Persephone Doupi

# National Reporting Systems for Patient Safety Incidents

## A review of the situation in Europe

# Acknowledgements

# Abstract

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Patient safety is a central aspect of healthcare system performance and an area of growing interest world-wide. After a series of studies in several countries, it is now generally accepted that about 10% of patients who receive care in hospitals experience some adverse effect in their course of treatment. In 1% of the cases the consequences are grave or even fatal. In terms of suffering as well as cost, these numbers are unacceptable for a modern healthcare system that makes a claim to quality. There is a clear need for improvement.

The Finnish Ministry for Social Affairs and Health launched in late 2005 the effort of coordinating and strategically guiding patient safety activities on the national level. In that context, a Steering Group was established to examine the patient safety situation in the country and make development proposals by the end of 2009. Working Committees were also created with the task of focusing on specific areas of patient safety: culture and education on patient safety, tools for patient safety and patient safety reporting.

The study presented in this report was undertaken with the purpose of supporting the processes of the Working Committee on patient safety reporting. The key question was whether it is worth investing in putting up a national level reporting system and if yes, what features it should have.

The aim was to investigate the experiences of other European countries with national level patient safety reporting and monitoring systems, analyze the data and provide information that would be meaningful in supporting the decision making process on the national level. Specific proposals as to how patient safety reporting should eventually be organised in Finland were outside the scope of this report. Concrete steps on this front are to be made soon through the appropriate channels; the Ministry's strategy on Patient Safety was announced in the first national Patient Safety Conference in January 2009, while the Working Committee on reporting will deliver its final report and suggestions in the beginning of 2010.

The materials forming the reference base of the report were collected through desktop research primarily focused on online resources, as well as through review of main reports and other patient safety publications. Only materials available in English were included, and the cut-off point for data collection was September 2008. Systems dedicated to reporting of adverse events related to medications, blood products and medical devices were excluded from the analysis.

Plans for, or operational national patient safety incident reporting systems were identified in thirteen European countries: Austria, Belgium, Czech Republic,

Denmark, Ireland, France, Netherlands, Norway, Scotland, Spain, Sweden, Switzerland and UK (England and Wales). The impact of the 1999 Institute of Medicine Report appears to have been crucial, with many activities starting around the year 2000. Most commonly, the national reporting system was launched in the framework of quality of care, followed by risk management and clinical governance. Either dedicated organisations or structures existing within the framework of health ministries have been utilized for co-ordinating national reporting activities.

Three different types of national patient safety incident reporting systems were identified: systems for sentinel events only (often mandatory by law), systems for specific clinical domains (reporting often voluntary) and healthcare system-wide, comprehensive reporting systems (which include also 'near misses'). Operational systems of the latter type exist presently only in the UK, Denmark, and Ireland, while plans to establish one were identified in Scotland. In these systems (anonymous) reporting is typically done by frontline personnel, but with differing level of detail. Reporting by the public, i.e. patients and/or relatives, is used in the UK, and is in development in Denmark. Collected data is most commonly utilized for hazard identification and issuing of alerts, as well as for trends-cluster analysis. Risk, causal and systems analysis which are utilized in more mature large-scale reporting systems in the USA and Australia are not currently available in European systems. Dissemination of findings takes place with a variety of means, depending on the objectives and available resources of each reporting system.

The scarcity of national patient safety incident reporting systems in Europe is perhaps a reflection of the relatively recent policy focus on patient safety. The decision making process around the establishment of a national patient safety incident reporting system needs to address a multitude of issues. Among the key questions are the practical and conceptual co-ordination between institutional (local) level reporting systems and the system operating on the national level, the balance between user-friendliness and adequacy of collected data, as well as the establishment of a truly effective feedback system between the national level and frontline healthcare personnel.

There is no one right way of building and utilizing a national patient safety incident reporting system. Learning from the experiences of other countries can therefore be a useful tool in informing national policy makers. Additional data collection and analysis, particularly including materials available only in the local language of each country would certainly provide more comprehensive information, but were beyond the resources available for this work.

Keywords: patient safety; adverse event; patient safety incident; reporting system; risk management; quality management; healthcare

# Abstract in Finnish

Persephone Doupi. National Reporting Systems for Patient Safety Incidents. A review of the situation in Europe [Kansalliset potilasturvallisuustapahtumien raportointijärjestelmät. Katsaus Euroopan tilanteeseen]. Terveyden ja hyvinvoinnin laitos (THL), Raportti 13/2009. Helsinki 2009. 59 sivua. ISBN 978-952-245-061-6

Potilasturvallisuus on terveydenhuoltojärjestelmän keskeinen osa, jota kohtaan tunnetaan kasvavaa kiinnostusta kaikkialla maailmassa. Useissa maissa suoritettujen lukuisten tutkimusten perusteella on todettu, että noin kymmenen prosenttia sairaalahoitoa saavista potilaista kokee jonkinlaisen haittatapahtuman hoidon aikana. Yhdessä prosentissa tapauksista seuraukset ovat vakavia tai jopa kuolemaan johtavia. Korkeaa laatua tavoittelevalle nykyaikaiselle terveydenhuoltojärjestelmälle nämä luvut ovat niin kärsimysten kuin kustannustenkin kannalta kestämättömiä. Tilanteen parantamiseen on selkeä tarve.

Sosiaali- ja terveysministeriö käynnisti vuoden 2005 lopussa toimet potilasturvallisuustapahtumien koordinoimiseksi ja strategisesti ohjaamiseksi kansallisella tasolla. Työtä varten perustettiin ohjausryhmän, jonka tehtävänä on tutkia potilasturvallisuuden tilaa Suomessa ja esittää kehittämisehdotukset vuoden 2009 loppuun mennessä. Potilasturvallisuuden erityisalueiden tarkastelua varten perustettiin työvaliokunnat: potilasturvallisuuskulttuuri ja -koulutus, potilasturvallisuuden työkalut ja potilasturvallisuuden raportointi.

Tässä raportissa esiteltävän selvityksen tavoitteena oli potilasturvallisuuden raportointityövaliokunnan työn tukeminen. Avainkysymys oli, kannattaako kansallisen tason raportointijärjestelmä perustaa ja millaisia ominaisuuksia sillä siinä tapauksessa tulisi olla.

Tavoitteena oli tarkastella niiden Euroopan maiden kokemuksia, joissa oli käytössä kansallisen tason potilasturvallisuusraportointi- ja -valvontajärjestelmät, analysoida kerätty aineisto ja tuottaa tietoa, jolla olisi merkitystä kansallisen tason päätöksenteossa. Varsinaiset esitykset siitä, miten potilasturvallisuusraportointi tulisi organisoida Suomessa, eivät kuuluneet raportin alaan. Asian ratkaisevat asianomaiset elimet lähiaikoina: ministeriön Potilasturvallisuusstrategia julkaistiin ensimmäisen kansallisen potilasturvallisuuskonferenssin yhteydessä tammikuussa 2009 ja raportointityövaliokunta jättää loppuraporttinsa ja ehdotuksensa vuoden 2010 alussa.

Raportin aineisto koottiin työpöytätutkimuksena, jossa keskityttiin pääasiassa verkkoaineistoon ja käytiin läpi tärkeimmät raportit ja potilasturvallisuusjulkaisut. Tutkimukseen sisällytettiin vain englanninkielinen aineisto, ja tiedonkeruu päättyi syyskuussa 2008. Lääkkeisiin, verituotteisiin ja terveydenhuollon laitteisiin ja tarvikkeisiin liittyvät haittatapahtumat eivät kuuluneet analyysin piiriin.

Potilasturvallisuuden vaaratapahtumien raportointijärjestelmä oli suunnitteilla tai käytössä kolmessatoista Euroopan maassa: Belgiassa, Espanjassa, Hol-

lannissa, Irlannissa, Isossa-Britanniassa (Englanti ja Wales), Itävallassa, Norjassa, Ranskassa, Ruotsissa, Skotlannissa, Sveitsissä, Tanskassa ja Tsekissä. Vuonna 1999 julkaistun Institute of Medicinen raportin vaikutus näyttää olleen ratkaiseva, sillä useita toimia käynnistettiin vuoden 2000 aikana. Useimmiten kansallinen raportointijärjestelmä otettiin käyttöön hoidon laadun, riskienhallinnan ja kliinisen johtamisen puitteissa. Kansallisten raportointitapahtumien koordinoinnista vastaavat joko tarkoitusta varten perustetut organisaatiot tai jo olemassa olevat terveysministeriöiden alaiset elimet.

Tutkimuksessa löytyi kolme erityyppistä kansallista potilasturvallisuustapahtumien raportointijärjestelmää: ainoastaan vakavien (sentinel) haittatapahtumien raportointijärjestelmät (usein lakisääteisiä), tiettyihin erikoisaloihin liittyvät raportointijärjestelmät (raportointi usein vapaaehtoista) ja koko terveydenhuollon-laajuisia, kattavat raportointijärjestelmät (jotka pitävät sisällään myös läheltä piti -tapahtumat). Jälkimmäisen kaltaisia järjestelmiä oli käytössä ainoastaan Isossa-Britanniassa, Tanskassa ja Irlannissa, ja suunnitteilla Skotlannissa. Näissä järjestelmissä (nimettömästä) raportoinnista vastasi usein etulinjan hoitohenkilökunta, mutta annettujen tietojen yksityiskohtaisuuden taso vaihteli. Yleisön eli potilaiden ja/tai läheisten raportointijärjestelmä oli käytössä Isossa-Britanniassa ja kehitteillä Tanskassa. Kerättyjä tietoja käytettiin yleisimmin vaarojen tunnistamiseen ja hälytysten antamiseen sekä myös trendiklusterianalyysiin. Riski-, syysuhde- ja järjestelmäanalyysit, joita käytetään kehittyneemmissä laajamittaisissa raportointijärjestelmissä Australiassa ja USA:ssa, eivät ole vielä käytössä eurooppalaisissa järjestelmissä. Tulosten levittäminen tapahtuu usealla eri tavalla riippuen kunkin raportointijärjestelmän tavoitteista ja käytössä olevista voimavaroista.

