of what is going on.

3. Impact of IOM report

Please assess the influence in your country of the report from the Institute of Medicine in the U.S., "To Err is Human."

The influence of the report is hard to assess but it has not been so much published about the report in Sweden. In my opinion are the figures in the IOM-report so enormous so it is difficult to understand. It could have the opposite effect. We are trying to use the Swedish figure from the Patients Insurance company. It is quite enough to talk about 9.000 patient injuries each year to get the health care professionals to understand that we have a problem.

The aim of the whole process concerning the Maria tragedy was to find a guilty part. The police explained that the reason they could not clarify how the mix-up had occurred was that the report from the hospital came in too late and that the hospital had forestalled the investigation. This contributed to the demands that were then made to establish requirements as soon as possible for hospitals to report serious events to the police. The main aim was for evidence to be determined, and the disciplinary aspect was considered the most essential. The original proclamation went into effect on 15 January 1936, only four months after the event.

Although the lex Maria regulations have changed over the course of the years, and prevention is nowadays intended to be a guide in the investigation, there is still a risk of punishment for the person who reports an incident. The risk for underreporting is therefore obvious. The question is therefore whether lex Maria legislation constitutes an obstacle to the development of effective work with safety within health care. The lex Maria system will be 65 years old in 2001, and perhaps it is time for retirement.

B. Action by Stakeholders

1. Government action toward medical accidents/errors and patient safety

Has the government instituted policies especially for medical accidents?

If so, please describe the policies including their historical development.

We have the mandatory reporting system since 1936, it´s 65 years old. The starting point was because of a medication mix-up that took the lives of four people. This event was the direct reason for the present Swedish Lex Maria system.

2. Action by other stakeholders

What policies have been instituted by provider associations such as medical doctors, nurses, or hospitals?

We have started a discussion with the Swedish medical association and the corresponding for nurses

3. Action by patients, patient groups or representatives

Do patients, patients' groups or representatives have a strong influence on governmental or health care professionals' activities for medical error prevention? If so, please describe.

4. Third Party Accreditation

With regard to quality, a third party organization evaluates hospital performance and accredits hospitals in many countries. And in some cases, the organization rates/ benchmarks hospitals or health care institutions. Is there such an organization in your country? If so, please describe its responsibility and activities briefly. Also, what results (if any) of the evaluation and accreditation process are made publicly available?

We only have that for laboratoriemedicine

C. Information Systems

1. Reporting system/ information system

Is there any nationwide reporting system for medical accidents, analogous to a reporting system in the aviation industry, or the adverse event reporting system in Australia?

If there is,

a. Is it obligatory or voluntary?

It is obligatory and the name is Lex Maria

b. Who collects the data?

*The health care providers report to a local system. If it is a serious injuries or serious incident it must be reported to the CEO who should do the report to the National *board of Healht and Welfare (NBHW) (the system is named Lex Maria).*

c. Who analyzes the data?

It should be analyzed at the local level, but even the authority are doing an investigation

d. Is there any legal protection for the information reported, so that it cannot be used in lawsuits?

No - and that is a big problem for the trust of the system. Although only a small part (9 %) of the cases from the NBHW are forwarded to the MRB for disciplinary actions it is obvious that we have a problem to receive data. There is a big opinion from the health care personnel in the medical press in Sweden against this system.

In 1992 the NBHW established a national risk data bas where every reported cases are classified and registered. The data bas contains today about 15.000 serious adverse events. But the feed back from the data bas has not been so good yet.

2. Complaints from patients or their families

Is complaint data collected and analyzed? If so, how?

Yes in some part from the local patients .... Patient and their family can complain in four different ways.

1. *to the National Board of Health and Welfare. Expect the reporting from health care personal described above, patient or their family can also complain to NBHW, but these data are not analyzed so well as the Lex Maria cases (yet). Last year NBHW received 900 lex Maria-roprts and above 1500 from patient or their family.*
2. *The Medical Responsible Board, Except reports from the NBHW the MRB receive most of their reports from patient and their family (about 85-90 %) In 2001 they received about 3000 reports totally.*
3. *Patient insurance scheme to get economic compensation (it is a no fault insurance which started in 1975. In 2001 above 9 500 patient asked for economic compensation. In general above 45 % get compensation. If you are further interstes I can send some information about the patient insurance system.*
4. *To the local system in every county council. This local system should help patient in different ay and try to help them with their complaints.*

3. Public availability of medical outcome information

Please describe the extent, if any, to which medical outcome information and other information on medical quality is available to the public. In particular, is such information available on a provider-by-provider basis?

