



Standing Committee of the Hospitals of the European Union  
Comité Permanent des Hôpitaux de l'Union Européenne  
Ständiger Ausschuss der Krankenhäuser der Europäischen Union

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## **INSURANCE AND MALPRACTICE**

Final report of  
HOPE's Sub-Committee on Co-ordination  
Brussels, April 12, 2004

# INSURANCE AND MALPRACTICE

## **INTRODUCTION**

A Sub-Committee on Co-ordination (SCC) questionnaire on Insurance and Malpractice was sent to all HOPE delegations in spring 2003. Part one of the questionnaire was answered by 15 countries. Only a few of them answered to the second part with detailed statistics. The first results were presented to HOPE's Plenary Assembly (PLAS) in Caramulo (Portugal) in May 2003, together with presentations by Benoit Guimbaud (France), Dennis Doherty (Ireland) and Douglas McKenzie (UK, Scotland). The report was also discussed during the SCC meeting held in Luxembourg (June 2003).

### ***HOPE's Plenary Assembly decided in Caramulo (May 2003):***

- ***To study and compare different systems for medical risk insurance*** and evaluate the scale of crisis facing many European hospitals (=this report);
- ***To work on patient safety***, partly mentioned in this report (a European Patient Safety conference is planed for end of 2004 or beginning of 2005, co-organized by the Standing Committee of European Doctors and HOPE together with several other European organisations);
- ***To study malpractice cover when patients are using health care in other European countries.***

The present report is based on the spring 2003 questionnaire and on the discussions of the SCC meeting in Brussels in December 2003. It was agreed at that time that a second questionnaire with complimentary questions would be sent to SCC in the beginning of January 2004 with request for answers by the end of February. Unfortunately, it was only possible for Denmark, Cyprus, France and The Netherlands to give complementary information. The report could have been more interesting with more answers. Some information have also been included that might be of interest especially on patient safety.

Finally, the report, written by Kaj Essinger, has been discussed and improved at the SCC meeting in Edinburgh on March 19th. The report is now sent to HOPE's Plenary Assembly in Malta, June 4-5, 2004.

***Kaj Essinger***  
***President of the SCC***



***What is the scale of the medical risk insurance crisis that many European Hospitals are facing?***

In some countries like Denmark, the Netherlands, Luxembourg, Malta and Germany, the insurance premiums are increasing to such an extent that it is difficult to bear the costs. Several hospitals have cancelled their insurance and pay claims directly out of their budget.

***What is the percentage of hospitals paying claims directly out of their budget instead of having insurance because of high costs or insurance companies withdrawing?***

In **Denmark**, most regions have cancelled their insurance and pay out of their budget.

In **The Netherlands**, all hospitals are insured. Some hospitals, especially Academic ones, are insured with a high threshold up to 500 000 Euros. It looks like self-insurance but the insurer handles the claims and is reimbursed by the hospital after payment.

In **Hungary**, some hospitals can no longer get malpractice insurance from private insurance companies because of the large number of malpractice trials. A majority of insurance companies did not want to take a position in the market. There are now only two private companies remaining.

Hospitals in **Cyprus** do not have any insurance for medical risk (Public and Private Sector). Each doctor is responsible for his/her patient and his/her actions.

***Insurance premiums have increased substantially in many countries, what is the average premium increase in one year in your country?***

Increase for one year:

<i>France</i> 2004 (SHAM)	39%
<i>Ireland</i> 2003	50%
<i>Spain</i> 2003	100%
<i>Denmark</i> 2004	85%
<i>Hungary</i>	25%

***What are the reasons?***

Insurance companies motivate their rising premiums and leaving the market by invoking difficulties to get accurate and reliable knowledge on the real number of injuries that occur and of the claims, they will have to pay in the future. Claims are often made a long time after the injury occurred. At the same time, insurance companies can no longer rely on income from the stock markets as they could in the late 90s.

In addition to the factors stated above, the new legislation on this area in **Denmark** has further increased the pressure on the insurance market as the new legislation makes it even more difficult to predict the number of injuries and of the claims, they will have to



cover in the future. Private insurance companies left the market in **France, Ireland and Hungary**.

***How many insurance companies left the market in each country?***

In **France**, two companies withdrew in 2002 (St Paul and ACE).

In **The Netherlands** St Paul left in 2002. Then three other insurers left: VVAA for the GP's, Dentists and other practitioners outside the hospital, Centramed and MediRisk (two mutual organisations for the hospitals).

In **Ireland** one company withdraw in 2000 from clinical risks, another was unable to secure reinsurance for obstetric risks in 2001.

In **Denmark**, the two largest insurance companies on the market have raised their premiums by 85% between 2003 and 2004. As a result, no Region has obtained any insurance agreement with these insurance companies in 2004. Those insurance companies have no activity in this area in Denmark.

***Why is it difficult to calculate the premium for medical injuries?***

This could be explained by **examples from Sweden and Denmark**. **The real number of injuries is not known** but studies on 1000 medical records in Copenhagen in 2001 showed that **2% of all inpatients had an adverse event** that could have been avoided. This means a non-desired event that is not part of the development of the patients own disease and which is caused by the treatment in the hospital. Other international studies show at least the same results.

