

E. THE NETHERLANDS

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1. Introduction

Medical liability is a comparatively new phenomenon in Dutch law. Until recently there was relatively little case law on this subject. This has now changed, although there are still relatively few judgments by the Netherlands' Supreme Court: the total is around 20. On the other hand, the number of decisions by the lower courts has increased sharply since the 1980s and there is a growing volume of literature on medical liability. There are also some new developments that coincide with the advent of the "claim culture" as a general phenomenon. For example, organisations have been established for lawyers who specialise in personal injury cases, notably the National Association of Personal Injury Lawyers (LSA) and the Physicians & Lawyers Working Group. The courts are adopting an increasingly patient-friendly attitude, in particular as regards proof of medical errors (see 10), and causation (see 8). This victim-oriented attitude is in fact found in other areas of the law too. Examples are the liability of employers for occupational accidents to their employees, liability for road accidents and product liability (see 7).

A special event in the Netherlands in this field was the introduction of the new Dutch Medical Services Act (WGBO) on 1 April 1995¹. The Medical Services Act contains rules of peremptory law governing the provision of medical assistance. Its aim is to strengthen the patient's legal position by means of civil law rules regulating the rights and duties of healthcare provider and patient. However, the new Act contains only a few rules on medical liability (see 2–4). Most of the provisions on this subject can be found in the general rules contained in the Civil Code. This Code too is relatively new, having been introduced only in 1992.

In order to successfully hold a healthcare provider liable under Dutch law there must have been a medical error, injury suffered by the patient or a third party and also a causal connection between the injury and the medical error. These conditions, which in fact apply in virtually all European countries, are described in more detail in 5–9. 10 will deal with the law of evidence in cases of alleged medical error. Who can be held liable for a medical error will be explained in 11. The central liability of the hospital is of particular interest in this connection. The general part ends with a section on the relevant periods of prescription (12) and the insurability of claims (13).

For a fine English translation of this Act see Ewoud Hondius and Annet van Hoof: *The New Dutch Law on Medical Services* [1996] *Netherlands International Law Review* XLIII 1 et seq. We have made grateful use of this translation in the present article. For a detailed discussion (in Dutch) of the Act see Sluyters B. and Biesart M C I H: *De geneeskundige behandelingsovereenkomst* (The contract on medical services) (1995) and the Dutch text and commentary on the Civil Code art. 7:446 et seq. (Stolker) Deventer: Kluwer (1998).

2. *The New Dutch Medical Services Act in a Nutshell*

The Netherlands are probably the first country in the world to have a separate, civil law scheme governing the provision of medical services. There were various arguments in favour of a separate scheme. First of all, the contract for medical services involves a number of peculiarities which require a solution of their own. Examples are the duty to keep medical records, the requirement of consent and the provision of information in the case of minors, informed consent and the use of patient data for scientific research. In addition, some subjects do not lend themselves to regulation by the courts, for example the period for which medical records must be kept. Clarity is also an argument in favour of a separate scheme. The various rules connected with the contract for medical services have now become a coherent body of law, which is easy to consult. There is also an argument of principle in that the legislator should not leave everything to the courts. This applies all the more to subjects that involve what are sometimes conflicting fundamental rights. An effect – albeit unintended – of the fairly lengthy gestation process of the Dutch Medical Services Act has been that healthcare professionals have started to become accustomed to the idea that their relationship with the patients is not only one of trust but also a legal relationship.

The Dutch Medical Services Act has been incorporated into the Civil Code². The legislator has therefore decided that the doctor-patient relationship should be treated as a *civil law* relationship. The Civil Code of 1992 has a so-called “layered” structure: it deals first with the general provisions and thereafter the specific provisions. The contract for medical services is a particularisation of a different type of contract, namely that to provide services. For medical liability it is therefore necessary to look first in Book 6, the “general part of the law of obligations”, thereafter in part 1 of title 7 of Book 7, “the general part of contracts for the provision of services” and, finally, in part 5 of title 7 of Book 7, “the contract for medical services” (article 7:446 Civil Code – article 7:468 Civil Code). Special rules prevail over general rules.

The content of the new Dutch Medical Services Act in a nutshell is as follows. The Act relates to medical acts, namely:

- a. all activities — including examination and giving advice — which directly concern a person and which are intended to cure that person of a disease, to prevent that person from contracting a disease or to assess the condition of that person’s health or which constitute obstetrical assistance (article 7:446, paragraph 2, Civil Code);
- b. activities other than those referred to under (a) which directly concern a person and which are carried out by a physician or dentist in a professional capacity (article 7:446, paragraph 2, Civil Code);

² For an English and French translation – albeit rather dated – see: Haanappel, P.P.C./Mackaay, E., *Nieuw Nederlands Burgerlijk Wetboek, Patrimonial Law*, (1990). For a German translation see Nieper, F./Westerdijk, A.S., *Niederländisches Bürgerliches Gesetzbuch*, various parts.

- c. nursing and care of the patient related thereto as well as the direct provision for the patient of the material framework within which such activities are carried out (article 7:446, paragraph 3, Civil Code)³.

The contract for medical services is concluded by a healthcare provider and a patient or the statutory representative of the patient (article 7:446, paragraph 1, Civil Code). For the purposes of the Medical Services Act a “healthcare provider” is an institution or a self-employed medical practitioner. The client is either the patient himself or another person who contracts on behalf of the patient. If a healthcare provider who performs a medical act does not have a contractual relationship with the patient, the Dutch Medical Services Act applies *mutatis mutandis* in accordance with article 7:464 Civil Code in so far as this is not inimical to the nature of the legal relationship⁴. The impact of the Act is therefore great.

The Dutch Medical Services Act lays down in particular patients’ rights. The physician should therefore inform his patient carefully about aspects of the examination or treatment (article 7:448 Civil Code) and the patient should give consent beforehand (article 7:450 Civil Code). Only in very special circumstances may the physician withhold certain information; this is known as the “therapeutic exception” (see also 5.). Special provisions apply to minors (see 3.).

Articles 7:454 and 7:455 Civil Code contain rules governing medical records (see also case 6). Article 7:456 provides that the physician should allow the patient, on request, to inspect and take a copy of his medical file at the earliest possible opportunity. Here, there is no “therapeutic exception” as referred to in the information article above. However, the file should not be supplied if this is necessary to protect the privacy of another person (see also footnote 8).

Article 7:457 Civil Code contains the duty to observe professional secrecy. An exception to this duty is given in article 7:458 Civil Code: under certain conditions information may nevertheless be provided about a patient without his consent if the information is used for statistical or other scientific research. A somewhat related provision is contained in article 7:467 Civil Code, which provides that anonymous substances and parts taken from the body may be used for medical statistical analysis or other medical scientific research in so far as the patient from whose body the material is obtained has not made any objection to such research and in so far as the research is carried out with due care.

³ The medical services do not include activities relating to the preparation of medicines within the meaning of the Act on the Supply of Pharmaceutical Products, where such activities are carried out by a registered chemist within the meaning of the said Act (art 7:446, paragraph 4, Civil Code). There is no contract for medical services if the activities are carried out to assess the condition of a person’s health or to provide medical care to a person under the authority of another person with regard to the settlement of claims or duties, acceptance by an insurance or care facility, or the assessment of aptitude for an education, an employment relationship or the exercise of certain work (art 7:446, paragraph 5, Civil Code).

⁴ In the case of a liability claim under art. 7:464 Civil Code, the person liable is the person who has performed the medical activity. This is not always the case under art 7:446 Civil Code (see § 9).