We have recently started a new national reporting scheme which is voluntary, but it just concern medical equipment. The system should be available for the public. The system is very good and refer to James Reason classification for active and latent failures. We have also discussed how to use other informationsystem such as the patient insurance system but one difficult question is that we don´t want to jeopardize thehealt care personnel's trust for the system

D. Legislation and Judicial Involvement

1. With regard to the legal system, if someone reports a case and the error is not caused by her/his negligence or system error, in some countries the reporter is protected from legal liability. Do you have the same system in your country as well?

No, but on the other hand it is rather unusual that an individual get sued in Sweden. They almost never get sued in an ordinary court. Among cases reported from health care sector to NBHW (Lex Maria) about 9 % are forward to MRB. Of these about 85 % get a reprimand or warning.

Among cases reported from the patient and their family about 30 % get a warning or reprimand. A lot of the reported cases

from patient are due to communication problem

Is there any no fault compensation scheme for medical errors similar to the no fault compensation scheme in some countries for side effects of drugs?

Yes as I described above and I think Sweden was the first country with that system in 1975

E. Concept of Quality and Safety

1. Health care quality and medical error/accident

In the IOM report, "To Err Is Human," there is a discussion that we have to take a measure against both health care quality and medical errors because they have the same root cause. Is this concept prevailing in your country?

We have that discussion, but I think we need to talk about patient safety separately. Of course they have the same root causes but in my opinion it is sometimes difficult to get al the personnel involved in the quality work. I think you must be very strategic and it is a great pedagogic demand to work specially with patient safety because of e.g. the blame trap.

2. "Risk management" and patient safety

The practice of "risk management" in some settings has come to signify the protection of hospitals against the risk of litigation by patients. The IoM report stressed, by contrast, the importance of patient safety as the proper goal of risk management. How would you assess the actual practice of "risk management" as it exists in your country, as between these two models?

There is a growing discussion about this question and from the Swedish county councils we are trying to put his on the agenda. Until now the risk management in Sweden only deal with security not for patient safety.

F. Risk Management at Hospital or Clinic level

1. Risk Managers

a. Are there organizations to train risk managers in your country?

There are some private consultancies and we have started a discussion with the university to arrange some education in this area

b. Do hospitals in your country have a specific post for a person charged with the responsibility of medical error prevention?

No, not yet! But in some years I think they will. From the NBHW they have stated in the new regulatory for Lex Maria that the hospitals should have a person in charge for dealing with medical error prevention

2. CQI (Continuous Quality Improvement) / Patient Safety

Do you have integrated managing units in hospitals for continuous feedback looks to improve quality and prevent error? If so, please describe.

I cant answer that question. A lot of quality project is ongoing within the health care sector, Almost every hospital have a quality unit working with quality and the safety issues are growing in these units. But it is a difficult question to work with and I think they need specific strategies for patient safety.

Quality registries in the Swedish health services

May it could be of interest to describe the national quality registries in the Swedish health and medical service which has been established in the last decade or so. These registries contain individual-based data on diagnosis, treatments and outcomes. They make it possible to monitor the effects of treatment on the individual patients and, above all, the data can be aggregated to show the effects of a certain type on treatment on entire groups of patients.

This enables individual hospital department to measure their treatment results with respect to certain types of patient's ant treatments and then to compare them with the national average and with the corresponding results in other departments. One of the purpose's of the national quality registries is therefore to provide benchmarking data. If you are interested in detail about the Swedish registries I can send a special article by mail to you.

3. Fail Proof and Fail Safe Fault Systems

Is there any package of systems to improve patient safety in each high risk area in a hospital, such as anesthesia, surgery, ICU, delivery and emergency room? If so, please describe

We have a lot of hospitals which have different system, and I have not get a good answer. May be I can try to contact different hospitals to ask the question later on.

