Patient Injury Compensation for Healthcare-Related Injuries

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Introduction

Prior to 1975 patients had little opportunity to receive compensation for injuries that occurred during medical treatment. In order for compensation to be paid, the patient had the often extremely difficult task of showing an error or negligence on the part of the medical professional. The complicated circumstances in medical care are often difficult to investigate and usually require the assistance of people with special expertise. Litigation was usually necessary and the process was often expensive and prolonged. As a result, few patients were awarded damages for treatment injuries.

In 1975 a voluntary patient insurance solution went into effect. Patients no longer had to initiate court proceedings to receive compensation for injuries sustained during treatment, but could instead turn directly to the insurer. On January 1, 1997, the voluntary patient insurance was replaced by the *Patient Injury Act* (1996:799), which is largely based on the terms and conditions of the previous insurance solution. Under the provisions of the Act, care providers are required to carry patient insurance which pays compensation for injuries.

However, it is important to note that the Patient Injury Act has no disciplinary purpose. Its sole purpose is to make it easier for patients to receive compensation for various types of injuries. The right to compensation is determined on objective grounds according to the provisions of the Act. For example, the patient is eligible for compensation if an injury could have been avoided. Neither these cases nor others that are compensable under the Act address whether the injury was due to error or negligence on the part of the medical professional and therefore no assessment of liability is made.

In addition to making it easier for patients to receive compensation for healthcare-related injuries, the selected solution has considerably improved relations between patients and medical professionals. Patients who believe that an injury occurred do not have to find any error or negligence during treatment in order to receive compensation. They can also more easily understand that healthcare-related injuries can occur without doctors or other healthcare workers showing negligence or making a mistake, while healthcare workers do not have to feel their actions will be scrutinized every time the issue of compensation for patient injuries arises because it must be ascertained whether anyone has been negligent or made a mistake. Under these circumstances medical professionals can feel free to help patients to receive compensation, without having to think about whether or not some-

one is liable for the injury. However, it is important to point out in this context that medical personnel should not express their opinion to the patient about whether the injury is compensable. This assessment must be left to the insurance company in question.

The Patient Injury Act covers both physical and mental injuries. With respect to injuries caused by medications, the Act only covers those injuries that arise due to incorrect prescription or administration of the medication. Compensation for other pharmaceutical injuries is covered by pharmaceutical insurance.

General information about the Patient Injury Act and patient injury compensation

Scope of coverage

The Patient Injury Act covers patient injuries that occur in connection with *health and medical care services in Sweden*. Thus the law does not cover patients who receive medical care abroad, even if referred for care by a Swedish care provider, nor does it cover care at facilities abroad run by Swedish associations and staffed by Swedish medical personnel. Patients who receive medical care abroad must therefore be covered by the voluntary undertakings of the care provider.

Concepts of patient, health and medical care services and care provider

The concept of *patient* is not defined in the Patient Injury Act. However, in the preliminary work for the Act, "patient" refers to all persons who have established contact with medical personnel with respect to their health. The idea is that anyone who receives care or treatment, or undergoes an examination, regardless of the reason for the intervention, shall be considered a patient. Under the Act, any person who voluntarily participates as an experimental subject in medical research or who donates an organ or other biological material for transplantation or other medical purpose is considered to be the equivalent of a patient.

The following cases that address the question of the patient concept, like all of the cases cited below, have been considered by the Patient Claims Panel. Some of these cases date back to the earlier voluntary patient insurance, but they are applicable even under the provisions of the new Patient Injury Act. The panel's reference number is given after each case description and if the case is cited in the Patient Claims Panel's citation index (PRS), the number of the case in the index is also given. The cases in this article are usually only described in brief. For the complete citation in Swedish, please refer

to the index which was posted in autumn 2007 on the Patient Insurance Associations website (www.pff.se).

FETUS

A fetus that receives treatment or fails to receive treatment was considered to be a patient if subsequently born alive (Reg. no. 221/1992).

PERSON ACCOMPANYING PATIENT

A mother who suffered from food poisoning when living in a patient hotel while her child was examined in the hospital for a hereditary illness was not considered to be a patient (Reg. no. 753/2000 – PRS 2001:01).

RELATIVES

Nor were the relatives of a child who contracted an infection in the hospital and who therefore was eligible for compensation, considered to be patients when they caught the infection from the child, regardless of whether this occurred in the hospital or at home after the child was discharged (Reg. no. 175–177/1990).

The term *health and medical care services* refers to such activities as are subject to the Swedish Health and Medical Care Services Act (1982:763); that is, medical measures to prevent, examine and treat diseases and injuries. Health and medical care also include ambulance transport services and similar forms of patient transport. In addition, dental care is covered under the Swedish Dental Services Act (1985:125). The Patient Injury Act further specifies "other similar medical activities." According to the preliminary work for the Act, such activities include what are usually referred to as *in vivo* studies for medical purposes, forensic psychiatric examinations and medical research on humans. Finally, the Act also covers retail sales of pharmaceuticals.

The concept of health and medical care services includes preventive care, vaccinations, blood donation, medical rehabilitation and other equivalent activities such as insemination, measures related to abortion and sterilization, and certain measures against infectious diseases. The concept only encompasses care with medical context aimed directly at individuals and therefore does not include measures aimed at larger groups in the community that are not directly medical, such as general health campaigns and similar activities.

A prerequisite for a case to be considered a matter involving health and medical services in the context of the Patient Injury Act is that the activity must be carried out by personnel subject to the Act (1998:531) on professional activity in health and medical care. For example, an unlicensed chiropractor or a podiatrist in private practice who provides treatment without working under the auspices of a licensed professional is not covered by the Patient Injury Act.

The following cases address the issue of what constitutes health and medical care services.

PREOPERATIVE SCRUBBING

Preoperative scrubbing prior to knee arthroplasty has been considered to be a crucial aspect of and in principle a prerequisite for treatment. The legionella infection a patient was afflicted with after being told to shower and wash with a disinfectant was therefore considered to have occurred in connection with health and medical services (Reg. no. 24/1999 – PRS 1999:08).

REFERRAL AND MEDICAL CERTIFICATE

Failure to write a referral has also been considered to be a measure covered by the Act (Reg. no. 76/1999), as has the issuing of medical certificates (Reg. no. 348/2000 – PRS 2000:04).

TRANSPORTATION

Transportation home from the hospital has only been considered related to health and medical care services if medical personnel ordered the trip home by means of the mode of transport in question (Reg. no. 125/2000 – PRS 2000:03).

DELEGATION BY MEDICAL PERSONNEL

Treatment received from a *massage therapist with a diploma*, which was delegated by a licensed physical therapist, has been considered to be provided by medical personnel; in other words, by a person subject to the Act (1998:531) on professional activity in health and medical care (Reg. no. 479/1999 – PRS 2000:06).

However, *policemen* have not been considered medical personnel even when assisting, at the request of a doctor, in the transport of a patient with an acute psychiatric problem to the hospital. In the case at hand, the policemen were not considered to have assisted the doctor with care, treatment or examination, but merely took care of transporting the patient to the hospital for care (Reg. no. 262/2001 – PRS 2001:09).

FELLOW PATIENT

The injury caused by a disoriented patient to a fellow patient was not considered to have occurred in conjunction with care or treatment by medical personnel. The Patient Claims Panel concluded in the case at hand that the Patient Injury Act only pertains to injuries that arise in conjunction with health and medical services and that "health and medical services" refers to medical measures provided by medical professionals to prevent, examine and treat diseases and injuries. This reported injury was therefore not considered to have occurred in conjunction with health and medical services, but was caused by a fellow patient. According to the panel it was therefore not covered by the Patient Injury Act. Nor did the panel, which according to the rules of procedure may also consider whether a patient is entitled to compensation under tort law, find anything suggesting that the injury was caused by error or negligence on the part of medical professionals, such as, for example, inadequate monitoring.

Consequently, the patient was not entitled to patient compensation or to compensation under tort law (Reg. no. 424/2001 – PRS 2001:10).

Care provider within the context of the Patient Injury Act refers to both public and private care providers who conduct and are responsible for health and medical service activities, in which the medical duties are performed by healthcare workers. Public care providers include, among others, the local healthcare authorities: the county councils and the three municipalities that do not have county councils, Göteborg, Malmö and Gotland. An example of a care provider at the national level is the National Prisons and Probation Administration, which is responsible for health care in correctional rehabilitation facilities. In addition to the public care providers, anyone who provides health and medical services in the private sector is subject to the concepts in the Act, including both sole proprietors and legal persons. A doctor or dentist in private practice is therefore to be considered a care provider.

Compensable injuries

Compensable injuries are divided into six categories:

- treatment injury
- material-related injury
- diagnostic injury
- infection injury
- accident-related injury
- medication injury

Patients are not entitled to compensation if the injury is the consequence of a necessary procedure to diagnose or treat an illness or an injury which, if left untreated, would be directly life-threatening or lead to severe disability. In addition, injuries caused by medications are not eligible for compensation unless the injury is due to a prescription or administration error.

Concept of experienced specialist

A fundamental question is what guiding principle of action to use to determine whether or not an injury was avoidable. The Act specifies that when assessing treatment and diagnostic injuries, the guiding principle of action is that of an *experienced specialist or other experienced practitioner in the field*. The

actual expertise and experience of a treating doctor is therefore irrelevant to this assessment. This means that the standard of a specialist applies, even if no experienced specialist was available at the time of treatment.

It can be difficult to interpret the concept of experienced specialist or other experienced practitioner within the field in individual cases. The preliminary work for the Act refers only to those specialties specified in the Ordinance (1984:545) On Authorization to practice professions within health and medical care.

One question that commonly arises is whether the assessment of an experienced general practitioner, who is a specialist according to the ordinance, should set the standard, or if the assessment should be based on the experienced specialist in the relevant field.

EXPERIENCED SPECIALIST

One case involved surgical excision of a skin lesion. The general practitioner whom the patient saw assessed the skin lesion as a pigmented nevus in which a wound had developed and excised the lesion. According to a report from a dermatologist, this action was not wrong, since the general practitioner could not rule out a malignant melanoma. At the same time it was concluded that a dermatologist probably would have made the correct diagnosis, seborrhoic keratosis, and either not taken any corrective action at all or used a simpler procedure to remove the lesion.

The panel concluded that the concept of specialist encompassed both the dermatologist and the general practioner and that a case like this should be interpreted in the same way as earlier, according to the voluntary insurance system. The panel felt that the assessment should be based on the guiding principle of action of the experienced general practitioner. Therefore no compensation was paid because the procedure was more extensive than necessary (Reg. no. 151/2000 – PRS 2000:12).

When assessing whether a general practitioner should have referred a patient with a herniated disc to the orthopedist for further treatment, the panel based its decision on the current practice of how an experienced general practitioner, and not an experienced orthopedist, would have interpreted the symptoms and what measures the former would have taken.

