DANISH PATIENT SAFETY
DATABASE

DPSD, July 2007
Danish Patient Safety Database

National Board of Health
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DK - 2300 Copenhagen S

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1 Background for The Act on Patient Safety

The debate on patient safety in the hospital sector really started to gain momentum in Denmark in 1999. This was the year the American report “To Err is Human” was published. The report showed that up to 98,000 patients died in the American hospital system each year as a result of errors and adverse events. Transposed to Danish conditions, these findings correspond to 5,000 mortalities a year in the Danish hospital system.

In autumn 2000, the Danish Institute for Health Services Research (DSI) together with the Ministry of the Interior and Health and a number of the Danish Counties carried out a prospective study, “The Incidence of Adverse Events in Hospitals”, aimed at determining the extent and nature of harmful adverse events during hospital admissions in Denmark.

The Danish Adverse Event Study was published in September 2001. Based on a review of 1,097 patient records the study found that 9% of patients admitted to a Danish hospital were involved in an adverse event. Of the adverse events, 40% were preventable and the remaining 60% were classified as complications. The adverse events prolonged the hospital stay by an average of 7 days.

The results of the Danish study indicated that efforts on the patient safety front needed to be intensified considerably. The need to learn from the experience of health care professionals with adverse events was also recognised. A project was thus initiated concerning the requirements for a registration system for adverse events at hospitals. This resulted in a number of recommendations regarding a registration system for adverse events.

Together with previous experience on patient safety the project results led to introduction of the Act on Patient Safety, which entered into force in January 2004.
The Act on Patient Safety

The purpose of the Act is to gather, analyse and communicate knowledge of adverse events in order to reduce the number of adverse events in the Danish hospital system. The Act requires frontline personnel to report adverse events, the hospital owners to act on the reports, and the National Board of Health to communicate experience from the reports.

The Act applies in connection with the treatment of patients in the hospital system. The health care professionals are required to report an adverse event, if one occurs:

“A health care professional who becomes aware of an adverse event in connection with a patient’s treatment or stay in a hospital shall report that event…”

Health care professionals are defined as “… persons authorised pursuant to special legislation to perform health care tasks and persons acting under their responsibility”.

The Act defines an adverse event as:

“… an event that results from treatment at or stay in a hospital, and which is not caused by the patient’s illness, and which is concomitantly either harmful or could have been harmful, but was prevented from occurring or did not occur for other reasons. Adverse events include both previously known and unknown events and errors.”

The adverse event has to take place as a result of the patient’s “treatment”, i.e.: “… examination, diagnosis, clinical treatment, rehabilitation, health care and prophylactic health care…”, or as the result of the hospital stay itself, e.g. falling out of bed.

The Act on Patient Safety provides important protection of health care professionals. A health care professional cannot be subjected to disciplinary action as a result of reporting an adverse event. This protection enables sanction-free reporting and is crucial for the willingness of health care professionals to report. To ensure this protection the learning system is strictly separated from the three other systems for handling adverse events: The supervision system operated by the National Board of Health, the complaint system and the patient insurance system.

In the Act on Patient Safety the protection of health care professionals is formulated as follows:

“A health care professional reporting an adverse event shall not as a result of such reporting be subjected to disciplinary investigations or measures by the employing authority, to supervisory reactions by the National Board of Health or to criminal sanctions by the courts.”
3 Dealing with adverse events

Representatives from the five Danish Regions and the hospitals are involved in collecting data on and analysing adverse events. The Regions each have a patient safety unit, which is often integrated with their quality assurance department.

The analysis and risk assessment of an adverse event are typically performed locally by the head of the department where the adverse event occurred. This is often done in cooperation with the department’s patient safety officer and the hospital’s risk manager, as well as with frontline personnel and representatives from middle management.

When an adverse event is severe or involves several institutions, the Region’s patient safety unit often becomes more involved in the analysis. In either case, the Region’s patient safety unit receives the analysed reports from the hospital in order to take action at the regional level and to ensure that the data are anonymised before being forwarded to the National Board of Health.