4. Specific Measures for High Frequency Risk Procedures

Have specific measures been developed and widely instituted to prevent common accidents such as medication errors, transfusion errors and falls? If so, please describe.

Of course a lot of measures have been developed but I am not sure that they are implemented nationwide. . For medication error for example we have unit dose package, but with new measures you get new risks. Fall prevention is another area but I must ask to come back with the answer about the measures.

5. Risk Analysis Methods

What methods are generally employed to analyze risks associated with medical errors at health care institutions?

We have no standard but we are trying to introduce the MTO-perspective witch include man

technology and organizations. The most important is that the perspective is holistic. At our stage in Sweden we have just started "the travel" and we are trying to get the managers in the health care sector to understand that the individual who make the "error" are not the only one who should be responsible. We work a lot from the influence from organizational accident theory and are also collaborating with the nuclear power industry. Concerning risk analysis there is a Swede, Lars Harms-Ringdahl who written a book "Safety analysis - principles and practice in occupational safety". Taylor and Francis 2001.

Below I will describe a project in Sweden which we recently have started. I is the first steps taken towards developing a methodology for the assessment of safety activities and their supporting organizational and administrative context in complex socio-technical systems. The method is based on a framework model that identifies four conceptual spaces, M-space (human related factors), I-space (information, methods, resources), T-space (technology) and O-space (relations within and among the other spaces). A set of so-called fundamental safety activity classes is defined (safety analytical activities, verification activities, human resource management activities, management activities, activities associated with building and using quality systems and experience feedback). These activity classes are used to support identification of specific activities within each general activity class. Departing from a set of tentative criteria and a set of assessment dimensions (communication, resources, integrity, learning etc) a quantitative assessment method has been developed and tested in a pilot project with the activity of PSA (probabilistic safety assessment) as the chosen assessment object. Lessons learned and possible further development of the method is discussed.

6. Education and Training for Employees

a. What special training courses oriented toward patient safety, if any, are offered or required for specific groups of hospital employees?

Not yet

b. Is there any hospital or clinic which develops educational tools and/or training materials designed to alter behaviors to prevent errors and increase safety?

They have started in one hospital with simulator training for doctors

G. Peer Review

Please briefly describe the peer review systems prevailing in your country, or provide descriptive references.

Others

I will attach a file concerning the Swedish quality system

Abstracts

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Ödegård S, Löfroth G (1996) Den svenska lex Maria, då och nu. (The Swedish lex Maria. Patient injuries in a historical perspecitve) Nordisk Medicin.

The Swedish system concerning injuries in the health care sector has its origin in a incident 1936 at the Maria hospital in Stockholm. Four patients died following injection of mercury oxicyanide instead of a local anaesthetic. The first law in 1937 focus on disciplinary actions with prescribed duties to report patients injuries both to the National Board of Health and Welfare and the local police. The regulation, often calls lex Maria, have changed during the past 60 years. It is now stressed, beside the punitive aspects, that organisational factors should be considered in the evaluations of incidents and that a main aspect of the system is prevention.

Ödegård S. From punishment to prevention? Medical errors reported in Sweden 1989 to 1993. Safety Science monitor 1999;3:1-10. www.ipso.asn.au

This study describes the Swedish self-reporting system for serious injuries caused by medical treatment, how the authorities handle cases reported by health care providers, and how this influences the willingness to report medical errors. The focus shifted from punishment to prevention when the state authority was reorganised in 1991. The present study was performed in order to identify whether there was a change in reporting medical errors between 1989 and 1993.There was a great increase in the number of reported cases, and the manner of handling lex Maria changed during that period. Cases forwarded for disciplinary action decreased from 31 to 5 % of reported cases. There was also a change in the categories of personnel reported, with an increase for medical doctors and a decrease for nurses. Employees with organisational responsibility were not reported to a greater extent than earlier. One of the major problems with the Swedish lex Maria system still remains, since the National Board of Health and Welfare retains the duty to report to the Medical Responsibility Board. The question can be posed as to whether the present self-reporting system, which is run by a state authority with the duty to forward reports for disciplinary action, really contributes to improved safety.

Key words: reporting system, medical error, disciplinary action, patient safety.