Kansallisten potilasturvallisuustapahtumien raportointijärjestelmien vähäisyys Euroopassa kertoo mahdollisesti siitä, että poliittinen kiinnostus potilasturvallisuutta kohtaan on suhteellisen uusi asia. Päätöksenteko kansallisen potilasturvallisuustapahtumien raportointijärjestelmän perustamisesta edellyttää useiden asioiden huomioon ottamista. Tärkeimpien kysymysten joukossa on käytännön ja käsitesisällön koordinaatio laitostason (paikallisen) ja kansallisen tason järjestelmien välillä, tasapaino käyttäjäystävällisyyden ja kerätyn aineiston riittävyyden välillä, kuten myös todella tehokkaan palautejärjestelmän perustaminen kansallisen tason ja etulinjan hoitohenkilöstön välille.

Ei ole olemassa vain yhtä oikeaa tapaa rakentaa ja hyödyntää kansallista potilasturvallisuustapahtumien raportointijärjestelmää. Muiden maiden kokemuksista saadut opit voivat siis olla hyödyksi kansallisen politiikan tekijöiden evästämisessä. Lisätietojen kerääminen ja analysointi, erityisesti huomioiden vain kansallisilla kielillä saatavilla olevat aineistot, antaisi varmasti kattavampaa tietoa, mutta ei ollut toteutettavissa tähän selvitykseen varatuilla voimavaroilla.

Avainsanat: potilasturvallisuus; haittatapahtuma; vaaratapahtuma; raportointi järjestelmä; riskienhallinta; laadunhallinta; terveydenhuolto

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# Background

Finland belongs to those countries that enjoy a fairly well-organised and advanced system for provision of healthcare services. Nevertheless, patient safety had not received adequate attention until recently.

Responding to the alarming evidence emerging from other countries, the Finnish Ministry for Social Affairs and Health launched in late 2005 the effort of coordinating and strategically guiding patient safety activities on the national level. In that context, a Steering Group was established to examine the patient safety situation in the country and make development proposals by the end of 2009 (1, 2). Work Groups were created under the Steering Group, focusing on specific areas of patient safety: culture and education on patient safety, tools for patient safety and patient safety reporting.

The study presented in this report was undertaken with the purpose of supporting the processes of the latter Work Group on patient safety reporting. The key question was whether it is worth investing in putting up a national level reporting system and if yes, what features it should have.

The aim was to investigate the experiences of other European countries with national level patient safety reporting and monitoring systems, analyze the data and provide information that would be meaningful in supporting the decision making process on the national level. Specific proposals as to how patient safety reporting should eventually be organised in Finland are outside the scope of this report. Concrete steps on this front are to be made soon through the appropriate channels; the Ministry's strategy on Patient Safety is due for announcement in January 2009, while the working group on reporting will deliver its final report and suggestions in the beginning of 2010.

## Patient safety landscape in Finland

Even before the official establishment of the Working Group on Patient Safety, there was considerable activity around this topic, both on the organizational and regional, as well as on the national level. In 2005, right before the establishment of the ministerial Steering Group, a memorandum making the first proposal for national policy guidance and actions to promote patient safety was published, addressing the period 2006–2008 (3). Already then, a variety of projects were underway, the focus and the output of which is summarized in Table 1.

TABLE 1. Patient safety-related projects in Finland (status at the end of 2005)

| | |
|---|---|
| Patient Safety Vocabulary /STAKES, National Agency for Medicines, ROHTO | Vocabulary published in 2006 and updated in 2007 (5) |
| Reporting: Viivi-project/Peijas; Development of organisation specific method for patient safety incident reporting/VTT, Peijas, NAM; KSSHP, KySHP | Project report and various related publications in 2004-2005 (6,7) |
| Organisational risk management of changes in healthcare /VTT, ESSHP, HUS, Medineuvo | Various publications and presentations (8,9) |
| Safe healthcare Unit: a model for risk management in healthcare units, NAM | Guide published in 2004 (10) |
| Safe medication treatment, STM | Guide published in 2005 (11) |
| Development of reporting of adverse events and revision surgeries, STAKES | Working Paper published in 2007 (12) |
| Electronic decision support development – Duodecim | Several publications (13) |
| System for reporting and analysis of adverse events in a hospital environment (HaiPro I)/VTT; NAM | Report published in 2007; second phase project 2007-2008 (14, 15) |

Modified from: U. Idänpään-Heikkilä, Presentation, 2005 (4).


## Patient Safety Network

The Patient Safety Network was established in 2005. With over 100 members, the network brings together a wide variety of stakeholders' representatives and it holds regularly annual seminar-type meetings. Until now, the Network has primarily functioned as a forum for keeping abreast with developments around patient safety, highlighting topical issues for discussion and, perhaps most importantly, bringing together the persons interested in the subject. Participation to the Network is open for any individual or organisation who would like to participate to the meetings. The Ministry of Social Affairs and Health manages the main co-ordination of the Network, in close collaboration with some of its agencies and institutes, such as TEO, STAKES and ROHTO (the first two agencies are by now named Valvira and THL respectively).


## National organisations with activities/roles relevant to Patient Safety

As the network depicted in Figure 1 shows, there is a multitude of different sorts of national level organisations with an actual or prospective role in patient safety activities. On the one hand, this fact illustrates the potential for advancing patient safety in Finland, since there is already a critical mass of relevant actors and a corresponding body of work, as well as accumulated experience. On the other hand,

it is precisely this multiplicity that calls for clear and efficient co-ordination of activities on the national level, in order to avoid fragmentation and duplication.
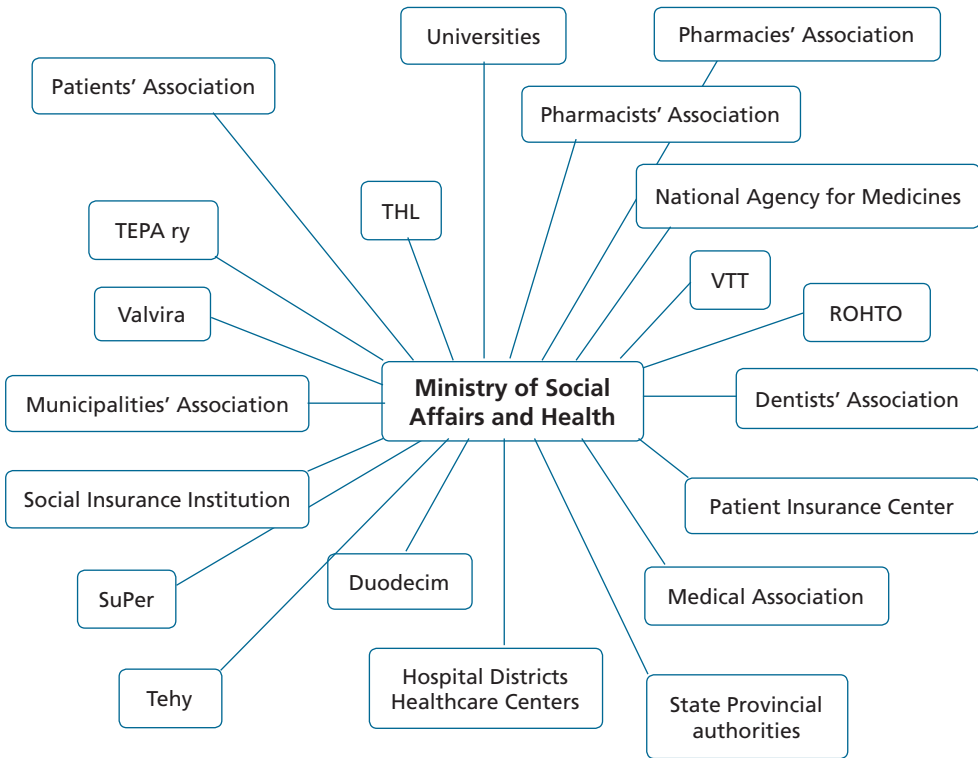


FIGURE 1. Some of the main patient safety actors in Finland.
Modified from: U. Idänpään-Heikkilä, Presentation, 2005 (4).

## National level data sources on patient safety incidents in Finland

- reminders issued to healthcare professionals *(TEO – now Valvira)*
- complaints of patients submitted to the state provincial authorities
- reports of patient harm submitted as claims *(Patient Insurance Center)*
- data from the Hospital Discharge and other registers *(STAKES – now THL)*
- Medication Safety Register (reporting of medication side-effects), *NAM and TEO (now Valvira)*
- Register of adverse events and near misses in blood transfusion (reported by the *Blood Safety Authority*)
- Incidents connected to medical devices and products (reported to *NAM*)
- Incidents connected to radiotherapy *(Center for Radiation Safety)*
- Incidents connected to the use of orthopaedic and dental implants *(NAM)*

- Hospital Infection Programme collects data on infections in participating hospitals and allows inter-hospital comparison *(KTL – now THL)*
- Causes of death collected in the respective register maintained by *Statistics Finland*

As this extensive list indicates, there are numerous sources of data that could be drawn upon in order to form an overall picture and further monitor patient safety on the national level (16). At least until now, however, these data have not been ever brought together.