**The 1991 Harvard Medical Practice population based study** on 30 000 medical records showed: **3.7% adverse events with harm** (acute care); out of that, 0.7% drugs (0.5% side-effects); app. 3% medical adverse events with harm; **58% preventable** (Lucian L Leape) **which means app. 2% preventable**.

**The National Patient Safety Agency (England)** gave in 2004 the following results: adverse events in 10% of admissions, a total of **5% potentially preventable adverse events and a preventable cost of health care budget of 5%**.

In **Denmark, Sweden and Ireland 0.2% of inpatients on average report a claim for a medical injury** to the malpractice insurance.





**This represents 10% of what was found in the studies.** Is this the top of an iceberg?

It is possible that patients with surgical procedures tend to report more since a medical injury caused by surgery is easier to feel and to see by the patient. This might explain why surgical procedures are reported more than general medicine ones. Older patients (who often have a multi-disease situation the last half year of their life) use many drugs at the same time and have reduced physical capacity. For them it might be difficult to see the differences between the development and interaction of their own diseases and what could be an adverse event caused by a medical treatment. Many adverse events that are seen in scientific studies done on medical records will never be reported as claims for the reasons mentioned above. Many adverse events create limited harm to the patient and then are not reported. But still there is a difference between the estimated number of medical injuries and the number of claims. It is also verified that older people make less claims than middle-aged people do. Women make more claims but their claims are more often accepted.

***Claims frequency to the medical injury insurance in Sweden as % of inpatients (approximately)***

Average for all reported claims is 0.2%. Half of them are accepted according to the law (only avoidable injuries accepted).

Cardio-thoracic Surgery	0.8%
Orthopaedics	0.7%
General Surgery	0.35%
Obstetrics/Gynaecology	0.3% (Ireland 0.4%)
General Medicine	< 0.1%
Geriatrics, Psychiatric	< 0.1%

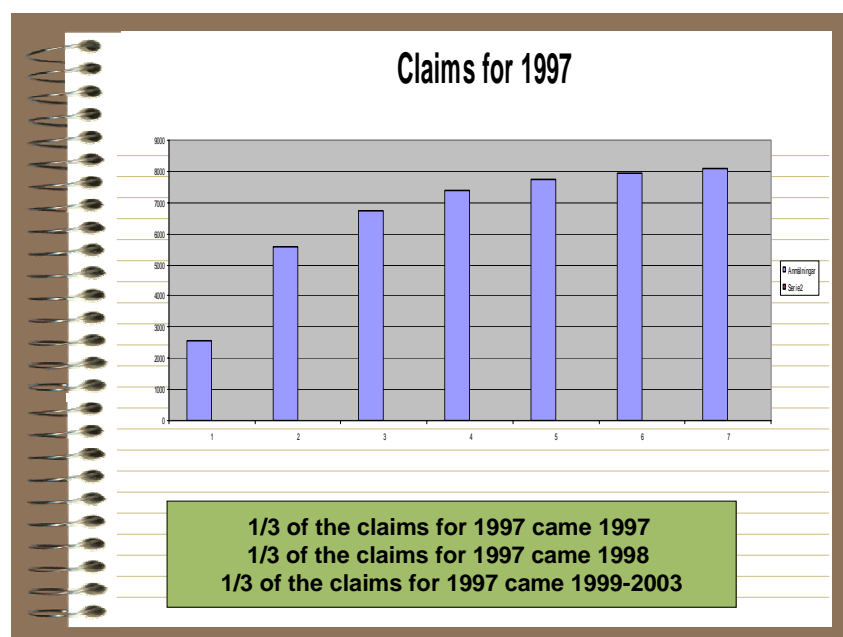
***Costs of medical injuries per department as percentage of total costs (Sweden)***

Obstetrics/ Gynaecology	27%
Orthopaedics	27%
General Surgery	15%
General Medicine	3%



**Obstetrics/Gynaecology** seems to have a lower claims frequency than Orthopaedics and Surgery General but **a high cost in all countries**. In **France**, Obstetrics' makes 3% of the claims and 32% of the costs. The reason is that medical injuries at delivery of babies could cause life long invalidity for the baby with very high costs. In **Sweden**, it would be about 800,000 Euros per case above what is covered by the social welfare system. In some countries (**Ireland** for example), there are special insurance solutions for gynaecologists. In some countries, the premium is calculated regarding the number of doctors in Gynaecology, Orthopaedics, General Surgery, etc... per hospital. In other countries, the premium is based on experience for medical injury costs over a five-year period, which gives a similar result.