The system is designed as a bottom-up process where the majority of the work is locally rooted. The point is that adverse events that are rooted locally should be analysed and corrected locally. This is also thought to have a considerable impact on the development of a safety culture.

3.1 The role of the National Board of Health

The National Board of Health harbours the national reporting system. The Board receives analysed and anonymised reports from the Regions, thereby enabling it to spot common patterns and trends and to provide feedback and knowledge to the Regions regarding specific risk situations. The information is disseminated from the National Board of Health in the form of newsletters, alerts and reports on specific subjects, for example medication errors (www.dpsd.dk). Furthermore, the National Board of Health publishes an annual report on general issues and results. It should also be mentioned that the information from the reports is also used as background material for the development of binding national standards for patient safety. The aim of these standards is to create a common foundation for the prevention and handling of adverse events.

The cooperation between the Regions and the National Board of Health takes place through two patient safety fora: a strategic forum and a technical forum.

The strategic forum was established in 2005 as an advisory organ charged with developing the reporting system and coordinating the work between the National Board of Health and the local units. The main task of the technical forum is to provide advice and serve as a forum for sharing information concerning the Danish Patient Safety Database, including the mutual exchange of local and national experience. In practice the forum has been considerably occupied with the IT solutions used.
4 Health care in Denmark

- Denmark has a population of approximately 5.5 million people
- Health care is primarily a public task
- The public hospitals were owned by the 14 Danish Counties and Copenhagen Hospital Corporation until January 2007, when the 14 Counties were superseded by five Regions following a reform of Danish administrative structure
- The primary sector consists of general practitioners and specialists, the home care service and nursing homes
- The secondary sector consists of hospitals
- Care provided by public hospitals, general practitioners and specialists, the home care service and to some extent nursing homes is free of charge.

In 2006 there were:

- 1.2 million discharges from the hospitals
- 1 million visits to hospital emergency rooms
- 1.8 million hospital outpatient visits
- 37 million visits to general practitioners
- 5 million visits to specialists.
5 The 2006 reporting results

In 2006, a total of 15,556 reports on adverse events were submitted to the Counties by health care professionals at the hospitals (primary reporting), and 12,370 analysed reports were submitted to the National Board of Health/Danish Patient Safety Database by the Counties (secondary reporting). The corresponding figures for 2005 were 11,401 and 9,096, respectively, while those for the first year the reporting system was in operation – 2004 – were 5,104 and 3,626, respectively.

The analysed reports for 2006 are subdivided into nine categories distributed as follows:

- 4,356 (35%) of the reports concerned events associated with medication
- 802 (6%) of the reports concerned events associated with surgical/invasive procedures
- 2,177 (18%) of the reports concerned falls
- 117 (1%) of the reports concerned suicide and attempted suicide
- 224 (2%) of the reports concerned events associated with anaesthetic procedures
- 1,210 (10%) of the reports concerned mistaken patient identity or staff miscommunication
- 1,163 (9%) of the reports concerned events associated with breaks in continuity
- 102 (1%) of the reports concerned cardiac arrest or unexpected death
- 2,219 (18%) of the reports concerned other types of event.

In the Regions the reported events are subjected to risk assessment using the internationally acknowledged Safety Assessment Code system. Each event is assigned a risk score on a scale from 1 to 3 based on its severity and probability of occurrence.

Only 320 – 3% of the reported events – were assigned a risk score of 3, i.e. were considered to be very serious. The corresponding figure for 2004 was 3%, while that for 2005 was 4%.

25% of the reports were submitted by physicians, and just under 60% by nurses and other care workers.
5.1 Follow-up on adverse events in 2006 and 2007

5.1.1 National Board of Health

Two national binding standards have been issued. One concerns elimination of wrong-site, wrong-patient, wrong-procedure surgery. The other concerns the prescription and handling of medication.

