

SAFETY MANAGEMENT IN CIVIL AVIATION - A USEFUL METHOD FOR IMPROVED SAFETY IN MEDICAL CARE?

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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.

INTRODUCTION

Medical errors are also a work environment problem

Within health care, incorrect assessment or a stressful situation with a fraction of a second's inattention can lead to devastating consequences for the individual patient. Medical errors also contribute to higher costs for society in the form of extended treatment, sick-leave and the loss of income (Bogner, 1994). In addition to the suffering incurred by the individual patient and his/her loved ones, the medical error also involves mental strain, and sometimes social trauma, on the part of the personnel involved in the event (Wu et al, 1991; Christensen et al, 1992; Bark et al, 1997). According to a study from the Swedish National Institute for Working Life, these concerns constitute a greater stress factor than to traditional work environment problems (Sundström-Frisk, 1994). Consequently, these issues related to improving safety within the health care sector are also significant from the work environment perspective.

The Swedish reporting system, lex Maria

The Swedish system for reporting medical errors (lex Maria) is the result of an event in 1936 when four people died after receiving mercuric oxycyanide instead of an anesthetic (Ödegård & Löfroth, 1996). Lex Maria requires by law that health care personnel report serious near-accidents and errors to the National Swedish Board of Health and Welfare (NBHW). The original purpose for reporting such events, which was to attain evidence to facilitate a police investigation, had a clearly disciplinary aim the result of which was that investigations came to be focused on the individual caregiver. Over the years the intention of the legislation has changed, and it now has a preventive aim where the purpose of reporting is to obtain

knowledge about the risks. Nevertheless, the state authority still has the responsibility of determining the need for possible disciplinary action. This means that health care personnel are required to report errors for which they may receive sanctions (SFS 1998:531). During 1998, 117 lex Maria incidents were forwarded to the Medical Responsibility Board (MRB) by the NBHW for possible disciplinary action.

The perception of mistakes

The culture in the health care sector is characterized by a striving for faultlessness and by the nonacceptance of mistakes (Rosenthal, 1994). This view contributes to feelings of guilt and shame. In addition to the fear of making mistakes, there is also the threat and fear of being reported (Wu et al, 1991; Vincent, 1997; Cristensen et al, 1992), and the one-sided focus of the mass media on the individual can contribute to this (Crane, 1997). Furthermore, the health care unit runs the risk of negative "publicity," since a report to the NBHW constitutes a public document that is accessible to the mass media. Another factor that further influences the perception of errors is the connection between the reporting system and sanctions, something that can also lead to a decreased tendency to report incidents on the part of health care personnel. It is probably the case that these factors affect the openness about discussing risks in health care and that they also contribute to the reduced reporting of risks (Lucas, 1991; Leape, 1994; Reason, 1997).

Medical errors

Various studies have tried to determine the scope of injuries resulting from health care and treatment. In 1960, a prospective study in the USA showed that the proportion of iatrogenic injuries amounted to 20%. Of these, 20% were comprised of serious injuries or death (Shimmel, 1964). In one of the studies receiving most attention, which was conducted in 1984 in 51 hospitals in New York State, 31,121 randomly selected medical records were examined. The percentage of "adverse events" was determined in the study to be 3.7% (Brennan et al, 1991). An "adverse event" was defined in the study *"as an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge or both"* (Brennan et al, 1991). If these figures are extrapolated to include the entire population of New York State, i.e. approximately 2.6 million patients, 98,600 adverse events would have taken place. For the entire USA, corresponding figures would mean that 1.3 million people are injured annually in the health care sector, which is more than double the number of traffic injuries occurring annually in the USA.

A similar study in Australia showed that the percentage of adverse events was 16% (Wilson et al, 1995). A later study from the US confirms the Australian results (Andrews et al, 1997). In the Australian study "adverse events" were defined as being unintentional injuries or complications caused by the health care sector resulting in disability, death or prolonged hospitalization. Of these adverse events, 13.7% resulted in permanent disability and 4.9% in death. However, the study also showed that 51% of the adverse events were deemed preventable. The corresponding figure in the USA was 69% (Leape et al, 1991). No similar studies have been conducted in Sweden.

The risks are increasing

Modern health care places high demands on personnel through the use of more technically complicated apparatus and advanced monitoring equipment. Furthermore, major structural changes are underway, often involving large financial incentives (NBHW, 1998). A larger number of more seriously ill patients are cared for at home, while at the same time fewer opportunities exist for further education for health care personnel, especially those lowest down in the health care hierarchy, i.e. nursing assistants and practical nurses. The substance of health care education is changing, which may result in erroneous expectations concerning, for example, the clinical skills of newly graduated nurses. And in combination with an inadequate introduction to a new job, this may constitute a risk factor. Furthermore, there are growing numbers of alarming reports on stress, the fast tempo and the poor staffing, as well as the unreasonably long length of work shifts, especially for doctors in emergency care. Baldwin et al (1997), have demonstrated the association between the number of estimated serious errors and a heavy workload and a feeling of incompetence.