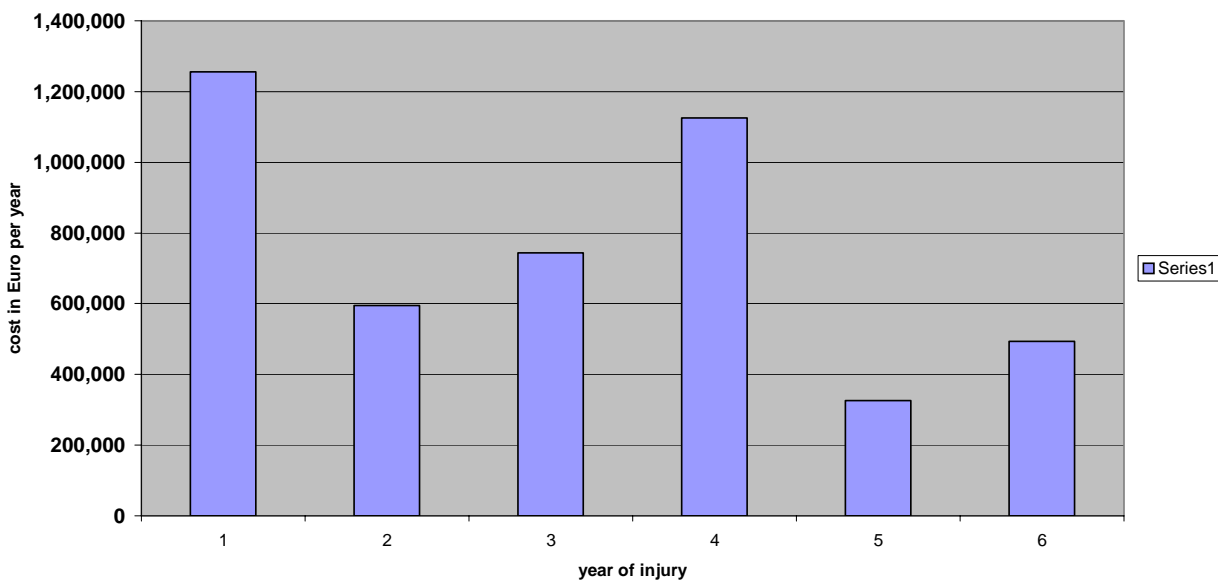
**Claims are often reported a long time after the injury occurs**. It might take five to seven years after the injury before most of the claims are reported to the insurance (**Sweden**).



This will make it difficult for a private insurance company to calculate how many claims that will be reported.

*The costs for medical injuries have a variation even for one hospital.* As one brain damage for a newborn baby could cost 800000 Euros, there is a substantial cost variation for medical injuries between years even for a large university hospital, which makes it difficult to calculate a correct premium in advance. The following chart shows the real figures for medical injury costs for one specific university hospital in **Sweden**, 1996-2001.

**Costs for medical injuries  
one university hospital  
Euro per year**



*Insurance companies do not benefit any longer of income from the stock market, they need higher premiums.* In the late 90s, many insurance companies had good income from the stock market, which allowed them to charge premiums for hospitals that did not cover the real costs for medical injuries. When that extra income from the stock market disappeared in the beginning of the first years of the new millennium, the insurance companies had to cover all their costs by the premiums, which caused a substantial increase of premiums in many countries.

***Medical injury insurance is a high-risk business for insurance companies***

As mentioned above there are difficulties to get good knowledge of the real number of injuries that occur and how many of them that will be reported. It is also difficult to know when they will be reported, often with a long time delay and there is a substantial variation in medical injury costs between years even in one large hospital. Insurance people say that medical injury insurance has "a long tail" which means that it is very difficult to calculate the premium and as a consequence of that, there are risks of economic losses for the insurance company, but that may be visible only after some years.



## ***HOW IS THE INSURANCE ORGANISED IN DIFFERENT COUNTRIES?***

***Is there a special legislation on economic compensation to patients for malpractice or is it part of a normal tort liability system?***

Special legislation on malpractice compensation exists in the Nordic countries. It is part of a normal tort liability system for others: **Germany, Portugal, Ireland, and Malta**. In **France**, there is a special legislation since the 4<sup>th</sup> of March 2002 law on patient's rights. In **Cyprus**, it is part of a normal liability system. **Denmark** has a special legislation on malpractice compensation: "The Danish Patient Insurance Act", which has been extended quite dramatically by January 2004. This means that the legislation now covers the public sector as well as the private sector. The Regions will now also compensate injuries due to treatment on private hospitals or other authorised private health personal such as physiotherapists, psychologists etc. Moreover the legislation now also covers both physical damages and to some extent also physiological damages.

***Is there a law obliging all hospital to be insured?***

In **Sweden**, there is a law from 1997 obliging every health care provider to have medical risk insurance.

In **France**, a law from 4<sup>th</sup> of March 2002 is obliging all hospitals and physicians to be insured.

In **The Netherlands**, the compensation is part of the normal tort liability system. There is no direct law, that obliges hospitals to have insurance, but they need a licence to be operational, in which liability insurance is asked.

In **Cyprus** there is no legislation obliging all hospitals to be insured.

In **Denmark**, the law on malpractice compensation from 1997 makes it compulsory for hospital authority –Regions, to cover claims on damages caused by treatment, etc, within the boundaries of the legislation. Either the insurance may be taken out with an insurance company or the hospital authority may choose to be self-insurer.

### **The Government or a state claims Agency is responsible – no real insurance**

On 1<sup>st</sup> April 2000, NHS **Scotland** introduced a new financial risk sharing arrangement known as "CNORIS" (Clinical negligence and other risk indemnity scheme). Membership is mandatory for all hospitals and health boards. Members finance a "pool" with an annual contribution that is calculated depending on the compliance with the nationally agreed risk assessment management standards and the predicted expenses. Hospitals are responsible to pay the costs for all awards (compensations to patients) which are less than 0.15% of the hospitals budget up to a maximum of £ 450,000 (around 660,000 Euros) and 25% of what goes above that, costs over that will be met centrally.