Article 7:459 Civil Code provides that a physician should perform acts in the context of the contract for medical services in such a way that persons other than the patient cannot observe them, unless the patient has agreed that the acts may be observed by other persons.

3. Minors

As regards the rights of minor patients a distinction must be made between three categories: minors aged between 16 and 18, minors aged between 12 and 16 and minors under the age of 12.

a) Minors Aged 16 and Over

A minor who has reached the age of 16 is deemed competent to enter into a contract for medical services on his own behalf and to perform juristic acts directly connected with the contract (article 7:447, paragraph 1, Civil Code). Such a minor is competent to exercise all patient rights⁵. He (the patient) should therefore keep himself informed, must himself give consent for a medical treatment, has the right of inspection, etc. The representatives of the minor should be regarded as third parties for the purposes of a contract for medical services.

b) Minors Aged 12 to 16

A system of double consent is required under article 7:450 Civil Code in the case of minors aged 12 to 16. This means that both the minor and his parents or guardian must give their consent, unless:

- a. the medical activity is manifestly necessary in order to prevent serious harm to the patient, in which case the consent of the parents or guardian is not necessary (article 7:450, paragraph 2, Civil Code);
- b. the patient has a considered wish to undergo the medical activity, in which case the consent of the parents or guardian is not necessary (article 7:450, paragraph 2, Civil Code)
- c. this would not be in accordance with the standard of care that may be expected of a conscientious healthcare provider (article 7:465, paragraph 4, Civil Code);
- d. the patient is deemed unable to make a reasonable assessment of his interests and far-reaching medical activity is necessary in order to prevent serious harm to the patient, in which case the consent of the patient is not necessary (article 7:465, paragraph 6, Civil Code).

A minor who is under the age of 16 is not deemed competent to enter into a contract for medical services independently (see article 7:447, paragraph 1, Civil Code). However, the rights to information and the exceptions to this right apply in full to minors aged 12 to 16 (see article 7: 448, paragraph 1, Civil Code).

⁵ Circumstances may occur where a minor is not (yet) competent in fact: he should then be deemed to be a patient lacking contractual capacity.

The obligations owed by the healthcare provider under the new Medical Services Act to a minor patient who has not yet reached the age of 12 must be performed by the healthcare provider in relation to the parents who exercise authority over the patient or to his guardian (article 7:465, paragraph 1, Civil Code). They must give their consent for treatment and must be kept informed. As regards the duty to provide information, article 7:448, paragraph 1, Civil Code lays down that the healthcare provider should also inform the minor and should do so "in such a way that it is within his mental grasp".

There are two exceptions to the principal rule that the parents or guardian of a minor patient under the age of 12 must give consent for medical treatment:

- a. if the consent or refusal of consent is not in accordance with the standard of care that may be expected of a conscientious healthcare provider (article 7:465, paragraph 4, Civil Code);
- b. if there is an emergency situation in which the healthcare provider must act without awaiting the decision of the representative in order to avoid serious harm to the patient (article 7:466, paragraph 1, Civil Code).

4. Medical Liability and the Medical Services Act

A notable feature of the new Medical Services Act is how little it contains on the subject of medical liability.⁶ And even the little that is said is mainly confined to what is known as the "central liability of the hospital" (article 7:462 Civil Code; see § 11). In fact, the explanatory notes to the Act contain little if anything of significance about establishment of the content of medical standards (article 7:453 Civil Code), about the danger of "American-style conditions" and "defensive medicine", about the liability of physicians if they have supplied insufficient or inaccurate information, about the problem of the causation, about the important subject of the burden of proof, about liability for defective materials, about the relationship with product liability, about the question of why liability may not be limited or about the possibility of patient injury insurance.

The Medical Services Act contains only three provisions on medical liability, with the exception of specific patient rights. First, the duty of the healthcare provider to provide the standard of care that may be expected of a conscientious healthcare provider and to act in accordance with professional standards (article 7:453 Civil Code, see § 6). Second, the central liability of the hospital. In order to save the patient from a laborious search for the precise person who is liable, article 7:462 provides that the hospital is liable for all errors made "within its walls" (article 7:462 Civil Code; see § 11). And, third, the provision that healthcare providers may not contractually limit or exclude their liability (article 7:463 Civil Code). Nor may the central liability of the hospital be limited.

The Medical Services Act therefore makes little change in respect of the subject of medical liability, first of all because the Act is mainly a codification

⁶ For a more detailed account (in Dutch) see Stolker, C.J.J.M., *Nederlandse toestanden*, [1996] *Verkeersrecht*, 1 et seq.

of existing law and, second, because the standard of professional liability is regulated for the most part in Book 6 of the Civil Code and not in the Medical Services Act. Nonetheless, the number of medical liability cases is increasing sharply. Our impression is that the gestation period of the Medical Services Act has played a role in this. For example, before the new Act was introduced there was no statutory regulation of informed consent. Nonetheless, the principle that the patient must be informed before he can consent to treatment has applied for a long time. Even a physician who did not properly inform his patient before 1 April 1995 could be held liable for this. Hence there is no substantive difference between the former situation and the situation under the new Act. However, it is our impression that since the informed consent rule has been recorded in writing the legal possibilities are beginning to dawn on patients and attorneys.

Roughly speaking, there are four categories of medical liability cases, namely cases involving information errors, treatment errors, defective equipment and organisational errors. There is still scarcely any (civil) case law and literature concerning the organisation of medical assistance, but we suspect that this will increase in the future.

5. *Information Errors*

a) **Scope of the Duty to Provide Information**

Information errors are central to the first two cases dealt with in this book. Before giving his consent to a particular form of medical activity the patient should be informed about the examination or treatment which is proposed. If the consent of the patient to proceed with a particular medical activity is based on insufficient and/or incorrect information the consent is deemed to be vitiated. A healthcare provider who performs a medical activity without the legally valid consent of the patient commits a medical error, even if the activity itself is performed correctly in a medically technical sense. The duty of the healthcare provider to supply information (and the therapeutic exception⁷) is regulated in article 7:448, paragraph 1, 2 and 3, Civil Code.

Article 7:448 paragraphs 1–3 Civil Code

“1 The healthcare provider shall inform the patient clearly and, if requested, in writing, about the proposed examination and treatment and about the developments concerning the examination, the treatment and the condition of the patient’s health ()

2 In pursuance of the obligations under paragraph 1 the healthcare provider shall be guided by that which the patient reasonably needs to know about

⁷ The therapeutic exception does therefore exist in the context of informed consent, however, no exception is possible in the case of a patient who asks to inspect his file. “If requested the healthcare provider shall provide the patient as soon as possible with access to and copies of the documents () The provision will not take place in so far as this is necessary for the protection of another’s privacy. The healthcare provider may charge a reasonable fee for the provision of copies” (art. 7:456 Civil Code). As regards the obligation in respect of the patient’s file *see* the discussion of case 6.

- a. the nature and the purpose of the examination or treatment which he considers necessary and of the activities which are to be carried out;
 - b. the likely consequences for and risks to the patient's health;
 - c. other possible types of examination or treatment;
 - d. the prospects for the latter's health from the point of view of the field to which the examination or treatment relates.
3. The healthcare provider shall only be entitled to withhold information as referred to above where the provision of such information would clearly be to the serious detriment of the patient. If the patient's interests so require, the healthcare provider should impart the said information to a party other than the patient. Such information shall still be communicated to the patient as soon as there is no further danger of the said detriment arising. The healthcare provider shall not use the competence referred to in the first sentence other than after consulting another healthcare provider about the matter."