## Systems and experiences on healthcare service organisation level reporting

In 2007, the Ministry of Social Affairs and Health undertook a questionnaire-based analysis of the status and associated challenges of patient safety promotion in hospitals, healthcare centers and elderly people's homes (17). According to the resulting report, in the majority of the organisations that responded to the questionnaire, patient safety was included in the general safety planning, while in every second organisation it was part of their quality management system. Among the several challenges mentioned by the respondents was also the creation of patient safety monitoring and alerting systems. At present, the personnel of healthcare service units are obliged to report to a number of authorities, regarding a series of possible adverse events types. Figure 2 depicts these reporting pathways, as well as those available to patients and their relatives, in case they doubt that an accident or error has occurred, or they have complaints with regard to the treatment (13).

A number of projects have tried to address the issue of organisation level reporting of patient safety incidents, in the context of organisational learning, development and quality improvement. One of the most widely known and successful projects has been *VIIVI* (Viisas oppi virheistä – The wise learns from mistakes), which was piloted in the Peijas hospital in 2004 (6,7) and contributed in increasing the interest towards the development of national level reporting of patient safety incidents. The concept of VIIVI was further taken up in use in the hospital of Porvoo, as of May 2006 (18).
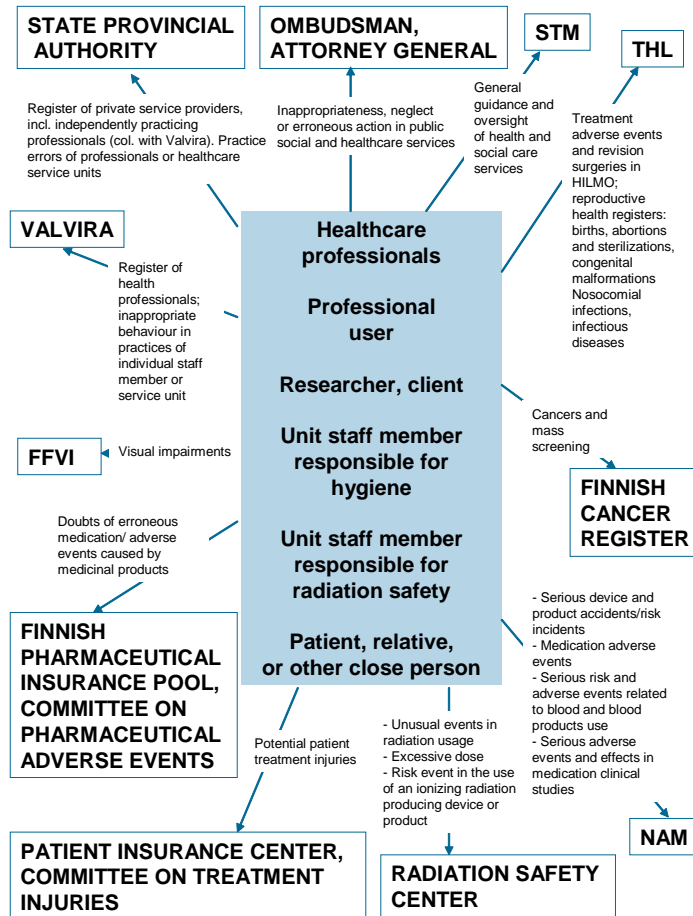
**FIGURE 2.** Reporting pathways of patient safety adverse events available to healthcare personnel (mandatory), as well as patients and their relatives (unofficial translation from 13)

STM: Finnish Ministry of Social Affairs and Health;
THL: National Institute for Health and Welfare;
FFVI: Finnish Federation of the Visually Impaired; NAM: National Agency for Medicines.

In Pirkaanmaa Hospital District and in the Tampere University Hospital there have been several systems piloted and taken into use relating to patient safety reporting and monitoring. *TURPO* is an application that enables the reporting, aggregation and evaluation of safety incidents and deviations that have threatened the activities of a work unit. The summary reports provide real data for the safety planning of the organisation and the assessment of the level of safety. The first report was submitted in February 2002 and by now over 8 200 reports have been accumulated

(19). The *pediatric clinic of TAYS* has also piloted and taken into use an own Web-based reporting method for patient safety incidents (20). An own reporting form has also been piloted in the *psychiatric departments of the University Hospital of Oulu* (21).

The *HaiPro* research project was launched in November 2005 and its first phase was completed in November 2007 (13). A model for the organisational level reporting of patient safety incidents was developed by the National Agency for Medicines and the Technical Research Center of Finland, in collaboration with Peijas hospital, the Medical Center of Tampere (Tampereen Lääkärikeskus Oy) and the Heart Center of the Tampere University Hospital. The second phase of the project took place between 2007 and 2008, during which period the system was piloted and disseminated much more broadly in over 40 healthcare service provider organisations (including representatives of almost all hospital districts) (15).

The main properties of the model developed by HaiPro are: anonymity, confidentiality and freedom from sanctions. In addition, the HaiPro approach incorporates a system model that takes into consideration the features of natural human behaviour and the pathway of divergent events development. The local incident reporting system is meant to prevent treatment adverse events through the improvement of operational procedures. At present, data is collected only at organisation level and not send forward to or aggregated and analysed on regional and national level.

## Patients' position in the case of safety incidents

In every healthcare service unit there is a patient ombudsman, who assists patients as needed in submitting a complaint or compensation application. The patient insurance (22) compensates for accidents that happen in the context of provision of primary and secondary healthcare services in Finland. The medication safety insurance (23), on the other hand, compensates sickness or disability caused to the patients as a result of medication treatment. Patient adverse events (related either to provision of healthcare services or to medication) are not reported to the authorities and are processed through separate channels. The rationale for this choice was specifically the encouragement and support of patient adverse event reporting.

Since spring 2008, and as a result of the work of the Steering Group for patient safety promotion, the Ministry of Social Affairs and Health has prepared and made available online material specifically targeted at patients and their relatives (24). The material consists of notifications on patient safety that can be placed e.g. in hospitals words and of four reminder lists.

# 1    Introduction

The review presented in this report concerns experiences with national level reporting systems of patient safety incidents in European countries. Although in the global landscape countries such as the USA and Australia, for example, have a longer and more advanced history in implementing patient safety reporting systems compared to most European countries, the context of implementation is markedly different. Hence, experiences 'closer to home' were sought. Published experiences on lessons learned from the implementation of both American and Australian patient safety reporting systems were, however, reviewed and their main conclusions distilled and placed in a separate section of this report, as useful input for the decision making process.

# 2    Methods, materials

The target of material collection was to identify existing or planned European national level systems for patient safety incident reporting, locate the homepages of responsible leading agencies or organisations and review their publicly available information and reports.

In the process of preparing their draft guidelines for adverse event reporting and learning systems, the WHO reviewed in 2004-2005 the status of several national reporting systems (25). In this context, also information on patient safety-related developments in specific countries was presented. The European countries included in the WHO report thus formed the initial target group for identifying further information.

Desktop research – primarily focused on online resources – as well as review of main reports and patient safety publications was originally undertaken between September and December 2007, and then updated and expanded between March and September 2008. The only exception for material inclusion after September 2008 was made for the publication of the Irish report on patient safety and on the evaluation results of STARS Web (which became public in October 2008). Only information and materials available in English were sought for analysis.

The type of materials collected included strategy papers, reports, evaluation programme publications, PowerPoint presentations, information provided on

pertinent authorities' or agencies' websites, as well as scientific articles. In addition, materials of major European conferences on patient safety, as well as the online references and key publications of leading international initiatives on patient safety and quality, such as the WHO World Alliance for Patient Safety and OECD Health Care Quality Indicators Project were utilized (26–28).

Systems for reporting adverse events related to medications, blood products and medical devices were excluded, as well as systems focusing exclusively on the reporting of sentinel events. The WHO checklist for adverse event reporting systems was used as the point of reference and expanded with additional details to develop a template for extracting the collected information per country.

# 3 NATIONAL PATIENT SAFETY INCIDENT REPORTING SYSTEMS IN EUROPE

Plans for, or operational national incident reporting systems for patient safety were identified in the following European countries: Austria, Belgium, Czech Republic, Denmark, Ireland, France, Netherlands, Norway, Scotland, Spain, Sweden, Switzerland and UK (England and Wales). Most commonly, the national reporting system was launched in the framework of quality of care, followed by risk management and clinical governance. Either dedicated organisations or structures existing within the framework of health ministries have been utilized for co-ordinating national reporting activities. Table 2 provides an overview of national level activities in the studied countries, in terms of their timeline, national coordinating body for patient safety and focus of national level reporting (the highlighted rows indicate countries where national level reporting systems are already operational, or in the planning phase).

TABLE 2. Overview of national patient safety activities in Europe

|    | Activities start | Agency | National Reporting system |
|----|---|---|---|
| UK | 1997/2000 | NPSA – 2001 | NLRS – 2004 |
| DK | 2000 | National Board of Health | DPSD – 2004 |
| IE | 2000 | Commission on Patient Safety & Quality Assurance – 2007 | STARS Clinical incident reporting (State Claims Agency) – 2004 |
| SC | 2000 | NHS QIS – 2003 | in planning/hospital focus first |
| AT | 1998 (legal framework) | proposed | focus on specific domains (medications, culture) |
| BE | 2003 | FPS Health, Food Chain Safety & environment | Strategy published in 2007 – focus first on hospital level |
| CH | 2000 | 2003/2004 | Critical Incident Reporting & Reacting Network – anaesthesiology pilot |
| ES | 2005 | Ministry of Health & Consumer Affairs | specific areas (ISMP) or regional focus |
| FR |  | HAS | specific areas (nosocomial infections) |
| NL | (1995)/2006 | Health Care Inspectorate | (nosocomial infections) hospital adverse incident reporting |
| NO |  | Directorate of Health – dedicated unit, 2006–2007 | sentinel events |
| SE | 1997 (legal) | National Board of Health | sentinel events |

# Motivation

The impact of the 1999 Institute of Medicine Report (29) appears to have been crucial in raising awareness of patient safety issues also in Europe, with many national level activities being launched around the year 2000. The existence of earlier patient safety or quality of care activities and actions also played a role in the development of such initiatives during the last decade. Some countries chose to launch their own studies for mapping the 'baseline' incidence of adverse events in their healthcare services (as e.g. Denmark, France, Spain and, more recently, the Netherlands) (30-34). In some cases, the wide publicity of grave sentinel events in a national healthcare system acted as the trigger for more co-ordinated patient safety activities on the national level (as, e.g. in the UK and Ireland) (35–37).

