hence, a specialist owes a different duty of care to the patient than a general practitioner but as Lord Scarman added in *Maynard v West Midlands Regional Health*

²³ [1964] AC 465 (HL) cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 78.

²⁴ [1957] 2 All ER 118.

²⁵ [1957] 2 All ER 118, 121 cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 190-191.

²⁶ E.g. *R. v Bateman* [1925] 94, LJKB 791.

Authority, ‘... a doctor who professes to exercise a special skill must exercise the ordinary skill of his speciality’.²⁷

In addition to exercising reasonable care, a physician is obliged to keep up to date with new developments in their particular field. In *Bolam* McNair J said that a health care professional cannot persistently and pig-headedly carry on with an old technique if it has been proved to be contrary to new medical practice. But the requirement is limited. It is considered to be too demanding to require a physician to read every article appearing in the medical press which is relevant to his practice. On the other hand the obligation to keep up to date is complicated because of the difficulty of determining when a new method has developed. In general, when the risks of the old procedure become known, so that it can be said that an ordinary and reasonably competent physician would have changed his practice, it will be negligent to continue to use the old procedure.

3.2.2.2. *Approved professional practice*

In general negligence will be avoided if there is evidence that the physician acted in accordance with common practice of similarly placed physicians. However, this evidence is not conclusive since the practice can be found negligent. In *Bolam* McNair J further stated that

‘... a doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that art ... a doctor is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view’.²⁸

Following this judgment, the courts considered compliance with an approved professional practice as conclusive evidence that the defendant was not negligent. The recognition of an approved practice further implies that health care professionals may adhere to practices which they have never followed before or with respect to a situation they have never encountered before.

In case where more than one approved practice exists, the *Bolam* judgement and the opinion of Lord Scarman in *Maynard* suggest that adherence to *any* of these responsible bodies of opinion will not lead to negligence since differences of opinion and practice will always exist in the medical profession. A court may prefer one body of opinion to the other but that is no basis for concluding negligence.²⁹

In 1997, the House of Lords issued the ‘new *Bolam*’ test in *Bolitho v City and Hackney Health Authority*³⁰. In the ruling, the court emphasised the need for any body of medical opinion to be reasonable and responsible. Lord Browne-Wilkinson said the following:

‘... in some cases, it cannot be demonstrated to the judge’s satisfaction that the body of opinion relied upon is reasonable or responsible. In the vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion ... a reasonable view necessarily presupposes that the relative risks and benefits have been weighted by the experts in forming their opinions. But if, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible.’³¹

²⁷ *Maynard v West Midlands Regional Health Authority*, [1985] 1 All ER 635 at 638 cited in D. PRICE, “United Kingdom”, in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2002, 96-97.

²⁸ [1957] 2 All ER 118, 122 cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 191.

²⁹ In *Hucks v Cole* [1993] 4 Med LR 393 cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 202, a different approach was taken. The court ruled that ‘... if the court finds, on an analysis of the reasons given for not taking those precautions that, in the light of the current professional knowledge, there is no proper basis for the lacuna, and that it is definitely not reasonable that those risks should have been taken, its function is to state that fact and where necessary to state that it constitutes negligence ...’. The fact that other professionals would have done the same was not conclusive evidence.

³⁰ [1998] AC 232.

³¹ [1998] AC 232, 243 cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 204.

This case shows that there is a greater judicial willingness to scrutinize the opinions expressed by the body of professional opinion.

In cases where an approved practice is recognised, departure from that practice can constitute negligence but this evidence is not conclusive. The ultimate remains whether the physician acted in accordance with reasonable skill and care in the circumstances. In *Hunter v Hanley*³² the court ruled that three elements are required to establish liability in cases where deviation from approved practice is alleged; there has to be a usual and normal practice (1) which the defendant has not adopted (2) and it has to be established that the actions of the physician would not be taken by a professional of ordinary skill if he had been acting with ordinary care (3).

3.2.2.3. Time

Whether or not a breach of the duty of care occurred has to be judged at the time of its alleged occurrence which implies that the state of medical and scientific knowledge at the time of treatment is essential in finding negligence.³³ However, it has to be acknowledged that the standard of care varies along the lines of the circumstances under which the physician operates.

3.2.2.4. Error in diagnosis and treatment

The circumstances which can lead to a claim for negligence are diverse. Treatment or diagnosis can be performed in a careless way or a treatment can be omitted. In all cases, the conduct of the physician has to be tested according to the *Bolam* test for negligence. Because of the limited space, a brief overview of the most common mistakes will be given.³⁴ In the first place, a physician can be held liable if he fails to attend his patient when a reasonable doctor would have thought it necessary in the patient's best interest. Errors in diagnosis are a second group of mistakes. They can arise for various reasons such as failure to take a full medical history, a wrong diagnosis, failure to detect a serious illness or failure to revise the initial diagnosis, under- or overtesting, etc. Another category concerns errors relating to advice and communication, in particular failure to warn about the risks attached to a treatment. Finally, a physician can also be held liable for failures in treatment.

3.2.3. Causation

The third element in establishing negligence concerns the causal link between the breach of the duty of care and the damage suffered by the patient. In English law a distinction is made between factual causation and legal causation.

3.2.3.1. Factual causation

A breach will be regarded a factual cause of the injury if it satisfies the 'but for test' that is to say would the patient have sustained such injuries 'but for' the defendant's breach of duty? It means that if the injury would have occurred in any event, then the breach of the duty will not be considered the cause of injury.³⁵ Consequently, when a physician has made an error in diagnosis but a correct diagnosis would not have led to a different treatment, it cannot be said that the error caused damage for which the physician was responsible. However, before embarking upon the 'but for test', it has to be established that the injury could have been caused by the breach of the duty of care. In cases where no scientific evidence supports this link, the test need not even to be posed. In case of more than one cause, causation can be established if the breach of duty materially contributed to the injuries. However, in many cases the cause of injury is

³² 1955 SC 200 (Court of Session) cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 208.

³³ *Roe v Minister of Health* [1954] 2 QB 66 (CA) cited in D. PRICE, "United Kingdom", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2002, 97.

³⁴ For a full, comprehensive overview, the authors refer to the M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 966p.

³⁵ See *Barnett v Chelsea and Kensington Hospital Management Committee* [1968] 1 All ER 1068, cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 376.

unclear which led the House of Lords to decide that to materially increase the likelihood of injury was not sufficient to establish causation.³⁶

In general, the 'but for test' can be seen as a filter to exclude actions that did not affect the outcome. But in some cases, it is inadequate. When there are two mistakes that both could have caused the damages but it is not clear which one substantially contributed to the damage, the test concludes that neither wrong caused the harm. The same can be said in case of successive causes.

3.2.3.2. Legal causation

In many cases, it is possible to have more than one cause that satisfies the 'but for test'. It is then up to the court to choose which of these has to be treated as the cause in law. The court is not obliged to establish one action as the sole legal cause. In case there are two unrelated potential causes which can both have caused the injury, causality depends on the nature of the events and the order in which they occurred. It is also possible that an act of another person, without which the damage would not have occurred, occurs between the physician's negligence and the patient's injury. In these situations, the court must decide whether the defendant is accountable or whether there was a so-called *novus actus interveniens* in which case the causal connection has been broken.