Reports in Sweden

Information concerning the scope of the problem in Sweden can be obtained by compiling the reported events submitted to the MRB, the Patient Insurance System, and the NBHW, which are the monitoring authorities for the health care sector. Patients who are dissatisfied with the care they have received can report personnel to the MRB, which can be likened to a court for medical issues. Financial compensation for medical errors can be obtained by applying to the Patient Insurance System, which is a "no-fault" insurance program. Therefore, the question of guilt is irrelevant with respect to compensation. The criterion for compensation is a complication that was not anticipated. Another source of information concerning medical errors is comprised of the events reported to the NBHW in accordance with *lex Maria*. The general public may also report complaints regarding health care to the NBHW. The compilation in Table 1 shows that reports from patients to both the Patient Insurance System as well as to the MRB are increasing, while reports from the health care sector to the NBHW have decreased in recent years.

According to the quality assurance regulations introduced in 1996 (SOSFS 1996:23) the health care providers are required to monitor unwanted events and to draw systematic conclusions from such information. The authorities believe that the decrease in the reporting of risk events partly is due to this increased responsibility. Therefore, the number of risk events can be assumed to be much greater than that reflected by the *lex Maria* reports.

Table 1 The number of injuries reported to the Patient Insurance System, the MRB, and the NBHW

Reports to	Years				
	1994	1995	1996	1997	1998
Patient Insurance System	7 311	7 371	7 321	7 775	8 283
MRB	2 414	2 521	2 659	2 860	3 107
The NBHW					
Lex Maria	1 567	1 418	1 371	1 202	1 133
Complaints from individuals				1 060	1 337

International Safety Research

The fact that patients are accidentally injured in connection with health care and treatment can naturally be related to the medical treatment and constitute a normal risk. An error may also be the result of human error, such as lack of concentration, forgetfulness, or a misinterpretation of a situation.

In international safety research, which has its origin in cognitive psychology and "human-error" research, terms such as *active* and *latent* errors (or latent conditions) are used (Reason, 1990; 1997). Active errors are usually committed by individuals who, last in a long chain of events, trigger the accident, such as pilots, nurses and doctors. The action leads to an immediate consequence. In contrast, latent errors originate from faulty decisions often made by people who are indirectly involved in production. These decisions can later result in negative consequences through chain reactions that lead to active errors. Examples of latent errors can be the restructuring of work units, insufficient resources that lead to staff reductions, faulty design of technical equipment, inadequate coordination of resources, poor access to competent professionals during on call hours, unrealistic scheduling, etc. These are factors that can affect the individual's actions and constitute the indirect cause of an "active error".

Another theoretical point of departure is Rasmussen's (1987) so-called "SRK model" which defines human error using three dimensions: Skill-based, Rule-based, and Knowledge-based levels. Skill-based behavior refers to routine tasks that require little or no attention to be completed, which also means that other tasks can be done simultaneously. Rule-based behavior refers to normal activities that require a certain degree of decision-making. The knowledge-based level refers to problem-solving activities such as when one is confronted with situations for which a solution is not yet known.

Research in behavioral science that explains the causes of human error in complex systems has for many years influenced work conducted in the area of safety in high technology areas such as aviation, offshore operations and nuclear energy (Perrow, 1984; Rasmussen, 1987; Reason, 1990). How these industries manage risks is becoming increasingly interesting to the health care sector, especially in technology-intensive areas such as surgery, anesthesiology, and intensive care (Eagle, 1992; Gaba, 1994; Helmreich, 1997).

PURPOSE AND METHODS

The overall purpose of this study is to examine whether the methods of risk management used by civil aviation are relevant to work with prevention concerning patient safety, and thereby the work environment of health care personnel, and whether it is also possible to apply these methods throughout the health care sector, even in non-technical areas. The foundation for this study includes not only civil aviation, but also military aviation and nuclear power. Only experiences from civil aviation will be reported in this article.

The material is based on interviews with those responsible for safety and quality in civil aviation in Sweden and the USA. Interviews were also conducted with representatives of the Board of Accident Investigation, as well as with the monitoring authorities for civil aviation in Sweden (the Aviation Safety Department) and the USA (the FAA - the Federal Aviation Administration). In addition, interviews were conducted at NASA regarding the incident reporting system used by the US civil aviation industry. The material is also based on regulations and other written documentation. A total of 12 interviews were conducted on location in aviation organisations, all of which were recorded and transcribed in their entirety. Following the interviews, supplementary questions were posed where appropriate via telephone. The questions were focused on safety, with emphasis on risk management. A compilation of the basic material was communicated to those interviewed. Those parts of the risk management system used in the civil aviation, and which are considered applicable to the health care sector, are presented in this study.