Determining the amount of compensation

Patient injury compensation is determined under the personal injury compensation rules of the Tort Liability Act. Compensation therefore covers *economic damages*, that is, loss of income and costs incurred due to the injury, as well as *noneconomic damages*, which refers to compensation for pain and suffering, disability and disfigurement, as well as inconvenience. In the event of death, compensation can be paid for funeral costs, loss of support and psy-

chological problems due to the death of a close relative. Such cases have both a ceiling for the amount of compensation and a deductible.

It is not uncommon for patients to believe they have been subjected to *offensive behavior* and demand redress for the alleged transgression. However, compensation for violation of personal integrity cannot be paid according to the Patient Injury Act. Such compensation can instead be paid under the Tort Liability Act (Chapter 2, Section 3) for serious violations caused by a criminal act (Reg. no. 073/2004).

Patient insurance

Under the Act both public and private care providers are obligated to carry patient insurance that covers compensation for patient injuries. Insurers that provide such insurance belong to a special organization, the *Patient Insurance Association*. The idea is that all patients shall have the same coverage, regardless of care provider. If a care provider does not have insurance the Patient Insurance Association covers the patient injury compensation, after which it can make a claim against the care provider that did not carry insurance.

Among care providers in Sweden, the county councils and the three municipalities without county councils are responsible for most medical services. Consequently they are the object of most compensation claims. They use a common insurer, Landstingens Ömsesidiga Försäkringsbolag (LÖF – The County Council's Mutual Insurance Company, www.patientforsakring.se), which in turn commissions the company Personskadereglering AB (PSR) to process the compensation claims. PSR processes over 90 percent of all patient injury claims.

Patient Claims Panel

The Patient Claims Panel promotes fair and consistent application of the Patient Injury Act and issues opinions at the request of a patient or other claimant, care provider, insurer, or court. Although the panel's opinions are advisory, in principle the insurer always complies with them. The panel's assessment differs from that of the insurer in about 10 percent of cases. Bringing a matter before the Panel is free of charge for the patient.

Damages

Even though patient injury compensation can be paid according to the Patient Injury Act, a claimant may instead claim damages under the rules of tort law. According to its rules of procedure, the Patient Claims Panel may render an opinion even if compensation can be paid under the rules of tort law. However, a patient may always initiate an action to recover damages in court.

Statutory limitation

A person who wishes patient injury compensation must submit a claim for compensation within three years from the time that the claimant became aware that a claim could be filed and in any case no later than ten years after the injury was caused.

Court procedure

A patient can always have the issue of compensation under the Patient Injury Act considered by a court. The patient may either go directly to court or, if dissatisfied with the insurer's decision, initiate court proceedings within a certain time period.

Statistics

Patients report approximately 10,000 injuries or treatment complications each year. Compensation is paid in about 45 percent of these cases. The total compensation cost paid per year is currently estimated at about SEK 400 millions.

Common injuries for which compensation is paid include nerve injuries, infections and dental injuries.

Table 1. Breakdown of percentage of claims and compensation costs, respectively, among medical centers and healthcare facilities

Medical center or healthcare facility	**Complaints**	**Compensation costs**
Orthopedic surgery	21.2 %	24.3 %
General surgery	15.1 %	12.9 %

Obstetrics and gynecology	8.1 %	23.8 %
Primary care	9.4 %	6.6 %
General and specialist dental clinic	10.3 %	2.1 %
Other	35.9 %	30.3 %

Source: Statistics for LÖF 1997–2004

As can be seen in Table 1, orthopedic surgery, general surgery and dental care account for the most reported injuries. Obstetrics and gynecology account for about 8 percent of claims, but almost one fourth of compensation costs. This situation is due to the fact that this specialty includes compensation for birth injuries to children. These injuries often cause extremely serious consequences and result in high compensation. However, dental care accounts for a relatively large percentage of complaints, though only about 2 percent of compensation costs – perhaps because dental injuries are usually relatively minor and therefore as a rule the amount of compensation is relatively low.

Table 2. Five most common reasons for rejection (decisions 1997–2004)

Reason for rejection	**%**
1. Unavoidable consequence	26.3 %
2. Not related to treatment, etc.	17.6 %
3. Not a diagnostic injury	17.0 %
4. Not a personal injury	5.5 %
5. Applicable insurance not carried at time of injury	4.5 %
Other reasons	29.1 %

Source: Statistics for LÖF decisions 1997–2004

As can be seen in Table 2, the most common reason for rejection is that the reported injury could not have been avoided through another procedure and the next most common reason for rejection is that no causal relationship was present between the medical care and the reported injury. These two reasons for rejection have always been the two most common reasons for rejecting patient compensation claims since the onset of the patient insurance system in 1975. Over the years it has become increasingly common for patients to report a delayed diagnosis of their problems. Claims for diagnostic injuries have thus increased relatively sharply over time. Even if many claims lead to compensation, in terms of numbers, many cases are rejected where the insurance company considers that actual observable symptoms were interpreted in a way that is consistent with generally recognized clinical practice.

Right to patient injury compensation

Concept of injury

Compensation under the Patient Injury Act is paid for *personal injuries*. This concept encompasses both physical and mental injuries. Physical injury refers to purely physical defects, as well as physical pain. Examples of mental injuries include shock, depression and posttraumatic neuroses. In order for a psychological injury to be considered a personal injury, a medically demonstrable effect must be present. General emotional manifestations that are a normal consequence of a tortious act, such as fear, anger, worry and sorrow, are insufficient (see Reg. no. 455/2001 – PRS 2002:01). Medically demonstrable effects may be that a patient is on sick leave or undergoing therapy as a result of psychiatric problems.

Rules of evidence

In order for an injury to be considered compensable there must first be a causal relationship between the injury and the medical service. The patient is charged with the burden of proof of showing that such a causal relationship exists. The requirement for proof is met if causal relation can be established with preponderant probability. It can be mentioned here that in the claims adjustment process, the insurer must objectively investigate an injury claim. If the insurance company does not find any correlation between the injury and the measure taken the patient has to prove a causal relatioship.

In many cases it can be difficult to assess whether an injury with preponderant probability is due to medical measures. The following examples illustrate this point.

IS THERE REALLY AN INJURY?

A boy who suffered from Wilms' tumor did not have his illness upgraded from stage I to stage II, as he should have, and therefore did not receive the increased chemotherapy dosage that would have been prescribed if the tumor had been correctly graded. The medical investigation concluded that it was not possible to comment on whether increasing the chemotherapy dosage earlier would have affected the course of the disease. Under these circumstances it was not considered that the omitted

treatment with preponderant probability entailed any injury. (Reg. no. 330/2001 – PRS 2002:03).

WAS THE INFECTION A DIRECT CONSEQUENCE OF TREATMENT?

The case involved a three-year old girl who, at the time of treatment, suffered from burns of the trunk, right hand and leg. The burns covered about 7 to 8 percent of her body. Three days after initiating treatment of the injuries it was concluded that the wounds were infected. The mother reported that the injuries were worsened because the nursing staff used non-sterile procedures. The Patient Claims Panel concluded that to be entitled to compensation, the personal injury must with preponderant probability have been caused by transmission of an infectious agent that led to infection in conjunction with examination, care, treatment or similar measures. The panel also concluded that for a patient injury to be considered present in the meaning of the Patient Injury Act, it is not sufficient that the patient's injury *may* have been caused by transmission of an infectious agent during treatment; rather, this reason must be *more probable* than any other conceivable cause of injury. According to the investigation of this case, it could not be said with absolute certainty whether the infection was transmitted in connection with a treatment measure or whether secondary infection was involved. However, the panel concluded that the risk of infection was particularly significant considering the burns, which caused a pronounced impairment of tissue viability in the affected areas. According to the panel, it therefore could not be said that the reported infection with preponderant probability occurred as a direct consequence of any treatment measure; rather, it represented with preponderant probability a "secondary infection" in an area of impaired tissue viability due to the burns. According to the panel it would not be possible to prevent or impede a similar complication through any alternative treatment. Therefore the patient was not entitled to patient injury compensation (Reg. no. 489/2001).

AN INJURY OCCURRED WITH PREPONDERANT PROBABILITY DURING MEDICAL PROCEDURE

In one case in which problems from a nerve in the axilla had their onset in conjunction with a gynecological examination under anesthesia, it could not be clarified exactly how the injury occurred. However, since similar injuries can arise through pressure on the inside of the upper arm and since a temporal correlation was present, the panel considered that the injury with preponderant probability occurred during the medical procedure (Reg. no. 40/1978).

A relatively common question is how to view the *value of patient records as evidence*.

PATIENT RECORDS AS EVIDENCE

In one case in which the opinions of the patient and the treating doctor differed with respect to which symptoms were present during a specific care episode, the Patient Claims Panel based its assessment on the assumption that the chart notes, which in

> this case were detailed, were recorded in the customary way and that crucial symptoms were noted. With the contradictory information available, the panel felt that given the background of what was recorded in the chart, it was not shown with preponderant probability that symptoms were present during the relevant point in time that suggested the injury the patient reported (Reg. no. 309/2001 – PRS 2001:14).

Since compensation cases under the Patient Injury Act are processed based on written documents, it is important that chart notes are thorough. Under Section 3 of the Patient Records Act (1985:562) if the information is available, a patient chart shall always contain essential information about the patient's medical history, information about the diagnosis and the reason for more significant interventions, as well as essential information about planned and executed measures.

Types of injuries and consideration of compensation

The Patient Injury Act contains a relatively detailed list of the terms and conditions for compensation for various types of injuries. This list was probably made to facilitate claims adjustment, though the clarity of the Act suffered. In some cases the formulation of the provisions has even involved problems in the practical application of the Act. Below is a discussion of the six categories of injuries that are compensable (Section 6, first paragraph, indents 1 to 6) and examples of assessments made in practice with respect to these injuries.

All types of injuries must involve a personal injury to a patient and the injury must with preponderant probability be caused by measures or conditions such as those specified under each point. Direct consequences of the underlying disease and injuries that would have occurred or developed anyway, regardless of medical care, are therefore not eligible for compensation.

One fairly common type of injury for which it can be difficult to determine whether the injury occurred because of a medical procedure or not is *birth injuries*. When childbirth takes place in the hospital and the child is injured as a consequence of the natural course of childbirth and not due to any neglect or actions on the part of medical personnel, the patient is not entitled to compensation. In order to be entitled to compensation, the injury usually must be caused by a direct medical procedure in conjunction with childbirth, such as the use of vacuum extraction.

NATURAL COURSE OF CHILDBIRTH

A woman suffered vaginal and rectal tears, as well as pain, blood loss and mental suffering in conjunction with childbirth. The Patient Claims Panel concluded that no indications were present for carrying out a cesarean section and that the medical management of the delivery and the assessments before, during and after childbirth were consistent with recognized treatment guidelines. Moreover, the panel found that the course of the delivery in itself was not a medical procedure but that use of vacuum extraction in the final phase of childbirth was a medical procedure. According to the panel, however, the procedure using vacuum extraction had with preponderant probability not caused the tears that occurred, as well as the after-effects that these injuries in turn led to in the form of pain, blood loss and mental suffering. Rather, the injuries that occurred were a direct consequence of the complicated but natural course of delivery when giving birth to a large baby. In the opinion of the panel, the injuries the patient reported were therefore not caused by any medical procedure (Reg. no. 531/2001 – PRS 2002:10).

