

Experiences from Denmark

Creating an Open Confidential System for Reporting and Learning from Adverse Events

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Patient safety came strongly on the Health Care Agenda in Denmark with the publication of the Danish Adverse Event Study in 2001⁽¹⁾. Before that, the issue of patient safety was not commonly known or acknowledged in Denmark. The study showed – not surprisingly compared to the international data - that 9 percent of the Danish patients experienced an adverse event resulting in an average of seven extra beds days.

When the data were published there was very little discussion about whether or not the data was correct. Basically most parties accepted the numbers and accepted the need to take action. Thus the Danish Study was an important part of raising a political agenda for promoting patient safety. And patient safety quickly became an important and influential issue on Danish Health Care Agenda.

The study led to the founding of Danish Society for Patient Safety in December 2001. The Board of the Society represents a wide range of stakeholders in Danish health care: Regional governments interest organisation (Hospital owners), Regional representatives, Professions, Patient organisations, Pharmacists, Industry and Research. The Goal of the Society is to ensure that patient safety aspects are a part of all decisions made in health care. The first aim was to put pressure on the political system to act on the results of the pilot study and make suggestions for a national reporting system.

Recommendations for a National Reporting System

The Department of Health asked a group of experts to make suggestions for a national reporting system. The experts recommended asking the health care providers themselves what kind of

reporting system they were actually willing to report to.

The results were clear⁽²⁾:

- It had to be a strictly confidential system with a sharp distinction between the disciplinary and the learning system
- Data collected locally should be anonymously transmitted to the national level

The Minister of Health adopted these recommendations basically without any changes and realized that an Act on Patient Safety that included a blame free national reporting system was a win/win situation, if none of the important stakeholders - for instance patient groups or other of the larger parties in parliament - would argue against it. A huge change like this had to have a broad and solid support both in parliament and in the population. As a consequence all the stakeholders in the Danish Society for Patient Safety contacted all important decision makers to advocate for blame free reporting system.

What seems to puzzle people outside Denmark most is why the patients would support a no blame reporting system. There are probably several reasons for this. First of all patient harm due to adverse events were no surprise to the patients or the Patient organizations. In patient surveys almost one out of five Danish patients responded that they personally had experienced mistakes during their stay in Hospital⁽³⁾. Secondly the Patient Organizations had an understanding of the systemic perspective via the work in the Danish Society for Patient Safety. And finally the Act on Patient Safety did not change the Patients' legal rights, since the system were added to the systems that were already in place. And none of these changed as a result of the Act.

The systems already there were:

- The Complaint system where Health Care providers can be sanctioned for making errors⁽⁴⁾
- A No-Fault Compensation System that compensate patients under certain circumstances for adverse harm⁽⁵⁾
- A supervisory system under the National Board of Health

To these systems were added a national reporting system with the sole purpose of learning in order to protect the next patient.

The Danish Act on Patient Safety

The Act on Patient Safety⁽⁶⁾ passed parliament unanimously in June 2003 and was put into force January 2004. The act states that:

- Frontline Personal are obligated to report adverse events
- Hospital owners are obligated to analyze and act on the reports
- The National Board of Health communicates the learning

The data collected through the national reporting system are totally protected. One of the paragraphs in the Act states that a frontline person who reports an adverse event cannot as a result of that report be subjected to investigation or disciplinary action from the employer, the board of Health or the Court of Justice.

Since the Act went into force in 2004, the number of reports has increased every single quarter and will probably increase for the coming years as well (Figure 1). Not because of more and more events are occurring, but because of more and more are reported. Not all events that should be reported are in fact reported, but more and more are.

And the understanding is that it makes more sense to spend the time and energy on acting on the reports, rather than to try to collect all possible reports.

Reported Adverse Events
Danish Patient Safety Database

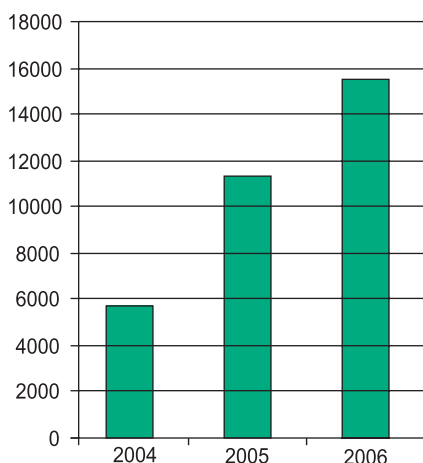


Figure 1

Almost all reports are filled by the Health Care Providers that were most involved in the event. Reports where nurses report doctors' errors or vice versa do almost not exist. All groups are reporting doctors as well as nurses, midwives pharmacists etc, etc.

It is possible to report anonymously but less and less people use this possibility. In data from Copenhagen Hospital Cooperation it has gone down from 8 to 3% of the report over the years.⁽⁷⁾

The National database and the National reporting system are very simple and low-tech systems.

They are both based on local reporting. The reports are analyzed and acted on locally or at regional level. Then the data is transferred to the national level. The National system will be revised during 2007 to meet a need for a greater flexibility in out data collection to the regional level and due to a coming revision of the Act on Patient Safety to include the primary sector and patient reporting in 2008.

Factors for success

Important factors for the success and effect of the reporting system are:

- Support by the leadership

- The reports are analyzed
- The learning is shared
- Action is taken based on the analyzes
- Monitoring of the changes

In 2006 an external Evaluation Centre evaluated the Act on Patient Safety. The study showed, that 2/3 of doctors and nurses agreed that reporting had lead to positive changes.⁽⁸⁾

In order to prioritize the reported events most hospitals use a scoring matrix. The scoring is based on a combination of risk and frequency. The higher the score the more intensive analyses is required. In the beginning root cause analysis were considered extremely time consuming and difficult to do. But like everything else there is a learning curve and experience clearly decreases the time spent on each analysis. Presently an average of 20 hours altogether is used on one root cause analysis.⁽⁹⁾

One of the major challenges is to make action plans that are realistic and possible to implement on the basis of a root cause analysis, and that have the power to prevent a similar event in the future.

Most of the reports and analyses result in local changes. But these changes are brought up on the National level as well. Here they should be evaluated in order to decide whether or not the particular solution should be suggested to the national level. This does not always take place and have caused different kinds of problems. Maybe it is not possible to do in a sensible way.

Three examples of improvements/solutions on the basis of the National reporting system:

- 11 pharmaceutical products have had their packaging changed. More are to come.
- It is recommended no longer to use a reusable ventilation bag that should be sampled in an emergency situation.
- It is now mandatory for the surgeon to sign the operational site together with the patient and to have a short briefing for everybody on the surgical team just before the procedure in order to prevent all kinds of wrong site surgical procedures.

Up until now the Act on Patient Safety has only been in force in the secondary health care sector. But it is expected that from 2008 it will also cover the primary health care sector. It is also likely that patients will be offered an opportunity to fill in reports to the learning system. These changes await a political process in Parliament during 2007.

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