The Danish patient safety experience: the Act on Patient Safety in the Danish health care system

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Abstract

This paper describes the process that lead to the passing of the Act for Patient Safety in the Danish health care system, the contents of the act and how the act is used in the Danish health care system.
The act obligates frontline health care personnel to report adverse events, hospital owners to act on the reports and the National Board of Health to communicate the learning nationally. The act protects health care providers from sanctions as a result of reporting. In January 2004, the Act on Patient Safety in the Danish health care system was put into force. In the first twelve months 5740 adverse events were reported. The reports were analyzed locally (hospital and region), anonymized and then sent to the National Board of Health.
The Act on Patient Safety has driven the work with patient safety forward but there is room for improvement. Continuous and improved feedback from all parts of the system is essential to maintain the level of reporting.

Keywords: patient safety, adverse event, Danish pilot study, Danish Society for Patient Safety, reporting system, learning system

Background

Patient Safety was put on the Danish health care agenda in 2001. A Danish pilot study [1], published September 2001, showed that 9% of patients admitted to a Danish hospital experienced an adverse event resulting in an average of seven extra bed days. The study was based on a review of 1097 patient records and found that 40% of the adverse events were preventable; the remaining 60% were classified as complications. The study was based on the Harvard Medical Practice Study design [2] and has the same potential and limitations as the other adverse event studies that have been carried out. (Box 1).

The Danish Pilot study was an important part of raising the profile of patient safety issues. Danish health care faces the same patient safety problems as other health care systems thereby highlighting the common need to address these. Patient safety has now become an important issue on the Danish Health Care agenda.

This study also led to the initiation of the foundation of the Danish Society for Patient Safety, which was established December 2001. The board members represent a wide range of stakeholders in Danish health care: the health care providers, patient and research organizations, the Danish Regions (hospital owners), the pharmaceutical and medical device industry, the Danish Consumer Council and Local Danish Government (the Danish municipalities).

One of the first important initiatives from the Danish Society for Patient Safety was to put pressure on the political system to act on the results of the pilot study.

In order to face the patient safety problem, the creation of a national reporting system for adverse events seemed to be a logical step – since you need to know the nature of the problems in order to do something about them. Although vision and logic is important it is another thing to face the challenge of creating a system that is both political acceptable, that the health care staff want to use and that works in practice.

An important step towards a general agreement on a reporting system was the stakeholder dialogue that took place within the Danish Society for Patient Safety. Through this process the major

Box 1.

Danish health care system
- Predominantly publicly financed – hospitals are owned by the regions
- Primary sector consists of general practitioners, home care and nursing homes
- Secondary sector consists of primarily public hospitals
- No visiting physicians

stakeholders in health care were able to reach a consensus decision on the recommendations for the design of the reporting system.

In this situation it was very easy for the Danish Minister of Health to agree to the idea of a reporting system. He was facing a serious problem and the Danish Society for Patient Safety suggested a logic solution that all the stakeholders supported. It became a win-win situation.

It should be emphasized that the suggestions for a reporting system took into consideration the attitudes of the healthcare personnel. These were obtained through a study [3] that was financed by the Ministry of Health and the healthcare administration in the Copenhagen Region and carried out by appropriate healthcare research institutions[1]. Based on focus group interviews with health care providers, a questionnaire to frontline personnel (doctors and nurses) and a literature review the study recommended that a national reporting system should be strictly confidential. The system should have learning purposes only and be separate from the disciplinary system. Local data should be transmitted anonymously to a national level.

On the basis of the recommendations from the study and the input and political support from the Danish Society for Patient Safety, the Minister of Health in April 2003 presented a bill on patient safety to the Danish Parliament which was then passed unanimously in June 2003. In January 2004 the act was put into force.

The Act on Patient Safety in the Danish health care system

The purpose of the Act on Patient Safety [4] is to gather, analyze and communicate knowledge on adverse events in order to reduce their number in the Danish health care system. The act obligates frontline personnel to report adverse events, the hospital owners to act on the reports and the National Board of Health to communicate the learning gained from the reports. At the present moment only adverse events occurring in hospitals shall be reported.

This act also protects healthcare providers from sanctions in order to facilitate the reporting of adverse events to the learning system. A health care provider cannot, as a result of reporting an adverse event, be subjected to disciplinary action. The learning system is strictly separated from the disciplinary systems, i.e. the complaints and supervision systems as well as from the patient insurance system.