The healthcare provider is not obliged to draw the attention of the patient to all possible risks. It is not yet clear either in the case law or in the literature whether the scope of the duty to provide information is determined by what a reasonable person needs in the given circumstances in order to take a responsible decision or by the needs of the relevant patient, i.e. the patient who must take the decision. In order to determine whether a physician has supplied sufficient and correct information, his acts are often tested by reference to the criterion of "a reasonably competent practitioner acting in a reasonable manner". The criterion in this connection is what is the usual level among fellow practitioners: the professional standard (see 6.). The answer to the question of what a patient should reasonably be told in practice is not easy to give because the scope of the information to be supplied by a healthcare provider depends on the circumstances of the case. The following circumstances are mentioned in the literature and the case law:

- a. in the case of a non-necessary clinical intervention higher demands are made of the extent of the information to be supplied than in the case of treatment for which there is a medical indication;
- b. if the proposed treatment is of an experimental nature the criterion governing the duty to provide information will be applied more strictly;
- c. the greater the chance of a given risk and the more serious the nature of the risk, the more information should be provided;
- d. facts that are common knowledge do not come under the duty of information;
- e. specific circumstances affecting the patient may influence the scope of the duty to provide information.

b) Who Should Provide the Information and When?

The Medical Services Act does not state in as many words who is required to perform the contract for medical services. In our view, the treatment which a healthcare provider has undertaken to give may not, in principle, be performed by another person without the consent of the patient.

In a case in 1998 the Supreme Court held as follows: "In addition, the District Court has failed to recognise that a physician cannot discharge his duty as described above by leaving it to another person who will perform the actual examination – and about whom it has not been established that he is a physician – to provide information as referred to above on request."⁸

Article 7:448 Civil Code provides that "the healthcare provider" should inform the patient. If the patient has concluded a contract for medical services with the physician himself, the physician and the healthcare provider coincide. In the "all-in" situation, by contrast, the patient contracts with the hospital and the hospital may be deemed to be the healthcare provider within the meaning of the Act. In this case an employee of the hospital must be able to provide information to the patient on the basis of the master-servant relationship. If the patient has contracted with a physician, the latter will, in our view, in certain circumstances be able to leave the provision of information to a fellow physician who is assisting him. This would be the case, for example, where a specialised physician performs a given examination.

Although it is preferable that the patient should be provided with information a number of days before an examination or treatment, for example about its risks, in order that he has time to assimilate the information and take a decision without undue pressure of time, this is not always usual or feasible in practice. In the event of radical examinations and treatment with a relatively large degree of risk the patient must not be informed immediately before the medical activity is to be performed. In the case of fairly routine examinations entailing only minor risks, the patient may be informed shortly before the examination. Needless to say, there is a grey area. Scarcely any attention has yet been paid to this subject in the case law and literature.

c) Has the Patient Understood the Information?

Naturally, the healthcare provider must also check that the patient has understood the information. In practice, it is very difficult to establish whether or not this obligation has been fulfilled. In our view, the healthcare provider should, in principle, be given the benefit of the doubt and it should be assumed that he has made the requisite effort.⁹

6. Treatment Errors

Cases 3–6 deal with specific treatment errors. Article 7: 453 Civil Code states that the healthcare provider must give the level of care that may be expected of a conscientious practitioner and must act in accordance with the responsibility to which he is subject and which result from the professional standard. The professional standard involves acting in accordance with the views of medical science and complying with generally accepted standards.

⁸ Supreme Court 9 January 1998, [1998] *RvdW*, 15.

⁹ Written information may not replace the provision of oral information to the patient.

Article 7: 453 Civil Code:

“In the course of his activities a healthcare provider shall exercise the level of care expected from a conscientious healthcare provider and shall act in accordance with the responsibility entailed by the professional standard for healthcare providers.”

The criterion that is often adopted in the case law for assessment of the actions of a healthcare provider (in defining the professional standard) is the care that may be expected of a “reasonably competent healthcare provider acting in a reasonable manner” (specialist, nurse etc.).¹⁰ It should, incidentally, be noted that in assessing the actions of a healthcare provider the courts do not merely assess whether the actions were reasonable but carry out a “full assessment”.¹¹ In the case of the professional standard they first look at the usual level of care.¹² The sources consulted for the professional standard include regulations, case law, codes of conduct, protocols and guidelines. If, however, the court considers that the usual level is unacceptably low it may apply a higher standard. It is also important to know what knowledge and skills the healthcare provider in question possessed at the moment when the alleged medical error was made. If the knowledge and skills exceeded the professional standard this must be taken into account in determining whether there was a medical error.

When the professional standard is determined account must be taken of the degree of specialisation of the healthcare provider. For example, a different professional standard will apply to general practitioners than to specialists in internal medicine. Furthermore, a different criterion may in certain circumstances apply to “super” specialists, for example professors, than to “ordinary” specialists. And, needless to say, the professional standard applicable to a general practitioner is different from the standard applicable to a midwife or a hospital orderly.

One category of standards has received extra attention in Dutch case law in recent years. This is the category of the “safety regulations”.¹³ Safety regulations are, in brief, the regulations intended to prevent personal injury. Safety regulations are found, for example, in medical protocols, codes of conduct and guidelines. If the standards are breached or ignored the criterion applied is often stricter than that of the “reasonably competent healthcare provider acting in a reasonable manner”. In brief, the reasoning is that if a safety standard is breached and the danger has materialised, liability is, in principle, a given.

In 1993, for example, the Supreme Court held in the so-called “leaking hot water bottle” case (in which a maternity clinic was held liable for the harm caused to a baby by a leaking hot water bottle that had been placed in the cot

¹⁰ It is not of importance to this criterion whether the claim is based on imputable breach or on unlawful act (tort).

¹¹ Supreme Court 9 November 1990, [1991] *NJ*, 26.

¹² See in particular case 5.

¹³ Safety standards may be defined as standards that are an implicit part of prescribed – or in any event generally accepted – medical procedures aimed at preventing injury and further damage to the health of the patient.

by a nurse) that when an explicit safety regulation is breached and the danger which the regulation was intended to prevent actually materialises liability must in principle be assumed, *unless* it can be alleged and proved that there were urgent reasons for not observing the safety regulation and that all the precautionary measures were taken which, according to the information available at that time, were required in order to prevent the use of hot water bottles from causing serious injury¹⁴.

The burden of proof was in this way shifted from the patient to the physician. This development could in due course transform medical liability into a kind of pseudo-strict liability instead of pure fault-based liability.

7. *Defective Devices, Equipment etc.*

If injury is suffered because a healthcare provider has made use of a defective device or equipment there are, generally speaking, three ways of obtaining reparation. If there is a contract, a claim may be brought under article 6:77 Civil Code (making use in the performance of an obligation of a tangible object (a “zaak”) that is unfit for the purpose), possibly combined with article 7:462 Civil Code (central liability of the hospital). If there is no contract a claim may be brought under article 6:173 Civil Code (making use of a “zaak” which does not meet the standards that may be set for it). Finally, a claim may be brought against a producer on the basis of product liability (article 185 et seq. Civil Code). We will deal with this briefly here.

The following are examples of defective objects. Blood is administered to a patient and is later found to be contaminated with the HIV virus. A dentist fits a prosthesis which does not fit. A patient dies because a weld in his artificial heart valve breaks off. An operating table falls apart during an operation and the patient falls to the floor.

During the progress of Book 6, Civil Code, through Parliament the Minister provided, however, that the possibility should be left open that a claim against a physician or hospital in respect of defective objects may be refused, for example because it would be more logical to hold the producer liable.