1. Treatment injury

This is the most common type of injury for which compensation can be paid if it can be concluded in an ex post evaluation (retrospective assessment) that the injury could have been avoided. Neither the severity nor the rarity of the injury has any bearing on the patient's right to compensation. The crucial question is whether the injury could have been avoided.

According to the wording of the Patient Injury Act, compensation is paid if the injury is caused by "examination, care, treatment, or similar measure provided that the injury could have been avoided either by a different performance of the chosen procedure or by choosing some other available procedure which, according to an assessment made retroactively from a medical point of view, would have satisfied the need for treatment in a less hazardous way."

Consideration of whether an avoidable treatment injury is present is a multistep process as described below.

1. Did the injury occur as a result of *health and medical services in Sweden*?
2. Is a *personal injury* present?
3. Is there a *causal relationship* between the medical care and the injury?
4. Was the treatment *medically justified*?
5. Was an accepted *method* used?
6. In a retrospective assessment, could the injury have been avoided by a *different performance of the chosen procedure* at the same time that the need for treatment would have been satisfied in a less hazardous way?
7. In a retrospective assessment, could the injury have been avoided by choosing a *different treatment method* while at the same time meeting the need for care in a less hazardous way?

If the matter involves a *personal injury* (2) that occurred *in conjunction with health and medical services in Sweden* (1), consideration proceeds to the question of whether a *causal relationship* exists between medical care and the injury (3).

Patients are not entitled to compensation for injuries that occur or develop without any connection to medical care. Direct consequences of the underlying disease present during the care episode or injury which by some other means developed, regardless of medical care, are therefore not eligible for compensation. It is relatively common for patients to report that they did not achieve the expected or desired treatment outcome. A patient for whom satisfactory results are not achieved, despite completely correct treatment according to recognized treatment guidelines, is therefore not entitled to compensation.

INJURY CAUSED BY TREATMENT?

A classic case in this context is when a patient sustains a *radius fracture* in conjunction with an accident that is not care-related and despite completely correct treatment according to recognized surgical guidelines, the patient has residual problems such as pain, weakness in the wrist and restricted mobility. These problems are therefore not caused by an injury resulting from treatment, or because treatment has been carried out incorrectly, but are due to the fact that the fracture does not heal satisfactorily despite proper treatment. This rather common complication is a direct consequence of the original accident-related injury and can not be avoided through a different procedure (Reg. no. 426/1999).

Another common case occurs during hip replacement surgery. Even if the procedure is done according to accepted guidelines a *leg length discrepancy* may occur. Such surgery always involves a risk of leg length discrepancy. It is not always possible to anticipate the extent to which leg length will change after the operation. The procedure alters the function of the hip musculature and the tension of the tissues. Leg length discrepancy of plus or minus three centimeters cannot be avoided through “any other performance” of the operation and may therefore be considered to fall within a normal surgical outcome. Therefore the patient is not entitled to compensation (Reg. no. 486/1999).

In *cosmetic procedures* it is not possible to exactly calculate appearance-related results in advance or during surgery. Even if surgery is performed in the customary manner, certain discrepancies may arise in relation to desired outcome and may require additional surgery. This situation is part of a normal surgical outcome and cannot be considered an injury in the meaning intended by the Patient Injury Act (Reg. no. 81/2001 – PRS 2001:13).

Incisional hernia after gastric ulcer surgery. Compensation was not paid because the condition was considered to be a consequence of poor healing conditions (Reg. no. 277/1990).

> In one case the patient's problems worsened in connection with *naprapathic treatment of shoulder problems*. Degenerative changes in the joint capsule were probably present prior to the treatment in question. However, it was initially during this treatment that a rupture occurred that caused the capsular changes/joint capsule injury. In the subsequent operation surgeons found an extensive rupture of the supra- and infraspinatus ligamental attachment site. Although this rupture could have occurred regardless of the naprapathic treatment, in this case it could not be determined when this might have happened. It may have taken years before spontaneous rupture occurred. In this case the patient was entitled to compensation because the naprapathic treatment triggered the injury (Reg. no. 869/2003 – PRS 2004:07).

If a causal relationship is present between medical care and injury, the consideration process next addresses whether treatment was *medically justified* (4) and whether an *accepted method* (5) was used.

The insurance terms and conditions previously in effect explicitly stated that compensation would be paid in the case of an injury due to a medically justifiable measure that could have been avoided. The claims adjustment process for injury cases therefore included an assessment of whether the measure was medically justified and, where applicable, if an accepted method was used. If the measure was not medically justified or an accepted method was not used, compensation was paid without further consideration.

The Patient Injury Act does not explicitly state that the measure must be medically justified. However, this should not be understood to mean that consideration should be carried out differently than in the past. In assessing injuries that could have been avoided or injuries due to incorrect diagnosis, the starting point must be the guiding principle of action that applies to an experienced specialist. Obviously the medical procedure must be medically justified and an accepted method must be used. The assessment is based on what was, or should have been, known about the patient's care needs and general state of health at the time of treatment. If this leads to a treatment that was not medically justified or if an accepted method was not used, the patient is awarded compensation for the injury.

PROCEDURE NOT MEDICALLY JUSTIFIED

> An example of a procedure that cannot be considered justified would be a patient who had surgery for a small, benign tumor in the wrist region. The tumor had not grown and caused only insignificant problems. During the operation nerves that infiltrated the tumor were injured. The nerve injuries caused the patient severe problems. The Patient Claims Panel did not consider the procedure to be medically justified since its benefits were not in reasonable proportion to the risk of complications, particularly nerve injuries. Therefore compensation was awarded, even though the injury in itself could not have been avoided with the treatment method selected (Reg. no. 47/1976).

Another example of a procedure that is not justified involved a man who had a radiographic examination involving contrast after heart surgery. When the contrast agent was injected a blood clot was formed and caused blindness in one eye. The examination was not considered medically justified from the patient's point of view, since it was not motivated by his underlying disease, but had been carried out solely for research purposes. Compensation was therefore paid, even though the complication in this type of examination could not have been avoided through a different performance (Reg. no. 24/1977).

The next step in the consideration process addresses whether the *injury could have been avoided through a different performance of the chosen procedure* (6). Consideration is based on knowledge of the patient's condition at the time of treatment that is available at the time of claim settlement. This applies to both the underlying disease and any abnormalities and anomalies, and regardless of whether the conditions were known or even possible to know when treatment occurred. Even in this consideration the experienced specialist's knowledge of the field serves as the point of departure.

This retrospective reasoning means a consideration of whether hypothetically, once awareness of the treatment outcome was obtained, the injury could have been avoided if the chosen procedure had been carried out in a different but equally effective manner with respect to the treatment of the underlying disease and, in addition, if the performance had been less hazardous. If after consideration the panel concludes that the injury could have been avoided by performing the chosen method in a different manner, compensation is allowed.

Cases involving avoidability are frequently found and it may be of interest to see how the assessment was made in various types of procedures.

BLEEDING DURING KIDNEY BIOPSY

One example of a case in which the injury could have been avoided and compensation was awarded involves a case in which a major bleeding occurred during a kidney biopsy when the needle hit an arterial branch and the kidney therefore had to be surgically removed. In retrospect, it was considered possible to avoid hitting the arterial branch and therefore such kidney damage would not have occurred (Reg. no. 49/1977).

INJURY OF VOCAL CORD NERVE DURING THYROID SURGERY

Injury to the vocal cord nerve may occur during thyroid surgery and in such cases nerve damage is usually a compensable injury. However, if the vocal cord injury occurs during reoperation or in conjunction with cancer surgery, it is usually considered unavoidable. Conditions can be difficult during reoperation because of scar tissue that developed following previous procedures, which can make it impossible to identify the vocal cords nerves. During cancer surgery in which a tumor surrounds

the vocal cord nerve, injury to the nerve when removing the tumor is unavoidable (Reg. no. 114/1987).

LACERATED SPLEEN DURING ABDOMINAL PROCEDURE

The spleen may be lacerated during stomach surgery, surgery for hiatal hernia and certain other abdominal procedures. In order to prevent damage to the spleen the surgeon usually places drapes between the abdominal wall and the spleen. Even if the surgeon took all conceivable precautionary measures, because of the connective tissue bands that extend toward the splenic capsule from the surrounding area, the spleen may become lacerated. In such conditions the complication could not have been avoided if the procedure had been performed in a different manner (Reg. no. 180/1988).

RADIATION REACTIONS

During radiation therapy of tumors the patient may suffer from severe radiation reactions, even though the treatment was performed in a correct manner with the standard radiation dose. In the opinion of the panel, such radiation reactions could not have been avoided if treatment had been performed in a different manner (Reg. no. 123/1989).

INJURIES TO SMALL NERVE BRANCHES DURING INGUINAL HERNIA SURGERY

Burning pain in a ten cm-wide swathe across the abdomen after an inguinal hernia operation was probably due to injury to small nerve branches during the procedure. The Patient Claims Panel concluded that such branches are essentially impossible to identify during surgery and that injury to small nerve branches, the exact location of which cannot be anticipated and which in principle cannot be seen during surgery, is therefore a complication that cannot be avoided (Reg. no. 360/2001 – PRS 2001:12).

NEEDLE STICK INJURY IN CONJUNCTION WITH DRAWING BLOOD

According to the panel, a needle stick injury to the median nerve in the right arm, which occurred while drawing blood, could have been avoided if the blood had been drawn in a different manner (Reg. no. 205/2000).

PANCREATITIS AFTER ERCP EXAMINATION

Because of past medical history and suspicion of stone located in the common bile duct a patient had an ERCP procedure; in other words, an instrument was introduced through the mouth, esophagus, stomach and duodenum to the common bile duct in order to investigate whether gallstones were present and if so to remove them. The Patient Claims Panel concluded that almost everyone who goes through this type of procedure experiences some impact on the pancreas without leading to major problems, but that sometimes inflammation develops in the pancreas. The panel decided that in this particular case the complication could not have been avoided if the procedure had been performed in a different manner (Reg. no. 220/1998).

INJURY TO DENTAL BRIDGE DURING INTUBATION ANESTHESIA

During intubation anesthesia and laryngoscopy the patient sustained an injury to a dental bridge in the lower jaw. The Patient Claims Panel concluded that it is important that the endotracheal tube is inserted correctly and without unnecessary delay to ensure that the patient receives an adequate oxygen supply. However, during intubation there is a small but known risk of injury to teeth. If an injury occurs under normal conditions, compensation is paid. If the intubation procedure is complicated because of individual anatomical abnormalities or other risk conditions, however, the risk of dental injury increases. In such cases dental injuries usually would not have been avoidable if intubation had been performed in a different manner. Since in the case at hand no information suggested that conditions that could increase the risk of dental injuries were present, or anything that otherwise suggested that the procedure as such had been difficult, the panel felt the injury was compensable (Reg. no. 36/1998).