3.2.4. Burden of proof

The burden of proof that the physician has been negligent and that that negligence caused damages to the patient rests upon the patient. Consequently, it is not up to the physician to show that he did not act negligently. This is even so in case where the doctrine of *res ipsa loquitur* applies. The patient has the burden of proof but the physician must adduce evidence to rebut the inference of negligence, in order to avoid a finding of liability. In these cases, the patient who has no or inadequate knowledge concerning the exact circumstances can rely on the mistake as evidence for negligence since the mistake would normally not have occurred in the absence of negligence and when it was under the control of the defendant.³⁷ This establishes a case against the physician and holds him liable unless the physician can offer an explanation of how the injuries might have occurred without any form of negligence.

With respect to causation, it is up to the claimant to prove that the physician's breach of his duty of care caused the damage to the patient. However, in cases where a connection between the negligence and the injury can be established, it can be difficult to show that the specific mistake of the physician actually caused the injury of the patient. In these cases, it is up to the court to decide whether there must have been some causal link. In some instances, the courts relieved patients from the 'but for test', in particular when there is scientific uncertainty. This means that when there are conflicting explanations, causation will be established if the patient can show that the breach of duty materially contributed to the injuries. He does not have to establish that it was the main cause.³⁸ In a later case, the House of Lords went further and stated that it was sufficient for a claimant to show that the defendant's breach of duty made the injury of risk more probable even though it was uncertain whether it was the actual cause.³⁹ With respect to multiple defendants in breach of a similar duty, *Fairchild v Glenhaven Funeral Services Ltd*⁴⁰ applies in which it was considered unfair or unjust as a matter of policy to deprive a claimant of compensation because he is unable to prove the impossible.

³⁶ *Wilsher v Essex Health Authority* [1986] 3 All ER 801, cited in D. PRICE, "United Kingdom", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2002, 101.

³⁷ *Scott v London & St. Katherine Docks Co* [1865] 3 H&C 596, cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 261.

³⁸ See *Bonnington Castings Ltd v Wardlaw* cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 386.

³⁹ See *McGhee v National Coal Board* [1956] AC 613 cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 387.

⁴⁰ [2003] AC 32, cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 390.

3.2.5. Defences

If a patient has succeeded in establishing the elements of tort, his action can still fail if the physician can rely on a general defence.

3.2.5.1. Volenti non fit injuria

This defence relates to the fact that the patient with full knowledge of the nature and extent of the relevant risk agrees voluntarily to the unreasonable risk of harm created by the defendant's action. However, it is not the same as consenting to a treatment as a patient does not consent to the possibility of negligence.

3.2.5.2. Ex turpi causa non oritur actio

This action prevents a patient from relying on his own illegal or immoral conduct.

3.2.5.3. Contributory negligence

Where damages are partly attributable to the fault of the patient, the damages may be reduced based on the principles of contributory negligence. Here the general principle in the Law Reform (Contributory Negligence) Act 1945 applies meaning that an award of damages will be reduced to the extent the court thinks just and equitable having regard to his responsibility for the damage.

3.2.6. Damages

The general principle in tort law is that the patient should be fully compensated for all the losses he suffered. The patient can bring one action in respect of a tort. It is not possible to bring a second action based on the same facts. In the first place the patient is entitled to be restored to the position that he would have been in had the tort not been committed. When this is not possible, damages will be paid. They can consist of pecuniary and non-pecuniary losses. Pecuniary losses will be directly calculated and include amongst others medical expenses and loss of earnings (past and future). Non-pecuniary loss on the other hand, consists of pain and suffering which occurred because of the injury. Restoring the patient in his old position is in these cases mostly not possible. Therefore, damages will be paid that are fair and reasonable.

3.3. The duty to disclose information and consent

3.3.1. Battery

In general, an intentional interference with the body of another person without a lawful excuse constitutes the tort of battery. In the medical context this means that a treatment requires the consent of a competent patient otherwise it will be unlawful. In addition, a physician will also be liable if he acts outside the boundaries of consent given by the patient. In general, the burden of proof with respect to informed consent rests upon the physician who has to prove that he acted with the patient's consent.

For consent to be valid a patient has to be competent, the consent should be real, voluntary and not reached as a result of undue influence and the patient should have received a minimum level of information concerning the nature of the procedure (purpose and effects). A patient's consent is real if he is adequately informed about what he is agreeing to. However, from *Chatterton v Gerson*⁴¹ it follows that a failure to inform the patient fully of the details of the possible consequences does not render the treatment an assault. Furthermore, once the patient is informed in broad terms and gives his consent, it is regarded as real. In these cases, actions for damages had to be based on negligence as result of which the patient must prove the breach of the duty to inform and, had the duty not been breached, that he would not have consented to the treatment. In *Sidaway v Board of Governors of the Bethlem Royal Hospital*⁴² the Court of Appeal repeated the doctrine by declaring that only when consent is obtained by fraud or misrepresentation of what has to be done, there is no true consent.

⁴¹ [1981] QB 432 cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 472.

⁴² [1984] QB 493 cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 474.

3.3.2. *Negligence*

Although the *Bolam* case was principally concerned with diagnosis and treatment, it also contained elements with respect to the standard of disclosure of risks. The leading case concerning the standard of disclosure to make consent valid was *Sidaway v Board of Governors of the Bethlem Royal Hospital*.⁴³ The case affirmed the traditional English view that the standard of disclosure was that of a reasonable doctor and not that of the prudent or reasonable patient which was acknowledged in other jurisdictions. The Court of Appeal, affirming the trial judge, stated that

‘the relationship of doctor and patient must carry with it some duty to give information to the patient which will enable him ... to reach a rational decision. ... What information should be disclosed and how and when it should be disclosed is very much a matter for professional judgment, to be exercised in the context of the doctor’s relationship with a particular patient in particular circumstances...’.

Furthermore, it was said that a duty of care included disclosing as well as withholding such information as was reasonable in all the circumstances to place the patient in a position to make a rational choice. The House of Lords affirmed the decision of the Court of Appeal by a majority of four to one. Only Lord Scarman dissented by referring to the prudent patient or reasonable patient test. Under this test, a physician must disclose all material risks unless one of the exceptions applies, that is to say an emergency or when the information would be harmful to the patient. The other Law Lords affirmed the reasonable physician test, applying *Bolam*. Consequently, they were of the opinion that to prove negligence a plaintiff must show that the physician fell below the standard of practice regarded as proper by a competent body of professional opinion and accordingly the physician was not under a duty to warn a patient of any material risk. However, an additional remark was made. In some circumstances disclosure of a particular risk might be obviously necessary to an informed choice on the part of the patient so that no reasonably prudent medical man would fail to make it even when no expert witnesses condemn the non-disclosure as being in conflict with accepted and responsible medical practice. In the later case of *Pearce v United Bristol Healthcare NHS Trust*⁴⁴, the court seemed to combine the prudent patient and the reasonable doctor test. It was held that

‘if there is a significant risk which would affect the judgement of the reasonable patient, then in the normal course it is the responsibility of the doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt’.

The facts that have to be disclosed to a patient are not easy to determine. In general it is easier to state what information need not to be disclosed. Amongst others, there is no obligation to disclose information which will, according to the doctor, be harmful to the patient (therapeutic privilege) or when the patient does not want to know the information. Furthermore, the doctor is not obliged to make sure that the patient understands, he must make a reasonable effort to communicate information, taking into account the patient’s condition at the time of explaining the risks. Since a few years the General Medical Council has issued advice on what has to be told to the patient before he gives his consent, *Seeking patients’ consent: the ethical considerations*.⁴⁵ In addition, a physician must disclose additional information if the patient specifically asked about the risks. The physician then has to tell the patient whatever he wants to know.