Three theme reports have been published containing recommendations. One concerns prevention of suicide and attempted suicide during admission. The second concerns the preparation of patients prior to surgery or other invasive procedures and major diagnostic imaging tests. The third concerns adverse events connected to blood and tissue tests and diagnostic imaging tests. The latter report will be followed up by a national binding standard.

Seven alerts have been published on the website.

In addition, quarterly and annual reports have been published.

Reports on patient falls, risk medicine, identification bracelets and cardiotocography have been started.

5.1.2 Regional

The regional patient safety organisations have undertaken numerous activities.

All the Counties have worked with:

- Root cause analysis of adverse events having a high risk score
- Implementation of concrete guidelines for improving patient safety
- Establishment of concrete solutions for local patient safety problems
- Courses and teaching.

Some Counties have paid special attention to patient safety culture in the hospital departments.

Some Counties have prepared aggregated analyses and/or theme reports on specific patient safety problems such as:

- Treatment of cardiac arrest
- The use of bed rails
- Patient falls
- Suicide and attempted suicide during admission.
6 Evaluation of the reporting system

The Act on Patient Safety specifies that the reporting system is to be evaluated after it has been operational for two years. The evaluation was carried out by the Ministry of the Interior and Health over the period June–August 2006, 2½ years after the reporting system began operation. The Ministry selected an independent firm of consultants, Rambøll Management, to perform the actual evaluation.

Among other things, the evaluation was based on a questionnaire survey among nurses, doctors and risk managers and on focus group interviews.

The aim of the evaluation was to answer the following main questions:

1. Does the local/regional reporting system function as intended?
2. Does the central reporting system function as intended?
3. How can the reporting system be expanded?

6.1 Functionality of the reporting system at the local and regional levels

The overall assessment is that the reporting system largely functions satisfactorily at the local and regional levels. Considering that the Act on Patient Safety was only passed in 2003, the hospitals and the Counties/Copenhagen Hospital Corporation have made considerable progress on the patient safety front. This assessment is based on the following conclusions of the evaluation:

- The Act on Patient Safety has been well received by health care professionals, and several emphasise that the Act is really beneficial for the work on patient safety
- The Act on Patient Safety has helped formalise the work on patient safety, imposes patient safety obligations on health care professionals and makes it clear that adverse events can be reported without the fear of sanctions
- The Counties and in particular the hospitals have built up an organisational structure for the work on patient safety. Patient safety officers and risk managers have been appointed, and in most cases guidelines and information leaflets have been prepared, and procedures have been developed for working with patient safety
- Courses and continuing education in patient safety are being offered
- Patient safety is being focussed on at the administrative level, and patient safety is now well established in the administration of the individual departments
- The majority of health care professionals have confidence in the system:
a. Two thirds of health care professionals state that they are extremely or very confident that the reports will be treated confidentially.

b. Fear of sanctions only stops a very small proportion of health care professionals from reporting specific adverse events in which they have been involved.

- Just under half of the health care professionals have been involved in an adverse event during the course of a year (Table 1). Physicians report 85% of adverse events, while nurses report 89% (Table 2).

<p>| Table 1 – Proportion of health care professionals who have been involved in an adverse event |</p>
<table>
<thead>
<tr>
<th>Have you been involved in an adverse event within the past year?</th>
<th>Physicians</th>
<th>Nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, in connection with medication</td>
<td>30%</td>
<td>28%</td>
</tr>
<tr>
<td>Yes, in connection with surgical or invasive procedures</td>
<td>14%</td>
<td>12%</td>
</tr>
<tr>
<td>Yes, in connection with other events</td>
<td>23%</td>
<td>23%</td>
</tr>
<tr>
<td>No</td>
<td>52%</td>
<td>53%</td>
</tr>
<tr>
<td><strong>N</strong></td>
<td><strong>861</strong></td>
<td><strong>1,158</strong></td>
</tr>
</tbody>
</table>