RESULTS

Safety in civil aviation is based on international guidelines in accordance with the Chicago Convention, and the guidelines have been operational since 1944. In order to administer the agreements from the convention, the International Civil Aviation Organization (ICAO) was formed. There are 183 member nations, and each nation determines its own regulations. The European unification efforts are having an increasing influence on Sweden's regulations. Work is underway to develop common inspection routines and a mutual inspection database for member countries in Europe. Since the regulations in Sweden and the USA are relatively similar, this account is mainly based on Swedish civil aviation and Scandinavian Airlines (SAS).

Monitoring

The National Aviation Authority monitors operations as well as individual pilots and flight technicians. The same is true regarding the FAA in the USA. SAS, which is the largest civil aviation company in Scandinavia, has its own monitoring authority, as a result of its ownership situation. This is because the company is under the jurisdiction of legislation in three nations, and is subject, in principle, to the most rigid requirements in each country. SAS is monitored by the Scandinavian Supervisory Office (STK). Aviation monitoring has previously focused to a large degree on checking the physical details of the equipment. The advanced technology characterizing the aviation industry today no longer permits this type of inspection and monitoring. This is one of the reasons why operational monitoring was instituted. Operational monitoring means that each company itself has the main responsibility for directing and monitoring safety. The existence of established routines and standards is monitored by the authority (SOU 1996:74).

Representatives of the aviation monitoring authorities in both Sweden and the USA have said that one of the difficulties at their level is the dual role involving both prevention as well as supervision and inspection. When regulations are violated in the aviation industry, sanctions are possible both in Sweden and the USA, but authorities are very restrictive with regard to sanctions.

Organization of work concerning safety

The larger airline companies in Sweden and the USA have a specific organization for work related to safety. In addition to the groups that work on general safety issues, there are groups concentrating on the development of methods and on analyzing reported incidents. And the Swedish Aviation Safety Department and its American counterpart, the FAA, have specific groups that work exclusively with safety analysis.

Investigations of serious aviation incidents in Sweden are carried out by the Board of Accident Investigation (SHK) which is an independent authority. The SHK investigates aviation accidents that result in death, serious injury or major damage to the aircraft or environment (SFS 1990:712). In addition, the SHK investigates marine and railway accidents and near-accidents. Other serious accidents may also be the subjects of SHK investigations. The SHK was established to avoid partiality, or in other words so that the authority responsible for monitoring safety would not also be responsible for investigations in this area, which could result in a situation where the authority would refrain from criticizing the area under investigation too harshly. The American counterpart to the SHK is the National Transportation Safety Board (NTSB).

SAS also has a special inquiry group within the company called "the Saint Group," which in principle works according to the same standards as the SHK. The composition of the group is determined by the type of incident that has occurred. The Chair of the investigation group is required to report all significant findings that are judged to require immediate measures to those responsible in the line of command. Those persons who are directly involved in the incident are given the opportunity to read and comment on the rough draft of the report.

Examples of safety-related work in the aviation industry

Risk reporting

In addition to reporting to authorities, each airline is responsible for an internal reporting system. These requirements are based on ICAO recommendations. In Sweden, reporting is to be done to the National Aviation Authority, and for SAS, reporting is to be done to their own authority. Reports are made using special forms or forms created by each individual company. A comprehensive reporting system exists within SAS for various types of risks, with detailed instructions for definitions, reporting criteria and the handling of information.

According to ICAO recommendations, an investigation should include information gathering, examination of the data and analysis of all available, relevant information, and if possible, it should identify causes of the event. The only purpose of an investigation is to prevent accidents and/or incidents. The final report should also suggest recommendations for measures to improve safety. All legal or administrative measures that may involve guilt or punishment must be kept separate from the investigation. A specific restriction states that information discovered during an investigation may not be disclosed if the information will be used for disciplinary purposes. *"If such information is distributed, it may, in the future, no longer be openly disclosed to investigators. Lack of access to such information would impede the investigative process and seriously affect flight safety."* (ICAO, 1994 Annex 13).

Risk Analysis - Monitoring

In order to increase information used for work with prevention and safety, SAS has established a special monitoring system for its cabin staff, in addition to the traditional reports for deviations related to safety. Through this certain predetermined items are investigated. The purpose of the system is to study how well established procedures are followed and whether these procedures have weaknesses. This insight provides the flight operative unit with a basis for improvements with respect to quality and safety-related issues. In order to make examination of possible trends possible, most items are repeated from month to month. And to maintain continuous interest in the system on the part of the flight operatives unit, there is space for temporary items for shorter periods of time (one or two months). This makes it possible, for example, to check the implementation of new procedures or to carry out special studies. The flight manager selects specific areas for examination. Approximately 3% of all SAS flights are monitored each month, which generates between 800-1,000 reports.

A new type of flight safety monitoring is planned for pilots, which means that their actions and a number of predetermined items will be evaluated. Prior to a flight the pilot will obtain a form with questions selected by the company concerning information of interest. An additional type of monitoring used in the aviation industry is the flight recorder, the so-called black box, which can measure up to approximately 1000 variables and which provides valuable information about how the flight is carried out. At SAS the flight recorder is analyzed after each flight. There is also a voice recorder, which is analyzed only after accidents.