We are of the opinion, however, there are strong arguments for holding the healthcare provider, in particular the hospital, liable and thus for not departing from the basic rule laid down in article 6:77 Civil Code. In our view, the basic premise that a healthcare provider should guarantee the objects which he uses deserves to be accorded great weight. Moreover, it is difficult for a patient to determine whether injury was caused by a defective object or because a healthcare provider made a mistake (for example in operating the equipment, administering a preparation or carrying out the maintenance, inspection or replacement of objects). In addition, we consider it important that the patient does not in general have any influence on the choice of aid, unlike the healthcare provider. A hospital, for example, is in a stronger position than patients in relation to pharmaceutical manufacturers. Furthermore,

¹⁴ Supreme Court 1 October 1993, [1995] *NJ*, 182.

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¹⁴ Supreme Court 1 October 1993, [1995] *NJ*, 182.

healthcare providers are accustomed to insuring against the risks of using aids; the patient cannot do so or cannot in any event do so as easily. The basic rule is also an incentive to healthcare providers to exercise the greatest possible care in choosing, maintaining and inspecting aids. Finally, it is conducive to legal certainty if the healthcare provider (generally the hospital) can always be held liable.

Product liability is regulated in article 6:185 et seq. Civil Code and is based on an EC Directive. Article 6:185 Civil Code provides that a producer is liable for the injury caused by a defect in his product. This is strict liability. Consequently, it is not relevant whether there was a culpable act on the part of the producer. A product is defective if it does not provide the degree of safety that may be expected of it (article 6:186 Civil Code). Examples of products are not only equipment but also medicines and blood-related products.¹⁵ In certain circumstances a hospital too may be deemed to be a producer.

8. Causation

A condition for the award of compensation is that there is a causal connection between the medical error and the injury. In general a distinction is made between two stages in causation. The first stage relates to the causal connection between the event giving rise to the liability (the medical error) on the one hand and the actual damage (injury or death) on the other. The second stage relates to the causal connection between the actual damage on the one hand and the consequential (material or non-material) damage on the other. The first stage concerns the *establishment* of the liability. The second stage concerns the *scope* of the liability.

a) *Sine qua non* Connection: The Lost Chance Theory

If liability is to be established it is in principle necessary that there is a *sine qua non* connection between the act and the damage suffered. If so, there is a causal connection, if not, there is no causal connection.

Depending on the question of whether the causal connection or lack thereof can be proved, the patient will be indemnified *fully* or *not at all*. This sometimes obliges the courts to make judgements of Solomon. This is particularly true in cases in which it is not certain whether the error caused the damage. This can be avoided if the loss of the chance of recovery is deemed to be damage resulting from incorrect treatment. In this way a *sine qua non* connection occurs after all between the medical error and the damage. The proportional imputation may be applied if it is uncertain whether the *sine qua non* connection exists. Reparation should be made for the part of the damage that corresponds to the scope of the lost chance.

The doctrine of lost chance has not yet been applied by the Supreme Court, and has been applied only by the lower courts and even then

¹⁵ See Stolker C.J.J.M., Aansprakelijkheid voor bloedprodukten en bloedtransfusies (Liability for blood-related products and blood transfusions), [1995] *Nederlands Juristen Blad*, 685–695.

only in a limited number of cases.¹⁶ The well-known “baby Ruth” case in 1996 concerned the following facts. A mother took her daughter – baby Ruth – to a hospital. The physicians present did not find any indications of a brain haemorrhage. However, the next day a brain haemorrhage was diagnosed. The District Court held as follows: “It is evident from the experts’ report that timely admission and intensive examination could have resulted in an earlier transfer and surgical therapy. As a result of the defendants’ error, Ruth’s chances of a better result in the event of adequate medical action were lost. The experts have not found and the defendant has not alleged that this chance was non-existent or negligibly small. (...). Taking all of this into account, the District Court estimates that the damage resulting from Ruth’s lost chance of a better result of treatment is 25%. The respondents are thus liable for this percentage of the damage suffered by Ruth as a result of the brain haemorrhage.” The Court of Appeal upheld this judgement.¹⁷

b) Imputation on the Basis of Reasonableness

Article 6:98 Civil Code provides that damage is eligible for compensation only if it is connected with the event giving rise to the liability of the debtor in such a way that it can be imputed (“toe te rekenen”) to him as a consequence of this event, taking into account the nature of the liability and of the damage. This doctrine of causation is also known as the “imputation on the basis of reasonableness” doctrine. Article 6:98 Civil Code relates to the scope of the reparation.

The nature of the *liability* is a relevant factor for imputation, in particular in the sense that in the event of damage against which a safety standard is intended to provide protection the requirements made in respect of foreseeability will be less stringent. Likewise, the damage (in particular serious damage) which is beyond what might normally have been expected will then in principle be imputed to the person liable.¹⁸

In the event of a breach of a safety standard not only does imputation within the meaning of article 6:98 take place more broadly but a different burden-of-proof rule is applied to the *sine qua non* connection. If a safety standard has been breached, thereby increasing the risk of damage, and the risk has also materialised, the causal connection is deemed to exist. It is up to the healthcare provider to prove that the causal connection does not exist.

A breach of a safety standard therefore has three important consequences:

¹⁶ See for example: Amsterdam District Court 28 October 1998, [1999] *NJ*, 406; Middelburg District Court 11 March 1998, [1999] *NJ*, 41; Amsterdam Court of Appeal 4 January 1996, [1997] *NJ*, 213.

¹⁷ Amsterdam Court of Appeal 4 January 1996, [1997] *NJ*, 213.

¹⁸ Supreme Court 2 November 1979, [1980] *NJ*, 77; 13 January 1995, [1997] *NJ*, 175; Arnhem District Court 10 September 1992, [1993] *NJ*, 278.

- (a) it constitutes in principle an unlawful act or non-performance;
- (b) it constitutes in principle a *sine qua non* connection;
- (c) it gives rise in principle to a broad imputation of damage.

Apart from the distinction between safety standards and other standards a distinction may be made in respect of the nature of the liability between fault-based liability and stricter liability. The greater the culpability involved in the act, the broader will be the imputation of liability. In the case of stricter liability (for example product liability) a closer connection is required between the damage and the event than in the case of fault-based liability.

The nature of the *damage* too is important in the context of imputation. It is generally assumed that damage that consists of death and personal injury should be more readily imputed than property damage, property damage more readily than (pure) pecuniary damage, and loss of assets more readily than loss of profit. Since medical liability usually involves personal injury, damage will be more broadly imputed to medical error.

The extent of *foreseeability* too plays a role. The greater the extent to which it was foreseeable that the damage would result from the event, the greater the likelihood of imputation. An exception concerns the situation in which safety and road safety standards are breached and/or the damage consists of personal injury or death. In these cases foreseeability does not play an important role.

The basic premise is that the person who invokes the existence of a causal connection should prove this if the other party puts forward a reasoned defence (article 177 Code of Civil Procedure). The Supreme Court has also held on a number of occasions that it is up to the healthcare provider to show by reference to facts and circumstances that the damage was partly or solely a result of factors other than the cause alleged by the patient.¹⁹

c) Causal Connection in the Event of Information Errors

The existence of a causal connection between an information error and the damage depends on the answer to the question whether the patient would have decided any differently if he had been adequately informed. This issue is dealt with in cases 1 and 2. If this question is answered in the negative there is no causal connection. The error (no adequate information) does not, after all, cause any damage in such a case; the damage would have been the same even without the information error. If the question is answered in the affirmative, however, the causal connection is present.