In **Ireland**, the government decided in 1999 to introduce a system based on the principle of enterprise liability. Hospitals accept liability for the acts and the omissions of the staff. Doctors working in the public system will no longer require separate insurance cover for this work. A Clinical Indemnity Scheme was established on 1<sup>st</sup> July 2002. It means that claims against hospitals and doctors will be managed by a State Claims Agency. The scheme is funded on a "pay as you go basis" by the Government without the purchase of any insurance. Special arrangements have been made for covering obstetric risks in the public and private sectors with a UK based medical mutual body (the Medical Protection Society) to which the Obstetricians pay less than the economic rate for their cover. These premiums are placed in a special fund to cover claims against these doctors. If the fund is not sufficient to meet the costs of these claims, the Government will meet the balance. A similar arrangement has been set up for the two private hospitals that deliver babies.

In **Austria** an extra amount of 0.73 Euro per day for patients insured within the legal social security system (in total 5 million Euros) could be used whenever there is no obvious or clear liability of the hospital. The main rule is that the hospital pays directly out of its budget.

In **Malta**, the Government provides indemnity cover for doctors working in public hospitals, the Government acts as insurance itself. However, it does not cover doctors when they work in the private sector.

In **Cyprus**, doctors practicing in the public sector are under the cover of the Government.

In **Denmark**, the Insurance companies, which offer insurance according to the legislation on malpractice compensation, and the self-insuring authorities have formed a joint association: "The Patient Insurance", which examines and decides all cases in accordance with the law. The Regions pay compensation either through the insurance companies or by self-insurance as stated above.

In **The Netherlands**, the government leaves it to the private market, which has to meet the rules from the insurance regulator for solvency etc.

### ***Mutual Insurance Companies owned by the hospitals***

In **France**, a Mutual Insurance Company called "SHAM" covers 70% of public hospitals (2003).

In **Sweden**, a Mutual Insurance Company "LOF" owned by the Regions insures all public hospitals and public GP's including care delivered by private hospitals according to a contract with the public sector (95% of the market).

In **Finland**, the Patient Insurance Pool provides all public sector insurance policies for provincial hospital districts.

In **The Netherlands**, there are two organizations. **MediRisk**, a mutual organization managed by VVAA (doctors -owned) insuring 74 of 98 general hospitals in Netherlands,



and Centramed, managed by ING, the largest commercial insurance group in The Netherlands.

In **Wales**, all Thrusts and Local Health Boards have started the **Welsh Risk Pool** for 3 million inhabitants.

### *Public hospitals/regions insure with private insurance companies*

In **Spain**, Public Centres have liability insurance coverage from the private insurance companies.

In **Denmark**, the Regions could have private insurance but have now cancelled many of them because of the cost. In Germany, most of the hospitals are covered by insurances of private insurance companies.

### *Private hospitals or doctors have private insurance*

Private hospitals or doctors have private insurance in **Luxembourg, France, The Netherlands, Denmark, Finland, Sweden and Ireland**. In **Cyprus**, in private hospitals, the insurance is made by doctors individually and not by the hospital.

### *No insurance – claims paid directly from hospital budget*

The **public hospitals of Paris** have the right to be without insurance.

The **regions in Denmark** have cancelled their insurance and pay claims directly out of their budget.

**Some university hospitals in Germany** have cancelled their insurance because of high premiums.

In **Austria**, the hospitals usually pay claims directly out of budget and have to find a compensation arrangement with the patient.

**Malta, and Spain** has no insurance system for private doctors.

In **Cyprus** the public hospitals have not insurance. In private hospitals insurance is taken by doctors individually and not by the private hospital.



## **WHAT IS COVERED BY THE INSURANCE?**

### ***Faure-Koziel study***

Michael Faure and Helmut Koziel did a study on: Cases on Medical malpractice in a comparative Perspective (Springer - Verlag /Wien 2001).

The summary comparative analysis (page 291ff) is well worth studying. Some findings from that study are:

- remarkably, most legal systems are apparently still based on a negligence rule, meaning that the health care provider is in principle not strictly liable. All systems therefore apparently still have a negligence rule and – at least formally- no system has adopted strict liability for medical malpractice;
- most countries in that study still adopt a fault regime for medical malpractice, whereby the fault consists in not following the required professional standards;
- usually the patient has the burden of proving the violation of the professional standard.

Some systems are very "victim friendly" and allow the patient to prove the fault on factual presumptions; others do not accept that. There seems to be a difference as far as the issue of causation is concerned. When there is uncertainty concerning the issue of causation some require that it must be more probable than not that the wrongful act caused damage (51%). If so, the patient gets full compensation - if not no compensation called "all or nothing approach". Others as **France** pay compensation according to loss of chance with a percentage of full compensation.

### **Medical malpractice liability: No Easy solutions**

#### **Extracts from Jos Duté, European Journal of Health Law 1: 85-90, 2003**

*This article gives a good overview of malpractice liability mostly from a patient's perspective in a way that could be understood even of those who are not lawyers. It has also information on pros and cons for no-fault compensation systems. That is why it is used here.*

"The patient who suffers damage from medical malpractice, and who wishes to be compensated, is often faced with a difficult task. A necessary condition is to hold the doctor (or the hospital ) liable for damage, is that the doctor is at fault, that is to say that (s)he failed to satisfy the required duty of care and that as a result the patient suffered damage.