The reporting system used by the civil aviation in the USA

The reporting system used by the civil aviation in the USA was established with the aim of increasing the reporting of incidents. The Aviation Safety Reporting System (ASRS) represents "transactional immunity". This means that the FAA refrains from issuing fines or other disciplinary measures in exchange for an open account of the causes of the incident. The ASRS may not be used for disciplinary purposes, which is regulated by legislation, with the exception of criminal acts (US FAR 91.25, 1985). Events that are reported concern risk situations as well as situations that could have involved risk situations. The significance of the human factor is an important focus in the ASRS. By means of analysis of reported incidents, the aim is to obtain a base for preventive measures and improvements in the system, as well as to obtain an increased understanding of safety-related problems within aviation. Three specific factors in the system are that it is voluntary, confidential and free from sanctions.

The reporting system has its origin in two events that occurred in the beginning of the 1970s that indicated, following analysis, that there had been inadequate management of reported information by the authorities. On December 1, 1974, TWA flight 514 collided with a mountaintop while flying into Dulles International Airport in Virginia, and all on board perished. The aircraft flew at too low an altitude because the pilot misunderstood information received from the air traffic controller. Six weeks prior to the accident, a United Airlines (UA) aircraft barely escaped a similar accident thanks to the attentiveness of the pilot. The pilot had informed United Airlines and the FAA about the incident. Unfortunately, all airlines were not made sufficiently aware of information about the episode, which the accident in Virginia made very plain.

One of the investigations initiated after these events called for a better reporting system, and in May 1975 the FAA established a "non-disciplinary" and anonymous reporting system. Few incidents were reported, however, because of a distrust of the authority's promise of no disciplinary action. Following intensive debate about the design of the system, where the pilots' union demanded not only immunity and anonymity, but also that the authorities would not be allowed to monitor the system, it was decided that the National Aeronautics and Space Administration (NASA) would be given the task of developing a confidential reporting system. Furthermore, immunity would be regulated through legislation.

Proficiency Tests

Within civil aviation, regular testing of theoretical and practical knowledge is required for pilots, flight controllers, and flight technicians. In Swedish civil aviation this is regulated by the BCL; Regulations for Civil Aviation (LFS 1993:7). From 1999 the regulatory framework (JAR-FCL; Flight Crew Licensing) has been coordinated throughout Europe. For pilots, the testing comprises both theory and practice, with, among other things, flight simulator training which is done each six months. In accordance with the ICAO, 80% of the questions in each test must be answered correctly. In addition to checking the pilot's knowledge of flight regulations, the theory part of the tests also comprises knowledge of the aircraft's technical system. It is the responsibility of each airline to make sure that these tests are carried out. Furthermore, the authority also requires that each pilot complete a "line check" each year. This means that the pilot flies with an observer who evaluates and observes how the flight is carried out and how communication functions in the cockpit, with air traffic controllers and with ground personnel. An evaluation is made based on a specific schedule and is communicated to the pilot after the flight. There are also proficiency tests for cabin personnel, but these are not related to individual performance.

Experiences from serious accidents within the civil aviation industry have shown that inadequate communication and collaboration are obvious risk factors (Helmreich, 1997). This resulted in the development of a special educational program where communication between the crew in the cockpit and

other crew members, as well as with air traffic controllers is the focus. The program is called Crew Resource Management (CRM), and has now been implemented in the civil aviation industry. The CRM approach seeks to utilize the human resources in the cockpit through well-planned cooperative routines, interactive support and the breaking down of negative authoritarianism. This promotes cooperation and teamwork in the cockpit; formally the Captain is still in charge, but in practice all decisions are made by the team.

Restrictions on work hours

In both Swedish and American civil aviation there is legislation concerning work hours as well as restrictions limiting the length of work shifts from a safety perspective. The regulations apply to all crew members. The Swedish system is based on points, and is regulated by the BCL (LFS 1980:6). When schedules are made up, the amount of time on duty is not allowed to exceed 90 points during active duty, and the total number of points during the period, which is to comprise 7 calendar days, may not exceed 270 points, not counting points for landing. However, the commanding officer can agree to a maximum of 18 additional points for events which could not have been foreseen when the schedules were made up (Table 2). The airlines are required to check the work shifts and rest periods for each individual ordered to work as a crew member, and those who work for more than one airline are required to supply the necessary information to the airline in question so that scheduling can be done according to regulations.