# Typology of national patient safety incident reporting systems

There appear to be three different types of national patient safety incident reporting systems:
* systems for sentinel events only (often obligatory by law),
* systems focusing on specific clinical domains (reporting often voluntary) and
* healthcare system-wide, comprehensive reporting systems (which include both adverse events and 'near misses').

Operational systems of the latter type exist presently in Europe only in the UK, Denmark and Ireland, while plans for establishing one were identified in Scotland. An overview of these systems' features is presented in the following section. More detailed information on each of these four countries is provided in Annex 1.

# Main characteristics of national reporting systems

Objective

Defining the objective that the reporting system is meant to serve is a critical choice that affects several other subsequent choices.

Learning from errors and/or 'close call' situations is a clear objective for all four national reporting systems. In addition, the Irish system has a clear accountability component, while the Scottish proposal touches upon accountability in the sense

of suggesting the utilization of data collected for legal purposes as a part of the data set for reporting adverse events.

## Nature

In one of the most controversial aspects of patient safety incident reporting, its voluntary or mandatory nature, the picture emerging is accordingly divided. Ireland and Denmark have opted for a mandatory system, while participation in both the UK and the Scottish system is voluntary.

TABLE 3. National Reporting Systems: Main Characteristics

|  | Learning | Accountability | Voluntary | Mandatory | Confidential | Public Reports |
|---|---|---|---|---|---|---|
| UK | X |  | X |  | X | X |
| DK | X |  |  | X | X | X |
| SC | X | X (partly) | X |  |  | considered |
| IE | X | X |  | X | X (partly) |  |

## Confidentiality aspects

Regarding the management of confidentiality, it should be kept in mind that it includes three distinct perspectives: the confidentiality of the organisation in which the event took place, the confidentiality of the patient involved and, most critically, the confidentiality of the reporter (usually member of staff). More information on this subject is provided in the following section on process features of national reporting systems. The national agencies of both the UK and Denmark publish reports of aggregated data in the general domain, but do not report on specific incidents. In that sense, their dissemination strategy preserves confidentiality on all aforementioned three levels. The provision of public reports is considered in Scotland, but since the system is still in the planning phase, there is no final decision made yet. Information on this subject was missing for Ireland.

   An overview of national reporting systems' main characteristics is provided in Table 3.

# Process features of national reporting systems

An overview of national reporting systems' process features is provided in Table 4.

## Who are the reporters

In national level systems (usually anonymous) reporting is typically done by frontline personnel, but with a differing level of detail. Patient reporting has been in use in the UK since 2006, and is in development in Denmark.

## How does reporting take place

The use of paper-based methods is still quite common, particularly at the local level, but the means available for reporting are increasingly utilizing information technology, following the steady growth in the general adoption of health IT applications.

In the UK, patients, their relatives and the general public have a wide array of options when wishing to report an adverse event: they can chose to do so through regular mail, phone and, since April 2006, through the Web.

## Anonymity

Anonymization - in the sense of stripping away any identifying details of the reporter, as well as the patient concerned, does take place in both the British and Danish systems, but at different phases in the reporting pathway. In the UK, anonymization takes place after the data has reached the NPSA (however, the reporter also has the choice of not providing his/her name when submitting a report of an incident), while in Denmark anonymity is provided already at the regional level, before data is sent forward for storage at the DPSD. In Ireland, where national level reporting takes place through the Clinical Indemnity Scheme (38), reports are anonymous (both in terms of reporter, and patient details), until they become claims. At that point, the organisation concerned is obliged to disclose the details of the patient and the staff involved to the State Claims Agency.

TABLE 4. National Reporting Systems: Main Process Features

|  | WHO | HOW professionals | HOW public | Confidentiality |
|---|---|---|---|---|
| DK | Frontline personnel (patients)/risk managers | Paper to regional risk management | In development | Anonymous at national level |
| IE | Enterprises (CIS – not GPs) | Paper to local risk management – electronically to CIS database (STARS web) | not applicable | Guaranteed until the event becomes a claim |
| UK | Health professionals Patients – public | LRMS – automatic forward / Web reporting form | Phone Web form (since April 2006) Regular post | Anonymous (reporter, organisation, patient) |

## What is reported

The number of elements and the subsequent level of detail in the data collected by each national-level reporting system for adverse events appear to vary considerably between countries. Denmark started off with a very 'lean' data collection form, whereas the UK and Ireland have aimed for more extensive detail.

There is a difficult balance that needs to be sought between, on the one hand, the amount of detail necessary for the extraction of useful information regarding patient safety incidents and, on the other hand the easiness and user-friendliness of the reporting form.

Categories of data elements that are common to all existing national level reporting systems are, as highlighted in Table 5: organisation information, details on the specific incident (type and description), contributing factors and patient-related information. All of the aforementioned data elements are also central in the development of the WHO International Classification for Patient Safety (39).

TABLE 5. Data element categories in national reporting systems

|  | UK | DK | IE | SC |
|---|---|---|---|---|
| organisation information | x | x | x | x |
| incident type / incident-injury description | x | x | x | x |
| phase of care | x |  | x |  |
| contributing factors | x | x | x | x |
| local area risk factors | x |  |  | x |
| patient information | x | x | x | x |
| medication/device incident | x |  | x | x |
| severity | x |  | x |  |
| legal & claims information |  |  | x | x |
| follow-up | x |  | x | x |

# Analysis

Collected data is most commonly used for hazard identification and issuing of alerts, as well as for trends-cluster analysis. Risk, causal and systems analysis which are utilized in more mature national reporting systems in the USA and Australia are not currently available in European systems. On the one hand, this difference in methods of analysis may reflect the present status of progress of national reporting systems, since both risk and causal analysis depend on the existence of large amounts of data that are classified and coded appropriately (25). Systems analysis, in turn, requires a well established and functional feedback loop between the local (organisational) and national level. On the other hand, both the US and Australian system, although indeed of a large scale, still function practically on the level of large (private) organisations, rather than that of national health service systems, hence they do not face the same challenges in standardized data collection and analysis.

# Dissemination

Dissemination of analysis results takes place through a variety of means, depending on objectives and available resources of each national agency, as displayed in Table 5. At least two levels of dissemination can be distinguished: on the one hand the

provision of feedback directly to the reporting organisation, and on the other hand the wider dissemination of important findings and updates to various target groups among healthcare professional communities and healthcare service providers.

TABLE 6. Overview of dissemination means of national reporting systems

|  | Response generation | Alerts | Newsletters (trends, themes, best practices) | Website | Reports |
|---|---|---|---|---|---|
| UK | Feedback (organisation level) – Reports (trends) | Patient safety alerts – Rapid Response Reports | Bulletins | Yes | Quarterly |
| DK | Feedback (regional offices) | Yes | Yes | n/a | Annual, specific themes |
| IE | n/a | n/a | Quarterly, plus seminars, topic-based fora | Yes | Specific to HSE enterprises |
| SC | n/a | n/a | n/a | Education | n/a |

# 4  LESSONS LEARNED

*Experiences from Europe: the evaluations of the UK, Danish and Irish system*

All three operational national level reporting systems for patient safety incidents have been evaluated for their performance and ability to meet the objectives for which they were set up.

In the UK, the activities of the National Patient Safety Agency were first assessed in 2006, by order of the House of Commons (40). The *National Reporting and Learning System (NRLS)* in specific was evaluated in 2007, after it had been operational for three years and had collected over 2 million incident reports in its database. This latter evaluation, which had the purpose of identifying and targeting areas needing improvement, was undertaken with the participation of 800 NHS staff members. The results were published at the end of February 2008 (41). The key improvement areas identified through this study, and the corresponding planned actions are presented in Table 7.

TABLE 7. Overview of NRLS evaluation results and corresponding actions planned

| Areas for Improvement | Corresponding changes to be introduced |
|---|---|
| build on the existing system and improve quality | – standardising and simplifying the existing dataset;<br>– less essential fields, tight core data set;<br>– utilization of international classifications;<br>– data quality standards focusing on information necessary for learning |
| make the system quicker and easier to use | – technical solution changes, which improved speed of incident upload<br>– work for defining the core data set |
| get to the most serious issues quickly | – pilot for rapid reporting of most serious incidents<br>– need for going back to the reporting organisation, even though no role in carrying out local investigations |
| streamline routes of reporting | – number of reporting systems; consultation for creation of a single-entry-point system, 'Patient Safety Direct' |
| provide more targeted feedback for organisations and specialties | – need for various forms of comparative feedback for organisations<br>– methods for providing specialty-specific feedback needed - pilot of specialty benchmark reports<br>– need to understand the hierarchy of risks in different specialties; provide feedback to frontline personnel |

The evaluation of the *Danish Patient Safety Database* was performed by Rambøll Management in 6-8/2006, 2 and a half years after the start of the project (42). The evaluation generated both positive and negative results, on the basis of which further plans were made. An overview is provided in Table 8.