4. Sweden

4.1. Introduction

The basic statute concerning health care in Sweden is the Health and Medical Care Act (HSL) providing the basic terms and conditions for the provision of health care and stipulating who is entitled to receive

⁴³ M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 524.

⁴⁴ [1999] PIQR 53 cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 529.

⁴⁵ February 1999, www.gmc-uk.org.

health care. One of the requirements of this Act is that health care should be carried out in a manner which complies with the requirements of *good care* (§2a).

In case of liability, a distinction is made between two forms of medical liability; medical guidance liability and medical professional liability. The former is a privilege of only a few health care professionals and entails a general duty to supervise and an authority to give subordinate practitioners directions and advice on how to perform their tasks in the best and most secure manner, whereas the latter is the personal liability of health care professionals for the way they are performing their tasks. Because of the limited scope of the study, only the personal liability of the physician will be scrutinised and no further attention will be paid to the medical guidance liability.

4.2. Standard of care

As stated in the introduction, the Health and Medical Care Act requires health care to be carried out in a way that complies with the requirements of good care. This implies in the first place that health care professionals possess the prerequisite knowledge and competence and that they have good material and equipment at their disposal since they have a duty to give all patients competent and appropriate care. A second implication of good care is the fact that physicians are obliged to treat their patients in accordance with scientific knowledge and professional experience. This implies that a physician has the duty to have a reasonable and competent degree of skills resulting from education and the experience obtained from working with patients. Giving improper treatment or withholding proper treatment constitutes negligence in the same way as carrying out a treatment without the proper and reasonable standard of skill and competence or omission of a treatment can be *contra legem artis*. What standard of skill and care is to be applied depends upon the state of medical science at the time of the treatment.

The requirement to act in accordance with scientific knowledge and professional experience is also expressed in the law. The General Instruction for Physicians gives some further guidance concerning the extent of professional liability. According to that instruction, all physicians shall in accordance with scientific knowledge and professional experience give the patient advice, and if possible, the treatment that the circumstances of the patient require. The National Welfare Board added that the purpose of the requirement is 'to assure the best possible care for the individual patient and to form a framework for the activities of the medical personnel. It does not necessarily require that, for example, new methods are excluded from use, but rather that clinical trials must be conducted in a scientific way so that an evaluation can be made. The requirement still allows for medical progress'.⁴⁶

4.3. Fault

4.3.1. Violation of the standard of care

A negligent mistake in diagnosis can be a ground for claiming compensation if the physician did not act in accordance with the required standard of care. When making a diagnosis, a physician must perform his function in conformity with the standard of due care which exists within the medical profession. As stated in the previous paragraph, that standard requires acting with scientific knowledge and professional experience. In general, a high standard is applied. An example of an erroneous diagnosis can be found in the so-called *Luxation Case*.⁴⁷ In that case, the Swedish Supreme Court found a mistake which could only have been avoided through an exceptionally careful examination negligent. This ruling implies that a doctor, making a mistake in diagnosis, can be exempted from liability if the mistake could just as well have been made by a careful and experienced specialist.

The abovementioned concerning the standard of care when making a diagnosis is also applicable to the choice of the method of treatment and how the treatment is to be performed. It follows that in all cases of malpractice Swedish Courts apply a high standard of care. However, it should finally also be mentioned

⁴⁶ Letter of the National Social Welfare Board on 10 February 1976, cited in L. WESTERHÄLL, "Sweden", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 1998, 57.

⁴⁷ *NJA* 1974, p. 99 cited in C. DAHLMAN and L. WENDEL, "Sweden", in M. FAURE and H. KOZIOL (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 193.

that the required skills and experience are adjusted to each individual health care professional (a nurse versus a physician).

4.3.2. Violation of individual rights of the patient (informed consent)

Before a medical treatment takes place, a patient has to give his consent which is based on the information given by the physician. According to the Health and Medical Care Act, a patient shall be given individually adjusted information about his or her medical condition and available methods of examination, care and treatment (2b§). The right to information further involves information about the aim of the suggested activity, possible alternative treatments and their results and also information about pain, discomfort or side-effects.⁴⁸ Consequently, the right to information implies a responsibility to inform the patient about everything he needs to know about his medical situation. However, the extent of information that needs to be disclosed depends on each individual case. In cases in which a patient cannot be informed, information should be given to someone close.

If it appears that a patient has not been properly informed about the risks and effects that might occur, and has thus not consented to the treatment, the patient can claim damages. This means that a physician can be held liable in tort if he failed to properly inform the patient. However, in order to hold a physician liable in tort because of lack of informed consent, two requirements have to be fulfilled. First, it has to be established that the damage was caused by the fact that the patient was not informed about the possible side-effects. In order to satisfy this requirement, it has to be shown that the damage would not have occurred if the patient had been informed about the risks of the treatment which implies that the patient should not have consented to the treatment if he was properly informed about the possible risks. Furthermore the failure to inform must have had practical consequences and may not entail emotional discomfort for simply not being asked. The second condition for holding a physician liable requires that it was negligent to perform the treatment without the patient's consent. In general, it is not regarded as negligent to take risks which are adequate within the medical profession. In a case before the Swedish Supreme Court, two doctors performed an operation under the presumption of a 'hypothetical consent'. The operation failed and the patient sued the hospital, however unsuccessfully. The Court ruled that the doctors had not acted negligently, although they had acted without the consent of the patient. It reasoned that the physicians had done what was medically adequate given the specific circumstances.⁴⁹

4.4. Causal link

4.5. Burden of proof and damages

4.5.1. Tort liability

In Sweden liability for medical malpractice behaviour is regulated in the Swedish tort act, the so-called *Skadeståndslagen*. It contains rules concerning liability for negligence arising out of an act or an omission. Sweden does not have a system of strict liability. Proving negligence is a task of the patient. He has to show that the health care professional who offered the treatment acted negligently. As a general rule the principle of the *bonus pater familias* is applicable which means that behaviour is negligent if it differs from the conduct of the good family father. In medical care there is further also a rule concerning superior responsibility meaning that an employer is liable for the negligence committed by his medical personnel in the exercise of their professional duties. In such a case, it is sufficient to prove that somebody committed an error and the employer must answer for this anonymous error.

The burden of proof rests with the patient who has to show that the health care professional who offered the treatment acted negligently. If proven, the patient can receive compensation from both, the hospital and the physician who made the error. A patient can be awarded damages for economic loss as well as for immaterial losses. When a patient is entitled to damages, it is up to the physician who has caused the

⁴⁸ HSAN 560/82:3, 1984 8:72 cited in L. WESTERHÄLL, "Sweden", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 1998, 63.

⁴⁹ *NJA*, 1990, p. 442, Kerstin H. Case cited in C. DAHLMAN and L. WENDEL, "Sweden", in M. FAURE and H. KOZIOL (eds.), *Cases on Medical Malpractice in a Comparative Perspective*, Vienna, Springer-Verlag, 2001, 192.

injury (intentionally or by negligence) and the hospital (because of maltreatment of one of its health care providers) to pay. However, receiving compensation under the Tort Act is quite difficult leading to a situation in which people try to get compensation via the patient insurance or the pharmaceutical insurance, operating under the principle of no fault.