Ödegård S. Säkerheten i vården bör fokusera på prevention. Lär av flyget, kärnkraftsverken och offshoreindustrin! (Prevention should be the focus of safety measures in health care; lessons to be learned from the aviation, nuclear energy and offshore oil industries). Läkartidningen 1999;96:3068-73.

In many respects the approach to questions of safety adopted in the aviation, nuclear energy and offshore oil industries is highly relevant to safety in health care sector, even where legislation is concerned. Characteristic features are emphasis on risk-factor identification, and such demands as risk analysis, knowledge checks, and the limitation of working hours. In addition, there is a need of disaster inquiries in cases of serious incidents, and of an organisation specifically responsible for safety issues. Regarding the development of an incident report system for use in health care, the importance of which increases with the risks involved, a commendable model is the risk report system adopted by civil aviation authorities in USA, where those submitting reports are guaranteed immunity.

Key words: patient safety, prevention, risk-factor identification

Ödegård S. (2000) Improving patient safety by methods used in other high risk activities-civil aviation, nuclear power and offshore oil industry.

Objective: The aim of study was to develop a basis for obtaining improved methods for increasing patient safety.
Methods and Material: A qualitative study was performed comprising semi-structured interviews with 25 professionals within the areas of aviation, nuclear power and offshore operations. The material was supplemented with regulations and other written material. A broad comparison was made with the health care sector and methods of relevance to the health care sector are discussed. This study reports on those areas judged by the author to be relevant to the health care sector.
Results: Safety-related work in the fields investigated is more clearly focused on risk identification than in the health care sector. Requirements for regular proficiency testing in civil aviation, restrictions in work hours for pilots, and stringent requirements for risk analyses in offshore operations are examples with no counterpart in the Swedish health care sector, but they are judged to be relevant. Safety-related work within the nuclear power industry is based upon established knowledge in behavioral and organizational science, which is not the case for

investigations of medical mishaps in health care. The Aviation Safety Reporting System (ASRS) is compared with the Swedish national reporting system for medical mishaps.
Conclusions: Safety-related work within the health care sector is judged to have much to learn from the areas investigated. A clearer focus on identification and analysis of potential risks is essential, as new risks are continuously arising.

Keywords: Patient safety, Risk identification, Risk analysis.

Ödegård S. (1999) Safety Management in Civil Aviation – A Useful Method for Improved Safety in Medical Care? Safety Science monitor 2000;4:1-12.
ipso.asn.au.

Abstract: Medical errors can result in the devastating consequences of life-long suffering for the individual patient. Studies have also shown that the fear of making mistakes, as well as the fear and threat of being reported, contribute to the psychological pressure experienced by personnel in the health care sector. Therefore, improving safety is vital from the work environment perspective. There are many indicators showing that risks in the health care sector are increasing, despite the fact that fewer reports are being sent to the monitoring authorities. This study attempts to analyze whether the methods of risk management used by civil aviation have any relevance to the health care sector. A comparison shows that the health care sector lacks an organization on both the local and national levels that specifically deals with safety-related matters. The system of risk reporting and management used in civil aviation can provide valuable insight in designing a similar system within the health care sector. Requirements for periodic proficiency testing and regulation of the length of work shifts are other areas in which aviation can serve as a model for improving safety in health care. The study shows that the safety-related efforts made in civil aviation are in many cases highly relevant to the health care sector, even in relation to the formulation of legislation.

Ödegård S, Andersson D, KG. (2001) Knowledge of diabetes among personnel in homebased care: how does it relate to medical mishaps? Journal of Nursing Management 9, 107-114.

Objective
To assess the influence of knowledge about diabetes on the performance of diabetes care for the elderly involving insulin treatment, with special attention to aspects of patient safety in home care.

Design A questionnaire was administered to nurse's aides and assistant nurses (3 144). Answers to questions about knowledge of diabetes were related to "relevant" or "risky measures" as judged from a hypothetical diabetes case. A 94 per cent response rate was obtained. The study took place in January 1997 in 15 of Sweden's 289 municipalities.

Results.