TABLE 8. Overview of DPSD evaluation findings and corresponding action

| Positive findings | Negative findings | Follow-up actions |
|---|---|---|
| • Danish Patient Safety Database (DPSD) used by risk managers & healthcare professionals<br>• Clear recommendations from Nat. Board of Health in demand by professionals – some problems so important that must be addressed on national level | Technical problems:<br>• response time<br>• inability for local adaptations<br>• inadequate support & training<br>• incompatibility with own IT system | • technical update according to current IT-system standards<br>• increased flexibility and functionality |
| • Easy Internet access available<br><br>• Reports have resulted in follow-ups & recommendations | • Supplementary systems in Counties – double work<br><br>• Frequency & quality of follow up to reporting not as expected | Closer collaboration of Nat. Board of Health & Regions:<br>• patient safety fora<br>• preparation of reports with regional relevance |
| • Number & quality of categories has improved | • Categories not suitable for all reports<br>• need for methodology improvement<br>• more precise & appropriate categories (contributing factors particularly) | Expansion of reporting system<br>• inclusion of primary sector, patients & relatives<br>• expansion of categories<br>• revision on basis of WHO International Patient Safety Classification |

The *STARSweb system* in Ireland was introduced by the Clinical Indemnity Scheme (CIS) in 2004, in order to provide organizations with a central point for the recording of clinical incidents and near misses. STARSweb is a confidential, highly secure, web-based IT system that links hospitals and other healthcare Enterprises to the CIS core database. Evaluation of the system was assigned to Health Care Inform (after a tendering process) in 2006 (43).

The evaluation process included the following parts:
- Literature Review
- Data Quality Audit
- Service Users Web Survey
- Enterprise Interviews

An overview of the evaluation's main findings and the subsequent remedial actions proposed is provided in Table 9.

TABLE 9. Overview of STARSweb evaluation findings and corresponding actions

| Main findings | Proposed Actions |
| --- | --- |
| Information currently submitted to the system not comprehensive; large number of fields left empty, part of them are necessary and need to be reinforced | Continuous monitoring of the quality of submitted data, and regularly performed in-depth audits |
| Bias in reporting towards patient slips, trips and falls (39,2%) - very few major or severe events reported (3%) | Development steps:<br>• reduction in the number of fields<br>• refinement of the classification system, either by mapping of organization-specific classifications to general classifications used by STARSweb or possibly by adopting the WHO international patient safety taxonomy (due for publication in 2008)<br>• re-development of the reporting system |
| Submitted data is generally appropriate, with the exception of incidents' risk ratings | Explore the potential for point of occurrence data entry |
| High level of anonymity across the free text incident report fields | Provide structured feedback to organizations (incl. data quality and benchmarking against national averages and peer organizations) |
| There was variance in the utilization process of STARSweb within organizations, which was reflected in a variety of reporting processes and forms | Increase staff training in risk management and in use of STARSweb. |
| When compared against paper records, STARSweb data lacked comprehensiveness and clarity | |

### Experiences from the US & Australian reporting systems

The US and Australia have been forerunners in bringing attention to issues of patient safety and subsequently developing and implementing the necessary systems and structures for patient safety monitoring and promotion.

In his 2002 article Lucian Leape set as objectives for the existence of patient safety incidents reporting the opportunity to learn from experience and to monitor progress in error prevention. In addition, he saw that the value of reporting beyond

and outside the local level lies in the possibility of sharing with others the lessons learned within ones own organisation (44).

The rationale and benefits of establishing a reporting system on the national level were also substantiated by both Leape, as well as Runciman, in the latter's summarizing of 15 years of experience of the Australian Patient Safety Foundation (45).

In short, the main points are the following:
- identification of events that are low-frequency on the organisation level, but through aggregation can allow the early recognition of previously unknown hazards
- possibility to identify common contributing factors, through the analysis of many events at different locations
- central analysis allows the dissemination of individual organisations' experiences and best practices.
- better understanding of types of injuries and their respective causes can guide preventive efforts.

On the basis of the APSA experience, Runciman also indicated specific requirements that the national incident reporting system should fulfil in order to be effective. These were:
- national standards for the basic attributes of the system
- use of a common classification system for patient safety
- need for feedback and evidence of action from the national to the local level.

The latter point was echoed by Wachter, in his assessment of progress in the US five years after the publication of the IOM Report, particularly from the point of view of incident reporting systems (46). Wachter claimed that reporting systems have had little impact, primarily because of the false belief that reporting is an adequate means for promoting patient safety as and of itself. Rather, the critical point is that the reporting system should be used as a tool to improve practices and educate providers, hence significantly more resources are needed in ensuring that this feedback loop – from local, to national and back to local level - functions effectively.

# 5    KEY ISSUES FOR DECISION MAKING

When considering the introduction of a national reporting system for patient safety incidents, there is a series of largely practical, but critical questions to be answered. A list of relevant questions is provided below and discussed on the basis of the evidence emerging from the reviewed materials.

- **Is a national level reporting system necessary?**

The necessity for supporting and developing local (i.e. organisation level) systems is evident – they are the cornerstone and primary source of any patient safety monitoring system. In addition, in-depth analysis and action need to be taken first and foremost at the organisation level (25, 47). Also in countries with established national level reporting systems such as the UK and Denmark, a large share of the work regarding response to patient safety incidents takes place at the local level. Scotland - even though the need for national level aggregation of data has been acknowledged there, too - has first placed the emphasis on improvement and developing of local (hospital level) reporting systems. The same approach can be seen in countries such as Belgium and the Netherlands (48, 49).

Is it then sensible to place emphasis and resources on a national level reporting system?

The answer to this question is not a straightforward one. It largely depends on certain features of healthcare services organisation, as well as on the status quo regarding patient safety and quality in the healthcare system of the specific country (i.e. existing structures, systems, legal framework etc).

In addition, a critical aspect is that of scalability. Using as reference the data available on the Aviation Safety Reporting System, Leape (44) demonstrated that the establishment of a national reporting system in the US would be non-feasible and non-sustainable due to its massive size and the huge resources it would require[1]. For most European systems, the problem of scale should not be equally daunting, even though allocating adequate resources is always a challenge.

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1    The total number of reportable events annually in the US -including near misses- could be as high as 5 million. Even if only 10% would be reported, that would mean 500 000 reports per year and a cost of $35 million, which would be prohibiting.

- Incident monitoring
- Medical record review
- **Routine data collections (ICD-10)\***
    - **death certificates**
    - **hospital discharges**
    - **surveys of general practice**
- **Existing registers and reporting systems for:**
    - **morbidity and mortality**
    - **adverse drug reactions**
    - **equipment failure and hazards**
- **Complaints**
- **Medico-legal investigations**
- **Investigations by coroners**
- **Results of enquiries and investigations**
- Literature searches

BOX 1. Sources of information about things that go wrong in health care (from Runciman, 2002)
\* Highlighted are those sources which are most relevant for national-level aggregation of data, rather than organisation-level analysis

- **Establish a separate national-level system or utilize existing sources?**

Directly connected to the aforementioned issue of efficient resource use is the concept of utilizing already existing information sources on patient safety and pulling their data together for analysis, instead of establishing a separate national level reporting system. The alternative is certainly a valid one, given the wide variety and richness of candidate material (as indicated in the list provided by Runciman in 2002 - Box 1), combined with the fact that at least some of these sources are already available in some form in most European countries. Further, some of these potential sources of data are discussed in more detail.

## Administrative and register data

Administrative and register data are primarily collected for general statistical purposes. Zhan and Miller (50) have documented a number of challenges that are associated with the utilization of administrative data for patient safety research purposes. In principle, these challenges would be of equal importance in the context of national level patient safety monitoring:
- problems with ICD coding: only events for which corresponding codes exist can be identified, coding errors, incomplete coding, variable utilization of codes,

difficulties in distinguishing between co-morbid diseases and complications or medical errors.

- low sensitivity but fair specificity in identifying quality gaps. Focus on specific adverse events for a specific patient population (as in the AHRQ Patient Safety Indicators – PSIs) improves considerably specificity. At the time of Zhan and Miller's article authoring, PSIs had not yet been validated or tested for reliability; in subsequent studies, however, they were found to be a relatively useful instrument (51–54).
- Lack of clinical details for risk analysis and risk adjustment.
- Analytical issues – risk of false impressions due to large sample size; findings of statistical significance may not be of clinical significance.

Because of the aforementioned limitations, register data (originally collected for other purposes) cannot be a *sufficient* tool for monitoring and promoting patient safety. Nevertheless, administrative data undoubtedly have a role in patient safety strategies, e.g. through indicators which – in the absence of a reliable reporting system – can provide information on overall incidence and trends, allowing to track progress on all levels (local, regional, national) (50).

## Specific domain reporting systems

Specific domain systems already exist in many countries, at least for known high-risk areas, such as blood products, medications, infections and/or specific clinical areas (such as ICU, anaesthesiology, surgery etc).

The clear advantage of specific systems is their ability to engage the frontline staff of the corresponding discipline and to tailor both data collection and dissemination to their specific practice needs which, conversely, is the weak link of national level systems (44, 47). On the other hand, domain-specific systems cannot cover the whole spectrum of patient safety, nor contribute adequately to the formation of a comprehensive picture without the presence and action of a co-ordinating party.

- **A national system for sentinel events or for near-misses?**

*Sentinel events* (i.e. events that result in death or serious physical or psychological injury of the patient - according to the JCAHO definition) require in-depth analysis, due to their legal nature and gravity. Partly, such events are covered through the reporting systems that focus on high-risk areas, as mentioned earlier in the context of domain-specific systems.

The analysis of a sentinel event has to first and foremost address the needs of the local organisation. Sentinel events are usually quite rare and exceptional – hence they are also an inadequate means as and of themselves for following up

and improving overall patient safety. Characteristics of systems for sentinel event reporting and analysis also tend to differ when compared to those for near-miss or other adverse event reporting (47).

With regard to sentinel events, what is perhaps more important on the national level is:
• guidelines, training, dissemination of best practices on how to manage such incidents within the organisation;
• aggregation of the findings of sentinel analysis, primarily for better dissemination of lessons learned and to a lesser extend for identification of hazards.