This does not mean that health care providers are no longer subject to disciplinary if the adverse event has been reported to the learning system. As previously stated the essence of the protection for healthcare providers is that reports to the learning system are inaccessible to the disciplinary systems and the patient insurance system. Disciplinary action therefore cannot be as a result of a report made to the learning system - but can be, for example, a result of a patient complaint. The disciplinary systems and the patient insurance system co-exist with the learning system but information is not interchangeable.

When a health care provider is involved in or observes an adverse event the person is obligated to report it. The adverse event can be reported electronically via a website, www.dpsd.dk. Some hospitals use local systems for reporting. In either case the regions (hospital owners) receive the reports, analyze them and take steps to prevent the event from happening again. When a region has finished with a particular case study, an anonymous version of the report is sent to the National Board of Health. This means that there is no identifiable information in the reports sent to the National Board of Health, neither on the patient nor on the health care providers involved in the adverse event. Only hospitals and departments are identifiable. The National Board of Health gathers the information from the regions and uses it for disseminating knowledge at a national level.

Three types of adverse events must be reported:

- adverse events in connection with medication
- adverse events in connection with surgical or invasive procedures
- other serious adverse events, for example events that are at risk of happening again.

Both actual adverse events and potential adverse events ("near-misses") must be reported. In September 2005 it was agreed that all types of adverse events should be reported from January 2006.

The health care providers can choose to report anonymously. This is not recommended though, as it makes the collection of further information difficult for the analyzing team. Most health care providers choose not to be anonymous, which indicates a fundamental confidence in the reporting system. (Box 2).

Organization of the work with patient safety at regional level

Standardized guidelines have not been implemented for the organization of the activities

([1]) Risoe National Laboratory, DSI Danish Institute for Health Services Research and the Danish Institute of Medical simulation.

Box 2.

The Act on Patient Safety in the Danish health care system – main points:

- The act is learning and system oriented
- It obligates frontline personnel to report adverse events, hospital owners to act on the reports and the Board of Health to communicate the learning
- Reported events are send to and analyzed by the relevant region/hospital, the data are anonymized and send to the Board of Health. The Board of Health gathers and analyzes the information and distributes knowledge on a national level
- The act protects health care providers from sanctions as a result of reporting

for patient safety. Therefore the hospitals administrations, consisting of the 14 Danish Regions and the Copenhagen Hospital Corporation, have had the possibility to organize the work around existing local structures and conditions.

There are some common features of these activities though. In almost all of the regions representatives from both the region, hospital and ward are involved in collecting and analyzing the data. Most regions have a patient safety unit, often integrated within the quality department. The patient safety unit can either refer to the hospital management or to the organization responsible for quality. The analysis and the risk assessment of the adverse events are typically carried out by the person in charge of the ward in cooperation with the ward's patient safety representative and the local patient safety manager from the hospital. (Figure 1).

In order to prioritize the analysis of the reported events most regions use the Safety Assessment Code Matrix, as suggested by the VA National Center for Patient Safety [5]. The higher the score the more intense the analysis, see table 1. Severity is the degree of actual or potential harm to the patients; potential harm is considered to be just as serious as actual harm. Probability is a judgment on how frequently a similar event is likely to occur.

To support the work in the regions the Danish Society for Patient Safety has provided training for a number of regional patient safety managers, developed tool kits on the Human Factor, Root Cause Analysis, Healthcare Failure Mode and Effect Analysis and legal issues as well as developed a website with illustrative case histories. Furthermore, the Society together with the National Board of Health has compiled a report on safe clinical practices. The report describes 22 clinical practices where there is potential for improvement and gives pointers on how to achieve the improvements suggested. The report is inspired by the National Quality Forums report Safe Practices for Better Healthcare [6].

Figure 1.