Table 2 Calculation of on-duty points in civil aviation in Sweden

Type of activity	Time of day	On-duty points/hour
Active flight duty	06.00-22.00	6 points/hour
	22.00-06.00	8 points/hour
Landings		5 points/landing
Flight training in an aircraft or simulator		14 points/hour
Passive flight duty on the ground		>4 hours = 0 points <4 hours = 3 points/hour
<i>Decrease in on-duty points</i>		
Rest periods	06.00-22.00	6 points/hour
	22.00-06.00	8 points/hour

Even the length of rest periods is regulated, and they are to be at least 8 hours in length, and at least every other rest period should be long enough to allow the total number of points to fall to 0. In addition, within a 14-day period a crew member should be allotted 2 long-term rest periods of at least 26 hours each. These should be calculated from the timepoint at which the crew member's total number of points falls to zero. The airline is required to maintain a running record of each crew member's total number of points, and this journal must remain accessible for at least a 12-month period.

COMPARISON WITH THE HEALTH CARE SECTOR

Organizations for safety and monitoring

An obvious difference when comparing the aviation industry with the health care sector is that the larger airlines in Sweden and the USA have separate units that work with safety-related issues. Examination of the three largest hospitals in Sweden shows that there are no corresponding units working with patient safety-related issues. Patient safety is most often combined with other quality issues.

Corresponding differences also apply to the respective monitoring authorities in that civil aviation in Sweden and the USA both have separate units that work with safety issues, with special sections for investigation and analysis of reported risks (Table 3), which are not found in the NBHW. Nor are special "accident investigations" required when serious incidents or accidents occur, despite the fact that arguments

about partiality are probably the same for the monitoring authorities of the health care sector and the aviation industry, respectively.

Table 3 A comparison between civil aviation and the health care sector with respect to risk management

Type of activity	Organization for work concerning safety	Regular proficiency tests	Restrictions concerning length of work shifts*	Regular risk analyses
Civil aviation	Yes	Yes	Yes	Yes
Health care sector	No	No	No	No

*over and above the law concerning work time

Both the Civil Aviation Commission and the NBHW have decentralized organizations, and they carry out both monitoring both of activities and of individuals. Of the approximately 140 employees at the Civil Aviation Commission 2 are lawyers (1%), which can be compared to 24 of the 110 (22%) employees working with monitoring activities at the NBHW.

Reporting System

The reporting of incidents comprises an important basis for work with prevention in civil aviation. Within the health care sector, the national reporting system, lex Maria, comprises only the reports of serious events or risks for serious events. Experience has shown, however, that in principle, the latter are not reported. This means that national reporting of both serious risks as well as near-accidents is lacking in the health care sector. Furthermore, the formulation of the regulations means that lex Maria reporting and health care providers' local systems for handling deviations have an indirect connection to sanctions, which can contribute to a decreased tendency to report incidents (Lucas, 1991; Reason, 1997). In this respect the American civil aviation industry's system for incident reporting, the ASRS, is of particular interest since the person making the report has legal immunity, provided that he or she can prove that the event has been reported. Furthermore, this system is voluntary, confidential and is outside the control of the authority. In addition, feedback of experience has a very high priority.

Proficiency testing

A pilot in Sweden or the USA must undergo proficiency testing every 6 months to retain his/her flight certificate. This requirement is regulated by law and is based on common international regulations. In the health care sector, a license is a guarantee that the individual has obtained a certain level of proficiency. This license therefore can be said to constitute society's label for safe health care and is valid for the individual's lifetime. Compared with the aviation industry, health care legislation has relatively vague requirements regarding proficiency testing of licensed personnel and other caregivers. It is true that regulations concerning quality issued by the NBHW (SOSFS 1996:23) state that health care providers should make sure that staff have the necessary competency for the duties they perform. Continuous proficiency testing, however, has thus far not been a tradition in health care. That this type of "risk analysis" can provide important information concerning patient safety was demonstrated in a study conducted in the municipal health care sector, where the knowledge of 3000 nursing assistants and practical nurses concerning diabetes was tested. Among other things, the study showed clear deficiencies in how the administration of insulin was delegated to these groups, as well as serious deficiencies in knowledge (Ödegård, 1997).

Human factor research has shown that inadequate communication and an unclear distribution of responsibility can contribute to obvious risk factors (Reason, 1997). In civil aviation, this knowledge has led the authorities to require Crew Resource Management training. An example of risks in health care where a counterpart could be relevant would be during surgery, where there can be some uncertainty in the communication between the surgeon and the anaesthesiologist, and between the operating room nurse and the nurse anaesthetist. Other examples of risk factors in this area can be found in connection with reorganization in a hospital or with organizational mergers of hospitals where established routines are

changed and the composition of personnel groups is split up. Therefore, the requirement for CRM by civil aviation should probably also be relevant to the health care sector, even in areas other than anesthesiology and intensive care, where similar programs are being tested (Holtzman et al, 1995).