4.5.2. No Fault compensation or patient insurance

In 1997 the voluntary Patient Insurance was replaced by a compulsory system in the Patient Damages Act. It contains rules concerning the right to compensation for damages and all health care providers are obliged to enter the insurance. An essential issue of the patient insurance is that it is based on the principle of no-fault. Negligence does not have to be proven. Instead, the right to compensation is based on the fact that the injury is related to a decision or an act for which someone in the staff of the care provider is personally responsible. Compensation will be paid if the injury was foreseeable and possible to avoid.

Under the Act, a patient will receive compensation (economic loss and non-pecuniary loss) in case of personal injury if there is a considerable likelihood that the damage is caused by the medical actions mentioned in §6 of the Act. This includes, amongst others, examination, care, treatment or other similar activity if the injury could have been avoided by choosing another method or different performance. Before compensation will be granted, it must also be shown that there was a causal connection between the act and the injury and the injury was not an unavoidable complication. A second action in the Act is the use of defective medical-technical products or health care equipment which is used during the treatment or a fault is made in managing such equipment. In case of an incorrect diagnosis, compensation will be paid if a symptom has been observed and not interpreted in a way that a skilled and experienced specialist would have interpreted it. A delayed diagnosis will be paid for if the symptom should have been observed by an experienced specialist. However, not all actions give a patient a right to compensation. A few exceptions exist. It is for example not possible to receive compensation in case of side-effects of pharmaceuticals or an underlying illness, nor in cases where the injury was a result of necessary activities when treating a life-threatening injury since there is always a risk involved in medical treatment.

5. Germany

5.1. Introduction

A physician can be held liable on the basis of a contract concluded between him and the patient or on the basis of a tort. In case of a contractual relationship, the contract is a service contract (§611ff *Bürgerliches Gesetzbuch* (BGB)) meaning that the physician is not accountable for the success of a medical treatment. Instead, he is only obliged to give a treatment without mistakes or faults. This means that in order to hold a physician liable, there has to be a violation of his professional obligations (faulty treatment). In addition, the physician is also liable for injuries done by his agents for which there is no possibility of exoneration. A second ground for holding a physician liable can be found in tort law (§823ff BGB). According to the BGB, each person involved in treating the patient is personally liable for the treatment he provides. Therefore, as a rule the physician avoids tort liability only by precluding the unlawfulness of the treatment by obtaining the patient's consent after being sufficiently informed and by adhering to standards of due care.

5.2. Standard of due care

The obligation of the physician to observe due care is the same in cases of contractual liability as in cases of tortious liability. In all circumstances, a patient has the right to be treated in accordance with professional standards of care based on the standard of an experienced physician in the particular field of medicine. This implies that a physician always has to practice with the degree of care that is required and that it is not sufficient to act as usually accepted. Due care further refers to the training of the physician (specialist knowledge) as well as to his experience and the state of science at the moment of the treatment. A treatment is considered not in accordance with the required standard of care at the moment of treatment if at a given time a new safely method is accepted by medical science and the use of it complies with the required care. However, it does not mean that every new treatment has to be used immediately. It only implies that a physician should have sufficient knowledge of the state of medical research (manuals and medical journals) and should become skilled at new methods. He should also look at medical opinion; a

physician should not uncritically use a treatment which is rejected by leading opinions. If a treatment is not in accordance with the state of medical science, it does not provide the due care which is required within the medical profession and as result, the physician can be held liable. If a claim is brought against the physician, it is up to him to prove that he acted according to the state of science at the moment of treatment.

German law requires that the standard of care is an objective one which is directed at what is expected in medicine. Consequently, a physician cannot exonerate himself by saying that he had (subjectively) insufficient knowledge or that there was for example a lack of equipment. However, this does not mean that a patient is entitled to the latest therapy or equipment. The older technique only becomes sub-standard in quality if the new method has been sufficiently tested, applied and approved, if the risks decrease and the chances of a successful treatment increase. The due diligence of a physician will be measured to the required medical standard at the time of treatment.

5.3. Fault

5.3.1. Treatment errors

A treatment error can consist of a wilful act or negligence in treatment. In respect of an active action of the physician, one can distinguish between a deliberate deviation from the required standard of care and an unintentional deviation. Negligence in treatment often occurs with respect to the diagnosis or the failure to carry out a treatment or with respect to an inadequate organisational structure.

Treatment errors are unlawful actions by health care professionals that are carried out without the necessary care and which are not in compliance with the current state of science in medicine. Treatment errors are widely interpreted by the courts in Germany. Whether a physician committed a treatment error causing the patient injury has, according to the German Supreme Court (*Bundesgerichtshof*), to be answered by determining whether the physician, applying his medical knowledge and experience, made different decisions about the diagnostic and therapeutic standard and whether these decisions were in accordance with the required standard of care.⁵⁰

It is possible for treatment errors to occur at different stages. With regard to diagnosis, the physician must use all relevant knowledge and experience to determine which treatment is best for the patient. In case of an incorrect diagnosis, one can distinguish between the misinterpretation of tests and not carrying out essential or necessary tests. The first group is not always a ground for liability. Because of the uncertainty that exists in medicine, courts do not often regard a diagnosis based on the wrong interpretation of tests and the results thereof as a treatment error. In order to be considered as a real treatment error, there has to be an essential diagnostic error. This reasoning does not apply to cases in which a wrong diagnosis resulted from the fact that essential medical tests were not carried out or because the initial diagnosis was not checked. Another form of a treatment error consists of choosing the wrong treatment method or using technical instruments. A physician bears in the first place the responsibility to choose the best option in case of more than one alternative. However, this does not mean that he always has to apply the safest option but if the treatment implies a higher risk for the patient, it has to be justified by the necessities of the individual patient or by a more favourable chance of curing the patient. Once a physician has chosen the treatment to be applied, he must show sufficient competence in handling the medical instruments. He has to know the technical aspects of them and to check them for possible defects before using them. Finally, a physician can also be held liable for a treatment error with regard to the examination of the patient, the duty to consult the patient and to inform him sufficiently.

5.3.2. Liability due to defects in information

A physician is obliged to inform the patient about possible risks which can occur during the treatment, about risks of non-treatment and about possible side-effects and complications. The obligation to inform the patient follows from his right to self-determination. When sufficiently informed, the patient can decide

⁵⁰ BGH, 10.03.1987, VI ZR 88/86, NJW 1987, 2291 cited in GIESEN, D., *Arzthaftungsrecht: Die zivilrechtliche Haftung aus medizinischer Behandlung in der Bundesrepublik Deutschland, in Österreich und der Schweiz*, Tübingen, Mohr, 1995, 85.

whether he agrees with a particular treatment or not. The details and the precise scope of the information depend on the particular situation. However, in all cases, the patient must receive basic, comprehensive but not too lengthy or complicated information so that he understands the implications of a treatment. If the patient is sufficiently informed and consequently, gives his consent, the treatment is legal and valid. Other requirements which a legally valid informed consent process has to comply with are in the first place a personal conversation between patient and physician about the treatment. A second precondition is the timeliness of the information. A patient must have sufficient time to consider all aspects of the treatment before he makes his final decision. In addition, the information has to be adapted to the individual circumstances and the patient.