For the purpose of determining what the patient would have decided if he had been adequately informed a distinction may be made between the objective criterion and the subjective criterion. In the case of the objective criterion it is a matter of deciding what decision would have been taken by a patient acting reasonably. In the case of the subjective criterion it has to be established what decision the relevant patient would have taken. There is a difference of opinion in the literature about

¹⁹ Supreme Court 17 May 1985, [1985] *NJ*, 683.

the question of which test should be applied. The Supreme Court has not yet given judgement on this matter. The lower courts are inclined to apply the objective criterion.

In the case of both a claim on the basis of non-performance and a claim on the basis of unlawful act (tort) the burden of proof and the risk of proof rest in principle with the claimant under Dutch law (see above). However, the case law on medical liability does not give a clear answer to the question of who should prove causal connection in the case of an information error. The law on this point has not yet completely crystallised.

For the purpose of determining whether there is an information error (or a causal connection in the case of such an error) it is not in fact important whether the risk about which no information was provided actually materialised or not. A healthcare provider who performs a medical activity without the legally valid consent of the patient fails in the performance of his duties even if the medical act was performed correctly in a technical sense. Reparation must be made for the damage which the patient suffers as a result of the examination or other activity.

9. Damage

For the purpose of determining the scope of the compensation a distinction must be made between physical and mental injury on the one hand and compensation for pecuniary and non-pecuniary loss on the other.

As regards the scope of the damage for which the patient may recover, it makes no difference on what ground the liability of the healthcare provider is based.

Pecuniary loss is the financial damage suffered by the person holding the healthcare provider liable. Items eligible for compensation as pecuniary loss include sickness benefits (or extra benefits), the excess (deductible) and own contribution paid for medical insurance, any increase in the medical insurance premium, loss of ability to work²⁰, costs of domestic help and district nursing, a modified vehicle, modifications to the home, costs of legal assistance and statutory interest. A special item of damage is formed by the educational costs of children, for example in cases of a failed sterilisation. Recently, the Netherlands Supreme Court, following many other European courts, held that this damage was eligible for reparation within certain limits.²¹

Compensation for pecuniary loss may be granted in cases of mental injury too. An example would be the costs of treatment by a psychologist and loss of earnings.

²⁰ In principle, the income which the patient would have earned if no medical error had been made can be claimed. However, it is very difficult to determine the (hypothetical) future income of very young victims. The family background may provide a basis for assessment.

²¹ Supreme Court 21 February 1997, [1999] *NJ*, 145. For an account in German of this judgment see: Tobler, Ch./Stolker, C.J.J.M., *Wrongful Birth, – Kosten für Unterhalt und Betreuung eines Kindes als Schaden*, [1997] *Aktuelle Juristische Praxis*, 1145 et seq.

Non-pecuniary loss is damage which the injured party suffers other than pecuniary loss (for example as a result of disfigurement and pain and suffering). Compensation is also provided in the event of a medical error only in the cases referred to in article 6:106 Civil Code.

Article 6:106 Civil Code reads as follows:

1. The victim has the right to an equitably determined reparation of harm other than patrimonial damage: (...) (b) if the victim has suffered physical injury, injury to honour or reputation or if his person has been otherwise afflicted. (...)

Mental injury suffered as a result of a medical error, which has not also caused physical injury, should be covered by the sentence "if his person has been otherwise afflicted" in article 6:106, paragraph 1 (b), Civil Code. Hitherto it has been fairly generally accepted in the literature and case law that mental injury cannot consist solely of grief or discomfort. It must involve serious mental injury. In other words there should be a recognised psychiatric illness. This is a matter to be determined in principle by a psychologist or psychiatrist.

It is still suggested by some authors that a patient who is the victim of a medical error must be aware of his suffering and of what he is missing in order to be eligible for compensation for non-pecuniary loss.²² Comatose patients are not, therefore, eligible for such compensation since it is not known whether they are aware of their suffering and of the attempts to alleviate such suffering. The same is true to some extent of victims of serious brain injury. The question has not yet been decided in the Netherlands, unlike in other countries.

Article 6:106 Civil Code has two functions. First of all, to make reparation: in other words as satisfaction for the shock to the sense of justice of the injured party. Second, to provide compensation for the injury suffered: the element of reparation. Determining the scope of the compensation is naturally a difficult matter. The Dutch courts have the freedom to fix the amount of compensation fairly, taking into account all the circumstances of the case. The Supreme Court has held that relevant circumstances are the nature of the damage and the nature, duration and intensity of the pain, grief and loss of enjoyment of life. In the same judgement the Supreme Court held that the court may, in estimating the damage, take account of trends in the amount of compensation awards abroad.²³ In order to give a very rough indication of the scope, we would mention that the damages awarded for pain and suffering in the Netherlands vary from a few hundred guilders in minor cases to a maximum of 250,000 to 300,000 guilders (113,445 to 136,134 EUR) in the most serious cases.²⁴ Finally, it should be noted that punitive damages are not awarded in the Netherlands.

²² Stolker, C J J M, The unconscious plaintiff consciousness as a prerequisite for compensation for non-pecuniary loss, [1990] *I C L Q*, 39, 82 et seq

²³ Supreme Court 8 July 1992, [1992] *NJ*, 714

²⁴ An important book on damages for pain and suffering has recently been published in the Netherlands: Lindenbergh, S D, *Smartengeld* (1998), p 266 As in Germany, lists cataloguing the amount of damages awarded for pain and suffering are kept in the Netherlands. These lists are published once every three years in the journal *Verkeersrecht*

10. Division of Burden of Proof

a) Burden of Proof Lies with the Patient, But ...

The golden rule in most countries and also in the Netherlands is that a person who alleges something must prove it (article 177 Code of Civil Procedure). According to the Supreme Court the burden of proof in respect of a treatment error lies in principle on the patient. Although it is generally unwilling to consider a shift in the burden of proof, this does not mean that such a shift is impossible. The judgements of the Supreme Court do not, after all, provide any reason why in a particular case the burden of proof should not be shifted to the healthcare provider. The patient is, however, aided in various ways in the case law. First of all, the Supreme Court has held that a healthcare provider should provide sufficient factual data to substantiate its denial of the allegations of the patient in order to provide the patient with a means of adducing evidence.²⁵ This is known as the “stricter duty of proof” of the healthcare provider.

If the healthcare provider fails to discharge the stricter duty of proof this may result after all in a shift in the burden of proof.²⁶ The court may even decide that there is no longer any need for proof to be adduced by the patient.²⁷ In such a case the patient is simply held to be in the right. Clearly, it is becoming increasingly important for physicians and hospitals to document their work properly beforehand. This is also true of the duty to provide information. The use of informed consent forms in the Netherlands has not yet, however, been generally accepted. Furthermore, there is still scarcely any case law on this subject. The case law does show, however, that a note in a medical file to the effect that the patient has been informed should be clear and unambiguous. If there is no clear note in the medical file that the patient has been informed (and what he has been informed about) there is a chance that the court will shift the burden of proof on to the healthcare provider.

Arnhem District Court held in 1995 that a note reading “knows the consequences” was insufficient evidence.²⁸ The entry “Pat. explained what she could and could not expect” was held by Arnhem Court of Appeal to be insufficient.²⁹

b) Other Methods of Lightening the Burden of Proof

The courts can also come to the aid of a patient by holding that a given fact has been proved simply on the strength of its presumption – based on certain auxiliary facts – that the fact did take place. Sometimes the court may give a party to whose detriment such a presumption has worked the opportunity to adduce evidence to the contrary. But in some cases a fact may even be held to have

²⁵ Supreme Court 13 January 1995, [1997] *NJ*, 175; Supreme Court 18 February 1994, [1994] *NJ*, 368; Supreme Court, 20 November 1987, [1988] *NJ*, 500.