Note: The figures do not add up to 100% as the health care professionals can have been involved in adverse events both in connection with medication, surgical/invasive procedures and other events.

| Table 2 – Proportion of adverse events that have been reported |
|---------------------------------------------------------------|------------|--------|
| Proportion of adverse events that the health care professionals have reported? | 85%        | 89%    |

- In the majority of cases the adverse events resulted in action being taken. Thus 70% of the adverse events that the health care professionals were involved in were followed up in some way or other (Tables 3 and 4)

- The patient safety system and the work with patient safety is predominantly assessed positively

- Technical problems do not comprise any marked barrier for reporting adverse events. One of the reasons for this, though, is that technical problems were avoided by the Counties and Copenhagen Hospital Corporation, especially in the start-up phase, due to the fact that the primary reporting was done on paper.
Table 3 – The significance of adverse events for change in practice

<table>
<thead>
<tr>
<th>Has the reporting of the adverse events that you have been involved in led to changes in the department?</th>
<th>Physicians</th>
<th>Nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, informal changes in routine practice</td>
<td>20%</td>
<td>26%</td>
</tr>
<tr>
<td>Yes, formal changes in procedures or practice</td>
<td>39%</td>
<td>34%</td>
</tr>
<tr>
<td>Yes, changes in safety procedures regarding the use of equipment</td>
<td>19%</td>
<td>16%</td>
</tr>
<tr>
<td>Yes, changes in safety procedures regarding the use of medication</td>
<td>23%</td>
<td>25%</td>
</tr>
<tr>
<td>No</td>
<td>29%</td>
<td>33%</td>
</tr>
<tr>
<td>Unsure</td>
<td>8%</td>
<td>8%</td>
</tr>
<tr>
<td>N</td>
<td>311</td>
<td>431</td>
</tr>
</tbody>
</table>

Note: The figures do not add up to 100% as it was permitted to give several answers.

Table 4 – Do changes in practice help prevent adverse events?

<table>
<thead>
<tr>
<th>Have the changes in practice helped avoid similar events?</th>
<th>To a great extent</th>
<th>To some extent</th>
<th>To a limited extent</th>
<th>Unsure</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>26%</td>
<td>44%</td>
<td>6%</td>
<td>24%</td>
<td>195</td>
</tr>
<tr>
<td>Nurses</td>
<td>39%</td>
<td>45%</td>
<td>3%</td>
<td>13%</td>
<td>269</td>
</tr>
<tr>
<td>Risk managers/patient safety officers</td>
<td>26%</td>
<td>51%</td>
<td>4%</td>
<td>17%</td>
<td>214</td>
</tr>
</tbody>
</table>

The evaluation also indicates areas where the reporting system functions less well at the local/regional levels, however. The following inadequacies have been identified:

- Despite the fact that a large proportion of the adverse events appear to be reported, a large proportion of health care professionals and an even greater proportion of risk managers are aware of adverse events that have not been reported (Table 5).
Table 5 – Knowledge of unreported adverse events

<table>
<thead>
<tr>
<th>Do you know of any adverse events that have not been reported?</th>
<th>Physicians</th>
<th>Nurses</th>
<th>Risk managers/patient safety officers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>28%</td>
<td>38%</td>
<td>66%</td>
</tr>
<tr>
<td>No</td>
<td>55%</td>
<td>46%</td>
<td>28%</td>
</tr>
<tr>
<td>Unsure</td>
<td>17%</td>
<td>16%</td>
<td>6%</td>
</tr>
<tr>
<td>N</td>
<td>862</td>
<td>1158</td>
<td>222</td>
</tr>
</tbody>
</table>

- There is some doubt about what an adverse event is and how it should be reported.
- Lack of time and resources comprises one of the most frequent reasons for failure to report an adverse event (Table 6).