If a physician violates his duty to inform the patient properly, carrying out the treatment will be against the law and can lead to liability of the physician. However, a violation of the informed consent requirement does not necessarily imply liability. The physician can claim that the patient would also have agreed to the treatment if the informed consent process had been carried out. In addition, a physician must also show that in case of insufficient information the patient would have given his consent if he knew all the information. Conversely, it is up to the patient to show why he would have refused the treatment if he was aware of all facts and circumstances. It is also possible to act upon a hypothetical consent but it will be denied if the patient states that in case the process had been done properly he would have thought over it again or would have asked a second opinion.

If a patient has given his consent and the physician starts the treatment, he may only do what the patient agreed to. If the physician during the operation considers it useful to do something the patient did not consent to, he has to stop the treatment and ask for a new consent. However, some exceptions are recognised. In case of complications or other life-threatening circumstances that make further treatment necessary, the physician is not obliged to stop the treatment and ask the consent of the patient.

5.4. Damages

A person found to be liable for causing injury, has to pay damages when it has become impossible to re-establish the situation as it was before. Damages have to be paid to the patient to an unlimited extent for all the damage that resulted from the act causing injury. They can be pecuniary or non-material. Pecuniary damages can include costs for healing treatment, loss of income and additional needs which are meant to compensate for the disadvantages the patient suffered. In case of non-material loss, only tort law offers the possibility to receive damages for pain and suffering (§253 and §847 BGB). In order to determine the amount of damages, the injured person has to be imagined in the same situation that he would be in if he had not suffered the damage.

5.5. Causality and burden of proof

In Germany the burden of proof plays an essential role because there is mostly no absolute certainty whether a mistake was made or whether the injury resulted from the illness itself. In general, the burden of proof is shared and rests on the patient for all facts and allegations that give a basis to the claim and on the physician for all facts and allegations that deny or dismiss the claim. Thus the patient carries the burden of proof for a faulty treatment which can include faulty acts as well as a failure to act. In addition, the patient also carries the burden of proof for facts on which the treatment fault is based. The reason for giving the patient the burden of proof is that in medical law, the physician is not obliged to deliver a successful treatment; he is only obliged to do a conscientious effort to cure. The burden of proof for the causal connection between the injury and the faulty treatment also rests upon the patient.

In general, it is recognised that in order to hold a physician liable for treatment errors, the patient has to prove the error, the causal link between the error and the damage and fault of the physician. The causal link between the actions of the physician and the injury suffered by the patient, is an essential element to hold the physician liable. The duty to observe due care is considered a *conditio sine qua non* for holding a physician liable. This will be the case if without the actions of the physician the injury the patient suffered would not have occurred. Once it is determined that the injury was caused by the errors of the physician (*Äquivalenztheorie*), it has in addition to be established whether the consequences were adequate, given the particular circumstances (*Adäquanztheorie*).

With regard to the issue of informed consent, the burden of proof rests upon the physician who has to show that he complied with the requirements of informed consent (§6.3.2.). However, the physician does not have to establish causality. The patient on the other hand has to gather evidence why he would have refused the treatment and he has to show a causal link between the lack of an informed consent and the damage suffered.

During the past years, court rulings have eased the burden of proof in numerous ways. In the first place, court rulings have established that in cases of gross faulty medical treatment the causal connection between the error and the damage suffered is assumed. This means that the physician, who alleges that the injury the patient suffered would also have occurred without the treatment error, carries the burden of proof in these cases. The reversal of the burden of proof is only possible if the error could have caused the damage in some way. In case of doubt, the plaintiff carries the burden of proof. Another case in which the burden of proof will be reversed is the situation in which the physician or the hospital has made organisational mistakes (e.g. surgery by a physician-in-training or risks which can be completely controlled).

6. Poland

6.1. Introduction

In this part of the study, we will focus on the civil liability of a physician in Poland. The basis for holding a health care professional liable under civil law is twofold: either a contract concluded between the physician and the patient or a tort. Liability *ex contractu* occurs when the physician fails to perform his obligations out of contract or fails to perform them properly (article 471 Civil Code). In contract, it is for a physician not possible to exclude his liability via specific clauses nor is it possible to limit the degree of liability. Liability *ex delictu* occurs when a physician causes damage to a patient by a tort without a contractual relationship (article 415 Civil Code).

6.2. Standard of care

According to the Law on the Physician's Profession and the Code of Medical Ethics, a physician is obliged, when practicing medicine, to practice his profession in accordance with the requirements of the current art of medicine, with the use of available methods and preventive measures for diagnosis and treatment, in accordance with principles of medical ethics and with due diligence. The Code of Medical Ethics furthermore imposes on the physician the duty to carry out diagnostic treatments and preventive procedures with due diligence devoting the necessary time to the examination of the patient.

Consequently, the duty of a physician generally consists of taking due diligence of high professional standards, meaning that a physician is liable for lack of this diligence (fault) and not for achieving successful results. However, in exceptional cases, a physician shall bear liability for the simple fact of inflicting injury regardless of the degree of diligence (e.g. injections, the use of medical tools, etc.). In these cases, the injury has no connection with the initial condition of the patient's health or with the expected development of the disease nor is it included in the risk which the patient could have expected in expressing his consent to the treatment by the physician.

6.3. Fault

6.3.1. *Failure to act according to the standard of care*

In Poland, a physician is in the first place liable for failure to act with diligence while treating a patient. If he has not fulfilled or has fulfilled his duties inappropriately, the physician to whom the fault may be attributed bears contractual liability pursuant to article 471 Civil Code. If non-fulfilment at the same time leads to any personal injury, the liability of the physician is at the same time tortious pursuant to article 415 Civil Code.

In addition to the obligation to act with diligence, the physician, when carrying out a treatment, must also act in accordance with the state of medical art at the moment of carrying out the treatment and it has to be conducted in accordance with the principles generally adopted in medical science and practice. Conduct of a physician contradictory to commonly recognized principles of medical learning shall also be regarded as an error.

In general, errors in the art of medicine are acts or omissions of the physician with reference to diagnosis and therapy, incompatible with medical science.⁵¹ In addition, the Supreme Court considers it also a fault if a patient is subjected to obvious unnecessary treatment which is a result of a culpable error in the medical arts or other form of negligence. It stated that allowing a very serious operational treatment to occur which was obviously unnecessary in the light of medical science and medical experience is the physician's fault.⁵² But, on the other hand, the court held that it was not possible to consider as errors in the art of medicine negligence consisting in the infringement of the duty to apply elementary principles of antiseptics while operating on a patient, as their maintenance is the essential duty of the whole staff employed while carrying out surgical operations, and at the same time, it does not require specialized knowledge and cannot give rise to any doubts, either of natural or theoretical character.⁵³

Consequently, one can say that a physician can be held liable for any negligence, carelessness lack of diligence if his conduct is contradictory to the elementary principles of medical arts. However, one can not expect a physician to perform impossible acts. This was also recognized by the appeal court in Warsaw which stated that the high due diligence requirements which are expected from physicians cannot cause attribution to them of duties which are practically impossible to be performed, and by the same meaning a *sui generis* liability based on the principle of risk, which in a particular manner refers to acts whose application is linked with danger, and which involves much more frequent than usual inflicting of damage. In such cases, with the application of any available precautions, the possibility of damage cannot be excluded as the risk is an inevitable element of these acts for which nobody is culpable.⁵⁴

A further ground for liability is transgression of professional duties by the physician since they are obliged to observe, in addition to legal provisions and clauses of regulations and circulars which are binding, the indications arising from the essence of the function they fulfil, and from the ethics with regard to a given vocation.