The intent with respect to this point regarding the requirement of satisfying the need for care in a less hazardous way is unclear. If a retrospective assessment demonstrates that an injury could have been avoided if the procedure were performed in a different manner, then usually this performance would also have been less hazardous than the performance that caused the injury. It should be obvious, without having to explicitly state this fact, that retrospective reasoning cannot be applied to a procedure for awarding compensation in a case where an injury could have been avoided if the procedure had been performed differently, but at the risk of another more serious injury.

If the injury could not have been avoided by performing the chosen procedure in a different manner, the panel proceeds to the next step and considers whether the injury could have been avoided by choosing "*another available procedure which according to an assessment made retroactively from a medical point of view would have satisfied the need of treatment in a less hazardous way.*" (7).

The first question to ask is: What does *procedure* mean? According to the preparatory work for the law, procedure refers to a treatment technique and method. Thus it is not a procedure in the linguistic sense, but has a broader meaning.

The following cases address the question of what is intended by the use of the term *procedure*.

ALTERNATIVE TREATMENT METHOD?

A patient came to the hospital with nonspecific chest pain. Because he had a history of suspected pulmonary embolism and a deep vein thrombosis after arthroscopy, due to suspicion of pulmonary embolism a venous canula was placed in the back of his right hand in case intravenous fluid treatment, blood samples, or other tests might be needed. After a "negative" (normal) lung scan the needle was removed and the patient

> was allowed to go home. However, as a reaction of the venous canula the patient experienced an unavoidable complication in the form of thrombophlebitis. The question arose whether the injury could have been avoided by choosing another available procedure and whether making the choice of not placing the venous canula should have been considered as "another available procedure" in the meaning of the law.
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> The Patient Claims Panel concluded that the expression "other procedure" according to the preparatory work for the law referred to a treatment method, but not to any other measure. The question then became whether the alternative of not placing the venous canula should be considered a treatment method. First the panel determined that non-treatment or conservative treatment could also be considered a treatment method. However, according to the panel, in order for this alternative to be considered such a method, it had to be a medically accepted method that constituted a clear treatment option. It would therefore involve a medical measure which, at the time of treatment, is consistent with science and proven experience, and which satisfactorily meets the patient's care needs. Under the circumstances in question, not placing the venous canula could not be considered to be an alternative treatment method (Reg. no. 21/1998 – PRS 1998:01).

Even non-treatment or conservative treatment can therefore be a procedure in the meaning of the law, but it must then involve a medically accepted method that constitutes a realistic treatment option from a medical point of view.

> In the case of a herniated disc the question of whether to choose conservative treatment or to operate often arises. This very question arose in a case that the Patient Claims Panel recently addressed. The patient had a large right-sided disc herniation at the L:3–L:4 level. At first he was treated conservatively with analgesics. The patient felt that the herniated disc should have been operated immediately after the first symptoms of drop foot appeared in summer 2001. Surgery for herniated disc was not carried out until early November of that year. No noteworthy improvement with respect to the drop foot was described in the patient's charts. Nor could the improvement that the patient mentioned be attributed with certainty to the operation.
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> According to the panel there was no absolute indication for surgery with respect to the problems with which the patient presented for care in July 2001. Both conservative treatment and surgical treatment were considered to be realistic treatment alternatives. The panel concluded that there were different opinions about which treatment was preferable and which gave the best final results, but there was no general scientific support that one treatment would be better than the other. According to the panel it could therefore not be claimed that the patient's symptoms in the summer of 2001 were interpreted in a manner that deviated from accepted practice and that consequently treatment moved in the wrong direction. Therefore the injury was not compensable under Section 6, first paragraph, indent 3 (Reg. no. 115/2004 – PRS 2004:09).

Not only must there be an alternative method, this method must

a) be available at the time of treatment
b) meet the patient's care needs
c) overall, offer a lower level of risk.

The requirement that the alternative method must be *available* (a) does not necessarily mean that it must be available at the care facility in question. For example, it can also be available at another care facility to which the patient can be referred. However, the necessary resources must be available to the care provider. Otherwise the treatment is not considered to be available. Thus the possibility of avoiding injuries must not be assessed based on an optimal standard of care.

For example, if a severely injured patient comes to a smaller hospital and the alternative method is only available at a university hospital, the method in this particular situation cannot be considered available if the patient's care needs are so urgent that referral to the university hospital is not possible.

The following case addresses the question of whether or not a method was available.

AVAILABLE METHOD

An injury occurred in conjunction with a cosmetic procedure. After retrospective assessment the panel felt that the injury could have been avoided by using an alternative method. Moreover, the alternative procedure in and of itself would have met the patient's care needs in a less hazardous way. However, the patient had not accepted the alternative treatment method and therefore it was not possible to use it. Since the alternative method was therefore not available, the panel felt that the patient was not entitled to compensation (Reg. no. 174/1999 – PRS 1999:01).

Lack of resources as a reason for compensation can only be claimed if it had been possible, in the individual case, to use existing resources in a different way or to use additional resources.

MONITORING OF INTRAVENOUS TREATMENT IN PREMATURE INFANT

A boy was extremely premature when born in week 26. Because of an intestinal injury it was necessary to administer hypertonic solutions intravenously for nutrition through an injection needle on the dorsum of the foot. At one point, while the boy was receiving care in the neonatal ward, the fluid infiltrated subcutaneously. An open wound developed on the foot which became infected with pseudomonas pyocyaneus, after which the boy developed septicemia and heart failure.

The Patient Claims Panel did not accept the claim of inadequate resources as a reason for failing to check the intravenous treatment frequently enough. Taking into account the circumstances in the relevant case, according to the panel, priorities could have been adjusted to allow more frequent controls. According to the panel, had this been the case the injury that occurred from the subcutaneous infiltration of the nutri-

tion solution essentially could have been prevented. Compensation should therefore be awarded for the injury (Reg. no. 259/1990).

UNSUCCESSFUL WISDOM TOOTH REMOVAL

A woman underwent an unsuccessful attempt to have a wisdom tooth removed. The tooth could not be removed surgically until one week later at an oral surgery medical center. According to the claim settlement company, the patient was not entitled to patient compensation for the extra suffering due to the long waiting time for surgery. However, according to the Patient Claims Panel, it was not consistent with good medical care to wait so long for the operation, considering that the patient suffered severe pain and anxiety. Considering the patient's problems and the amount of time needed for a procedure of this type, the care provider should have reallocated existing resources—and according to the panel, it must have been possible to have done so—and arranged for surgery emergently at the local hospital or at another available hospital. The panel therefore concluded that the unnecessary suffering due to the long waiting time constituted an injury (Reg. no. 644/2001 – PRS 2002:04).

MONITORING AFTER SURGERY

The patient had prostate surgery. The day after the operation the patient became disoriented and pulled out the drain tube, which may have caused injury. According to the Patient Claims Panel, the patient's action could not have been prevented with the available medical resources (Reg. no. 39/1982).

The condition that the alternative method, in addition to meeting the patient's care needs (b), must pose *an overall lower risk* (c) means that it is not sufficient for it to be possible to avoid injury through another method. In general the method must also involve a lower risk of injury. Below are some examples of assessments on this point.

IMPACT ON SENSITIVITY DURING GASSERIAN GANGLION BLOCK

The patient had severe pain on the right side of the face, known as trigeminal neuralgia. Pharmacologic therapy proved to have no effect and therefore the doctor carried out a glycerol block of the gasserian ganglion. The treatment affected the sensitivity in this neuron's area of distribution, which in turn gradually caused a serious visual impairment because of a wound on the cornea. According to the Patient Claims Panel, this injury could not have been avoided by performing the chosen treatment in a different manner.

Thereafter the panel concluded that three alternative methods were available. In addition to the drug therapy that was tried, treatment could be aimed at the nerve's ganglion, either through so called thermocoagulation or microsurgery. According to the panel, neither thermocoagulation nor microsurgery would have met the patient's care needs in a less hazardous way. Consequently, according to the panel the patient was not entitled to compensation (Reg. no. 157/1998 – PRS 1998:08).

EMBOLIZATION OF VASCULAR MALFORMATION IN THE BRAIN

The patient had a vascular malformation in the brain. The angiography showed bleeding from the malformation. This was treated with embolization, which was carried out without complications. Subsequently, however, a large cerebral hemorrhage occurred in the area of the malformation, which led to extensive brain damage and total paralysis.

The Patient Claims Panel concluded that it had been necessary to treat the hemorrhage from the vascular malformation and that this was done using an accepted method. Nothing suggested that any incorrect technique was used during the procedure. The hemorrhage that occurred after the embolisation was an unavoidable complication of the procedure. According to the panel, the alternative treatment methods discussed – radiation or open surgery – did not meet the requirement that the patient's care needs would be handled in a less hazardous way. Compensation was therefore not awarded (Reg. no. 379/1998 – PRS 1999:02).

PANCREATITIS AFTER ERCP EXAMINATION

The Patient Claims Panel concluded that the pancreatitis the patient sustained after the ERCP examination could not have been avoided if the chosen procedure had been performed in a different way. However, given that three previous ERCP attempts were made without successfully mapping the deep bile ducts, according to the panel the indication for the examination was weak and the patient's care needs could have been met in a less hazardous way by not performing the ERCP and instead just examining the patient with a contrast-enhanced radiography of the biliary tract. In this case the inflammation could have been avoided and therefore the patient was entitled to compensation (Reg. no. 30/2000 – PRS 2000:05).

NERVE DAMAGE WITH SPINAL ANESTHESIA

The patient received spinal anesthesia with a planned cesarean section. The patient reported an injury because the anesthesia left her with residual pain in the hip, leg and lumbar spine. The Patient Claims Panel initially concluded that during the anesthetic procedure the tip of the needle probably hit a nerve, which caused the problems, and that the injury could not have been avoided since it was not known exactly how the nerves run in the space in which the needle was inserted. According to the panel the reported injury could not have been avoided by performing the chosen procedure in a different manner.

The question then was whether a different pain relief method could have been used that would have met the patient's care needs in a less hazardous way. According to the panel, the method that came into question—performing the cesarean section under general anesthesia—did not particularly fulfill this requirement considering the effect of the anesthetic on the child. Therefore a compensable injury was not considered to be present (Reg. no. 53/2001).

In another case the Patient Claims Panel stated that generally speaking, general anesthesia poses a greater risk of injury than central blocks (spinal and epidural anesthesia). In the case at hand, a nerve root injury occurred after spinal anesthesia

for prostate surgery. The panel concluded that spinal anesthesia was the preferred method for this type of procedure and that although general anesthesia would pose little risk of nerve root injury, it could entail other complications, such as myocardial infarction and pulmonary complications. The choice of general anesthesia would therefore have posed a greater risk of injury (Reg. no. 156/2002).