²⁶ Supreme Court, 18 February 1994, [1994] *NJ*, 368.

²⁷ Supreme Court 13 January 1995, [1997] *NJ*, 175.

²⁸ Arnhem District Court, 19 January 1995, [1995] *TvGR*, 53.

²⁹ Arnhem Court of Appeal 29 September 1992, [1993] *TvGR*, 65.

been proven on the basis of a presumption, without the other party being given the opportunity to adduce evidence to the contrary.

There is, incidentally, no rule, such as the one in German law, that serious errors are more likely than less serious errors to give rise to a presumption of a causal connection between the medical error and the damage.

The burden of proof has been switched in a number of cases before the lower courts on the grounds of reasonableness and fairness, in particular because the healthcare provider had not fulfilled his stricter duty of proof and/or because there was a presumption that a medical error had been made. The equitableness argument, namely that the patient is in a more difficult evidential position than the healthcare provider, is sometimes used to justify switching the burden of proof to the healthcare provider. As we have said, these are no more than one-off judgements of the lower courts.

In the case of safety standards the patient is greatly assisted by the Supreme Court. When an express, stringent and customary safety regulation that is intended to prevent very serious injury is breached and the danger against which it is intended to provide protection materialises, it must be assumed that liability for the injurious consequences has in principle been shown. The person held liable can escape liability only by submitting and proving by means of an adequately reasoned argument that there were sufficiently urgent reasons for not observing the safety regulation and that all precautionary measures needed to prevent the danger from materialising were taken.³⁰

Furthermore, it can be seen in the case law dealing with liability in non-medical fields, in particular in the area of occupational and road traffic accidents, that a different burden-of-proof rule is applied in the event of an infringement of a safety standard in relation to the *sine qua non* connection (see 8.). The reasoning is that when a safety standard is breached, thereby increasing the risk of damage, and the risk actually materialises, the causal connection is deemed to be present unless the person held liable shows that observance of the breached standard would not (or probably would not) have prevented the damage. This doctrine in respect of “increasing the danger” has not yet crystallised.

11. Who is Liable in the Event of a Medical Error?

a) General Provisions: Book 6 Civil Code

If a healthcare provider works on the basis of a contract of employment, the patient concludes with the hospital a contract which extends not only to nursing and care but also to the medical treatment in the narrow sense (i.e. an “all in” contract). In such a case, the hospital is the contractual partner of the patient. The specialist himself does not enter into a contractual relationship with the patient. If a physician is not in employment but works on a consultancy basis the patient concludes (at least) two contracts for medical services: one

³⁰ Supreme Court 1 October 1993, [1995] NJ, 182.

with the hospital for nursing and care and one with the physician for medical treatment (in the narrow sense).

Unlike the situation under German law, it is not necessary to discuss expressly with the patient the fact that he has a contract for medical services (in the narrow sense) with the physician and not with the hospital. Such matters are not generally discussed with the patient.

In the event of a medical error committed in a hospital the hospital is liable: on the grounds of non-performance (article 6:74 Civil Code in conjunction with article 7:453 Civil Code) if there is a contract for medical services with the hospital or, in the absence of such a contract, on the basis of an unlawful act (article 6:162 Civil Code). In addition, the hospital may also be liable for medical practitioners in its employ: on the basis of article 6:76 Civil Code if a contract for medical services has been concluded with the hospital (the liability for auxiliary personnel) or, in the absence of such a contract, on the grounds of article 6:170 Civil Code (liability for employees). In certain circumstances the hospital may also be held liable under article 6:171 Civil Code (liability of a business³¹ for non-employees to whom work has been contracted out).

If a patient knows who has committed the error he may also hold the relevant healthcare provider liable directly: on the basis of article 6:74 Civil Code in conjunction with article 7:453 Civil Code if there was a contract, and on the basis of article 6:162 Civil Code if there was no contract. This also applies to errors committed by persons who assisted the healthcare provider in his duties: article 6:76 Civil Code if there was a contract with the healthcare provider and article 6:170 Civil Code or article 6:171 Civil Code if there was no contract.

b) Central Liability: Medical Services Act

It is, however, not always clear to a patient which person should be held liable for a medical error or on what basis the claim should be made. This problem occurs in almost all the cases under consideration, but particularly in case 6. The difficulties arise among other things because the legal relationship between a hospital and the healthcare providers associated with it is often unclear to the patients. In order to assist patients the Medical Services Act (article 7:462 Civil Code) introduces the concept of the central liability of the hospital. It is sufficient for the patient to hold the hospital liable for damages.

Article 7:462 Civil Code provides that the hospital, if it is not itself a party to the contract for medical services, may be held (contractually) liable in respect of breaches in the performance of the contract in so far as they occur in the hospital.

Article 7: 462 Civil Code:

“If activities in pursuance of the contract for medical services are carried out in a hospital which is not a party to the contract the hospital

³¹ A hospital may be deemed to be a business. A consultant who works there is not deemed to be a business, since he practises a profession and does not carry on a business.

shall be jointly liable in the event of any deficiency, as if it were itself a party to the contract.”

By introducing the concept of central liability the legislator did not intend to introduce a broader concept of liability. The intention is merely to provide a “central address” for a patient seeking redress. In short, simpler but not broader redress.

Central liability also provides a solution in cases where the medical error is due not so much to the act of a single healthcare provider but to the way in which the care is organised. For example, the lack of a protocol or insufficient supervision of a mental patient. In order to avoid the need to search for the person responsible, for example the head of medical care of an institution or the *chef de clinique* of a department, the patient can invoke the central liability of the hospital.

12. Statute of Limitations

Claims for compensation in respect of a medical error become barred five years after the day following that on which the injured party becomes aware both of the damage and of the person liable for it (relative prescription) and in any event twenty years after the event causing the damage (absolute prescription) (article 3:310 Civil Code). It seems likely that the expression “becoming aware” refers to the actual knowledge of the patient, although it is not entirely possible to avoid an interpretation based on an objective approach. The text of the Medical Services Act does not contain any separate periods of prescription in this respect.

Mention should also be made of another important development for all future cases of *personal injury*.³² A bill was presented in September 1999 to alter the period of prescription. The Minister of Justice considers it unacceptable that in cases in which the damage remains concealed for a long time an action in law may be barred even before the damage becomes known. This highly undesirable situation has occurred in the case of asbestosis victims. The new rule provides, in essence, that in cases where the damage or the person liable is not known, only the five-year period of prescription applies.