But on the other hand, a physician will not be held liable for the harmful effects of medicine unless prescribing the wrong medicines was a consequence of an improper examination and consequently prescribing the wrong drugs. The same applies if he did not know the side-effects of medicines in cases where he should.

6.3.2. Liability due to defects in information and consent

Besides liability for malpractice, a physician is also liable for every culpable act which does not refer to medical technique, e.g. failure to inform the patient. Before a physician can start a treatment, he has to seek the patient's consent. Consent is only valid when the patient is sufficiently informed before taking a decision. The information which has to be given to the patient concerns information about the health condition, diagnosis, possible treatments, possible risks and results, etc.⁵⁵ In general, a physician is obliged to warn the patient about normal, typical and ordinary effects and about foreseeable risks even when they do not occur often. Conversely, a physician is not obliged to inform the patient about extraordinary, unforeseen and improbable effects.

When the patient gives his consent, he accepts the possible risks of the treatment. If no consent is given or if it is defective because a patient consented without being sufficiently informed and damage is incurred,

⁵¹ Supreme Court, 1 April 1995, IV CR 39/54, *OSN* 1957, item 7 cited in NESTEROWICZ M., BAGINSKA, E. and DEN EXTER, A., "Poland", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2002, 40.

⁵² Supreme Court, 12 April 1976, IV CR 83/76, *OSPika* 11/1978, item 199, cited in NESTEROWICZ M., BAGINSKA, E. and DEN EXTER, A., "Poland", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2002, 43.

⁵³ Supreme Court, 17 February 1967, I CR 435/66, *OSN* 1967, item 177, cited in NESTEROWICZ M., BAGINSKA, E. and DEN EXTER, A., "Poland", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2002, 40.

⁵⁴ Appeal Court in Warsaw, 3 Marc 1998, I ACA 14/98, *Wokonda Journal* 10/1998, cited in NESTEROWICZ M., BAGINSKA, E. and DEN EXTER, A., "Poland", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2002, 39.

⁵⁵ Article 31 Law on Physicians Profession and article 13 of the Code of Medical Ethics.

the physician can be held liable, whether or not he acted according to the required standard of care. However, this does not mean that, once consent is given, a physician can perform any kind of intervention. He should always consider the individual circumstances of the patient. In two cases, acting without consent is allowed, that is to say in case of an emergency where immediate help is necessary and the patient cannot give his consent and in case obtaining consent would take too long given the urgent circumstances of the patient.

6.4. Causal link

With regard to the issue of causality, Poland adheres to the *theory of adequate causality*, meaning that the person liable to pay compensation bears liability only for normal consequences of his acts or omissions from which the damage resulted (Article 361 Civil Code). The normal consequences of acts or omissions are those that generally occur in the given circumstances. It is not important whether the same effect occurs every time. A causal link between the injury and damages may be direct or indirect provided the damage falls within the range of normal consequences. It is furthermore not required that the causal link between the physician's conduct and the injury is determined in a sure manner since in the field of medicine, many factors can contribute to the occurrence of damage or injury. It is only necessary to determine to which degree the negligence of the physician is a probable reason when compared to other factors. If there is a probability of a high degree that the action or the omission of a physician was the reason for the injury, the causality may be recognized. The evidence that other reasons besides neglect, could but did not have to cause the patient's injury shall not release the physician from his liability. Nor can multiple reasons or the increased risk of the treatment exclude liability if at least one of the reasons was negligence of the physician.⁵⁶

6.5. Burden of proof

The patient has to prove the physician's fault. The objects of proof are the facts which are essential for the settlement of the case. Proof is often very difficult for the patient. Medical documentation is a crucial exhibit. With respect to medical documentation the Supreme Court ruled that possible defects in the documentation which cannot be removed cannot be used to the disadvantage of the patient.⁵⁷ Expert evidence may be introduced in court to help the court in the assessment of the evidence, especially in cases where specialized knowledge is needed. However, it cannot be the source of the facts of the case. Therefore, experts should limit themselves to the appraisal of the facts of the case and of the compliance of the physician's conduct with the principles of medical arts and his obligations and to answering the parties' and court's questions.

6.6. Damages

There can be two kinds of damage: pecuniary loss and moral or non-pecuniary loss. Damage can be caused by the physician himself, by his medical staff, or as a result of the organizational negligence of the institution. Damage may be a result of medical malpractice or even of a treatment in compliance with the principles of medical arts but carried out without the patient's consent or with his consent scope being transgressed. Bodily injury by a physician will not always be considered damage. If occurred while performing *lege artis* a treatment which was necessary to rescue the patient, nobody will consider it damage.

Following the Polish Labour Code (article 120§1), the medical care entity bears civil liability for damage inflicted by a physician because of a faulty treatment or other form of negligence. Consequently, the physician's civil liability towards the person injured is abrogated, unless the damage occurred because of an intentional fault or the employer is insolvent or improperly insured, or the damage was inflicted not

⁵⁶ Supreme Court, 11 January 1972, ICR 516/71, OSN 1972, item 159 cited in NESTEROWICZ M., BAGINSKA, E. and DEN EXTER, A., "Poland", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2002, 44.

⁵⁷ Supreme Court, 15 October 1997, III CKN 226/97 cited in NESTEROWICZ M., BAGINSKA, E. and DEN EXTER, A., "Poland", in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2002, 43.

while performing the duties. As a result, the injured patient must pursue his claim against the health care institution which is obliged to redress the damage. The value of the damages will be determined by comparing the condition the patient would enjoy had the physician not failed and the condition which occurred as a result of medical malpractice of the physician. In addition, the independent development of the patient's disease which has an impact on his health condition shall also be taken into account, along with the future damage as a result of the malpractice. In case there is damage, other than those existing at the moment of adjudication, the injured patient may demand the establishment of the physician's liability for any damage which may be revealed in the future.

7. Hungary

7.1. Introduction

Legal liability, in contrast to moral liability, encompasses legal sanctions for the damages that have occurred. The goal of compensation is in the first place the restitution of the conditions that existed before the injury occurred, and if this is not possible, the provision of adequate financial compensation. Hungarian civil law makes a distinction between damages arising out of contract and damages done outside contract, arising from tort. In most liability cases, the rules of delictual liability are used. In that respect, the Civil Code states that anyone who causes unlawful damage to others is required to compensate that damage but if the defendant can prove that he lived up to the expectations in a given situation, he is free from liability (article 399§1).

If an injured patient decides to sue a health institution for the suffered damages, four elements need to be satisfied before liability can be established: damage, causality, medical intervention *contra legem artis* (fault) and unlawfulness of the damage.

7.2. Duty of care

Health care professionals' most important duty is the duty of care which is not necessarily based on a contractual relationship between the physician and the patient (e.g. medical emergency cases). The boundaries of the duty are set by the physician's professional competence. Therefore, if a certain treatment goes beyond his competence, he has to refer the patient to a specialised health care institution. When exercising their profession, health care providers have a therapeutic privilege which gives them the opportunity to choose between alternative remedies and treatments that are allowed by the professional rules and standards. However, the duty of care does not allow that that privilege extends to situations in which the risks of medical intervention go beyond the advantages of the recommend treatment. Furthermore, the duty of care also requires that a physician should refuse to treat a patient if the treatment prevents him from treating another patient or if the personal relationship with the patient makes a refusal necessary.