In principle, the burden of proof rests with the patient. This can be a real problem, especially when it comes to proving fault and the causal link between fault and damage.

It is generally accepted that medical negligence arises not only from wrong diagnosis and treatment, but also from failure to inform the patient properly, more in particular with regard to the risks that are connected with the treatment. From case law, it appears that



patients only have to be informed on normal and foreseeable risks. Unusual risks do not have to be told, unless they are serious. The less vital the intervention, the more information will have to be given on less frequent or less serious risks.

The physician avoids liability when he can show that the patient also would have agreed with the treatment should he have been sufficiently informed.

The question of causation remains a difficult one. Many actions fail because the patient cannot prove the casual link between the doctor's break of duty and the damage the patient has sustained.

As a general rule, the burden of proof is on the patient. Especially the Spanish courts are very strict in the sense that causation must be proven with certainty, leaving no room for any presumption.

The claims have increased in many countries. As a result, the communication between doctor and patient is becoming less open. Furthermore, doctors become afraid of making faults and overlooking symptoms, and therefore perform unnecessary extra diagnostic procedures and treatments. Likewise, they try to avoid risky procedures. More claims lead to higher insurance premiums for doctors and hospitals. ***Private insurers are less and less interested in the market of medical malpractice insurance. Medical negligence may become an uninsurable risk.*** (My highlighting)

It is argued that no fault systems would solve nothing. After all, the burden of proof that the doctor has breached his duty of care remains with the patient. However, this will be denied by the fact that in the existing no-fault compensation systems much more claims are sustained than in the liability systems. Moreover, claims are settled much quicker. A possible explanation for the better and quicker functioning no-fault compensation system might be the fact that the examination of the facts is usually less profound than in liability system. Furthermore, review is limited and the standard of proof is lowered.

A second objection that is raised against no-fault compensation system is that such a system would harm the damage preventive effect of the liability law. The damage preventive effect of liability law in health care is of minor importance and will at most play a role in certain sectors, like high tech surgery. The "shame and blame" approach will block information channels and might lead to an atmosphere of reproaches and of hiding faults, which might lead to overlooking (latent ) system errors. To prevent injuries, it is not of great importance who has made a mistake, but what could be done to prevent the occurrence of future damage. A no fault system creates better terms for communication on faults and near accidents. Besides, the no- fault compensations systems itself can also be a valuable source of information on quality.

A third objection that can be heard against no-fault compensation system is that it does not provide full compensation of the damage. That difficulty could be overcome if the access to courts is not blocked. The experience from the Scandinavian countries shows that in actual practice liability law is hardly turned on.

A real drawback is the high costs that a no fault system brings along. A no fault compensation system is an inviting option, but it should not be considered as a panacea. Improvements in the liability system might probably overcome many difficulties. ***One thing is clear: there are no easy solutions for the problems connected with medical malpractice.*** (My highlighting)"



## *HOPE-study*

All the studied countries cover culpa.

All the studied countries cover negligence.

All studied countries cover avoidable mistakes, except **Portugal** and **Ireland** if the possibility of complications was not fully explained in advance (informed consent).

In **Denmark**, the conditions for damages can be divided up into two main groups: avoidable injuries and unavoidable or accidental injuries.

Avoidable injuries are covered if the injuries could have been avoided if:

- the experienced specialist had acted differently (The Specialist Rule). Defects in or failure of the technical equipment had not occurred (The Equipment Rule);
- another treatment technique or method had been chosen (The Alternative Rule).

Unavoidable injuries are covered if:

- The injury is rare and more extensive than the patient must reasonably endure (The Endurability Rule).

***Unavoidable complications (an experienced specialist could not have avoided the injury) is not covered in any country***, except **France** where the Government covers invalidity over 25% even if it is unavoidable, which means a real no fault. In **Ireland**, the Government covers if there is a lack of informed consent (in **Denmark** see above).

As the so-called ***no fault*** system does not compensate unavoidable injuries (injuries that an experienced specialist in that speciality could not have avoided) it might be better to call it ***no blame system (for the doctor) – no cost system (for the patient)***.

***No blame means*** that the doctor does not have to go to court, there is not any legal or economic risk for the doctor.

***No cost means*** that the patient does not need to go to court, does in practice not need to prove that the doctor made a mistake/was negligent and does not need to make own investigations or use own lawyers. The patient does not take any economic risk by making a claim.



*What is percentage of the claims that go to court in your country?*

In countries with no blame systems, very few cases go to court, in Sweden and Finland it is respectively 0.1% and 0.3%.

In Denmark, it is less than 1%. The creation of "The Patient Insurance Association" in Denmark has resulted in a decrease in the cases that go to court. The impartial association employ physicians and legal experts who handle the cases on behalf of the patients, so that the patient does not require legal assistance. Finally, as result of the renewed legislation the procedural system has changed so that the onus of proof is made less stringent for the patient and the cases bypass the courts of first instance.

In the Netherlands (Medirisk) the figure is 3-5% and in France (SHAM) is 11%. In Spain, it is approximately 15%. In Malta 98% goes to court and in Portugal 100%.