Insufficient theoretical knowledge about how the blood sugar is related to an insulin reaction led to an almost threefold increased risk of taking a "risky measure." Insufficient knowledge about reasons for an insulin reaction also resulted in a higher risk, as was the case for personnel working in home based care in contrast to those working solely in institutional care. In addition, the risk that a nurse's aide would take a "risky measure" was higher than that for an assistant nurse. This may indicate that the basic theoretical knowledge of nurse's aides is inadequate.

Conclusion.

Deficiencies in basic knowledge of diabetes among nurse's aides and assistant nurses constitute a major cause of potentially serious mishaps in home care of elderly diabetic patients treated with insulin.

Response to the international comparative survey of medical Accident prevention and patient safety policy
The Denmark situation

Respondent: Danish Society for Patient Safety

A Survey of Medical Accident Prevention Policy

Questionnaire on international comparison of medical accident prevention policy

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Background: Japanese Situation

In January 1999, unthinkable medical error occurred at one of the prestigious hospitals. Patient was mixed up at surgery and lung was taken out from the wrong patient. Since then several serious medical errors have been reported at prestigious medical center. Trust on Japanese health care system by Japanese people has been shaken. The government has to respond to the situation. A committee to investigate the root cause of those medical errors has formed in March 1999 and reported the need for integrated activity to prevent medical errors. Other professional associations, such as Japan Medical Association, Japan Nursing Association, Japan Pharmaceutical Association, Japan Dental Association and Japan Hospital Association have also formed a committee to develop preventative measures from their perspective. Particularly, 240 central government hospitals have developed a manual to deal with medical errors in October 1999. 2 million USD is allocated to the research on patient safety in 2001 fiscal year budget. National committee on patient safety was formed in June 2001 to develop a comprehensive policy.

The main aim of this survey is to investigate medical accident prevention policy in the following countries: the U.S., the U.K., Germany, Sweden, the Netherlands, France, Australia, and New Zealand.

Denmark

Response by (revised as per September 20, 2002):

Danish Society for Patient Safety

There might be relevant information that is not included in the answers below, if information has not been shared with us.

www.patientsikkerhed.dk

Question

A. Situation on Medical Error

1. Studies and research activities on medial accidents/errors

a. Is there any study on facts and occurrences of medical accidents/errors?

The Danish Hospital Evaluation Centre (www.ecs.dk) now called: The Danish Centre for Evaluation and Health Technology Assessment published two reports on patient safety in March 2001 (nr. 11 Patientsikkerhed – Mål, ansvar og procedurer (Patient safety – goals, responsibility and procedures), Nr. 12 Patientsikkerhed – fejl og læring (Patient safety – failures and education)); unfortunately, none of them have been translated into the English language.

But the Danish study that has had the most important influence on the development of patient safety is a Danish pilot study of the epidemiology of adverse events. It was finalised in 2001 and financed and further published in September 2001 (Ugeskr. Læger 2001; 163: 5370-8, Incidence of adverse events in hospitalised patients. The Danish Adverse Event Study, ISBN 87-7488-3593) by a cooperation of the Ministry of Health, DSI (Danish Institute for Health Services Research), Copenhagen Hospital Corporation, the County of Southern Jutland, the County of Viborg and the County of Aarhus. See enclosure 1 for a summary of this study. It was concluded that the pilot study was not to be followed by a large scale study, since the results were similar to the American and the Australian study.

A research group financed by The Danish Ministry of Health and The Copenhagen County has just finalised a study on how to develop a system to the learning from adverse events and medical errors. Amongst the findings, is the fact that, it is essential to have a sharp line between systems which propose blame, and systems which propose to gather information in order to increase patient safety.

There are also a few local studies in specific areas of the Danish Health System and a few currently in progresses.

b. Is the number of medical accidents increasing?

There has not yet been any scientific study of this development.

c. How much is the budged for those studies and research activities?

The survey published September 2001 had a budget of around DKK 1 million. There are no permanent funds as yet dedicated only for patient safety. At the moment the budget for different patient safety research projects is around DKK 5 million where the Ministry of Health provides the majority and private funds contribute too. Furthermore there are budgets for patient safety research on different local or regional levels, but since there is no national list of these activities and budgets, it is difficult to estimate the Danish total budget for patient safety research.

d. Is the status of medical errors understood well in your country?