7.3. Fault and unlawfulness

Medical liability in Hungary is based on fault. A wrongful act or omission is considered as medical malpractice if it is negligent, hence subjectively avoidable. It is the defendant who has to prove that the act was not negligent by showing that he did everything that was prescribed by professional rules (exculpatory liability).

Unlawfulness refers to all forms of behaviour (active or passive) or results from behaviour that violate legal standards. However, there are some exceptions. The first is damage caused under duress meaning that there is a direct threat that can only be avoided by unlawful behaviour. Secondly, an action will not be unlawful if the injured party agreed with the treatment. Lawful self-defence is the third exception and finally, legal permission also excludes the unlawfulness of some forms of behaviour.

Generally, a medical intervention is not unlawful because in most cases there is an agreement between the patient and the physician and because medical treatments are in general related to assistance and not to damage. However, a badly, unnecessarily or carelessly carried out treatment can still be unlawful regardless of its objective goal.

Unlawfulness or the lack thereof should be established by looking at the possible unlawfulness of the intervention at two stages; with regard to the information given to the patient prior to the treatment and with regard to the treatment and the quality thereof. With respect to the issue of information, a procedure

will be unlawful and performed without a legally valid consent if a patient has consented to a medical treatment but has not been fully advised of the inherent risks, complications and possible side effects. In addition, lack of unlawfulness can be established if it can be shown that the law was not violated and the injured party agreed to the cause of the injury that is to say in case of a *volenti non fit inuria*. Therefore, no matter what kind of treatment will be given, it is unlawful if it occurs without the patient's approval.

7.4. Causality

The causal link between the wrongful act or omission and the occurred damage has to be proven by the patient. In cases where there is a lack of sufficient information and there are no medical protocols, it is difficult for the patient to prove the link between the symptoms and the medical intervention. Courts do not apply the principle of *res ipsa loquitur* (the things speak for themselves).

7.5. Burden of proof

Hungarian medical law applies a shift in the onus of proof in cases of delictual (non-contractual) liability. This means that it is up to the hospital or the private physician to prove that their acts were not negligent and that they did everything which could be expected of them in a given situation and thus that they acted in accordance with the law. Consequently, the plaintiff is not required to prove that the doctor mistreated him in the course of treatment. However, sometimes the courts make exceptions. In one case the court refused to hear the case because 'the plaintiff was unable to prove that the doctor assisting at birth or the paediatrician had acted incorrectly'.⁵⁸

7.6. Damages

Legal liability, in contrast to moral liability, encompasses legal sanctions. The goal of compensation is primarily the restitution of conditions existing before the injury occurred, and if this is not possible, the provision of adequate financial compensation for the injured party. Damages can be material or personal. The scope of compensation is set according to the extent of the damage suffered and is not to exceed it. However, compensations are meant to fully compensate the victim for all damages suffered.

⁵⁸ Marcali City Court 4. P. 20560/1985. Somogy County Court 1, Pf 21084/1986, cited in SANDOR, J., "Hungary" in NYS, H. (ed.) and BLANPAIN, R. (general ed.), *International Encyclopaedia of Laws. Medical Law*, Kluwer Law International, The Hague, 2003, 50.

B. Factual situation

Due to lack of time and the use of limited resources, the data concerning the factual situation are not exhaustive nor are they up to date.

1. Sweden

If a patient believes malpractice has occurred, he can file a claim with the Health and Medical Care Liability Board (HSAN) which is an independent branch of the national social welfare board. The HSAN board hears cases concerning disciplinary proceedings but its authority is limited meaning that it cannot order that the individual must receive another treatment or award financial compensations for treatment injuries. Possible outcomes can only be the punishment of medical personnel whose actions were found to be negligent or unprofessional and the administration of disciplinary action against the person responsible for the improper treatment. Decision of the HSAN board can be appealed with the administrative court of appeals and further to the supreme administrative court.

The number of cases brought before the HSAN board augments every year: from 768 cases in 1980 to about 2000 cases in 1997. The growth in the number of cases can be explained by several factors, i.e. the fact that care has become worse, increased participation by patients, growing expectations concerning the benefits of health care etc. The decision of the Board in the majority of cases is that 'neither fault nor negligence is found on the acts of the medical personnel' and that 'what has happened will not lead to any measure by the Board'. In case where fault or negligence has been committed but which is not insignificant, the health care professional receives a disciplinary measure consisting of an admonition or a warning.

As already said in part I, it is for patients difficult to receive compensation in court under the general principles of tort law. Therefore, Sweden has set up a system of no-fault compensation which does not require fault of the physician to be established. The introduction of this system has led to a significant increase in the number of claims. It is less problematic to obtain damages and claims are handled at a rapid pace but compensation for the injury suffered is considerably lower than the amount of compensation paid in countries where malpractice cases are tried in court in accordance with the tort act.

Some figures:

	Sweden
Average number of claims per year	9.500
Population	8.5 million
Average number of claims per inhabitant	1 ‰
Compensation/claims ration	45%
Total compensation paid per year	300 million SEK = ca. € 33 million
Compensation per inhabitant	€ 3,9

Source: DUTE, J.C.J., FAURE, M.G., and KOZIOL, H., *No-fault compensatiesysteem*, Den Haag, ZonMw, 2002, 251p.

2. France

Some figures:

- 1970-1985: 5788 medical liability cases of which 183 were judgements on liability
- 1988: 2000 new cases opened by mutual Insurance companies and 95 actions of which 24 criminal (8 convictions) and 71 civil (28 declarations of liability)
- 1991: 2676 declarations of accidents of which 140 criminal

These figures have further increased in the nineties.

3. Belgium

Over the years, courts have altered the medical liability rules to protect patients. They have introduced new concepts such as loss of chance, a reversal of the burden of proof, etc. These changes have in the first place led to an increase in malpractice claims (loss of chance is frequently invoked) and a rise in the amount of damages which injured patients receive. Secondly, one can detect a trend toward a system of no-fault compensation which, as already explained above, will in turn also lead to an increase in the number of claims.⁵⁹

4. United Kingdom

The Department of health⁶⁰ estimated the total number of adverse events in the United Kingdom on 850.000 of which half might be avoidable and which could result in a direct extra cost of £2 billion. Another recent but limited study⁶¹ found that 10.8% of the 1014 patients questioned in the study experienced an adverse event and the overall number of adverse events was 11.7% of which almost the half (48%) was preventable. 66% of the patients who suffered from an adverse event had minimal impairment, 19% suffered from a moderate impairment, 6% from permanent impairment and 8% of the patients died as a result of the adverse event. Each adverse event led to an average of 8.5 additional days in hospital with an additional cost of £290.268 to the hospital.