*Risk sharing arrangements and maximum pay to one patient*

In France, the Government pays no fault injuries over 25% invalidity.

In The Netherlands, there is no risk-sharing arrangement. There is no limit, but the cover of insurance is capped at 2,500,000 Euros and the judge will take that into account and will not award more

In Scotland, hospitals pay 0.15% of income, with a maximum of 650,000 Euros/year and 25% of cost over that. The Government pays the rest.

In Ireland, obstetricians pay less than the economic rate to special fund, if that is not sufficient the Government will meet the balance.

In Sweden, the regions are paying 5 Euro per inhabitant/year (pay as you go basis) which means solidarity responsibility for claims costs.

Many countries has maximised the payment to one patient, in Sweden it is around 800,000 Euros, The Netherlands have a cap of 2,50, 000 Euros.



## **FACTS ON COSTS AND PAID CLAIMS**

***What is the premium/cost for medical risk insurance for one year for a university hospital?***

### **University hospital**

France	790,000 Euro
Sweden	760,000 Euro
Scotland maximum 0.15% of budget Then the hospital has to pay + 25% of the cost above that amount	max 650,000 Euro
The Netherlands	400,000-800,000 Euro
Germany for 800 beds 400E beds	320,000 Euro

***How many claims are paid one year in the country for hospitals?***

<i>Sweden</i>	<i>2650 paid claims</i>	<i>9</i>	<i>million/inhabitants</i>
<i>Denmark</i>	<i>1500 paid claims</i>	<i>5</i>	<i>million/inhabitants</i>
<i>Spain</i>	<i>350 claim</i>	<i>40</i>	<i>million/inhabitants</i>
<i>France (SHAM)</i>	<i>400 paid</i>		<i>(70% of public hospitals)</i>
<i>The Netherlands (Medirisk)</i>	<i>500 paid</i>		<i>16 million/inhabitants</i>
<i>Germany (C.Thomeczek)</i>	<i>&lt;12000 paid claims</i>		<i>80 million/inhabitants</i>
<i>Malta</i>	<i>15 claims</i>		<i>0.4 million/inhabitants</i>

***How many claims are paid in a university Hospital one year?***

Germany	40 to 50 claims/year
Sweden	140 claims/year

***What is the average compensation per patient?***

The Netherlands	10,000 Euro for 500 paid claims
Finland	10,000 Euro for 2100 paid claims
Sweden	10,000 Euro for 2650 paid claims
Denmark	22,610 Euro for 1500 paid claims
France	13,000 Euro for 400 paid claims
Spain	48,000 Euro for 350 paid claims
Ireland	65 000 Euro for* 1300 claims

\*Covers also costs for social insurance



## Risk prevention and patient safety

As mentioned above the real frequency of avoidable *adverse events might be higher than 2% of the inpatients.*

Studies from England and Denmark show that patients with adverse events stay 6-8.5 days longer in hospitals and have additional visits and surgery sometimes for many years. *The additional cost in hospitals might be more than 400 Euro for additional bed days etc for every adverse event.* Those resources might be better used to take care of more patients and to reduce waiting times.

The scientific evidence by **professor James Reason** and others shows that the old way of "*name, blame and shame*" the individual medical doctor or nurse *has only very limited effects on reducing the number of medical mistakes* that lead to injuries. Some acts are negligent or reckless, but they amount to less than 10% of all unsafe acts.

### Awkward fact

Highly trained, responsible professionals make frequent errors, but most are either inconsequential or detected and recovered.

### Event rates in surgery

*Events largely due to errors*

- Based on direct observation of 165 arterial switch operations: 21 surgeons, 16 UK centres.
- Average rate: 7 events per procedure
  - 1 major event (life-threatening)
  - 6 minor events (disrupts flow, irritates)
- Over half of the major events were successfully compensated.

### A system model of accident causation

Some holes due to active failures

Other holes due to latent conditions

Hazards

Losses

Successive layers of defences, barriers, & safeguards

### Learning to live with error

- Errors can't be eliminated, but they can be managed.
- Errors are consequences as well as causes.
- Errors are opportunities for learning.
- Naming, blaming and shaming have no remedial value.
- We need error management tools for those at the sharp end who can't easily change the system.

### Bottom line

- Fallibility is part of the human condition.
- You can't change the human condition.
- But you can change the conditions under which people work to lessen the impact of error-provoking situations and to increase the opportunities for error-detection and recovery.





*To error is human, but it is inhuman to avoid learning from mistakes and is unacceptable that mistakes lead to injuries on patients* (quotation based on a statement from Chief Medical Officer Liam Donaldsson, England).

Health care should be *an organisation with a memory*, which means that it should learn from mistakes.

**Professor Charles Vincent** has studied the *effects of medical injuries on patients* and what they expect from health care when it happens. According to his studies, patients want:

- a. an explanation on what really happened;
- b. an excuse that the patient had an injury or that the staff regrets what happened to the patient;
- c. a commitment from the staff that they will learn from what happened so no other patient will have the same injury;
- d. help with treatment to reduce the effect of the injury;
- e. help to economic compensation for the injury;

Most of all the patients want empathy from the staff for the situation.