SENSORY LOSS AFTER MANDIBULAR ANESTHESIA

During treatment of tooth 44 the patient sustained a sensory loss because of a nerve injury in conjunction with anesthetic blockade (mandibular anesthesia). The injury was considered unavoidable for the chosen procedure.

However, according to the panel, during treatment of tooth 44 (unlike, for example, tooth 46), an alternative anesthesia method—infiltration anesthesia—could be used. Had this method of anesthesia been chosen the nerve injury could have been avoided. Infiltration anesthesia, which was an available method of anesthesia, would have both met the patient's needs for anesthesia and been less hazardous. Therefore the panel found that a compensable injury was present (Reg. no. 323/1999 – PRS 1999:04).

2. *Material-related injury*

Patient compensation is allowed for an injury caused by a defect in, or the defective use of, a medical device product or hospital equipment used for examination, care, treatment or any similar measure.

The concept of "medical device product" includes appliances, instruments, equipments and other assistive devices used in the healthcare setting. Appliances and instruments include both simple items such as knives, forceps, syringes and cannulae and complicated appliances such as dialysis machines and respirators. The product concept also includes implants. In effect, this refers to materials that are connected to, inserted in or replace biological tissue, such as pacemakers, spirals, artificial joints and blood vessels, as well as tissue-integrated dental prostheses. The concept of medical device product also includes sterile disposable items and other consumables. In one case the Patient Claims Panel concluded that even crutches are covered by the concept of medical device product (Reg. no. 14/2000 – PRS 2000:11).

Hospital equipment includes items such as beds, lamps and chairs. "Defective" means that a product does not work as specified in a manual, product specification or similar document. "Defective use" refers to situations such as when medical personnel use an instrument without following instructions.

If patient injury compensation has been paid for an injury covered by the Product Liability Act the insurer has the right to recourse against the party who is liable to pay damages under this Act.

Material-related injuries are rarely reported. According to statistics from LÖF, fewer than 1 percent of all claims involve material-related injuries. Over the years the panel has only considered a few such cases.

Injury because of defective medical equipment

The case at hand involves a 30-year old male who suffered a cerebral hemorrhage from what later proved to be a large arteriovenous malformation. He was treated with a ventricular drain and recovered well without any permanent neurological sequelae. Since there was risk of recurrent hemorrhage doctors planned to treat the malformation. Open surgery would have been associated with major technical difficulties along with a risk of permanent injury. The vascular malformation was even too large to treat with stereotactic radiosurgery. Therefore the doctors chose selective embolization in order to first reduce the size of the malformation so that later it could become appropriate for radiation or possibly open surgery. Doctors made a total of three attempts at embolization. When the patient came out of anesthesia after the third treatment he had a right-sided paralysis and speech difficulties.

The Patient Claims Panel felt that it was highly probable that the complications of right-sided paralysis and speech problems arose due to an occlusion of the vessels that supply the internal capsule, which occurred during catheterization. It was highly probable that the small emboli, which occluded the vessels, were due to technical problems that arose during treatment because the microcatheter and the guidewire did not fit together. Moreover, the panel concluded that the purpose of the provision in Section 6, first paragraph, indent 2 of the Patient Injury Act was to protect patients against injuries caused by medical device products and medical equipment that are not sufficiently safe or handled safely enough as can reasonably be expected in the healthcare setting. The concept "defective" in the provision has its equivalent in the Product Liability Act's "safety defect." The concept of safety defect usually refers to three categories: design defect, manufacturing defect and instruction defect. The latter category, instruction defect, refers to such defects that arise when incorrect, incomplete or omitted instructions make a product hazardous. Thus "defect" in the Patient Injury Act also refers to these defective instructions. In this case the documentation enclosed with the catheter did not indicate, even though it should have been known, that the catheter did not work well together with the guidewire used during treatment. The defective instructions for the catheter led to the situation in which the personnel handled the catheter and the guidewire incorrectly and caused an injury. The patient was therefore entitled to patient compensation for the injury (Reg. no. 6/1999 – PRS 1999:09).

3. Diagnostic injury

Compensation can also be paid in the event of incorrect diagnoses. Unlike other patient injuries, here the patient injury involves compensating some of the effects of the underlying disease and not actually an injury caused by the medical care provided. A diagnostic injury is present when an actual observable symptom was ignored during diagnosis or was interpreted in a manner

that deviates from the normal standards applicable to an experienced specialist in the field in question and therefore no treatment outcome is achieved, or is delayed or worsened.

Retrospective reasoning is not used when applying this provision. Therefore it is the knowledge possessed by the experienced specialist at the *time of diagnosis* that is relevant. In other words, if at the time of diagnosis the correct diagnosis is made, based on what was known at that time, the injury is not compensable, even though knowledge acquired subsequently may prove that the diagnosis was incorrect.

Typical compensable diagnostic injuries include overlooked fractures and dislocations, as well as tendon and nerve injuries. Fractures can often be missed because of failure to carry out x-ray studies or function tests. Other medical conditions that often result from diagnostic injuries are malignant diseases and blood clot formation.

In order for compensation to be paid for a delayed diagnosis injury must have occurred due to the delay in diagnosis. The injury usually consists of the absence of an otherwise expected improvement and can be described as an added injury in relation to what would have been the outcome if the patient's disease had initially been diagnosed and appropriate treatment initiated for that diagnosis.

INTESTINAL PERFORATION

Intestinal perforation occurred during surgery for uterine cancer. This could have been diagnosed earlier, in which case the consequences of the injury would have been less extensive. The *added injury* was considered compensable (Reg. no. 113/1989).

HERNIATED DISC

The patient had been treated for back pain over a period of time. Conventional examinations including x-ray did not show any herniated disc. After more time passed myelography was done, showing a herniated disc that motivated surgery. Subsequently the problems essentially disappeared. The Patient Claims Panel felt that adequate examinations were done and that no compensation for the problems that resulted from not carrying out the surgery earlier was justified (Reg. no. 61 and 69/1988).

As mentioned above, patients report delayed diagnosis of malignant disease relatively frequently and it is usually a question of breast cancer. However, even if it can be concluded that the correct diagnosis could have been made earlier, this situation does not always mean that physical injury arose as a consequence of delayed diagnosis. For example, an earlier correct diagnosis would have made no difference to therapy with respect to surgery, radiotherapy, chemotherapy, or endocrine therapy than what actually occurred in the individual case. As long as the delayed diagnosis had no effect on future

prognosis, no actual physical injury occurred because of the delay in making the correct diagnosis. However, if in such a case the delayed diagnosis with preponderant probability entailed some growth of the tumor, compensation for non-economic losses of SEK 25,000 is always paid for the mental anguish that the patient thereby suffers, including worry and anxiety with respect to a possible increased risk of recurrence and death from the disease (Reg. no. 587/2002 – PRS 2003:01).

4. Infection injury

Patient injury compensation is also allowed if an injury with preponderant probability is caused by an *infectious agent that has led to transmission of the infection to a patient* in conjunction with examination, care, treatment or any similar measure. Injuries caused by infectious agents present in the patient before treatment is therefore not compensable on these grounds. Examples include bacteria in the intestines or mouth. However, it can be difficult to determine whether an infection is caused by bacteria found on the patient's skin or if the bacteria came from some other source, by some other means.

When an infection is due to transmission of an infectious agent compensation still is not allowed in cases where circumstances are such that the infection *must reasonably be tolerated*. During this assessment the panel considers the nature and severity of the underlying disease, the patient's general state of health, the possibility of anticipating the infection and the severity of the infection. The more serious the underlying disease, the greater the complications the patient must tolerate without the right to compensation. Similarly, the higher the risk of infection, the lower the chance for compensation. If the risk of injury was negligible or difficult to predict, however, the conditions for compensation may be fulfilled. The assessment of reasonableness, which can often be difficult, therefore presumes that the panel makes a total assessment of the various criteria.

Below are examples of cases in which an infection was considered to have been caused by the patient's own bacteria and therefore not transmitted.

INFECTION AFTER DENTAL TREATMENT

A middle-aged man was afflicted by a cerebral abscess in conjunction with dental treatment. The Patient Claims Panel concluded that if an infection arises after a procedure in a part of the body that may be considered "unclean" from a bacteriological point of view, in other words, an infection that arises in conjunction with treatment in the oral cavity which has a natural and abundant presence of bacteria, it cannot be considered that the infection with preponderant probability was transmitted in conjunction with the treatment procedure. In order for an infection to be considered to have been transmitted in conjunction with a medical procedure in an "unclean" area, according to the panel, it must be possible to demonstrate that the infection was not

caused by the body's own bacteria. In this case the infection was caused by streptococcus milleri bacteria, which are normally found in the oral cavity. The panel concluded that in conjunction with the actual dental treatment an increased risk arose that the patient's own oral cavity bacteria could enter the bloodstream and that in extremely rare cases this could lead to development of an abscess in the brain. According to the panel, in this case the infection had thus been caused by the patient's own bacteria. Patient compensation could therefore not be awarded for the infection (Reg. no. 51/2002 – PRS 2002:09).

INFECTION AFTER PROCEDURE VIA THE RECTUM

An infection occurred in conjunction with a rectal procedure. The infection had been caused by bacilli which are normally found in the intestine. It was therefore the patient's own bacteria that caused the infection and consequently compensation was not allowed (Reg. no. 741/2001).

INFECTION AFTER GALL BLADDER SURGERY

A woman was operated emergently for inflammation of the gall bladder. After the procedure she suffered an abdominal abscess. The Patient Claims Panel felt that it was highly unlikely that the infectious agent was transmitted from the outside during gall bladder surgery and that the source of the infection was considered to have been the gall bladder which was already inflamed prior to the procedure. Patient compensation was not allowed (Reg. no. 680/2003).

UMBILICAL CORD INFECTION – NEWBORN CHILD

About a day before discharging a neonate, doctors observed that the umbilicus was infected with bacteria, including staphylococcus aureus. The infection healed after about one month. The panel did not consider it likely that the infection was transmitted through some medical procedure, but probably arose through bacteria from the skin. Consequently no compensation was allowed (Reg. no. 18/1988).

OPEN WOUND

The patient was treated for an open wound and was not considered eligible for compensation because the infection was not considered to have been transmitted through the medical measure (Reg. no. 323/1990).

An infection considered to have occurred because the infectious agent was transmitted usually has to be tolerated, without the right to compensation in the following circumstances: The infection was minor and only caused problems for a short period. The underlying disease is considerably more serious than the infection. The infection did not affect treatment outcome or duration. The infection is an expected complication that must be calculated into the equation.

Examples of treatments that have an elevated risk of infection are certain catheter treatments, transplantations and treatment that compromises the

immune system. Infections that occur during such treatments must therefore often be tolerated. Another type of case in which conditions are such that the injury can be accepted are when the infection arises in conjunction with a procedure in a field with impaired circulation.