Restrictions on work hours

Within the aviation industry, the total number of points is not allowed to exceed 270 points during a 7-day period, or 90 points for one work shift, which corresponds to approximately 12 hours including landings (Table 3). In the Swedish health care sector a corresponding limitation in number of work hours from the perspective of patient safety is lacking. When a work schedule at an emergency department at a middle-sized hospital in Sweden was examined, it was found that a substitute doctor's schedule for a 7-day period amounted to 850 points according to the system of calculating used by the airlines - without anything extra for landings. One of the continuous shifts involved working from 7:45am on Friday until 5pm on Monday, or slightly more than 80 hours. In civil aviation this corresponds to 470 points, which is more than is allowed for a 7-day period. These calculations include planned "on-call" duty.

DISCUSSION AND CONCLUSIONS

In this study, methods for risk management used by civil aviation have been examined. The focus has been on systems for reporting risks, investigation and analysis, the organizational prerequisites for working with safety issues, the existence of proficiency testing, and restrictions in work hours as related to safety.

When compared with the health care sector, it appears that the thinking in civil aviation regarding safety is focused to a great extent on what the health care sector calls "primary prevention", i.e. measures directed at preventing the occurrence of errors. The foundation for the safety-oriented work in civil aviation is based on international research on safety, which has shown that human errors cannot be completely prevented (Rasmussen, 1987; Reason, 1995). It is also probable that the causes of human error, which may result in hundreds of people on a plane losing their lives, may be the same as when a newborn in a neonatal clinic receives the incorrect dosage of medicine, or when a patient has the wrong kidney removed. Within the aviation industry, the knowledge generated from human-factor research, for example, has resulted in a change in the thinking about safety that has influenced both legislation as well as attitudes regarding errors (Rasmussen, 1996).

Risk Reporting

A functional system for reporting risks in health care is particularly important since there are many indications that risks in the health care sector are increasing. With the present formulation of legislation regarding the reporting of risks (*lex Maria*), there is an obvious risk that work with prevention will be made more difficult because the risks are not reported. This means, therefore, that legislation that is intended to increase patients' safety instead constitutes an indirect obstacle to prevention. This issue is especially interesting against the background of the fact that the number of *lex Maria* reports continues to decrease while reports to both the MRB and the Patient Insurance System are increasing in number.

Everyone interviewed in this study felt that the most important aspect of a reporting system, irrespective of whether the reporting is to a central or a local reporting system, is that the person doing the reporting trusts the system and does not risk sanctions. The fact that sanctions can be assumed to have an inhibiting effect on the tendency to report, with the risk that serious deficiencies are not reported by the individual who committed the error, is discussed in a number of studies (Leape, 1994; Bark et al, 1997; Vincent, 1997).

Based on the association between sanctions and the reporting of errors in the Swedish reporting system, *lex Maria*, there is reason to consider a change in the design of the system. Sanctions against an individual who is usually very familiar with the task but who made a serious error on one occasion, probably does not result in improved safety. Work should instead be directed towards other solutions (Leape, 1994; Vincent et al, 1998; Reason, 1997). An example is mistakes with medication which, despite disciplinary measures for the individual, are one of the most frequent medical errors in health care. So-called "active errors" in handling medications constitute an area where today's technical possibilities regarding prevention

are probably greatly underutilized, which may be explained by the insistent assertion that the personnel "must learn to read".

In an information system with the purpose of gathering information for preventive measures, "near-errors" are important because they help achieve the necessary volume and because they provide important information about weaknesses in the system (Van der Schaaf, 1992). Near-errors are events that could have had negative consequences, but did not. Reason (1997) states that near-errors provide free lessons and can, if analyzed in the right way, function as a vaccine in order to mobilize resistance. In contrast to the aviation industry's incident reporting system in the USA, where the reporting of incidents is encouraged, the Swedish health care sector has restricted the criteria for what should be reported. Two examples are injuries due to falls and medication errors.

Restrictions in work hours

There have been recurrent discussions in the health care sector concerning the work hours of doctors, in particular, although usually not in terms of patient safety. Despite the fact that extremely long work shifts are not as common today as in the past, long shifts regularly occur at some departments. Scheduling a doctor in an emergency department to work an 80-hour shift is an example of what is considered a latent error in safety research. Using this example in which a doctor has an unrealistic work schedule, the reason for an error should be sought in the organization and the administrative manager. It is true that in this example on-call duty is included, but a doctor on first call or second call in the area of emergency care has a high probability of being called. That an individual's judgment and ability to react are reduced as a result of sleep deficiency and fatigue has been demonstrated in simulator studies (Howard et al, 1997). In addition to these risk factors, an extremely long period of on-call duty can mean that other staff members take this into consideration and incorrectly hesitate to "disturb" the doctor. Arguments focused on increased costs and technical scheduling difficulties should be considered in relation to the individual patient's safety, but they are also relevant from a work environment perspective

Risk analyses

Within the aviation industry, it appears that work concerning prevention, including legislation, is more offensive and focuses on identifying risks before they result in errors, which can be explained in terms of the nature of the industry. In a comparison between a cockpit and an operating room, however, it is probable that the activity in the operating room would be judged to be more risk-filled. This indicates that the thinking about safety should be as well-developed in the health care sector as it is in the aviation industry. Similar clear requirements, with restrictions concerning the length of work shifts, and risk analyses when organizational changes are planned and prior to planned vacations, when making work schedules and on-call systems, as well as proficiency testing, would all contribute to increased safety. Introduction of new equipment and methods is another area where risk analyses are motivated. This would also increase awareness about risks in health care and thereby result in an improved basis for measures to increase safety.