The period of prescription may be interrupted.³³ In addition, a healthcare provider who is held liable may, in certain circumstances, claim tacit waiver of rights.³⁴ Moreover, the fact that a claim is instituted only many years after the event causing the damage may influence assessment of the question whether a party has fulfilled its obligation to furnish evidence and has discharged the burden of proof.³⁵

³² Lower House of Parliament 9900–26824, nos 1–3

³³ The prescription of an action to secure performance of an obligation can, for example, be interrupted by a written warning or by a written communication in which the creditor clearly reserves his right to obtain performance (art. 3:317, par 1, Civil Code)

³⁴ See for example Supreme Court 24 April 1998, [1998] *NJ*, 612, Supreme Court 26 September 1997, [1998] *NJ*, Supreme Court 30 May 1997, [1997] *NJ*, 544, Supreme Court 29 November 1996, [1997] *NJ*, 153

³⁵ Supreme Court 1 October 1993, [1995] *NJ*, 182

The period of prescription in the case of product liability within the meaning of article 6:185 et seq. Civil Code is shorter. Under article 6:191, paragraph 1, Civil Code a right of action against a producer is extinguished after the lapse of three years from the start of the day following that on which the injured party became aware — or should have become aware — of the damage, the fault and the identity of the producer. The right to compensation is extinguished by the lapse of ten years from the start of the day following that on which the producer “put into circulation” the object which caused the damage (article 6:191, paragraph 2, Civil Code).³⁶

13. Insurability

Some physicians and hospitals fear that they will no longer be able to obtain insurance cover as a result of the increasing number of claims. Although Dutch physicians and hospitals are still paying relatively modest premiums, almost all insurers have abandoned the medical liability market in recent years and so-called “mutuals” have been established. In addition, a few hospitals are insured abroad or have arranged their own cover. A comparable development occurred in the United States when the medical liability crisis was at its peak. Another development is the switch from loss-occurrence policies to claims-made policies, which are much more unfavourable from the point of view of the healthcare providers. It is in fact undeniable that in any event the number of claims is rising and that entirely new types of claims too occur from time to time. An example is the large number of claims in respect of information errors and the application of the doctrine of lost chance. On the other hand, similar developments are occurring in road traffic liability law and, more generally, in professional liability. In our view, medical activities cannot (yet) be said to be uninsurable in the Netherlands.

14. Discussion of the Cases³⁷

a) Case 1

As it has been established that the radiologist works in the employ of the hospital, the patient concluded a contract for medical services, namely for an examination, either with the hospital or with the physician whom he saw on 8 February 1990, but in any event not with the radiologist. If the physician whom the patient first saw is in the employ of the hospital it should be assumed that the contract for medical services was concluded with the hospital. If the physician works as a consultant, the patient probably concluded the agreement for the carrying out of the examination with the physician whom he saw on 8 February 1990.

In this case the patient was not informed about the risk of an epileptic attack or the risk of paralysis. These are serious risks which cannot be said to be

³⁶ However, the injured party may still hold the producer liable even after the expiry of the period of prescription under art. 6:162 Civil Code.

³⁷ It has been assumed for the purpose of the discussion of the cases that new Medical Services Act is applicable.

common knowledge. Whether information must be provided in a concrete case is often a question that must be answered by a physician/expert. It is possible that in this case there was a duty to provide the information. This is not altered by the fact that the treatment was necessary. As regards the scope of the duty to provide information as well as the importance of the chance that the risks will materialise and the seriousness of the risk, see also 5.

In our view, the physician who saw the patient on 8 February 1990 was entitled to leave the provision of information about the risks of myelography and CAT scanning to the radiologist. The radiologist should, as an expert, be deemed best placed to inform the patient. See 5.

For the requirement of causal connection see 8. It is possible that in circumstances where the risk of paralysis does not materialise the healthcare provider may still be liable if a different risk does materialise, as happened in case 1. We are hesitant about the admissibility of such a claim. It would, after all, mean that a victim who merely points to a single aspect of defective information (in respect of a risk which has not even materialised) would immediately be entitled to compensation. Is that reasonable? As reporters for Dutch law, we tend to favour the elegant solution put forward by the English reporter (see the relevant report and also the concluding chapter by Michael Faure). For the different categories of compensation which the patient could claim see 9. We estimate the compensation for loss (or partial loss) of function of an arm at NLG 50,000 (22,689 EUR) (non-pecuniary damage).

As regards the question of who may be held liable for a medical error see 11. In the present case it is in any event the hospital that is liable, whether or not on the basis of central liability, provided that the surgery clinic is part of the hospital. This is because it is a requirement of central liability that the medical error should take place "in the hospital".

b) Case 2

As it has been established that the second defendant works in the employ of the hospital, the patient concluded a contract for medical services, in particular for his recovery, either with the hospital (the first defendant) or with the physician whom he saw on 6 June 1987.³⁸ In addition, the patient may have concluded a (separate) contract for medical services, namely for the performance of an operation, with the physician who performed the operation (the third defendant). In any event, the patient did not conclude a contract with the second defendant. As regards the question of who may be held liable for medical error see 11.

The risk of paraplegia is a serious risk which cannot be said to be common knowledge. In addition, it concerned a non-essential operation. There will therefore be a ready assumption that the patient should have been informed. Views differ on the question of whether the patient should have been informed of alternatives. Besides a dorsal inlet there was also the possibility of a thoracic inlet. If the risk of lethality is greater in the case of one method than the other the

³⁸ The patient presumably concluded a contract for nursing and care with the hospital, but this is not mentioned.

patient should, in our view, be informed of this unless this would be undesirable in the special circumstances of the case. The duty to provide information does not extend to medico-technical questions which do not entail any difference in risks or other consequences. As regards the scope of the duty to provide information see also 5.

As regards the law of evidence in respect of a medical error see 10. In the present case there is a note in the file, namely a (signed) consent form. The healthcare providers presumably thought that this consent form was sufficient to discharge them from their stricter duty of proof. We would point out in this connection that written information can never entirely replace oral information. The patient in this case, who was accompanied by his son, has not, in our view, succeeded in making out a *prima facie* case that he was not informed. The statement of the physician that he did inform the patient of the risks and that the patient's consent must therefore be regarded as valid should, incidentally, be treated as insufficiently specific. Furthermore, this evidence, which flatly contradicts the statement of the patient, cannot be attributed decisive significance.

As regards the question of who should provide the information and when see 5. The case shows that the patient was not informed by the surgeon who performed the operation. Although this is in our view permissible, the surgeon should have checked that the patient had been properly informed. Moreover, the surgeon may be held liable if the patient received inadequate information. In our view, the patient was probably informed in good time, namely one day before the operation (see 5.).

The patient in the present case has stated that he would not have agreed to the operation if he had been aware of the complications. His complaints were not so serious that an operation was necessary without delay. On the day of admission he was able to move without assistance or crutches. He merely had difficulty in climbing the stairs. In these circumstances it must be assumed that if the patient had wrongly not been informed about the risks there would have been a causal connection. As regards causal connection in general and in the case of an information error in particular see 8.

In our view, the patient has not made out a *prima facie* case that he would not have opted for the operation and the method used in it if he had been informed of the existence of the other method. In addition, there is no causal connection since the dorsal inlet method was used and this is precisely the method that offers a lower risk of paraplegia than the alternative thoracic inlet method.

c) Case 3

As regards the criterion by reference to which the actions of a healthcare provider are tested see 6. It is assumed in the present case that the conclusions of the experts' report will be adopted and that it will be held that there has been a medical error.

As regards causal connection see 8. If the conclusions of the experts appointed by the court are accepted it must be concluded that there is no indis-

putable *sine qua non* connection between the medical error and the damage. It has, after all, proved impossible to ascertain in retrospect whether the medical problems could have been avoided or reduced if the patient had been treated in the right way in good time. In such a case the doctrine of lost chance may be applied and it could, for example, be decided that a percentage of the damage should be compensated (see 8.).

It could even be submitted that there has been a breach of safety standards, which would in principle constitute an unlawful act and give rise to a presumption of causal connection (see 6. and 8. respectively).

As to the compensation which the patient could claim see 9. (in general) and for the question of who may be held liable for a medical error see 11. In the present case there is an exceptionally grave injury, which could give rise to a claim for compensation for non-pecuniary loss of between NLG 250,000 and NLG 300,000 (113,445 and 136,134 EUR). It could, however, be argued that the child is not aware of the condition and that a lower sum would therefore be justified (see 9.).

d) Case 4

As regards the criterion by reference to which the actions of a healthcare provider are tested see 6. It appears from the case history that there is nothing in the medical file about the type of positioning, specifically the details of the abduction angle used. In our view, the healthcare provider has therefore not discharged his stricter duty of proof. The burden of proof could then be shifted or the existence of a medical error could be accepted as proven (for the law of evidence in respect of a treatment error see 10.).