Table 6 – Reasons for adverse events remaining unreported

<table>
<thead>
<tr>
<th>What is the primary reason why some of the adverse events were not reported?</th>
<th>Physicians</th>
<th>Nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Considered the event to be trivial so there was no reason to report it</td>
<td>51%</td>
<td>30%</td>
</tr>
<tr>
<td>It takes too long to submit a report</td>
<td>28%</td>
<td>40%</td>
</tr>
<tr>
<td>We do not usually report events of that type</td>
<td>20%</td>
<td>23%</td>
</tr>
<tr>
<td>Reporting would in any case not have prevented repetition of the event</td>
<td>16%</td>
<td>20%</td>
</tr>
<tr>
<td>I did not know how to submit a report</td>
<td>21%</td>
<td>15%</td>
</tr>
<tr>
<td>I think that follow-up on the reported events is inadequate</td>
<td>10%</td>
<td>16%</td>
</tr>
<tr>
<td>The event was due to lack of proficiency</td>
<td>8%</td>
<td>14%</td>
</tr>
<tr>
<td>Fear of sanctions</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Technical problems</td>
<td>3%</td>
<td>5%</td>
</tr>
<tr>
<td>Pressure of work, stress, etc.</td>
<td>7%</td>
<td>14%</td>
</tr>
<tr>
<td>N</td>
<td>103</td>
<td>134</td>
</tr>
</tbody>
</table>

Note: The figures do not add up to 100% as the health care professionals were permitted to give several answers.

- Lack of knowledge of how to report an adverse event comprises a significant reporting barrier, and is a contributory reason for failure to report in 21% of the adverse events left unreported by physicians and 15% of those left unreported by nurses. Based on the data it can be concluded that a
higher proportion of young physicians and nurses believe that lack of knowledge prevents the reporting of adverse events.

- Inadequate follow-up on adverse events comprises a barrier to the reporting of an adverse event. Ten percent of physicians and 16% of nurses state this as a reason why they failed to report an adverse event (Table 6). Eighteen percent of health care professionals state this as a reason why their colleagues failed to report an event. “Functional error” in the system thus becomes an explicit barrier hindering the work on patient safety.

- Follow-up on adverse events and the sharing of information between departments and between hospitals does not function optimally

- Despite the fact that the evaluation shows that there is confidence in the system, 15–18% of health care professionals still state that health care professionals refrain from reporting due to fear of sanctions (Table 7). It should be emphasised that this figure is for the health care professionals’ general opinion as to why health care professionals do not report adverse events.

<table>
<thead>
<tr>
<th>Table 7 – Fear of sanctions</th>
</tr>
</thead>
<tbody>
<tr>
<td>In your experience, does fear of sanctions prevent health care professionals from reporting adverse events?</td>
</tr>
<tr>
<td>Yes, from the employer</td>
</tr>
<tr>
<td>Yes, from the supervisory authority</td>
</tr>
<tr>
<td>Yes, from complaint bodies</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unsure</td>
</tr>
<tr>
<td>N</td>
</tr>
</tbody>
</table>

Note: The figures do not add up to 100% as the health care professionals can have selected several answers.

The conclusions of the evaluation lead to the following recommendations:

(1) More precise and comprehensive information about the definition of adverse events. Consideration should be given to making the information material more precise and comprehensive by adding specific examples of what adverse event are, in what connection they should be reported, etc. This is necessary to minimise doubt.
Support the continued focus on learning. Continued efforts need to be made to emphasise that the primary aim of the work on patient safety and of the reporting system is educational. Even though the health care professionals do not state that fear of sanctions is a reporting barrier as regards themselves, some of them consider that the fear of sanctions comprises a reporting barrier for colleagues. This underlines the need for continued information, management support and continuing education.

Focus on follow-up. Follow-up on reported adverse events needs to be improved, i.e. feedback to the departments and the sharing of information with other departments and hospitals. The National Board of Health can support this by more frequently making specific information available from the Danish Patient Safety Database, but it is also a local and regional responsibility to ensure that the departments receive relevant feedback on adverse events and that information is widely distributed.