Organizational prerequisites

A number of factors may have contributed to the fact that the health care sector does not have the well-developed awareness concerning safety as does, for example, the aviation industry. It may be that the effects of an error are of some significance, since an error in civil aviation can mean that hundreds of people lose their lives, while an error in the health care sector is not as obvious, which has therefore meant that the problem has not received more attention. Today the health care sector does not have an authority with prevention as its sole purpose, which investigates adverse events in health care. The same is true on the local level. Insufficient insight about the causes of human error and what is called "organizational accidents" in safety research (Reason, 1997) can result in an incorrect focus on those at the lowest end of the health care hierarchy, who make a mistake. This means that the latent errors remain, with the risk that the errors will be repeated.

The possibility of examining the issue of guilt when an error has occurred is naturally important to the general public. The Swedish model with the MRB is therefore valuable and should be maintained. The "court-like" function of the MRB is probably advantageous for "accused" health care personnel. On the other hand, it is doubtful whether safety in health care benefits from the fact that both the MRB and the

NBHW investigate possible issues of guilt, particularly when there is no authority/organization that explicitly works with safety in health care from a national perspective.

CONCLUSION

The conclusion of this report is that organizational prerequisites for working with safety should be improved at both local and national levels, with units working explicitly with patient-related safety issues with no focus on issues of guilt. A national, voluntary reporting system which also includes so-called near-errors, without any connection to sanctions or the monitoring authority, should be considered. Work with prevention should be based to a greater extent on identifying weaknesses and deficiencies in both existing and planned activities. For example, there should be clearer requirements for carrying out risk analyses. Restrictions concerning length of work shifts should be considered for all health care personnel, as should regular proficiency testing. Patient safety in the health care sector should receive increased attention as a problem area, and research and development should be promoted. Furthermore, the prerequisites for work with prevention and patient safety should be optimal, and the legislation intended to increase patient security and safety should be clear, unambiguous and readily applicable.

One year after the airline accident in the USA, the resultant reporting system, the ASRS, became legislation. In the Swedish health care sector, a serious dialysis accident occurred in 1982, costing three people's lives. The debate still continues regarding the need for an increased focus on the system instead of on the individual when medical errors are investigated. Questions pertaining to organizational prerequisites for secure and safe health care, such as work conditions and the length of work shifts, were discussed in an editorial in one of Sweden's daily newspapers as early as 1936 in connection with a serious medication error at Maria Hospital in Stockholm.

Cognitive psychology and safety research have shown that certain incorrect behaviors cannot be eradicated by education or punishment. For such cases, other types of barriers must be developed that make it more difficult or impossible to make errors. Not until this is understood will safety consciousness in the health care sector develop - which is something that would benefit both patient safety as well as the work environment of the staff, who, in addition to experiencing the fear of committing an error and the threat and fear of being reported, often work in a hard-pressed situation.

REFERENCES

- Andrews, BA, Stocking, C, Krizek, T, Gottlieb, C, Vargish, T & Siegler, M. (1997) An alternative strategy for studying adverse events in medical care. *Lancet* 349; 309-13.
- Baldwin, PJ, Dodd, M & Wrate, RW. (1997) Young doctors health: How do working conditions affect attitudes, health and performance? *Social Science & Medicin* 45:35-40.
- Bark, P, Vincent, C, Olivieri, L, & Jones, A. (1997) Impact of litigation on senior clinicians: Implications for risk management. *Quality in Health Care* 6, 7-13.
- Bogner, MS. (1994) Human error in medicine. A frontier for change. In: Bogner, MS (Ed): *Human error in medicine*. Lawrence Erlbaum Associates, Hillsdale, N J.
- Brennan, TA, Leape, LL, Lairs, NM, Hebert, L, A Russel Localio, JD, Lawthers, AG, Newhouse, JP, Weiler, PC & Hiatt, HH. (1991) Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 324, 370-376.
- Crane, M. (1997) When a medical mistake becomes a media event. *Med Econ* 74 (6) 158-71.
- Christensen, JF, Levinson, W & Dunn, PM. (1992) The heart of darkness: The impact of perceived mistakes on physicians. *J Gen Intern Med* 7, 424-31.
- Eagle, CJ. (1992) Accident analysis of large-scale technological disasters applied to an anaesthetic complication. *Can J Anaesth* 39, 118-22.
- US FAR 91.25 (1985) *Aviation Safety Reporting Program*. US Federal Aviation Authority.
- Gaba, DM. (1994) Human error in dynamic medical domains. In Bogner, MS. (Ed) *Human error in medicine*, pp 197-225. Lawrence Erlbaum Associates, Hillsdales, NJ.
- Helmreich, RL. (1997) Managing Human Error in Aviation. *Scientific American* 276 (5) 40-45.