*The way to reduce medical mistakes is to change the perspective from the individual to the system* (routines, protocols, organization). It should be the responsibility of the hospital to organise the work so that there are *barriers to stop mistakes from leading to medical injuries on patients*. There is experience from aviation, nuclear industry and offshore oil industry to learn on safety.

Many organisations now are starting computerised *incidence reporting system*. Evidence from many countries so far show that doctors tend to report less than nurses do and that the serious events not are reported at least in the beginning. It is necessary to shape a *safety culture* first that promotes openness on mistakes and a blame free - non-punitive reporting. In **Denmark**, there is now a law on national anonymous incidence reporting system

*Medical injuries should be analysed*. There are several techniques such as Root Cause Analysis from the beginning used by the Veterans Administration in the USA, by the Hospitals in Copenhagen in **Denmark**, and now transformed and improved by *National Patient Safety Agency in England as a web-based interactive learning instrument* ([www.npsa.nhs.uk](http://www.npsa.nhs.uk)). NPSA are now training trainers in every NHS trust in Root Cause Analysis. The theory is to ask why the medical injury happened many times. The answer to the first why-question is usually to point at an individual that was present. The answer is in 80% of the cases that the real cause of the injury is the system, the routines or the organisation - not the individual. Other techniques for analysis such as Man - Tool - Organisation (MTO) would give the same result.

*A further step is to go on from reacting on what has happened to proactive analysis of what could happen*. Training in risk analysis should be made in order to find and prevent



risks so they do not cause medical injuries. Many organisations such as SHAM, MediRisk, The hospitals in Copenhagen, The Danish Patient Safety Society, The Welsh Risk Poll, the Swedish Mutual insurance company, the NPSA/NHS and others have found that **risk prevention and patient safety is the best way to reduce medical injuries** and as a consequence of that to reduce the future costs for medical injuries.

**NPSA in England** has a extremely good web page [www.npsa.nhs.uk](http://www.npsa.nhs.uk) where you can find most of the information that you would like to read for example: **Seven steps to Patient safety, Root Cause Analysis E-learning, The Incident Decision Tree** (treating staff fairly after a patient safety incident), A new **National Reporting and learning system (NLRs)** and most of the lectures from **NPSA conference on Patient Safety** held in Birmingham, 24-25 February 2004.

As part of the new legislation, a new patient safety system has been established in order to improve **the Danish health care system**. The act shall reply to the reporting of adverse events occurring in connection with the treatment of patients within the health care system so that this information can be used to advise the health care system on patient safety and hopefully preventing the faults and mistakes from happening again. The patient safety system is not part of the Patient Insurance Act. The patient safety system is a learning system and the purpose are to collect mistakes, failures etc. in order to change procedures and advice the hospitals on patient safety.

The **Standing Committee of European doctors** is planning a European Conference on Patient Safety in December 2004 together with other European organisations among them HOPE. The **Council of Europe** has a working party on Patient Safety in which HOPE is represented. A report will be published this year.

### **NATIONAL QUALITY FORUM 2003**

#### **CULTURAL BARRIERS THAT IMPEDE IMPROVEMENT OF SAFETY (Joanne Thurnball)**

- **perpetuation of myth that "good" healthcare professionals will perform perfectly; adverse events caused by carelessness, negligence, incompetence;**
- **legal/liability concerns stifle open communication about safety problems/data sharing;**
- **lack of awareness of prevalence of adverse events;**
- **denial of severity of the problem even when confronted with data;**
- **lack of effective reporting systems;**
- **lack of systems thinking and knowledge about the systemic nature of healthcare accidents;**
- **A LACK OF LEADERSHIP REGARDING SAFETY**



## ***DISCUSSION AND CONCLUSIONS***

***How to get medical injury insurance coverage for hospitals and how to get costs for insurance that are more acceptable?***

**Based on the experiences from this study the main ways could be:**

- **Involvement or payment from the State,**
- **Limitation of economic compensation to patients,**
- **Mutual insurance companies owned by the hospitals,**
- **No fault or no blame systems,**
- **Risk prevention and patient safety.**

### ***Involvement or payment from the state***

As reported earlier in this study, medical injury insurance is a high-risk business for insurance companies. There are difficulties to get good knowledge of the real number of injuries that occur and to know how many of them that will be reported. It is also difficult to know when they will be reported, often with a long time delay and there is a substantial variation in medical injury costs between years even in one large hospital. Some groups of doctors such as gynaecologists, orthopaedics and general surgeons represent the highest costs for medical injuries. For gynaecologists the costs could be so high that it is difficult to solve within a market situation.

The example of Ireland and other countries shows that one possibility would be to make hospitals (Enterprise Liability) responsible for acts and omissions of their staff, instead of the single doctor, which would reduce the single doctors insurance cost. An additional possibility would be that the State would pay part of the insurance cost for high risk professions as gynaecologists or that the State would pay the cost increase for insurance when it goes up too fast, as it did in France.

The State might also, as it did in England and Scotland, set up a maximum cost for insurance for one hospital (0.15% of the budget) and subsidise with State money if the cost would be higher. It means that the State would take the economic risk for higher costs. In France, the state will pay if a patient gets more invalidity than 25% and if nobody could have avoided the injury.

It is possible for the State to create some kind of *risk fund* as mentioned above to reduce the risk for hospitals and private doctors.