With regard to the number of claims, information is since 1995 distributed by the National Health Service (NHS) Litigation Authority. It is a special health authority, responsible for handling negligence claims made against the NHS bodies in England. In general, one can say that since the eighties claims have significantly increased and at the same time there was also a substantial increase in the value of damages which were awarded. This trend led to an increase of subscription rates of doctors to the medical defence organisations which in turn led to the practice of defensive medicine and the development of a malpractice crisis. The increase in claims went on in 1999-2000 and 2000-2001. However, the following years, reductions in claims were reported by the NHS Litigation Authority. In 2003-2004 the NHS Litigation Authority received 6251 claims for clinical negligence and 3819 claims for non-clinical negligence against NHS bodies (in 2002-2003, the numbers were 7798 and 3667 respectively). Equally, damages that were paid to injured patients also decreased significantly in 2003-2004 compared with the situation in 2002-2003.

⁵⁹ J.-L. FAGNART, "Rapport betreffende het Belgisch medisch aansprakelijkheidsrecht", *T. Gez. / Rev. Dr. Santé*, 2000-2001, 113-115.

⁶⁰ DEPARTMENT OF HEALTH, *An Organisation with a Memory*, 200, cited in M. JONES, *Medical Negligence*, London, Sweet & Maxwell, 2003, 7.

⁶¹ C. VINCENT, G. NEALE and M. WOŁOSHYNOWYCH, "Adverse events in British hospitals: preliminary retrospective record review", *BMJ*, 2001, 322, 517-519 at 518.

From its establishment, the NHS Litigation Authority handled a significant amount of claims. The figure below gives an overview of the outcome of the claims since 1995.

Outcome of claims for clinical negligence made against the NHS as at 31/03/04		
Outcome	Number	Percentage
Abandoned by claimant	13,626	34.76%
Settled out of court	16,970	43.29%
Settled in court in favour of claimant*	653	1.67%
Settled in court in favour of NHS	194	0.49%
Outstanding	7,755	19.78%
Total ('files opened')	39,198	100.00%
* this figure includes claims in respect of minors, where a settlement is agreed out of court, but court approval is still required to protect the child's interests.		
Note: These data do not include claims settled within their excess or incidents investigated but not yet proceeded with as a claim.		

Source: <http://www.nhs.uk/>

Part II: Possibility of drafting an international legal instrument containing major common standards in the area of medical liability.

1. The study in part I has made it clear that the standard applied to evaluate medical liability is an objective one. Decisive is the competence of the reasonably careful and competent practitioner in his area of competence. This formulation fails to make clear who in the final analysis determines the standard of care: the medical profession(al) or the courts.
2. It is also generally accepted that medical liability arises not only from wrong diagnosis and treatment (technical errors) but also from failure to inform the patient properly or from failure to obtain his informed consent (violation of the rights of patients).
3. **With regard to the first source of medical liability (technical errors) the decisive element is the standard of care.** That standard can be derived from the actual state of medical science. Because medical science is an international science one could be inclined to conclude that also the standard of care physicians have to adhere to in an international one. In its decision *Geraets-Smits and Peerbooms* of 12 July, 2001 the European Court of Justice of the EU was of the opinion that the condition that medical treatment must be regarded as “normal in the professional circles concerned” should not be interpreted as normal in the national medical circles but as normal “according to the state of international medical science and medical standards generally accepted at international level”. This suggests that international standards of medical care already exist. This may be true but one has to consider also that the application of these standards can differ widely from country to country because of differences in the way medical care is delivered. These differences are attributable to varying standards of training of physicians and other health care practitioners, different health care and health insurance systems and so on. They may ultimately result in varying standards of care between and even in national states. **As long as these differences exist one may have serious doubts regarding the possibility of formulating and applying common standards of medical care.**
4. **With regard to the second source of medical liability, the violation of the rights of patients, some member states of the Council of Europe already have enacted laws to protect the rights of patients** (e.g. Belgium and France among the countries studied in this report) while others have not. However, on December, 1, 1999 the Council of Europe Convention for the protection of human rights and dignity of the human being with regard to the application of biology and biomedicine, in short, the Convention on Human Rights and Biomedicine has entered into force. The title of this Convention may be misleading regarding its contents. Biomedicine makes us think about highly technical developments such as cloning, xenotransplantation and the like. The Convention indeed contains rules governing these developments. However, this Convention contains the core of a common approach of patients’ rights in Europe. The Convention as a whole “will provide a common framework for the protection of human rights and human dignity in both *longstanding* and *developing* areas concerning the application of biology and medicine”.⁶² In this respect the Convention may be considered as offering protection of the rights of the patient in ordinary health care. The Convention “covers all medical and biological applications concerning human beings, including preventive, diagnostic, therapeutic and research applications”.⁶³ For that reason the Convention is really a “patients’ rights treaty”. The basic patients rights such as the right to informed consent (article 5), the right to respect for private life in relation to information about his health (art.10.1), the right to know any information collected about his or her health and the right not to know this information (art.10.2) and the right to complain and to receive a fair compensation (art. 23). In the preamble, reference is made to the “aim of the Council of Europe to achieve a greater unity between its members and that one of the methods by which that aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms”.

⁶² Explanatory Report §7

⁶³ *idem* §§10 and 29

The Convention reflects the need to make a greater effort to harmonise existing standards in the Member States of the Council of Europe.⁶⁴ The Explanatory Report demonstrates the need to harmonisation only in respect to the protection of the human being in the context of the biomedical sciences. This is understandable because especially in these fields the need for harmonisation is more pressing as these practices are often activities that cross the border of different nations. Organs are often removed in one country and implanted in a patient in another country. Clinical trials are often multi-centre and therefore performed in more countries. This creates a pressure from bottom up (e.g. patients on the waiting list, transplant centres, the pharmaceutical industry, the research community) to harmonise the standards. Although the Convention has the ambition to harmonise also the principles reflected in basic patients rights, the Explanatory Report makes no effort to explain that there is also a need to harmonise the standards in the field of daily health care delivery. One possible explanation for this lacuna may be that the authors of the Convention were convinced that this harmonisation already is a matter of fact. Commenting on article 4 of the Convention the Explanatory Report indeed states : “ the content of professional standards, obligations and rules of conduct is not identical in all countries. The same medical duties may vary *slightly* from one society to another. However the fundamental principles of the practice of medicine apply in all countries. Doctors and in general all professionals who participate in a medical act are subject to legal and ethical imperatives. They must act with care and competence and pay careful attention to the needs of each patient”.⁶⁵ Maybe, the authors of the Convention have been overoptimistic as to the actual state of harmonisation of basic patients’ rights.

5. Whatever the case, the **Convention on human rights and biomedicine in itself has created in many countries a strong impetus towards the legal recognition of individual patients’ rights.** As of 14 March 2005 the Convention has been ratified by 19 Member States of the Council of Europe. Of the eight countries included in this study, only Hungary has already ratified the Convention, while France, Poland and Sweden have signed it. The other countries (Belgium, Germany and the UK) did not sign yet. The Convention offers a framework that can be elaborated more in depth by so called protocols (see article 31 of the Convention : protocols may be concluded in pursuance of article 32, with a view to developing in specific fields, the principles contained in this Convention). **I suggest elaborating the professional obligations and standards mentioned in article 4 of the Convention in such a protocol. Also article 24 of the Convention (right to fair compensation in case of undue damage) can be the subject of such a protocol.**
6. Finally there are the procedural aspects of medical liability such as the burden of proof, causality and so on. There are marked differences between the countries studied. In my opinion it will be very difficult to harmonise these differences because they derive from general rules regulating civil and criminal liability.

⁶⁴ idem §4

⁶⁵ idem §31