- Holzman, RS, Cooper, JB, Gaba, DM, Philip, JH, Small, S & Feinstein, D. (1995) Anesthesia crisis resource management: Real-life simulation training in operating room crises. *J Clin Anest* 7: 675-687.
- Howard, SK, Smith, BE, Gaba, DM, Rosekind, MR. (1997) Performance of well-rested vs. highly-fatigued residents: A simulator study. *Anesthesiology* A-981
- ICAO (1994) *International Standards and Recommended Practices for Aircraft Accident and Incident Investigation*. Annex 13, 8th Edition, July 1994.
- Leape, LL, Brennan, TA, Laird, N, Lawthers, AG, A Russel Localio, JD, Barnes, BA, Hebert, L, Newhouse, JP, Weiler, PC & Hiatt, H (1991) The nature of adverse events in hospitalized patients. Results of the Harvard medical practice study. II. *N Engl J Med* 324; 377-84.
- Leape, LL. (1994) Error in Medicine. *JAMA* 272; 1851-57.
- LFS 1980:6. Regulations for civil aviation (BCL-D 1.15) Operative Regulations. General regulations, Restrictions on hours on duty crew members (in Swedish).
- LFS 1993:7. Regulations for civil aviation (BCL). Operative regulations. General regulations for flight safety (self-monitoring) in the aviation industry, 1993-06-01 (in Swedish).
- National Board of Health and Welfare (1998) *Sjukvården i Sverige* (in Swedish). Stockholm.
- Perrow, C. (1984) *Normal accidents*. Basic Books, New York.
- Rasmussen, J. (1987) Cognitive Control and Human Error Mechanisms. In Rasmussen, J, Duncan, K & Leplat, J (Eds) *New Technology and Human Error*. John Wiley & Sons, New York.
- Rasmussen, J. (1996) *Integrating Scientific Expertise into Regulatory Decision-Making. Risk Management Issues - Doing Things Safely with Words: Rules and Laws*. European University Institute. Working Paper RSC 96/5, Badia Fiesolana, San Domenico (FI).
- Reason, J. (1990) *Human error*. Cambridge University Press.
- Reason, J. (1995) Understanding adverse events: human factors. In Vincent CA (Ed) *Clinical risk management*. pp 31-54. BMJ Publications, London.
- Reason, J. (1997). *Managing the Risks of Organizational Accidents*. Ashgate, Aldershot, UK.
- Rosenthal, MM. (1994) *The incompetent doctor: Behind closed doors*. Open University Press, London.
- SFS 1990:712. Lag om undersökning av olyckor. *Svensk författningssamling*.
- SFS 1998:531. Lag om yrkesverksamhet på hälso- och sjukvårdens område. *Svensk författningssamling*.
- Shimmel, EM. (1964) The Hazards of Hospitalization. *Ann Intern Med* 60;100-10.
- SOSFS 1996:23. Anmälningsskyldighet enligt lagen 1996:786 om tillsyn över hälso- och sjukvården (lex Maria) samt lokal avvikelshantering. *Socialstyrelsens författningssamling*.
- SOU 1996:74. Description of safety philosophy and regulatory practices in Scandinavian civil aviation, pp 331-344.
- Sundström-Frisk, C. (1994) The risk of making treatment errors - an occupational stressor. In Hagberg, M, Hoffman, F, Stössel, U & Westlander, G (eds): *Occupational Health for Health Care Workers*. 2nd International Congress, Stockholm. ICOH/CIST pp 56-62.
- Van der Schaaf, WT. (1992) *Near miss reporting in the chemical process industry*. Profscript. Technische Universiteit Eindhoven.
- Vincent, C. (1997) Risk, safety and the dark side of quality. *BMJ* 314; 1775-76.
- Vincent, C, Taylor-Adams, S & Stanhope, N. (1998) Framework for analysing risk and safety in clinical medicine. *BMJ* 316; 1154-57.
- Wilson, MR, Runciman, WB, Gibberd, RW, Harrison, BT, Newby, L & Hamilton, JD. (1995) The Quality in Australian Health Care Study. *Med J Aus* 163; 458-71.
- Wu, AW, et al (1991). Do house officers learn from mistakes? *JAMA* 265; 2089-94.
- Ödegård, S & Löfroth, G. (1996) The Swedish Lex Maria - then and now. Patient injuries in health care in an historical perspective. *Nordisk Medicin* 111; 352-355 (in Swedish).
- Ödegård, S. (1997) *Does municipal primary care result in improved collaboration with home-help services? Nursing assistants' and practical nurses' knowledge about diabetes - a measure of the collaboration between professions*. Study for the Municipal Primary Care project, Swedish National Board of Health and Welfare (in Swedish).