The State can also make special laws about compensation for patient injuries with other rules than in tort law especially if a "no fault" system is desired.



### ***Limitations of economic compensation to patients***

In most countries, the social welfare system (social insurance) pays for the loss of income up to a certain level when a patient must go on sick leave or have an early retirement because of a medical injury. *The medical injury insurance only pays for the difference between the actual income and what is paid by the welfare system.* In most countries, the national health system or the health care insurance pays for any additional medical treatments caused by a medical injury. In the United States the medical injury insurance pays for all loss of income and extra medical treatments, which makes the malpractice costs much higher there.

In some countries, legislation sets the *maximum economic payment to one patient.* In Sweden it is limited to 800 000 Euros. In some countries, it would be against the constitution to limit economic compensation to patients.

In some countries, the *insurance only pays if the cost of the injury is over a certain limit.* In Sweden over 110 Euro, in Finland 170 Euro, in Spain 300 Euro, in Denmark over 1100 Euro. That is a way to reduce the number of small claims for the insurance.

### ***Mutual insurance companies owned by the hospitals***

Hospital owned mutual insurance companies exist in France (SHAM), in the Netherlands (MediRisk), in Sweden (the Regions Medical Injury Insurance), in Finland (The Patient Insurance Pool) and in Wales (the Welsh Risk Pool). A discussion is ongoing in Hungary of the possibility to start a mutual insurance company.

The benefit with Mutual insurance companies is that they are non-profit. The premium should only cover the real costs for compensation to patients and the administrative cost to settle the claims. In the long run, they should be able to have lower premiums than for profit companies. Some of them such as MediRisk and the Welsh Risk Pool have introduced criteria/standards for safe performance in order to reduce the number of injuries.

By their size, the mutual insurance companies could also balance the risk sharing between hospitals.

### ***No fault or no blame systems***

The so-called No Fault system seems to have higher number of claims per inhabitant than the systems who use the tort law court system. It would be interesting to know the total cost for compensation to patients and claims handling/court costs in those two systems. However, the answers on the questions so far are not detailed enough to tell that.

One example is The Swedish Law on Compensation for medical injuries, which allows more than 2600 accepted claims for hospitals every year. The number of doctors who get a reprimand from the national Agency for professional liability is about 300 per year – that could be the number who could loose a case in court if there was only tort law.



Another example might explain the different “administrative costs”: in England the cost for lawyers are in one case approximately 15000 Euros for each part, in total 30000 Euros regardless of the compensation to the patient. In the Scandinavian countries the total administrative costs for claims handling is about 700 Euros for one case.

The time to make decisions on claims is shorter in no fault systems than in court systems. In Sweden 50% will have a decision on whether they will get compensation or not within 6 months and about 80% within 8 months.

An interesting way of handling smaller disputes easier and quicker has been introduced in the Netherlands with the so-called Dispute Committee for Hospitals. This arbitration board deals with claims up to about 4500 Euro and applies the ordinary rules of tort law. It provides a cheap and fast solution of smaller disputes (Jos Duté).

The no fault systems seem to have more accepted claims, but less administrative costs. The compensations to patients seem difficult to compare. It is more of a national political question if patients should have extended right to compensation for medical injuries without having to go to court. A special solution is made in France which has introduced a no fault solution for invalidity over 25%. Austria has a limited solution. Ireland has ideas of no fault solutions for brain damages on children. In Belgium there is an on-going discussion at the government level on a no fault system.

### ***Risk prevention and patient safety***

The real number of adverse events in hospitals is at least 10 times higher than the reported claims in countries with good reporting. Increased reporting could follow according to public debate on patient safety and according to that middle-aged people report more and soon will be high consumers of health care. The economic consequences of more reported claims could be dramatic for hospitals.

The most effective way to reduce the economic threat of medical injuries should be to work very actively with risk prevention and patient safety. The national patient safety agency NPSA in England is a good example of what could be done as a national priority. The mutual insurance companies in France, The Netherlands, Wales, Sweden, Finland and the hospitals in Copenhagen, have taken similar initiatives.

The Welsh Risk Pool has 38 Risk management standards, which they assess through an audit of documentation and staff interview. They are discussing to let the insurance premium be partly depending on the result of the audits. Medirisk in the Netherlands also has a risk assessment by audits in the hospitals in order check how they follow standards for emergency, operating theatres etc.

An exchange of experience between all these organisations and conferences on a European level on patient safety might be a good initiative.

***The SCC is of the opinion*** that a national involvement in the costs for medical injuries is important. It could be combined with a national interest for clinical standards. A good reporting system for incidents and injuries might be useful but requires serious consideration



especially on the ethics. Experiences from other sectors show that only anonymous reporting systems could gain confidence from the profession and help to learn from mistakes and near misses. Denmark has now made a law on an anonymous reporting system. Systems which include the risk of naming, blaming and shaming the individual doctor have only a limited effect on reducing medical injuries due to the low frequency of reporting to such a system. Injuries should be analysed to find the real cause. Usually that is to find in organisation, routines and procedures in the local working place – not in the individual.

***To learn from mistakes and avoid medical injuries is*** according to the author of this report:

- humanitarian for the patients,
- good for workplace wellbeing, young doctors are afraid of making mistakes
- economic for the hospital
- economic for the welfare systems.