Resource considerations. It is considered possible to undertake more comprehensive follow-up and feedback to the departments based on local reports using the currently available resources. However, it will not be possible to improve the collation and sharing of information among departments and hospitals without additional resources being allocated to the system. It will cost additional resources if the relevant analyses are to be performed and the relevant information shared and exchanged among the departments and hospitals.

6.2 The central reporting system

The evaluation concluded that the central reporting system largely functions as intended as far as concerns the main tasks specified in the Act on Patient Safety relating to the registration of adverse event reports and the provision of guidance to the health service. This positive evaluation rests partly on the fact that after a difficult start-up phase the central reporting system is making increasingly satisfactory progress – both as regards processing of the reports and guidance of the health service.

This evaluation is based on the following conclusions drawn from the evaluation:

- The Danish Patient Safety Database is used by the health service’s risk managers and health care professionals. The trend over the period 2004 to 2005 shows that an increasing number of persons are submitting reports to the database. As discussed below, however, there are reservations regarding its use in the Regions.

- Risk managers have now become well acquainted with the Danish Patient Safety Database.

- All health care professionals, risk managers and patient safety officers have easy Internet access to the Danish Patient Safety Database. This increases the probability that a large number of adverse events will be reported.

- The number of categories and their quality have improved considerably since the Danish Patient Safety Database began operation. Risk managers are therefore more easily able to submit precise reports.
• Even though the quality of the reports submitted to the National Board of Health can be improved, they have generally been of such a standard as to enable the National Board of Health to draw up qualified guidelines for the health service. The reports have resulted in specific improvements and recommendations.

• Guidance has been provided to the health service through many different types of follow-up by the National Board of Health. There is increasing satisfaction in the health service regarding the scientific content of the follow-up and number of follow-ups.

• The National Board of Health’s follow-ups on the reports are used by the Regions, and the health care professionals have some knowledge of material received directly from the National Board of Health.

• The follow-ups, for example in the form of clear recommendations from the National Board of Health, are in direct demand by the health care professionals because some of the problems are considered to be so important that they have to be resolved at the national level.

The evaluation also concluded that the reporting system largely complies with the WHO’s 10 recommendations about patient safety reporting systems. One exception, though, is that the system is only partly independent of persons with punitive powers (recommendation no. 5). This is not at the formal level (regulations, legislation, complaint bodies, supervisory authorities), but rather in relation to practice, for example because the system is not fully independent of the employing authority. A further exception is that the reporting system only partly complies with the recommendation that preventative strategies are to be disseminated rapidly (recommendation no. 10). The follow-up on the reported adverse events should be strengthened locally, regionally and nationally. The evaluation further concluded that the Danish patient safety system can be improved so as to more closely follow the recommendations issued by the EU Commission in 2006.

The evaluation also reveals areas where the central reporting system functions less well, however. The following inadequacies are emphasised:

• The information about and training in the Danish Patient Safety Database could have been better in the start-up phase.

• Not all parts of the Danish Patient Safety Database are used by all the Counties. The reason for this is the restricted flexibility of the Danish Patient Safety Database and technical problems in the use of the system. The technical problems relate to:
  o The system response time.
  o The lack of possibility to adapt the system to one’s own organisation.
  o Inadequate support and training.
  o Compatibility with own information technology system.
• Systems have been established in the Counties to supplement the Danish Patient Safety Database. This results in double work, especially for the risk managers.

• The categories used in the Danish Patient Safety Database do not yet encompass all the reports precisely. The methodology still needs to be improved, and more precise and appropriate categories are needed. The respondents mention, for example, that not all the answer categories are mutually exclusive, and that it is difficult to subdivide into contributory causes. They also mention that the event categories could be more precise.

• The frequency and quality of the follow-up during the 1–2 years the system has been in operation have not lived up to the expectation of the users.