Below are examples of cases where an infection must reasonably be tolerated without the right to compensation.

INFECTION AFTER CATARACT OPERATION

A patient who had a cataract and elevated pressure in one eye was operated in an attempt to save the vision in that eye. After the operation an inflammation in the eye's inner structure occurred, which resulted in vitreous body surgery. The infection prolonged the healing and treatment period, but then healed without affecting the surgical outcome. The patient's vision improved compared with before surgery. The Patient Claims Panel concluded that the ophthalmic disease was significantly more serious than the infection and that the operation was necessary to save the vision in the eye, since the patient otherwise probably would have become blind in this eye. Moreover, the panel concluded that the infection was relatively mild, that it only caused problems during a short period, that it healed and that it did not affect surgical outcome. Even if the risk of infection was minor and difficult to anticipate, it had to be reasonably tolerated without the right to compensation (Reg. no. 63/1998 – PRS 1998:03). However, in a similar case in which infection led to blindness compensation was allowed (Reg. no. 99/1998 – PRS 1998:05).

INFECTION AFTER KNEE SURGERY

An older man had knee replacement surgery because of pain in his left knee. Examination before surgery showed pronounced osteoarthritis. In connection with the operation an infection occurred that healed after about three months. The patient continued to receive antibiotics for a period thereafter and surgery on the patient's other knee was postponed. However, the infection did not produce any residual problems. Especially taking into account the serious underlying disease – knee osteoarthritis – and that the infection, even though it could not be predicted, did not jeopardize the function of the prosthesis, the Patient Claims Panel felt that the infection must reasonably be tolerated without the right to patient compensation (Reg. no. 7/1999 – PRS 1999:06).

INFECTION AFTER SURGERY OF ANKLE FRACTURE

The case involved a middle-aged man who suffered a right-sided ankle fracture. Three weeks after the operation a staphylococcal infection was noted. Antibiotics were initiated. The patient was on sick leave for a total of four months and the infection healed without any residual disfigurement. According to the claim settlement company, the ankle surgery and the reported infection were related. In this case the patient is entitled to compensation unless circumstances are such that the infection must reasonably be tolerated. According to the Patient Claims Panel, in this case the original right-sided ankle fracture was much more serious than the infection. The panel noted that the ankle fracture was relatively extensive with a spiral break in the

lower portion of the fibula, a tibiofibular separation—that is, the connection between the fibula and the tibia—and malpositioning of the ankle. Surgery was therefore necessary to treat the fracture and the connective tissue which was simultaneously injured. According to the panel the infection was relatively mild. It was superficial and therefore did not involve the joint, affect healing of the fracture, or have any damaging effect on joint cartilage and therefore did not cause any residual problems. Moreover, according to the panel it was not highly probable that the infection prolonged the period of acute illness. According to the required assessment of reasonableness, the panel determined that the patient would therefore have to tolerate the infection without being entitled to compensation. Thus no compensable patient injury was present (Reg. no. 83/1998 – PRS 1998:04).

As an example of circumstances that suggest the right to compensation the following can be mentioned. The infection was more serious than the underlying disease or was not reasonable in relation to the conditions of treatment. The infection resulted in a life-threatening condition, chronic treatment or residual deformity. The risk of infection was minor and infection difficult to anticipate. The expected surgical outcome was worsened or absent because of the infection.

The difficulties of reaching a reasonable balance between when an infection has to be tolerated and when it should not be tolerated can particularly be seen in cases involving patients with serious cardiac diseases, illustrated by the following case.

INFECTION AFTER CORONARY ARTERY BYPASS SURGERY

A patient, who underwent coronary artery bypass surgery because of unstable angina pectoris after multiple myocardial infarctions, suffered a mediastinal infection after the operation, which led to surgery with evacuation of infected liquid in the pleura and pericardium. The patient was then treated with drainage and needed breathing support in a respirator. After discharge the patient returned because of fistula formation and a new wound infection. The wound had to be opened and a partial skin transplant carried out. Following discharge the patient continued with antibiotics and returned for regular wound checks.

The Patient Claims Panel concluded that the coronary artery disease was serious and that the patient ran the risk of developing a new infarction with lethal outcome and therefore the coronary artery bypass surgery was medically justified. The panel also concluded that there was an elevated risk of complications because the patient suffered from diabetes. However, apparently the patient was in good condition before the operation and also in good health, the diabetes was adult-onset diabetes controlled by diet alone and the operation was not emergent, but planned. Even with a risk for new myocardial infarction, according to the panel it would have been possible for the patient to continue living a normal life without surgery. Moreover, the panel concluded that the deep infection that arose could not have been predicted and that the infection was extremely serious and placed the patient in a life-threatening situation requiring an emergency procedure with uncertain outcome. The direct acute course

of the disease due to the infection was also prolonged with intensive care treatment and multiple reoperations. Finally, the panel concluded that the course of the disease even after hospitalization was prolonged and that there was a risk that the infection could cause permanent problems. The Patient Claims Panel therefore felt that the infection was not reasonable in relation to the underlying disease, even though this disease was extremely serious, and therefore compensation should be awarded (Reg. no. 81/1999 – PRS 1999:07).

In a similar case (Reg. no. 293/2001 – PRS 2001:15) the consequences of the infection were not as serious. After the period of acute infection the patient was completely restored and able to work. Thus the infection did not entail any permanent disability. In an overall assessment of the circumstances in this case the panel found, unlike in the previous case, that the patient could reasonably be expected to tolerate the infection without the right to compensation.

INFECTION AFTER TOTAL HIP REPLACEMENT SURGERY

The patient, a 76-year old man, had suffered from years of pain in the right hip due to osteoarthritis. Doctors found a seriously worn hip joint verified by x-ray and decided to perform a total hip replacement on the right side. The routine procedure was unremarkable and the patient received the usual antibiotic prophylaxis. Postoperatively an infection developed that was treated with antibiotics and an irrigation drain was inserted on two occasions. The doctors thought that it was necessary to remove the prosthesis but were able to avoid this through an operation about 1½ months after the original procedure. During reoperation the patient received a new irrigation drain and the muscles were resutured. Following this the infection healed. Doctors believed that the infection was due to an infectious agent transmitted during the first operation. The Patient Claims Panel concluded that the patient had the right to compensation unless circumstances are such that the infection must reasonably be tolerated. In this case the risk of infection according to the panel was minor and the infection was difficult to anticipate. Regarding the consequences of the infection the panel concluded that it was evident that the patient was hospitalized for an estimated one and a half months and that the infection thereafter required daily intravenous treatment with antibiotics until three months after discharge from the hospital. According to the patient chart, the patient also had a deep vein thrombosis which was considered to be related to the infection. According to the Patient Claims Panel the infection in addition probably had some effect on the final outcome after hip surgery. Given the factors specified above, according to the panel the consequences of the infection had to be considered relatively serious. The Patient Claims Panel felt – when making the required assessment of reasonableness – that under these circumstances in which the infection was difficult to anticipate, combined with the severity of the infection in relation to the basic injury, the patient should not reasonably have to tolerate the infection and was entitled to compensation. According to the panel a compensable patient injury was therefore present (Reg. no. 292/ 2000 – PRS 2000:17).

INFECTION IN DISC AFTER HERNIATED DISC SURGERY

The patient, a 42-year old woman, arrived emergently at the department of orthopedics because of right-sided sciatica and CT-verified disc herniation L5 to L6, right side. Onset of the problem was 1½ months earlier and the pain did not respond to conservative treatment with oral analgesics. When the patient arrived at the department of orthopedics she had problems urinating. Since the pain was pronounced doctors found that surgery was indicated and the operation was carried out the next day. Almost one month later the patient experienced an increase in pain in the lumbar spine with paresthesias along the left buttock and back of the left calf. An MRI showed soft tissue swelling and edema. Infection could not be ruled out, so antibiotics were initiated for suspect discitis. The patient was subsequently hospitalized several times because of pain that required morphine. She received long-term antibiotic treatment for about eight months. Shortly after finishing the medication she returned for hospital care with increasing pain, vague discomfort and general malaise and was admitted for pain relief and further examination. After contact with infectious disease specialists she was referred for MRI and antibiotics were re-initiated. Since the discitis entailed pain that was difficult to control the patient was referred to the university hospital for an opinion on fusion of the vertebrae in the discitis area.

The Patient Claims Panel concluded that the infection was due to an infectious agent transmitted during surgery for the herniated disc and that the patient was entitled to compensation, unless circumstances were such that the infection must reasonably be tolerated. In this case the risk of infection according to the panel was minor and the infection was difficult to anticipate. The panel also concluded that the patient's infection was extremely prolonged and that one note in the patient chart 13 months after the operation stated that at this point in time the infection still had not definitely resolved. Moreover, the infection also required long-term treatment with antibiotics. According to the panel, the infection caused the patient considerable suffering for a lengthy period with pain that was difficult to control and periodically required morphine. In addition, according to the panel, because the infection resulted in sequelae it jeopardized the surgical outcome. Finally, the panel concluded that it was also evident from the investigation that fusion of the vertebrae in the discitis area was discussed. In an assessment of the total picture the Patient Claims Panel felt that the consequences of the infection were more serious than the underlying disease. The panel also concluded that the risk of infection had been minor and that the infection was difficult to anticipate. The infection therefore was not considered to have been reasonable in relation to the underlying disease and therefore the patient should not have to tolerate the infection without the right to compensation. In other words, the patient was entitled to compensation (Reg. no. 305/2000 – PRS 2000:19).

5. *Accident-related injury*

Patient injury compensation is allowed if an injury has been caused by an accident occurring in conjunction with examination, care, treatment or any similar measure, during patient transport, or in conjunction with fire, or in connection with damage to healthcare premises or equipment.

An important principle of this rule is that coverage applies to accidents that are related to and typical of healthcare activities. The right to compensation is therefore limited to the particular risks related to that field. Normal accidents that may occur anywhere, regardless of the healthcare context, are excluded from coverage. For example, a patient who can usually manage independently should not receive compensation for an accident that occurs during an ordinary hospitalization if the patient trips on the way to the patient lounge or toilet facilities. Such an accident cannot be considered to be care-related. However, compensation should be paid for an accident that occurs in conjunction with treatment, such as if a patient in connection with an examination is dropped from a bed, or if the patient falls down while practicing walking while accompanied by personnel.

It is not necessary for the patient to have direct contact with healthcare workers; it is sufficient for the patient to be placed in a situation that increases the risk of accidents.

The following cases are examples of assessments of accident-related injuries.

SLIPPING INJURY

An older patient who was lying on an examination table while waiting for help with dressing after an ECG, tried to get up and climb down from the table, slipped and was injured. At the time that the accident occurred the patient was still considered to be under treatment and compensation was allowed (Reg. no. 118/1980).