## Near misses (close calls)

The case for inclusion and placement of emphasis on near misses in the context of national level patient safety monitoring has been made repeatedly. Near misses have been identified as a central component of any national strategy to reduce patient safety injuries (47, 55).

Near misses should be reported, followed up and analysed for a number of reasons:
• less emotionally charged (probability of reporting higher)
• means of preventing actual incidents can be identified
• particularly relevant source of 'weak signals', therefore aggregation should take place both on a local and national level.

In Denmark, even though the Patient Safety Act explicitly includes both adverse events and near misses, the DPSD has so far focused and encouraged the reporting only of incidents leading to actual patient harm. Nevertheless, also near-miss reports have been submitted to the DPSD. The value of near-misses has hence been acknowledged and it has been discussed that their reporting and analysis needs to increase also in the DPSD (56).

There have also been problems identified from experiences thus far: when there is a separation of systems for reporting adverse events and near-misses, filing a near-miss report tends to become too cumbersome.

In their review of reporting systems, NHSScotland has proposed the following features for a near-miss reporting system (47): it should be easy to use, not time demanding, and not as detailed as the reporting system for adverse events. However, it is critical to maintain the overlap in the type and content of data collection, i.e. the two systems should be integrated and accessible through the same application

and have the same profile (except that actual incident reporting needs to be more detailed).

- **Should reporting be mandatory or voluntary?**

Typically, reporting systems for near misses are voluntary, with the notable exception of the Danish system. The same often applies to reporting systems for actual adverse events (except in the case of sentinel events).

Closely connected to the issue of mandatory or voluntary reporting are the questions of reporting *confidentiality*, as well as the *legal framework* within which the reporting system is implemented, which is different in every country. To a large extent, the debate is focused around the thorny aspect of preserving the reporter's anonymity. Unless healthcare personnel perceive that they will not suffer judicial or other consequences when reporting patient safety incidents, they may be very reluctant to do so. Hence the need for a non-punitive reporting system has been strongly brought to the foreground. On the one hand, this is an issue of patient safety culture within each organisation, and on the other hand it is a matter also addressed through legislation, as the Danish example has demonstrated. The legal and regulatory framework relevant to patient safety reporting is a topic that warrants a separate investigation, due to both its complexity and variability from one country to the other, as well as to its central role in promoting or hindering patient safety data gathering. The flip-side of non-punitive (and hence often anonymous) reporting systems is the difficulty of getting access to in-depth or additional data regarding a specific incident, as well as the challenge in preserving accountability.

- **How to ensure professional involvement?**

Most commonly, the involvement of physicians in patient safety reporting has been reported as disappointingly low; usually well below a 10% representation among reporters. At present, the only exception to this rule is Denmark, presumably because of the combination of two features: mandatory and sanction-free reporting. Another effective means that has given positive results in enlisting the participation of physicians has been active solicitation, provided that it has been continuous (57). However, also criticism has been expressed towards the notion of low physician engagement in patient safety reporting. It has been suggested that it could simply be a reflection of the smaller percentage of physicians in hospital staff, or of their involvement in the type of events sought by certain reporting systems (58). Either way, the matter of professionals' participation in patient safety reporting would require more sophisticated study approaches, able to capture the true reasons for observed differences and variations.

- **How to promote patient/citizen involvement?**

It largely seems that the patients and citizens are an inadequately tapped resource in patient safety reporting. The only country that has actually implemented public reporting is the UK, since 2006. Denmark has indicated the need to expand the reporting system in that direction, but the decision has not yet been implemented.

Considerably more experience exists with educating patients with regard to how their behaviour can promote patient safety causes during their stay in a hospital. A variety of examples exist: campaigns, posters, handbooks, etc. (59–61).

- **What is the role and impact of IT in patient safety monitoring?**

Considerable experience has already been gained on the benefits of utilizing information technology (IT) for patient safety activities on the organisation/local level, particularly with regard to the detection and monitoring of medication-related adverse events (62–64). Also with regard to patient safety incident reporting, computerized tools have been viewed and adopted as an improved and efficient means to support the reporting process (65, 66).

On the national level, the utilization of IT seems to be primarily focused on the Web, through the establishment of online reporting systems (like in the UK), and the use of the Internet as a dissemination channel for patient safety news, alerts and materials.

These developments, however, are only the beginning. In parallel to the overall progress made on patient safety issues, in most countries there is a parallel development of introducing IT-enabled systems throughout healthcare organisations - most notably electronic patient record systems. The potential for synergies and benefits between patient safety efforts and the increased availability of patient data in digital form is considerable and thus far barely explored. Should this potential be realized, it would open up new possibilities of detecting, and even more so preventing patient safety incidents, as well as monitoring changes on the system level (67–69).

Key prerequisites for reaping the benefits of IT use in the context of patient safety are -among others- the development and adoption of common definitions and classifications, combined with the investment in systems that are able to manage the demands and complexities of information retrieval and analysis in the specific domain (58, 67).

- **Is there a need for a national level organisation to coordinate patient safety activities?**

The countries which have opted for the establishment of a national level reporting system, have accompanied their decision with the appointment of a dedicated national level co-ordination and dissemination point (see Annex for more details).

The need for patient safety leadership on the national level has been acknowledged and underlined strongly (47, 70, 71) with the following focus areas: patient safety knowledge advancement and dissemination, development and learning, standards setting and evaluation, and promotion and sharing of good practices. One could argue that in case the option of pulling together data from existing information sources is chosen over that of establishing a national level reporting system, the need for co-ordination and leadership becomes even more pronounced.

# 6 Discussion

In spite the increasingly growing attention to patient safety matters in Europe, national level systems for monitoring, supporting and promoting patient safety objectives are still very rare. The fact that all-inclusive national level systems for reporting of patient safety incidents are operational only in three European countries came as a surprise. Partly, this was due to the fact that the WHO report on Guidelines for Adverse Event Reporting and Learning Systems used the terms 'adverse event' and 'patient safety incident' in a different manner than the later on developed draft International Classification for Patient Safety[2], thereby generating a different picture about the frequency of national level reporting.

On the other hand, there are limitations to this work which might have influenced the accuracy of the findings. This is not an extensive and exhaustive review of the subject, but rather a focused review on existing systems and their experiences, which in turn were combined with evidence from scientific literature (which, however, tends to focus more on organization level systems and to a lesser extend on national level systems).

As often the case when attempting to collect European level data, one of the major challenges was the multilingual nature of the targeted material. The primary working language for this review was limited to English. Therefore, there may well be relevant and important information on several countries that was not included in the materials as it was available only in the local language. The sensitive nature of the topic of patient safety makes this likelihood considerable.

This challenge will certainly be addressed by EU-wide projects such as the recently launched EUNetPaS (72). The project has the advantage of local national contact points and networks in all 27 EU Member States, as well as a dedicated Work Package to study different approaches to patient safety reporting.

It is important to keep in mind that a national reporting system is just one of a number of resources that can be utilized for patient safety monitoring; it has specific strengths, as well as specific reported weaknesses and limitations e.g. underestimation of the true level of reportable incidences. For a comprehensive picture and progress overview on patient safety there is the need to triangulate (existing and new) data sources and combine methods, depending on several features and factors in each country.

The main shared findings emerging from the experiences of the four European countries that are presently at the forefront of national patient safety reporting are the following:

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2    In the draft International Classification 'adverse event' is specifically linked to patient harm, while the Guidelines text used the term 'adverse event' to include also near misses. As a result, both systems focusing on sentinel events and all-inclusive systems were grouped in the same "category'"

- Need for constant development and improvement of the system, based on regular assessment of performance and user input. Although considerable resources and commitment are required to launch a national reporting system, these are only the first essential step. In addition, a plan and preparation for continuous update and upgrade should also be in place from the start.

- There is a challenging trade-off to be achieved between user-friendliness of the reporting system and the detail of data requested. Relevant parameters in this task are system design, effective use of technology and adoption of international standards and classifications.

- Follow up work and dissemination of findings are of paramount importance. There is always the risk of focusing excessively on data collection aspects. However, putting in place appropriate mechanisms for bringing the findings back to field, and at the level where the knowledge can have the most impact is at least as crucial as any system for the monitoring of patient safety. Feedback and dissemination strategies need to be thought about and planned in a way that ensures fast and relevant delivery of information both at the right level, as well as vertically (from the national to the local level and back) and horizontally (across pertinent organisations on each level). Interestingly, systems for reporting do not consider this aspect already at their inception phase, neither do they place some specific relevant target. As Norway's representative in the WHO's Futures Forum phrased it (73), patient safety authorities "should first deliver the 'goods', that is the useful learning information, before asking for the 'payment', that is the information from health workers about adverse events".

The planning of national level reporting and/or monitoring of patient safety is still an open question for many European countries. There is clearly not one right answer either, but rather each country will need to tailor its solution to fit its particular needs, taking into account their starting point and forthcoming developments. In this strategic process, the need to place emphasis on standardization, particularly of terminology, cannot be stressed enough. It is a critical aspect both for national level analysis and benchmarking, and for the international sharing of experiences and the comparability of strategies and results.

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ANNEX 1

National Patient Safety Incident Reporting Systems

Country Profiles

# United Kingdom (England, Wales, Northern Ireland)

## Responsible Agency: National Patient Safety Agency

### Profile

Special health authority status, established July 2001. Comprised of three divisions (see below).

### Main function

Promotion of patient safety in all NHS organizations operational in England, Wales and Northern Ireland.

The Agency maintains contact with all relevant NHS organisations and collaborates with national level stakeholders for the development and dissemination of recommendations on the basis of their findings. In addition, NPSA acts as the national contact point and collaborating organisation in international level patient safety activities, such as the WHO patient safety network.

### Vision

Make patient safety a true priority in the NHS.