Based on the evaluation the firm of consultants made the following recommendations:

(1) **Activities to improve the reports.** The Danish Patient Safety Database has been well used. In future it is also necessary to focus on the quality of the reports. One way could be to initiate information campaigns centrally concerning the positive results obtained through good reporting or by focusing on a single theme at a time and provide guidance on what is particularly important to consider when submitting a report.

(2) **Rendering patient safety more visible.** Patient safety is just one of many aspects of national efforts in the health area. Rendering the use of adverse event reports in other activities more visible emphasises the value of submitting reports and enhances commitment to the reporting system. An example could be to include the adverse event reports in health technology assessment reports or to emphasise when the reports are used as background material when drawing up guidelines or altering medical equipment.

(3) **Closer cooperation between the National Board of Health and the new Regions.** The cooperation between the National Board of Health and the Counties/Copenhagen Hospital Corporation was good and should be strengthened even further with the five Regions under the new administrative structure.

(4) Among other means this cooperation is facilitated by fora concerned with patient safety. The cooperation could usefully be expanded, however, for example by preparing more reports in close cooperation between the new Danish Regions and the National Board of Health, or by the National Board of Health more frequently making analyses that focus attention on problems that are common for a group of Regions or a single Region.

(5) **Continued development of the Danish Patient Safety Database.** There can be several reasons why work is being done on several local patient safety systems concomitantly with the Danish Patient Safety Database, but the firm of consultants concludes that it is inappropriate to have several different patient safety systems in operation. Greater priority should therefore be
given to ensuring that the Danish Patient Safety Database functions better in future from the technical point of view and that the categories better meet the needs of the users.

6.3 Expansion of the reporting system

When the Act on Patient Safety was passed in 2003 it was considered inappropriate to include the primary sector in the reporting system in the first instance. However, calls have been made to expand the system to encompass patient safety in the primary sector. The evaluation had to answer the question of how the reporting system can be expanded to the primary sector and to patients and relatives.

The evaluation shows that there is considerable support for expansion of the reporting system to the primary sector. Experience gained through a number of pilot projects shows that this is achievable.

Health care professionals and other stakeholders look positively on expansion of the system to patients and relatives. However, the evaluation also shows that expansion to patients and relatives would require thorough preparation.
7 Follow-up on the evaluation of the reporting system

7.1 Expansion of the reporting system

During 2007 a Bill will be placed before Parliament to expand the adverse events reporting system to the primary sector as well as patients and relatives.

As a consequence, the existing first version of the Danish Patient Safety Database will be discontinued and instead replaced by a new version. This will enable:

- Inclusion of the primary sector, patients and relatives in the system.
- Development of a system that meets current standards for information technology systems.
- Development of a system that better meets user demands for flexibility and functionality.
- Development of a system based on a sustainable classification system.

7.2 Categorisation/classification of adverse events

The evaluation indicated that the categories used in the Danish Patient Safety Database do not accurately encompass all the reports. Not all the answer categories are mutually exclusive, and it is difficult to subdivide into contributory causes. It is apparent from the evaluation that the categorisation should be more precise. The number of categories was expanded from three to nine as per 1 January 2006. While this has partly met the need for more precise reporting by the hospitals, it will be inadequate when the reporting system is expanded to encompass the primary sector, patients and relatives.

Based on the evaluation and the experience gained with the present categorisation at the central and local levels a project will be initiated to revise the categorisation/classification based on the WHO International Patient Safety Classification.
Links

Danish National Board of Health: www.sst.dk
Danish Patient Safety Database: www.dpsd.dk
Danish Society for Patient Safety: www.patientsikkerhed.dk
Danish Regions: www.regioner.dk
Ministry of the Interior and Health: www.im.dk
Patient Complaints Board: www.pkn.dk
Patient Insurance Association: www.patientforsikringen.dk
Personal Electronic Medication Profile: www.medicinprofilen.dk
Danish Electronic Health Record Observatory: www.epj-observatoriet.dk