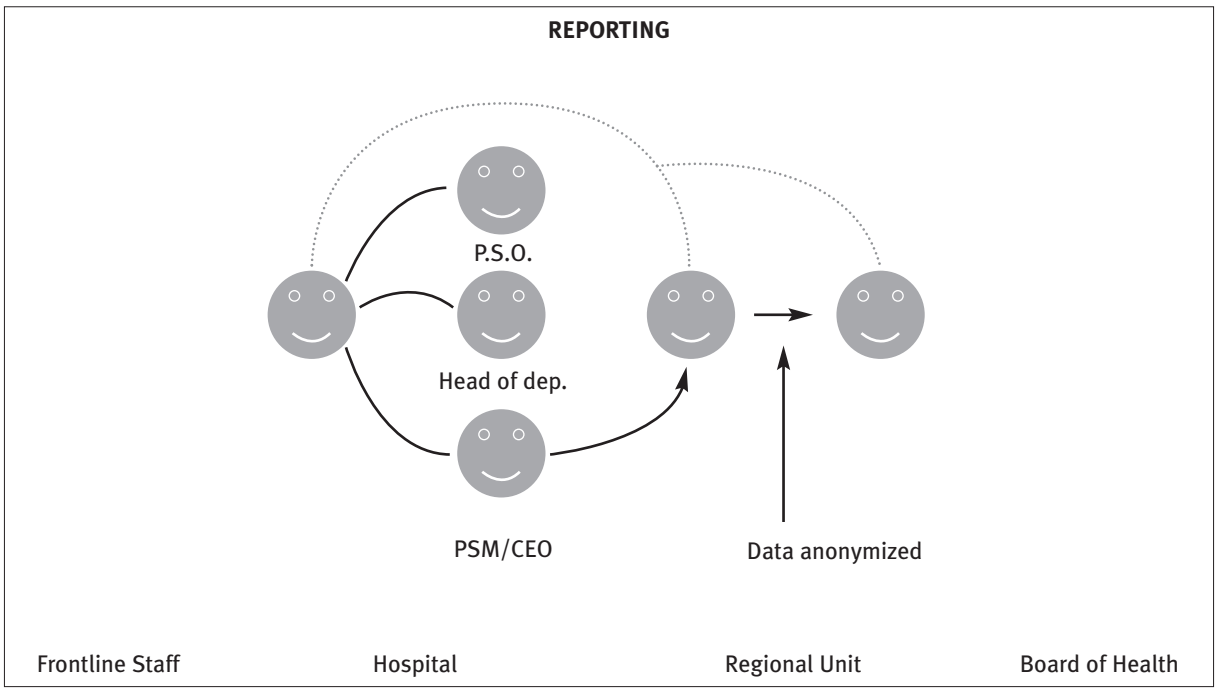


Table 1. Safety Assessment Code (SAC) Matrix

Severity and Probability	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

Results at the regional level

There are no published data on the results from the regions, so the following examples are taken from the Copenhagen Hospital Corporation. The Copenhagen Hospital Corporation has had its own reporting system since 2002 and the number of reports is steady increasing, see figure 2.

A few examples of preventive actions taken, based on local reports, are as follows:

- A protocol to ensure correct surgery (avoiding wrong site/wrong patient) was adapted and implemented in May 2005 after 12 reports of wrong site surgery were received (1:32.000 surgical procedures); 5 of the 12 incidents were avoided before incision. A protocol to ensure correct surgery has been implemented in all surgical departments in the corporation and is very similar to the protocol from the VA National Center for Patient Safety (7,8).
- Elimination of different types of look-alike medications based on either adverse events or near miss reports.
- Implementation of a protocol to improve suicide risk assessment.This was based on 27 Root Cause Analyses on inpatient suicides.
- A safer use of infusion pumps including redistribution of infusion pumps so that only one type of pump is present in each department.This was based on 1a Root Cause Analysis and 56 other reported adverse events.