The release of the Danish pilot study on adverse events has improved the understanding of medical errors as well as improved the recognition for the need to put a lot more effort into research and action on this issue.

Within the Health Sector there is a growing understanding of the importance of changing the culture from a blame culture to a culture where learning is the primary focus. There is a major and growing consciousness around the understanding and acknowledging of the need to improve patient safety. Although the understanding of the concept of patient safety has not reached quite the same level in the public sphere, this is not a matter of unwillingness, but simply due to the fact that the history of patient safety in Denmark is relatively new. In brief the headlines of the history has been as following (see for example 2 a for further details):

March 2000: A Danish delegation went to a conference in London on how to reduce medical errors and improve patient safety arranged by BMJ. Members of the delegation had the decisive power to enact a proposal; this resulted in the decision that the Danish Adverse Event Study should be done.
October 2000: Pilot study starts
November 2000: A National Conference on Patient Safety
September 2001: The Results of the pilot study published (Ugeskr Læger 2001; 163:5370-8) and furthermore a theme issue on patient safety and quality assurance in The Journal of the Danish Medical Association (no. 39/2001). Once again a national conference on patient safety.
December 2001: The establishment of The Danish Society for Patient Safety.
2002: Patient safety is made into a core area in the Danish National Strategy on Quality Assurance 2003-2006
September 2002: A theme issue on patient safety and quality assurance in The Journal of the Danish Medical Association (no. 38/2002).

There have been several initiatives on local/regional levels, such as the launchings of County hospital patient safety units. This occured in the Copenhagen Hospital Corporation in September

2001, and recently also in the counties of Southern Jutland, Vejle, and Aarhus.

The conclusion fortunately as of now is that there is a rapid development in the area of patient safety.

2. Public concern for medical accidents/errors

a. To what extent are medical accidents/errors getting public concern in your country?

As a consequence of the growing attention from private and state institutions to these and related issues, medical risk has had growing public attention. Evenso, our impression is that medical errors here, do not get as much public attention as for example in the US.

Our impression is that the public focus is slightly more on malpractice rather than on the whole underlying process that ultimately results in patient harm. As an illustration of this, a search for articles in the national newspaper Jyllandsposten gave 11 matches on the Danish word for patient safety (patientsikkerhed) and 32 matches on the Danish word for malpractice (lægefejl). In another national newspaper Politiken the related matches were 6 to 9. Still, the public focus is a lot less on individual errors than compared to other European countries and the US.

The Danish pilot study (mentioned for example in 1a) did not get as much public attention as expected because the publishing time of the study coincided with the terror action of September 11th 2001.

On the professional health care worker's side the focus on patient safety can be illustrated by the fact that there has been a large theme issue on risk management and patient safety in the Journal of the Danish Medical Association No. 39/2001. This was followed by a conference on patient safety. Recently another theme issue on patient safety and quality assurance was just published by the same Journal No. 38/2002. There is also another large patient safety conference organised in April 3, 2003 (arranged by the Danish Society for Patient Safety).

In Denmark, there is a political consensus that patient safety is a core area in the health sector. This has resulted in the fact that the Danish National Board of Health, in conjunction with its revision of the 1993 Danish National Strategy on Quality Assurance, has made patient safety one of the four core areas for the future. This includes:
Primarily, that explicit security measures and procedures have to be implemented in every risk area, and that the control and responsibility of this has to be explicitly designated.

Secondly, as a prevention of adverse events, there have to be implemented national reporting systems of adverse events in order to establish a learning strategy.
Thirdly, a nationwide electronic patient journal system has to be established in order to optimise the availability of information across systems in the health sector.
Finally, The National Board of Health has requested the Danish Society of Patient Safety to cooperate in the preparation of a set of standards on patient safety, which may be included in the future Danish accreditation system.

The strategy is not yet published in English but for further information contact Jytte Burgaard, the National Board of Health, phone +45 72 22 78 22.

Internationally, The Danish Medical Association has put patient safety on the agenda in The Standing Committee of European Doctors (CPME) – a European federation of national medical associations. Also, many other Danish health associations and organisations (for example The Danish Nurses Organization www.dsr.dk) have come a long way in prioritising patient safety and generally putting this issue on their agenda.

b. Is the number of lawsuit against medical accident increasing?