Since the plexus paresis occurred immediately after the operation and there is no evidence that such an injury occurs spontaneously it is also possible for there to be a presumption of medical error during the operation. This is even more true since the patient was anaesthetised during the operation and cannot therefore explain of his own knowledge how the injury occurred, and the evidence of the healthcare provider, who is obliged to provide sufficient information on this point, is not conclusive.

It is sometimes argued that a special category of medical liability cases exists in the case law, namely cases in which pressure injuries of peripheral nerves are caused while a patient is under anaesthetic. In these cases, a shift in the burden of proof seems to be generally accepted. In our view, however, there still cannot (at present) be said to be a rule.

According to the experts' report the chosen method of positioning was correct. However, the question is whether an angle of at least 70 or 80 degrees was used. We would observe that insufficient data are available to warrant the conclusion that a safety standard was breached, but the possibility can certainly not be excluded.

We would refer to 8. for an explanation of the law on causation in the event of a treatment error, to 9. and case 1 for an explanation of the damages which the patient can claim, and to 11. for an explanation of the law on the person who can be held liable.

e) Case 5

As regards the criteria by reference to which the actions of a healthcare provider are tested see 6. and as regards the law of evidence on a treatment error see 10. In the present case the experts appointed by the court have taken the view that it is incomprehensible why the caesarean section was not performed immediately after it became clear that the contractions could not be stopped. If it was impossible to perform the caesarean section before 11 a.m. the patient should, according to the experts, have been continuously monitored by means of a CTG. The lack of oxygen was not noticed because there was no CTG monitoring. If such monitoring had been carried out there is a good possibility, in the view of the experts, that the damage could have been avoided. The experts therefore consider that two medical errors were made. Although a court has its own responsibility and is not obliged to adopt the view of the experts appointed by it, this often happens in practice. An experts' report is, after all, the ideal way of determining what the professional standard is in respect of a given subject.

The fact that the amniotic fluid was clear is, according to recent research, not a certain indication that labour will be normal in the case of a premature delivery. If this research was not yet known at the time of the (alleged) medical error, the actions of the healthcare provider cannot be assessed by reference to it. The criterion is, after all, the professional standard at the time of the litigious act (see 6.).

The defendant has put forward as a defence to the claim of liability that none of the CTG machines present were available. By analogy with the standard that applies to individual healthcare providers ("reasonably competent and acting in a reasonable manner") we would suggest that the standard in such cases could be "a reasonably well-equipped healthcare provider or hospital". Whether the defence would succeed in the present case is therefore dependent on the answer to the question of what equipment a "reasonably well-equipped healthcare provider" should possess. The court could order an experts' report. Furthermore, there are all kinds of guidelines and other regulations prescribing the equipment which a hospital should possess. In the context of the present case we would, however, point out that the defendant has not made out a *prima facie* case as to why the CTG machines that were present were assigned in such a way that no CTG machines was available for the mother of the claimant. Financial constraints will certainly have played a role.

We would refer to 8. for an explanation of the law concerning causation in the event of a treatment error. It should, incidentally, be noted that, unlike German law, there is no rule that the burden of proof in respect of causation switches from the patient to the healthcare provider if there is a failure to perform necessary tests. Reference should be made to 9. for an explanation of the damages which the patient can claim and to 11. for an explanation of the law on the person who can be held liable. As the case contains too few detailed data about the damage suffered by the (young) patient, it is hard to assess the amount of damages for pain and suffering. If we were obliged to make an estimate we would settle for NLG 200,000 (90,756 EUR).

f) Case 6

As regards the criterion by reference to which the actions of a healthcare provider are tested see 6. In the present case the experts' report provides sufficient grounds for holding that there were various medical errors.

It is notable in this case that the first CTG strip was lost. This strip should be part of the patient's medical file. The duty to keep the medical file is laid down by law.

Article 7:454 Civil Code:

"1. The healthcare provider³⁹ shall open a file on the patient's treatment. In this file he shall keep notes of data concerning the patient's health and the activities carried out in relation to the patient and he shall place therein other documents containing such data as necessary for a conscientious provision of healthcare for the patient.

2. If requested, the healthcare provider shall add a declaration by the patient concerning the documents contained in the file.

3. (...) the healthcare provider shall keep the documents referred to in the previous paragraphs for a period of ten years, effective from the date on which they were drawn up, or as much longer as may reasonably be expected from a conscientious healthcare provider."

The data provided are insufficient to determine the identity of the party or parties who concluded the contract with the patient in the present case and accordingly who was under duty to ensure that the file was complete.

The fact that the healthcare provider cannot produce the first CTG strip can be decisive for the division of the burden of proof. This is because a "rule of evidence" containing a stricter duty of proof has been formulated in the case law, in particular for cases concerning medical liability. According to the Supreme Court a healthcare provider should supply sufficient factual data to substantiate his denial of the submissions of the patient in order to provide the patient with a basis for adducing evidence, in the absence of which the burden of proof can be shifted. In principle, however, the burden of proof lies on the patient. See 10.

We would refer to 8. for an explanation of the law on causation in the event of a treatment error. In the present case it is important to note that the brain injury occurred, according to the experts' report, as a result of oxygen starvation, which was in turn caused by a complete placenta detachment.

We would refer to 9. for an explanation of the damage for which the patient can claim compensation (and to cases 3 and 5 for an indication of the amount of damages for pain and suffering, and to 11. for an explanation of the law on the person who may be held liable). Too few data are available in the present case to determine which of the defendants can be held liable. It is in any event certain that the hospital can be held liable for the damage which the patient has suffered as a result of the medical error(s), (whether on the grounds of central

³⁹ The healthcare provider is the person with whom the patient has concluded a contract for medical services.

liability or otherwise), irrespective of who committed the medical error and irrespective of who entered into the contract with the patient. It follows that under Dutch law the question of what share each of the healthcare providers had in the total number of errors made in the present case is of no real interest.

15. List of References

- Haanappel, P.P.C./Mackaay, E., *Nieuw Nederlands Burgerlijk Wetboek, Patrimonial Law* (1990).
- Hondius, E./van Hooft, A., *The New Dutch Law on Medical Services*, [1996] *Netherlands International Law Review*, XLIII, 1 et seq.
- Lindenbergh, S.D., *Smartengeld* (1998).
- Nieper, F./Westerdijk, A.S., *Niederländisches Bürgerliches Gesetzbuch*, various parts.
- Sluyters, B./Biesart, M.C.I.H., *De geneeskundige behandelingsovereenkomst* (The contract on medical services) (1995).
- Stolker, C.J.J.M., *The unconscious plaintiff: consciousness as a prerequisite for compensation for non-pecuniary loss*, [1990] *I.C.L.Q.*, 39, 82 et seq.
- Stolker, C.J.J.M., *Aansprakelijkheid voor bloedprodukten en bloedtransfusies* (Liability for blood-related products and blood transfusions), [1995] *Nederlands Juristen Blad*, 685–695.
- Stolker, C.J.J.M., *Nederlandse toestanden*, [1996] *Verkeersrecht*, 1 et seq.
- Tobler, C./Stolker, C.J.J.M., *Wrongful Birth – Kosten für Unterhalt und Betreuung eines Kindes als Schaden*, [1997] *Aktuelle Juristische Praxis*, 1145 et seq.