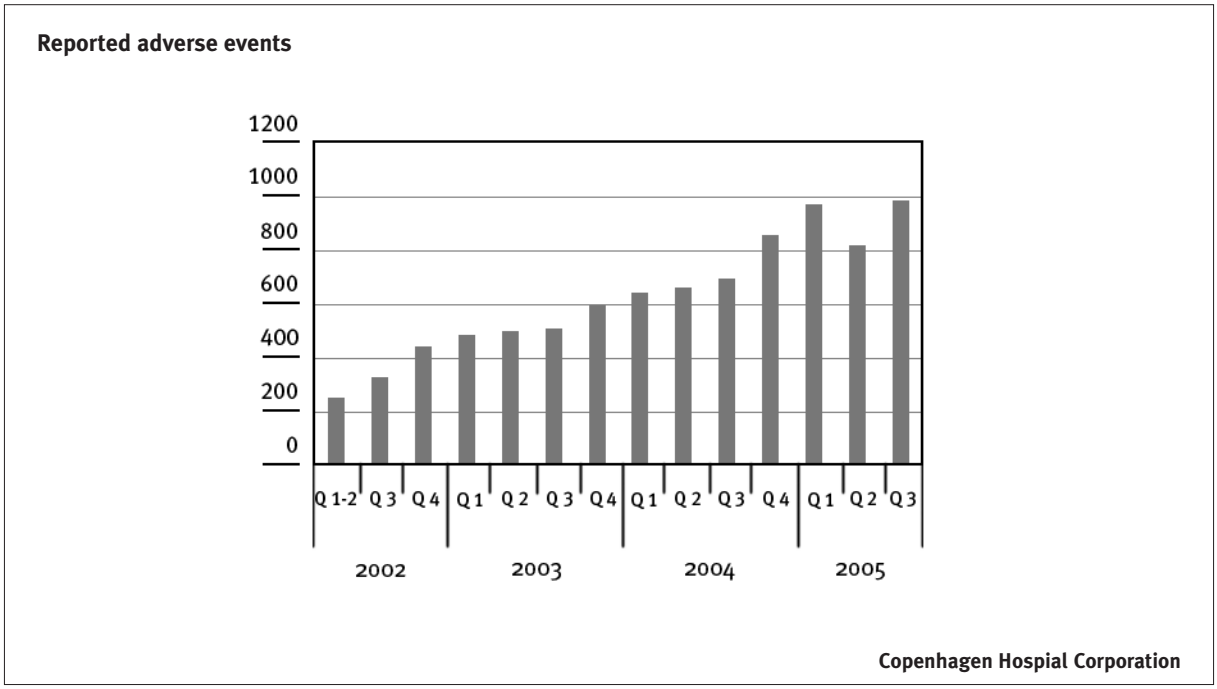
Results at the national level

The Act for Patient Safety in the Danish health care system, along with the national reporting system, was put into force January 1st 2004. In the first year, from January 1st 2004 till December 31st 2004, 5740 adverse events were reported (9).The National Board of Health had anticipated that only around 3000 reports would be filed during its first year of operation.

A working group with representatives from the National Board of Health, the regions and the Copenhagen Hospital Corporation has been set up to deal with the issues relating to the dissemination of the learning from the reports.

Feedback with specific suggestions on patient safety improvements from the national level was expected but so far the output has been limited. At this moment the knowledge from the National Board of Health is distributed through quarterly

Figure 2.



electronic newsletters[2], alerts[3] on the reporting system website (www.dpsd.dk) and through the publishing of the first annual report. Since the majority of the reports are on medication errors the National Board of Health is composing a special report to address this issue.

Discussion

The Act for Patient Safety in the Danish health care system has bought the work on patient safety in Denmark to the forefront. At the local/regional level (wards, hospitals and regions) adverse events are being analyzed and changes in organizational structures and procedures are occurring. In many ways the reporting system is therefore already a success, although at the national level, there have only been just a few suggestions for changes so far. So there is still room for improvement, since reporting to the national system is of little value if it is not followed up by recommendations for change. One might say that creating an efficient and constructive response system is even more important than creating a reporting system. The greatest weakness of the Danish reporting system is the lack of specified output requirements at the national level.

Some regions have carried out culture surveys as a surrogate for measuring improvements in patient safety. There are, although this would be desirable, at the present time no plans for patient safety culture surveys at a national level.

In the spring of 2006 the Act on Patient Safety in the Danish health care system will be evaluated. Discussions will, amongst other things, focus on the planned expansion of the reporting system. At the present moment only health care providers are supposed to log reports on events that have occurred in secondary (hospital) care. In the future, the system should also facilitate patient reporting and include adverse events occurring in primary care, for example in general practice, pharmacies or in nursing homes.

Conclusions

The Danish act on patient safety and the national reporting system for adverse events generates valuable knowledge about the root causes of adverse events. Furthermore, the existence of a reporting system is believed to support the development of a safety culture, because it obligates stakeholders from the chief director down to the front line personnel to commit to patient safety. The high number of adverse events reported to the national reporting system in 2004 is a positive sign. However, in order to maintain the high level of reporting, it is crucial to have continuous and improved feedback from all parts of the system. It is also important to keep in mind that reporting is only the first step. To create real changes and safety improvements the implementation and monitoring of solutions on patient safety issues must also take place.

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Consulted web sites

English translation of the Danish Act on Patient Safety. www.patientsikkerhed.dk/about
Danish National Board of Health. www.sst.dk

([2]) The newsletters typically contain an overview of the number and types of reported adverse events and some general information on the reporting system. One newsletter also contains a few suggestions for changes and some of the newsletters describe the alerts on the reporting system website.

([3]) At the present moment 6 alerts are available at the reporting system website, for example an alert on the risk of suffocation when using soft fixing belts and an alert drawing the attention to the fact that plastic bags in litter bins should be reconsidered at psychiatric wards because they can be used for suicide purposes.