Very few of the Danish patient complaints actually reach the Danish civil court system. This is because there are two separate institutions established to handle Danish health care complaints. These were established for primarily two reasons; (a) in order to secure a quick decision on the complaint, and (b) to alleviate the pressure on the "normal" civil court system. The two institutions are the Patients' Board of Complaints and the Patients' Insurance Scheme.
For an explanation of the Patients' Insurance Scheme please see http://www.patientforsikringen.dk/uk/virksmhed.htm and as a short explanation of the Patients' Board of Complaints the following taken from John Elders book "Who cares about the health victim?"

A series of laws have been passed in Denmark formally and legally ensuring patients' rights, establishing a complaints process and putting in place a system for compensation claims. The aim of this legislation was to create a set of rules to secure for patients the best available treatment and care in all situations.

The key body spearheading the complaints process in the Danish health service is the Patients' Board of Complaints. The Board is an independent public authority which deals directly with complaints against medical practitioners, and may submit particularly serious cases to the public prosecutor with a view to legal action. It is also empowered to investigate complaints concerning health care professionals and other personnel in the private sector.

However, matters concerning damages are not within the competence of the Patients' Board of Complaints. Patients may claim damages in connection with treatment in public hospitals through the Patients' Insurance Scheme which was set up in 1992. They may also receive compensation for harm caused by pharmaceuticals.

The scheme simplifies and speeds up the process of obtaining damages for loss of pay, loss of economic potential, as well as compensation for permanent disability and for pain and suffering. A special damages agreement is in operation for HIV positive haemophiliacs and those infected through transfusions. (All of Denmark's public health service hospitals are insured against liability.) Claims for damages concerning treatment given outside the state health service are pursued through the civil courts in Denmark.

For further details of the system please see chapter 9 in John Elders book "Who cares about the health victim?"

In 2001 for example, just 10 cases out of 2057 were transferred to the courts. Of the reported complaints transferred to the civil courts, the absolute numbers are declining or stable. Though, the number of complaints are on the increase. Enclosure 2 gives an overview of cases reported to the National Board of Patients Complaints.

c. Is the industry interested in patient safety?

Yes, the industry is interested in patient safety as can be seen for example by the establishment in December 2001 of the Danish Society for Patient Safety. This was formed by a broad coalition of all the stakeholders in healthcare amongst others, also industry, hospital owners and patients groups. The board of the society consists of representatives from the medical and nursing professions, social and health assistants, midwives, bio-analysts, the Association of County Councils, the Copenhagen Hospital Corporation, the Danish Pharmaceutical Association, the Danish Association for the Pharmaceutical Industry, the Medicinal Industry and various patient associations. The President of the society is the immediate past president of the Association of County Councils (the hospital owners' association).

A sign of the industry's interest in patient safety can also be seen by the fact that The Danish Board of Technology (Teknologi-Rådet) has researched and published the report on implants mid 2001. In short, the project on implants investigates the following questions:
- What is the extent of the problem, and how many Danes have had surgical implants?
- How can the already careful control of the implants be improved?

- How can clinical conditions be brought into consideration during processes of authorization and approval?

The project was carried out by a group of experts, and at this point the only information available about this project is in Danish (For further information, contact the project manager. Anne Funch Rohmann: afr@tekno.dk).

3. Impact of IOM report

Is a report from the Institute of Medicine in the U.S., "To Err is Human", published in November

2000 known in your country? And if so, did it have influence?

The report is indeed known and it has had a positive influence on the attention on patient safety. Please see the patient safety history in Denmark under A d. for events that have had an even greater impact on the Danish development on patient safety.

B. Action by Stakeholders

1. Government action toward medical accidents/errors and patient safety
Is there a governmental policy especially for medical accidents?
If there is, please describe the policy including the historical development of the policy.

Government action is for example the national strategy mentioned in 2A. Also in the government's status paper 2002[56] on health politics, patient safety is an explicitly mentioned area.

Any governmental policy would have to be a parliamentary decision. As the National Board of Patient Complaints and the Danish Patient Insurance System are both institutions constituted by law, they are also partly governmental policy.