### Mission

- **National Reporting and Learning Service**
  http://www.npsa.nhs.uk/patientsafety/
National reporting and learning about safety problems reduces risks to patients across the NHS quickly and effectively.

(The following two divisions were integrated to the NPSA in 2004–2005).

- **National Clinical Assessment Service**
  http://www.ncas.npsa.nhs.uk/
Concerns about the performance of doctors and dentists are resolved so that safer practice is maximised.

- **National Research Ethics Service**
  http://www.nres.npsa.nhs.uk/

The research ethics review process protects participants and facilitates quality research.


## Budget

Data on budget for NPSA for the year 2007/2008 are available in the Business Plan (Way Forward)
Total Expenditure: £31,771,000 of which £16,822,000 for Patient Safety (incl. Confidential Inquiries).


## Other Patient Safety Activities

In addition, NPSA is responsible for commissioning and monitoring the three National Confidential Enquiries, as presented below. The Confidential Enquiries work independently of the NPSA, the Department of Health and other organisations, although they are funded, in part, by the NPSA. Their membership and details of their work can be seen on their individual websites.
- NCISH – Suicide and Homicide (by people with mental illness),
- CEMACH – Maternal and Child Health
- NCEPOD – Patient Outcome and Death (http://www.ncepod.org.uk/)


# National Reporting System: The National Reporting and Learning System (NRLS)

The National Reporting and Learning System (NRLS) was launched in 2004, covering 607 NHS organisations. Full roll-out of the system was preceded by a testing and development phase between January and May 2003, in which 39 organisations participated.


## Data Collection and Analysis Methodology

*Coverage*

NPSA activities address all levels of care, as is reflected in the nine 'localized' variants of the NRLS reporting form (see Data Set section below).

In terms of clinical areas, specific domains are selected to be the focus of work for certain periods of time. For example, in the Business Plan for 2007/2008, the

following focus areas have been selected: neo-natal care, radiology/radiotherapy involving cancer treatment and anaesthetic care; obstetric intra-partum care.

## Data Set

The NPSA dataset (the standard information about a patient safety incident that should be collected) was finalized in 2003, and on that basis a version of the electronic reporting form – eForm was developed. The NPSA has tailored the reporting form to various healthcare settings, and for this reason the dataset is available in nine versions, as shown in Box 1.

BOX 1. NPSA Dataset Clinical Versions

Acute / General Hospital Service Dataset

Ambulance Service Dataset

Community and General Dental Service Dataset

Mental Health Service Dataset

Primary Care Organisations Service Dataset (Including Community Nursing, Medical and Therapy Services and Community Hospitals)

Learning Disabilities Service Dataset

General Practice Service Dataset

Community Optometry / Optician Service Dataset

Community Pharmacy Service Dataset

## Reporting pathway

NHS staff anywhere in England and Wales can report patient safety incidents, including prevented patient safety incidents (i.e. near misses), that they are involved in or witness.

Incidents are reported locally, where they are also investigated and analysed so that suitable learning and actions can follow.

The NRLS has been designed to complement local reporting arrangements. For the majority of NHS organisations with a commercial local risk management system (LRMS), reporting is therefore seamless. All patient safety reports are entered into the organisation's own system and then sent automatically directly to the NPSA.

Also an electronic web-based reporting form has been developed as an interim measure for those organisations that have not yet established an LRMS. In addition,

staff not willing to report through their local organisation can use the form to report directly to the NPSA.

An electronic form for use by patients and their carers was launched in 2006.

*Analysis*

At the national level, the information relating to individuals (staff or patients) is removed.

Information provided to the NPSA is therefore stored anonymously and analysed further to identify national recurring patterns, pinpoint patient safety priorities and develop practical solutions.

Key features of the new NRLS include computerised data analysis tools to help identify potential clusters, patterns and trends.

# Feedback and Dissemination

## Feedback – Statistical Publications

The statistics of incident data collected through the NRLS are reported back to the NHS and the public as:

a.   **Feedback reports to each NHS organisation that sends data regularly to the NRLS**

There is a web-based system for NHS trusts to receive feedback from the NRLS. In organisational feedback reports the following indicators are used:
- for acute trusts: rate of reported incidents per 100 admissions
- for ambulance trusts: rate of incidents per 100,000 journeys (currently being re-evaluated since it can not accommodate differences in size and activity between trusts)
- for mental health and learning disability trusts, as well as for primary care organisations with inpatient provision: rate of reported incidents per 1000 bed days.
- for primary care organisations with no inpatients: the rate of reported incidents per 100,000 population.

b.   **Quarterly data summary reports giving an overview of data from NRLS**

This quarterly publication sets out the number of patient safety incident reports received by the NPSA, and describes patterns and trends in these incidents.

Data are from the NPSA's National Reporting and Learning System and include all patient safety incidents reported from NHS organisations in England and Wales.

Two sets of data and analysis are presented:
- Reporting to the NRLS. Using data labelled by the date that the report is received by the NPSA, these data show the numbers of patient safety incident reports received by quarter.
- Trends and patterns in patient safety incidents. This uses data labelled by the date that the patient safety incident occurred and covers four quarters.

**c.  Bulletins and Newsletters with updates on patient safety issues**

**d.  PSAT Reports**

The newly-established Patient Safety Action Teams (PSATs) are working to build a stronger culture of safety on the frontline of healthcare within each Strategic Health Authority (SHA).

To improve patient safety at local NHS level it is important to have regular information about the types of incidents that are being reported by trusts in each SHA.

## Other Publications

- Rapid Response Reports (advice on patient safety issues that need immediate local attention)
- Patient Safety Alerts (advice on patient safety issues that are important and have a specific timeline for implementation)
- Safer Practice Notices (guidance on patient safety issues that contribute to improving patient safety)
- Patient Safety Guidance (Includes advice and information)
- Patient Safety toolkits and e-learning packages (tools and modules that help and contribute to education and training sessions at a local level)

# Other patient safety reporting systems in the UK

In addition to the NRLS, there are separate reporting systems for medical device incidents and adverse drug reactions (14), healthcare associated infections (15) and serious hazards of transfusion (12).

# Other relevant organisations or actors in the UK

| Organisation name | Brief description |
|---|---|
| Health and Safety Executive<br>www.hse.gov.uk | The HSE ensures that risks to people's health and safety from work activities are properly controlled. |
| Health of Wales Information Service (HOWIS)<br>www.wales.nhs.uk | HOWIS, the official website of NHS Wales, is a seamless service bringing together information sources about the health and lifestyle of the population of Wales into a simple, electronic-based service. HOWIS provides you with: A one-stop shop to health information; Easy and instant access to health information; Timely, accurate and complete information; The corporate website of the NHS Wales, and; Links to the wider information base for healthcare. |
| Healthcare Commission<br>www.healthcarecommission.org.uk/<br>Homepage/fs/en | The Healthcare Commission promotes improvement in the quality of the NHS and independent healthcare. We have a wide range of responsibilities, all aimed at improving the quality of healthcare. |
| Regulation and Quality Improvement Authority<br>www.rqia.org.uk | The RQIA has overall responsibility for monitoring and inspecting the availability and quality of health and social services in Northern Ireland, and encouraging improvements in these services. |
| The Health Foundation<br>http://www.health.org.uk/ | An independent charity working to improve the quality of healthcare across the UK and beyond. |
| NHS Institute for Innovation and Improvement<br>http://www.institute.nhs.uk/ | The NHS Institute for Innovation and Improvement supports the NHS to transform healthcare for patients and the public by rapidly developing and spreading new ways of working, new technology and world class leadership (Among others, responsible for development and training on the UK version of the GTT). |
| National Patient Safety Forum<br>http://www.dh.gov.uk/en/Publichealth/<br>Patientsafety/DH_073927 | The report 'Safety First' recommended establishing a National Patient Safety Forum to influence the development of the patient safety agenda and to facilitate its delivery. The Forum brings together senior representatives of key organisations to be the national conscience of patient safety. It has a strategic, rather than performance management focus. The Forum held its first meeting on February 14th 2007 and has since met another four times. |

# United Kingdom – NHS Scotland

## Responsible Agency: NHS Quality Improvement Scotland (NHS QIS)

### Profile

NHS Quality Improvement Scotland is a Special Health Board that was established in January 2003. Prior to that, responsibility rested with the Chief Medical and Nursing Officers of the Scottish Executive Health Department. The agency was formed through a merger of six quality improvement organisations. It is a special health board – independent in its advice, assessments and recommendations.

### Actions

NHS QIS established the Clinical Governance and Patient Safety Support Unit (CGPSSU) that commissioned a review of incident and near-miss reporting in Scotland. The aim of this review was to establish a baseline picture of incident reporting across NHS Scotland, including the associated strengths and challenges. The study was conducted between April and October 2005 and published in January 2006, containing the recommendations for further action that are listed below.

RECOMMENDATIONS
Formulate a national core minimum dataset for incident and near-miss reporting
Introduce integrated but separate near-miss reporting
Extend and systematise RCA
Extend and systematise local learning groups (LLGs)
Become pro-active in patient safety
Share data effectively
Address barriers to reporting
Cultural change and learning from others
Resource issues
Act now to maintain momentum

In July 2006 the Action Plan of NHS Quality Improvement Scotland was published, where strategic objectives were set forward in four thematic areas: National Coordination, Culture and Reporting, Sharing and Learning, and Inclusivity (with regard to Patients and Public).

Specifically relevant:
*   Establish and develop an NHS QIS national patient safety reference forum to advise and inform work on clinical governance and patient safety.
*   Lead the development of a standardised approach to incident and near-miss reporting across NHSScotland, while supporting the use of local information to learn and improve patient outcomes (2007–2008).