ACCIDENT DURING TOILET VISIT

The accident happened to a patient admitted to a long-term care facility, when the patient was en route to the toilet and was not considered to constitute a compensable accident covered by the compensation provisions (Reg. no. 43/1989).

ADDICT WHO TRIED TO ESCAPE

The patient was hospitalized under the Act on care of addicts. On an unguarded occasion the patient tried to leave the hospital by tying a blanket to the balcony railing and then climbing down. However, he lost his hold and fell, whereby he was injured. The accident was not considered to have been caused in conjunction with a medical measure (Reg. no. 8/ 1990).

6. Medication injury

Patient compensation is also paid if an injury is a consequence of a medication that was prescribed or distributed in conflict with regulations or instructions. Compensation is therefore allowed for injuries that arise because the medication is used incorrectly, with an incorrect dosage or if a contraindication is present. Other injuries caused by medications—medical drug side

effects—are not covered by the Patient Injury Act. These injuries can be considered instead under the compensation provisions of the pharmaceutical insurance.

INCORRECT DISTRIBUTION

A pharmacy incorrectly gave the patient 100 Imovane (hypnotic) tablets instead of the 10 tablets specified in the prescription. Three days later the patient came in to an emergency room after taking an overdose of Imovane. According to the Patient Claims Panel, the mistake made when the patient was given the tablets did not relate to the overdose three days later such that adequate causality could be considered to be present. Therefore the patient was not entitled to patient injury compensation (Reg. no. 2/2003).

A few other issues related to the right to compensation for patient injuries

Significance of patient information and patient consent

Healthcare legislation

Swedish healthcare legislation imposes relatively extensive requirements for medical treatment with respect to consultation with the patient. In principle, patient consent is required for planned procedures and information must be provided about such procedures, as well as any associated risks. The question of information and obtaining consent is particularly important in procedures for which no actual medical indication is present, such as certain cosmetic procedures.

The comprehensive healthcare legislation consists most notably of the Health and Medical Services Act (1982:763) and the Swedish Act on professional activity in health and medical services (1998:531). Three statements in these laws in particular have significance for patients' opportunity to exercise their right to self-determination. Medical care shall be based on *respect for the patient's self-determination*, and insofar as possible it shall be planned in *consultation* with the patient and the patient shall be given *personalized information* about their individual state of health and about available methods for examination, care and treatment.

Healthcare legislation also includes the Swedish Patient Records Act (1985:562). An important addition to this Act beginning on January 1, 1999, is that, if information is available, the patient chart should always include a "statement about the information provided to the patient and about the opinions reached about the choice of treatment options and about the possibility of a new medical assessment".

The Patient Injury Act

In many of the cases in which the patient reports an injury the issue of inadequate information is addressed. The Patient Injury Act does not specifically address the information issue nor does it have any independent significance for the right to compensation. Consequently, the compensation provisions

do not say that the patient would be eligible for compensation because the patient was provided with inadequate information or because of failure to gather consent from the patient in conjunction with medical treatment. Instead, the panel shall investigate the objective medical course of events and compensation shall be allowed regardless of whether or not information about special risks associated with the treatment was provided.

Compensation under the rules governing tort law

However, as previously, a patient who feels that he or she has sustained an injury due to inadequate information or failure to obtain consent, can assert a claim for compensation under the rules of general tort law. In such cases the patient however must show that the injury resulted from an error or omission by the medical personnel.

In these cases the Patient Claims Panel, which must submit advisory statements in compensation cases according to the voluntary patient insurance or according to the Patient Injury Act, can also deliver its opinion on the general tort claim from the patient or other injured party. In a number of cases the panel has also considered more closely the patient's right to compensation under the rules of tort law because of the claim of an injury that resulted from inadequate information or failure to obtain consent in conjunction with medical treatment.

If a patient states that certain information was not provided, as current practice is understood, the care provider has the burden of proving that the necessary information was provided. The exact degree to which the burden of proof shall fall on the care provider is unclear since the Supreme Court of Sweden has not considered this particular question. In most cases settled in District Courts or Courts of Appeal, the care provider has been required in each case to at least be able to *establish probability* that the obligation to provide information to the patient has been met. However, in some cases the care provider must meet a higher burden of proof by *demonstrating* that adequate information was provided.

Even if the information was inadequate, it does not always have to mean that the circumstances can be blamed on an error or omission on the part of medical personnel. If a complication is extremely rare, inadequate information about the risk of this complication in and of itself would not constitute negligence. The treating doctor's obligation to provide information cannot be considered to cover all conceivable risks and complications that may result from a procedure. The requirement for information must be reasonable in relation to the planned treatment.

If a doctor is not considered to have met the obligation to provide information, the next question is whether failure to inform and obtain consent can be considered to be related to the injury in such a way that liability for

damages arises. In other words, would the patient have refused treatment if he or she had been informed about the risk of injury of the type that arose? While weighing this question it may be found, for example, that a severe injury could not have been avoided if the doctor had met the obligation to provide information, since the patient would still reasonably have agreed to the procedure, considering that it was essential for the patient.

SCOPE OF DOCTOR'S OBLIGATION TO PROVIDE INFORMATION

A patient suffered from severe chest pain and underwent a "sympathectomy," which involves cutting nerves bilaterally on the inside of the chest. After the operation the patient had severe problems with pain, in part of the same type as previously and in part a newly added deep pain posteriorly in the back. The patient was afflicted with anxiety, worry and depression because of what happened. The patient stated, among other things, that the operating doctor should have informed him of the risk of the complication that afflicted him.

The Patient Claims Panel, which found that the newly suffered painful condition could not have been avoided, i.e., prevented or stopped, through another procedure, also considered whether there was such a lack of information that compensation could be allowed under the general rules governing tort law. When considering this issue the panel felt that the treating doctor's obligation to provide information cannot include each and every conceivable risk and complication that the procedure might cause. In a decision from the Health and Medical Care Liability Board (HSAN, Hälso- och Sjukvårdens Ansvarsnämnd), which was available at the time of the assessment, HSAN concluded that when providing information to a patient before a procedure, doctors usually do not discuss the risk of extremely rare complications such as the one suffered by this patient. The Patient Claims Panel felt that because the unexplained painful condition was considered to be extremely unusual, the doctor or care provider could not be blamed for negligence due to inadequate information. Consequently, the patient was not entitled to compensation under the general rules governing tort law (Reg. no. 655/2000 – PRS 2000:09).

FAILURE TO OBTAIN CONSENT

A case involved a farsighted young man who no longer wanted to be dependent on eyeglasses. He therefore had laser surgery on one eye. The procedure went smoothly. At his recheck one month after the procedure his doctor noticed worsening vision and "haze" (cloudy cornea). Eight months later the patient's vision had further deteriorated. A relatively large scar had formed.

Among other things, the panel found that the scarring could not have been avoided by performing the laser treatment differently and that compensation therefore could not be paid from the voluntary patient insurance. The panel then considered the case with respect to the rules of tort law. By way of introduction, the panel concluded that it is particularly important to inform the patient and obtain consent for procedures in which there is no actual medical indication, which at the time of

treatment involves a healthy organ from a healthcare point of view, when the patient wants to correct his farsighted vision in order to avoid wearing glasses.

HSAN's investigation of the case did not show that the doctor orally informed the patient about the risk of permanent visual impairment and in his written information the doctor had omitted essential information about the risks of permanent functional impairment. The patient therefore did not have reason to interpret the written information in any other way than that laser treatment in the worst case could not improve his farsighted vision and that he would also have to keep wearing glasses. The doctor was therefore considered negligent because he did not meet the obligation to inform the patient about the risk of permanent visual impairment and HSAN gave him a warning. The Patient Claims Panel shared HSAN's opinion that the doctor did not meet his obligation to provide information due to negligence. The patient therefore did not have the opportunity to give his consent specifically for the laser treatment.

The question was then whether the doctor's negligence to inform and obtain consent was related to the injury in such a way that liability for damages arose. In this assessment the panel had to decide whether the visual impairment could have been avoided if adequate information had been provided. In other words would the patient have refused to have laser treatment if he had been informed that his vision could be permanently impaired?

The patient stated that he would not have had the treatment if he had been aware of a risk of permanent injury. Considering that the treatment involved was not necessary and that there was a risk of permanent visual impairment, the Patient Claims Panel found no reason to question this information. A causal correlation was therefore found to be present between the negligent failure to inform and obtain consent and the injury. The patient was therefore eligible for compensation under the rules of tort law for the visual impairment of his left eye (Reg. no. 495/1999 – PRS 2000:07).

NO CAUSAL RELATIONSHIP BETWEEN INADEQUATE INFORMATION, IF ANY, AND INJURY

A 44-year old man with an aortic valve problem had heart surgery with a heart-lung machine. After the operation he suffered from concentration problems, memory lapses and inability to carry out moderately complex intellectual tasks. A blood flow study showed signs of brain damage. The patient stated, among other things, that no one told him before the operation that the procedure was associated with the risk of brain damage.

The Patient Claims Panel concluded, among other things, that the reported brain damage, which seriously impaired the patient's cognitive ability, was probably caused by particle or air embolization related to the heart surgery and the heart-lung machine. The complication, which is well known, occurs in 2 to 4 percent of operations of this particular type and could not have been avoided through another management of the chosen procedures or through the choice of another available procedure, which according to a retrospective assessment from a medical point of view, would have met the patient's care needs in a less hazardous way. Therefore the injury was not compensable.

Because of the patient's statement about inadequate information the panel agreed with the claim settlement company that the Patient Injury Act did not contain any

provision for compensation for any inadequacies in the information provided to a patient before treatment about the specific treatment risks that may occur. For this reason the panel also considered whether there was such an inadequacy in the information that compensation could be allowed under the general rules governing tort law. In this consideration the panel concluded that all heart surgery of this type poses a risk of a complication such as the one that occurred in this case. Patients of all ages are at risk, though the risk is greater in older patients. Neurological damage occurs, as was mentioned above, in 2 to 4 percent of these procedures. Since the risk cannot be considered insignificant, the question may arise whether the patient should have been informed about it before the operation. However, the panel did not examine this question in greater depth because it was highly probable that the patient would have undergone the relevant procedure even if he had received complete information about the risks. This assumption is based on the fact that the involved procedure was essential for the patient's life. If the operation had not been carried out the patient would have died in the near future. Therefore the panel did not find a causal relationship between the possibly inadequate information and the patient's brain damage. The right to compensation under the general rules governing tort law was therefore not present either (Reg. no. 224/2003 – PRS 2003:03).