2. Action by other stakeholders
Is there a policy by provider association, medical doctor, nurse, or hospital?

Yes, The Copenhagen Hospital Corporation, which is responsible for about 20% of the Danish hospital capacity, and has from the 1st of September 2001, established a Patient Safety Unit. It's task, to organise and control the handling of adverse events in The Copenhagen Hospital Corporation. The employees and the administration must learn from adverse events, and therefore

[56] Sundhedspolitisk Redegørelse 2002, May 2002, The Ministry for the Interior and Health

root cause analysis is compulsory. The Copenhagen Hospital Corporation is trying to implement a blame free culture through campaigns and education. The policy is inspired by the US' V.A. NCPS policy. The patient safety officers are also trained by the V.A.'s NCPS.

Patient safety policies are being developed in many others of the 14 counties in Denmark. An example of this is the county of Southern Jutland, which is developing the first project in Denmark that also involves the primary care sector both on the county and on the municipality level and as such includes the patient sequence across all sectors in the health system. For further information contact quality manager Linda Schumann Scheel.

In the county of Vejle, for further information please contact Vejle special consultant Mads Haugaard, phone +45 75 83 53 33 or Dr. Helle Ørding, Vejle Hospital phone +45 79 40 62 00. In the county of Aarhus contact Dr. Paul Bartels, Sundhedsfagligt Sekretariat, phone +45 89 44 69 74, they too are working on such models.

3. Action by patients, patient groups or representatives
Do patients, patient groups or representatives have a strong influence on governmental or health care professionals' activities for medical error prevention?

Patients do have an influence on medical error prevention especially by the active engagement of different patient groups in the Danish Society for Patient Safety, but probably not what you could characterise as a strong influence.

4. Third Party Accreditation

With regard to quality, third party organization accredits and evaluates hospital performance in many countries. And in some cases, the organization rates/ benchmarks hospitals or health care institutions. Is there any such an organization in your country?

At the moment there is no such national organization in Denmark, but in a 3-year perspective, the goal of the National Strategy (mentioned in 2A), is to develop a common national model of accreditation.

The Joint Commission International accredited in March 2002 the Copenhagen Hospital Corporation, as the first of all hospitals in Scandinavia. For further information please contact phone number +45 36 32 21 71.

There are other systems of accreditations in other parts of Denmark. In Southern Jutland they are developing a model of accreditation themselves in cooperation with the British Health Quality Service.

C. Information System

1. Reporting system/ information system

Is there any nation wide reporting system for medical accidents, e.g. a reporting system in aviation industry or adverse event reporting system in Australia?

At the moment no, but the Minister of Health is 1. of October expected to approve and announce a nation wide reporting system for medical accidents like the ones in aviation industry. It is expected that it will be implemented in 2003-2004. It is expected also that it will be based on a no-blame voluntary reporting system.

Of nationwide reporting systems there are at the moment three compulsory nation wide reporting systems for medical accidents:

1) Danish Medicines Agency and the National Board of Health
   Users and producers of medical equipment are obligated to report to the Danish Medicines Agency[57] (DMA) any error or near errors on or in connection with medical equipment. Furthermore, there are laws on specific areas to compulsory report to the National Board of Health on any adverse events in connection with radiotherapy equipment and x-ray equipment along with other high-risk areas. In this connection it is absolutely mandatory to describe these events in the chart of the given patient.
2) Police
   A doctor is obligated by law to notify the police if there is a suspicion that a patient's death is a result of a medical error. The police usually hands over the case to the medical officers.
3) The Medical Officers (an institution under the National Board of Health)
   Anybody or any organisation can complain or raise questions to these Medical Officers about any individuals and/or of current systems. As such, this is a form of a voluntary possibility to lodge a complaint. After The Medical Officers receive a complaint or a question raised, they decide whether they want to investigate it further. This occurs in order to ensure that every individual working in the health care system actually has the right competence, and as well as to ensure that no organisational structure causes

[57] The DMA is an agency under the Ministry for the Interior and Health and their main assignments are to authorise and control medicinal products and companies, including pharmacies, and to monitor the economy and consumption of medicinal products.