# Other relevant organisations or actors in Scotland

## Scottish Patient Safety Alliance

The Scottish Patient Safety Alliance was set up in March 2007 to drive forward improvements in patient safety and to oversee the development of the Scottish Patient Safety Programme. The Scottish Patient Safety Alliance brings together a wide array of stakeholders, in an effort to significantly reduce adverse events and improve patient safety.

Members of the Alliance include:
*   The Scottish Government
*   NHS Scotland
*   NHS Quality Improvement Scotland
*   The Health Foundation
*   The Scottish Consumer Council
*   The Royal Colleges and professional bodies
*   Institute for Healthcare Improvement (USA)
*   Health and Patient experts
*   Public partners

In the Alliance's first programme of work, acute hospitals across the country are taking part in the Scottish Patient Safety Programme. The Scottish Patient Safety Alliance is supported by a National Advisory Board which oversees the development, implementation and management of the Programme.

## The Scottish Patient Safety Programme

The vision of the National Patient Safety Programme is that Scotland will be leading the way in Patient Safety.

The programme has identified specific areas where evidence shows that interventions do make a difference. The target is to implement these interventions uniformly across all acute hospitals in the country, in the course of the next five years. The initial goals are to drive improvements in:

- Intensive care units
- Medicines management
- General wards
- Perioperative care
- Safety leadership

# Other patient safety reporting systems in Scotland

## High Priority Systems

A number of systems for reporting incidents in high-risk areas are already in place in the NHS, and operate separately from local risk management and incident reporting systems. For example:
- the Scottish Surveillance of Healthcare Associated Infection Programme (SSHAIP),
- the Scottish Audit of Surgical Mortality (SASM),
- Serious Hazards of Transfusion (SHOT) - a collaboration of all four UK Blood Services, plus several Royal Colleges and professional bodies, and
- the Confidential Enquiry into Maternal and Child Health (CEMACH) - in collaboration with the NPSA and Department of Health, Social Services and Public Safety (DHSSPS) of Northern Ireland.

RIDDOR

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (introduced in 1995) is a statutory obligation under Health and Safety legislation. Employers, the self-employed and those in control of premises must report specified workplace incidents, which are: work-related deaths, major injuries or over-three-day injuries, work related diseases, and dangerous occurrences (near miss accidents). The reports enable the enforcing authorities to identify where and how risks arise and to investigate serious accidents. The primary focus is on occupational occurrences, however also injuries of patients during their hospitalization belong to the reportable events under this scheme.

# Ireland

The Minister for Health and Children, Mary Harney T.D., announced in January 2007 the establishment of a Commission on Patient Safety and Quality Assurance. The Commission is chaired by Dr Deirdre Madden, BL, a leading expert on medical law and ethics. It includes nursing and medical representatives, management representatives and, importantly, two representatives of patients and carers. The Commission reported to the Minister after 18 months of work, in July 2008.

The purpose of the report was to provide clear and practical recommendations that would ensure the safety of patients and the delivery of high quality health and social services. The Commission's report contained recommendations with regard to the following areas:

1. Patients, Carers and Service-Users as Partners
2. Leadership and Accountability
3. Organisational and Professional Regulatory Framework
4. Quality Improvement and Learning Systems
5. Implementation aspects (options, timeframe, benefits and costs).

## State Claims Agency – Clinical Indemnity Scheme

The Clinical Indemnity Scheme (CIS) was established following enactment of legislation in 2002, with a dual remit:

(a) to manage all claims relating to professional clinical services in the Irish public health sector and
(b) to lead and support the development of clinical risk management in the sector.

The Clinical Indemnity Scheme has been established on the basis of "enterprise liability". The most significant change that has resulted from the introduction of enterprise liability is that doctors and dentists are incorporated into the liability borne by each agency. The Scheme will cover all claims alleging medical malpractice or clinical negligence against an agency and/or its staff arising from the delivery of professional medical services by those employed by the agency. This includes services provided at hospitals, clinics, other facilities owned or operated by the agency as well as in patients' homes and other community based facilities.

The Clinical Indemnity Scheme does not cover General Practitioner Services.

Agencies are obliged to report incidents and claims to the State Claims Agency through the IT system provided to each agency (the STARS Clinical Incident Reporting System).

The objective of the Clinical Indemnity Scheme is to settle valid claims for compensation as quickly and at least cost, as possible. In addition, a very important

objective for the CIS is sharing of learning to support patient safety. This is achieved in a variety of ways: once claims are closed, they are subjected to analysis in order to capture any learning from them. Feedback is provided to the individual enterprise and any generic lessons are fed back into the system through workshops, seminars, the CIS website or newsletter.

# Other patient safety actors in Ireland

## Health Service Executive (HSE) – Office of Quality and Risk
Established in 2005

The purpose of the Office is to support the assurance of good governance in respect of all services provided by the HSE. The HSE is engaged in an integrated system-wide process of implementing a Quality and Risk Management Standard which conforms to the requirements of the Australian/New Zealand Risk Management Standard.

## Health Information and Quality Authority (HIQA)
Established in 2007

The object of the Authority as set out in legislation is 'to promote safety and quality in the provision of health and personal social services for the benefit of the health and welfare of the public'. The Authority is undertaking a range of work programmes that include its mandatory functions and is engaged in a range of activities that facilitate collaborative working with statutory, voluntary, educational, professional, advocacy and patient organisations. These activities currently include:
- the development of standards in collaboration with relevant patient representative organisations, academia, service providers, statutory agencies, professional bodies, special interest groups
- undertaking national quality assurance reviews of priority service areas e.g. symptomatic breast disease and hygiene
- carrying out investigations into serious adverse events with involvement from the relevant specialty experts and lay people
- participation in international projects and networks on patient safety dealing with issues such as open communication and safe surgery
- participation in the Health and Social Care Regulatory Forum.

# Denmark

## Responsible Agency: National Board of Health

### Profile

Central authority on health care.
The National Board of Health itself has a very long history (established in the early 20th century), but patient safety activities became part of its profile as of 2001 (Sundhedsstyrelsen - Quality, Monitoring and Supervision Division).

### Mission

The National Board of Health contributes, through monitoring, supervision, administration and development to ensuring a high quality and efficiency within prevention and treatment so as to improve the possibilities for a healthy lifestyle for citizens in Denmark.

### Vision

The National Board of Health must continually seek to strengthen its position and expertise as the central authority on health care in order to improve the quality and efficiency within prevention, treatment and patient safety. The National Board of Health must ensure an increasing transparency in connection with this work, as well as the effective involvement of citizens and patients.

## National Reporting System: Danish Patient Safety Database (DPSD)

In January 2004 a national reporting system for adverse events was launched in Denmark. This was a result of the Act on Patient Safety in the Danish health care system (Reference) that was unanimously passed in the Danish parliament in June 2003.

   The purpose of the act is to ensure the gathering, analysis and communication of knowledge of adverse events in order to reduce the number of adverse events 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 learning from the reports.

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, which are at risk of reoccurring

Important to note that although the act essentially includes near-misses, the guidance given to the local level has been to report only actual AE's and not near-misses. Nevertheless, near-misses reports have also come in - Their value in providing clues to effective preventive strategies and measures, as well as potential problems has been identified and the intention is to start collecting and analysing also such data.

Main features of the reporting system:
- Mandatory for all frontline personnel
- Confidential (on the national level)
- Sanction-free

## Data Collection and Analysis Methodology

### Coverage

The reporting system at present covers all public and private hospitals in Denmark. There are plans and projects underway to expand coverage to primary care and include patients and relatives.

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

### Reporting pathway

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 – relatively liberal and variable in their structure and organisation.

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 (i.e. no confidentiality of patient, report or organisation at the local and regional level).

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.

It is not mandatory for a health care professional to state his/her name or other identifiable information when reporting, but anonymity makes the collection of further information difficult for the analyzing team. The reporting system is strictly confidential, the health care professionals are protected from sanctions, and data is anonymized before it is sent to the National Board of Health. Less than 10% of health care professionals choose to be anonymous.

*Analysis*

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.

## Feedback and Dissemination

Dissemination of findings derived through national level analysis is achieved by a variety of means:
1. Newsletters
2. Alerts
3. Reports on specific subjects (e.g. medication errors)
4. Development of binding national standards for patient safety (Reports utilized as background material)
5. Quarterly and annual reports
6. Theme reports containing recommendations
   - prevention of suicide and attempted suicide during admission
   - preparation of patients prior to surgery or other invasive procedures and major diagnostic imaging tests
   - adverse events concerned with blood and tissue tests, and diagnostic imaging tests.

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

### Regional Level Activities

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

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

- Treatment of cardiac arrest
- Use of bed rails
- Patient falls
- Suicide and attempted suicide during admission.

# Other patient safety reporting systems in Denmark

The supervision system operated by the National Board of Health, the complaint system and the patient insurance system.

# Other relevant organisations or actors in Denmark

## Danish Society for Patient Safety

The Society was founded in December 2001 as a non-profit organization. It creates an organizational framework, gathers and spreads international and national knowledge and participates in the dialogue on how to improve patient safety. The aim is to ensure that patient safety aspects are included in all decisions made in health care. A wide range of stakeholders in Danish health care are represented in the Society as board members: Health care professionals, patient and research organizations, the Danish Regions and the Copenhagen Hospital Corporation, the pharmaceutical and medical industry, the Danish Consumer Council and Local Government Denmark. This composition ensures that the Society has a significant political position.

The Danish Society for Patient Safety supports the handling of adverse events with a number of learning-oriented activities, for instance:

- Patient Safety training on Root Cause Analysis, Health Care Failure Mode and Effect Analysis, legal aspects in relation to patient safety, and the Human Factor approach.
- Tool Kits for the aforementioned education topics
- Website with pertinent information and case stories analysed through Root Cause Analysis
- Patient empowerment support.

## Additional references for Annex 1 – Country profiles

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