Conclusion

The Patient Injury Act, like the previous compensation provisions of the voluntary insurance, has made it considerably easier for patients to receive compensation after suffering injuries caused by medical services. Although the Act is largely based on the previous compensation provisions of the voluntary insurance system, certain points have been changed. Compensable injuries now do not only include physical injuries as previously, but also *mental injuries*. Moreover, *retrospective reasoning with respect to choice of method* has been implemented together with the previous provision for retrospective reasoning on performance of the chosen method. The rules for compensating *infection injuries* have also changed so now no difference is made as to whether an infection is transmitted to "clean" areas, for which compensation in principle would be allowed, or to "unclean" areas which were not eligible for compensation. The decision is instead based on an assessment of reasonableness. Finally, in the Act an earlier provision for *catastrophic injuries* was dropped, which meant that compensation could be paid even if, for example, an injury that could not have been avoided occured during treatment of a trivial condition, provided the patient was afflicted by a severe disability or died. With respect to several of the specified points while drafting the legislation misgivings were mentioned about application problems and increased costs for investigation would arise and also that the new rules in certain respects could mean a worsening for the patients. For these reasons, among others, when the Patient Injury Act was first enacted it was stated that an overview would be carried out after the Act had been in force for a period of time.

In 2002 the Government appointed a commission of inquiry, "the Patient Injury Commission," which in 2004 submitted the report "The Patient Injury Act and Pharmaceutical Insurance – an overview" (SOU 2004:12). In the case of *mental injuries* the inquiry concluded that misgivings were unfounded with respect to the difficulty of investigating mental injuries and the attendant generation of increased expenses. At the same time the commission concluded that relatively few cases have been addressed to date and no reliable conclusions could be drawn. The commission did not recommend any amendment to the Act.

With reference to *retrospective assessment of choice of method* the commission recognized problems defining limits, but recommended no amendment on this point either. With respect to *infection injuries* the commission con-

cluded that medical science is making rapid progress and procedures are becoming increasingly sophisticated. The investigation also concluded that in many cases the risk of infection is obvious, but that it is difficult to determine whether infection is caused by infectious agents already present in the patient or if the bacteria derive from an external source. Given this background, according to the commission, from a medical point of view it was not justified to draw a strict boundary between clean and unclean areas, nor between the patient's own bacteria and bacteria transmitted or derived from an external source. The commission therefore proposed an amendment to the provision in the Patient Injury Act for infection injuries specifying that the point of departure be an infection arising in conjunction with a medical procedure, regardless of the area involved and regardless of whether or not the bacteria derive from an external source. When the panel draws such a conclusion it must consider the issue of reasonableness.

With respect to *catastrophic injuries*, the commission found cause to implement such a provision once again. According to the proposed legislation compensation shall therefore also be allowed in the absence of any other condition for compensation, when a medical procedure leads to severe disability, any other extremely serious complication, or death, and the injury is not reasonable in relation to the illness or injury that motivated the procedure or to the expected results of this measure.

Finally, it can be mentioned that the Patient Injury Commission proposed that the scope of this Act should be expanded to include care provided abroad upon referral by a county council and for which the county council accepts the responsibility for costs. The investigation also proposed editorial changes and clarifications in the paragraph regulating the possibility of compensation for various types of injuries.

The Ministry is currently addressing the Patient Injury Commission report. The proposed amendments appear to be well-founded and if implemented will result in improved opportunities for clearly and predictably assessing compensation issues for healthcare-related injuries. It is therefore important that it will not be long before these changes can be implemented.

The Patient Injury Act (1996:799)

Introductory provisions

SECTION 1

This Act contains provisions governing the right to patient injury compensation and the obligation of health care providers to have an insurance covering such compensation (patient insurance)

SECTION 2

Under this Act a person who voluntarily participates as an experimental subject in medical research or who donates an organ or other biological material for transplantation or for other medical purpose is considered to be equivalent to a patient.

SECTION 3

This Act only applies to injuries which have arisen in connection with health and medical care services in Sweden.

SECTION 4

The right to patient injury compensation may only be limited on the basis of circumstances which have occurred after the event during which the injury was incurred and which, according to the Insurance Contracts Act (2005:104), may entail a limitation of the insurer's obligation to pay the amount insured.

SECTION 5

In this Act

health and medical care services means: such activities as are subject to the Health and Medical Care Services Act (1982:763), the Dental Services Act (1985:125) or the Act (2001:499) on circumcision of boys, or other similar medical activities and activities within the retail trade with pharmaceuticals, always subject to the precondition that it is the matter of activities carried out by staff subject to Chapter 1 of the Act (1998:531) on Professional Activity In Health and Medical Care.

care provider means: state authority, county council or municipality as regards such health and medical care services as the authority, county council or municipality is responsible for (public care providers) as well as private persons who provide health and medical care services (private care providers). **Act 2001:501**

Entitlement to patient injury compensation

SECTION 6

Patient injury compensation is paid for personal injury to patients if the injuries with preponderant probability were caused by

1. examination, care, treatment or similar measure provided that the injury could have been avoided either by a different performance of the chosen procedure or by choosing some other available procedure which according to an assessment made retroactively from a medical point of view would have satisfied the need of treatment in a less hazardous way,
2. defects in the medico-technical products or hospital equipment used in the performance of an examination, care, treatment or similar measure, or improper use thereof,
3. an incorrect diagnosis,
4. transfer of a contagious substance entailing infection in connection with an examination, care, treatment or similar measure,
5. accidents in connection with an examination, care, treatment or similar measure or during a patient transport or in connection with a fire or other damage to health care premises or equipment, or
6. prescription or provision of pharmaceuticals in contravention of regulations or instructions.

When considering the right to compensation in accordance with the first paragraph, items 1 and 3, the guiding principle of action applicable is that of an experienced specialist or other experienced practitioner within the field.

There is no right to compensation in accordance with item 4 of the first paragraph in those cases where the circumstances are such that the infection must reasonably be tolerated. In that connection regard shall be paid to the nature and degree of severity of the illness or injury which the measure is related to, the patient's health status in other respects and the possibility of anticipating the infection.

Exceptions to the right to patient injury compensation

SECTION 7

Patient injury compensation is not paid if

1. the injury is a consequence of a necessary procedure for the diagnosis or treatment of an illness or injury which without treatment is downright life-threatening or entails severe disability, or
2. the injury is caused by pharmaceuticals in cases other than those mentioned in Section 6, first paragraph, item 6.

How the patient injury compensation is determined

SECTION 8

Patient injury compensation is determined in accordance with Chapter 5, Sections 1–5 and Chapter 6, Section 1 of the Tort Liability Act (1972:207) with the limitations stated in Sections 9–11 of this Act.

SECTION 9

When patient injury compensation is determined, a sum shall be deducted which is equal to one twentieth of the base amount under the National Insurance Act (1962:381) applicable when the compensation is determined.

SECTION 10

Patient injury compensation is for each event limited to at most 1,000 times the base amount under the National Insurance Act (1962:381) applicable when the compensation is determined. However, for each injury event the patient injury compensation is limited for each injured patient to at most 200 times this base amount.

The amounts stated in the first paragraph do not include interest or compensation for litigation costs.

SECTION 11

If the liability sum applicable under Section 10, first paragraph, first sentence is not sufficient to satisfy those who are entitled to compensation, their compensation is to be reduced by the same quotient portion for each of them.

If, after the occurrence of a case of injury there is a risk that a reduction under the first paragraph will be required, the Government or an authority appointed by the Government may order that for the time being only a certain quotient portion of the compensation shall be paid out.

Insurance obligations etc.

SECTION 12

Health care providers shall have a patient insurance that provides compensation for injuries covered by this Act. If an activity is conducted by a private health care provider under an agreement with a public health care provider, it is the public health care provider which must have the insurance.

SECTION 13

Patient injury compensation is to be paid out by the insurer. If several patient insurances cover the same loss, the insurers are liable jointly for the compensation. In such a case the insurers shall among themselves incur equal parts of the compensation liability.

SECTION 14

In the absence of patient insurance, the insurers affiliated to the Patient Insurance Association in accordance with Section 15 are jointly liable for the patient injury compensation which would have been paid if a patient insurance had existed. In such a case the Association will represent the insurers.

The insurers' compensation liability among themselves is to be distributed according to the relationship between the patient insurance premium amounts that apply for each of them to the next preceding calendar year.

Patient Insurance Association

SECTION 15

Those insurers who issue patient insurance shall be affiliated to a patient insurance association.

The Government or an authority appointed by the Government is to determine the by-laws of the Association.

Patient insurance fee

SECTION 16

The Patient Insurance Association is entitled to compensation (patient insurance fee) from the health care provider for the period during which the health care provider did not have insurance in accordance with this Act.

The patient insurance fee charged may at most amount to a sum which equates per year to fifteen percent of the base amount applicable under the National Insurance Act (1962:381) in force when the fee is decided. If the amount which equates to two times the annual insurance premium applica-

ble to health care providers of an equivalent category when the fee is determined, is higher, then the fee may instead be computed on the basis of that sum.

Patient Claims Panel

SECTION 17

The insurers affiliated to the Patient Insurance Association shall together maintain and finance a patient claims panel. The Panel shall include representatives of the patients' interest. Further regulations concerning the Panel's composition are issued by the Government, which shall also approve the rules of procedure of the Panel.

The Panel shall at the request of a patient or other person suffering loss, a health care provider, an insurer or a court pronounce its opinion in compensation cases.

Damages

SECTION 18

Although patient injury compensation may be paid under this Act the person suffering the loss may instead demand tort damages in accordance with the rules applicable thereto.

SECTION 19

A person who has paid tort damages by reason of an injury referred to in this Act assumes, up to the sum paid, the rights of the injured person to patient injury compensation. However, this does not apply if the patient injury compensation could have been reclaimed by the party liable for tort damages in accordance with Section 20, first paragraph.

Reclaim

SECTION 20

If patient injury compensation has been paid for a loss caused intentionally or by gross negligence, the insurer assumes the rights of the injured party to tort damages up to the sum paid.

If patient injury compensation has been paid for an injury covered by the Product Liability Act (1992:18), the insurer assumes, up to the sum paid, the rights of the injured party to damages under that Act.

If an injury is covered by traffic insurance in accordance with the Traffic Damages Act (1975:1410) and if patient injury compensation has been paid for the injury, the insurer assumes the right of the injured party to traffic damages compensation up to the sum paid.

SECTION 21

If patient injury compensation has been paid under Section 14, first paragraph, the compensation may be reclaimed from the health care provider who was liable to take out a patient insurance. In that case the Patient Insurance Association represents the insurers.

SECTION 22

A health care provider from whom a sum has in accordance with section 21 been demanded, assumes, up to the amount paid, the rights which under Section 20 accrue to the insurer.

Statutory limitation

SECTION 23

A person who wishes to obtain patient injury compensation under this Act loses his right to compensation if he does not institute proceedings within three years from learning that a claim could be made and in any case within ten years from the time when the injury was caused.

If a person who wishes to obtain compensation has reported the injury to the health care provider or the insurer within the time stated in the first paragraph, he always has six months within which to institute proceedings after having received the insurer's final decision concerning the matter.

That which is stated in the second paragraph concerning the insurer shall, in the cases mentioned in section 14, first paragraph, apply to the Patient Insurance Association.

This Act comes into force on 1 January 1997.