Copenhagen (Denmark) - 24 January 2007

PATIENT SAFETY and REPORTING SYSTEMS

A study tour was organised in Denmark by the Danish Regions at the request of HOPE, inviting HOPE members and several other European healthcare organisations (doctors, nurses and pharmacists) to join the visit. HOPE had strongly expressed (Board of Governors April 2006, Amsterdam) the need of the adoption in all member states of reporting systems that enables to learn from adverse events.

PREVIOUS ACTIVITIES CONCERNING REPORTING

LUXEMBOURG DECLARATION

The collective action of stakeholders started in 2004 with the organization of a European conference on patient safety. This conference “Patient safety – Making it happen” took place in Luxembourg on 4-5 April 2005. They convinced the European Commission and the Luxembourg presidency to support it. The conference statement (Luxembourg Declaration) lists a certain number of recommendations, in which one is devoted to National Authorities: “to consider the benefits of a national voluntary confidential reporting systems of adverse events and near misses”. Building upon the Luxembourg Declaration, all stakeholders worked together to prepare “Stakeholders’ position paper on Patient Safety” (=call for action) which again included this disposition.

SIMPATIE

In this context the SIMPATIE project on Patient Safety, financed by the EU Public Health programme, started in 2005 for the duration of 2 years. Of the stakeholders mentioned earlier, only HOPE and CPME (Standing Committee of European Doctors) are involved as partners. It contains a “mapping exercise” in order to establish systematic knowledge repository on patient safety related to legislation, regulation and actions in EU states. In the framework of the project a Consensus Conference was organized in Luxembourg 18-19 September 2006 “Building a strategy for Patient Safety”. Regarding reporting and risk management systems, discussions mainly focused on their scope and format, including the relevance of insurance schemes to provide compensation, and the meaning of open-and-fair systems in practice.

WORKING GROUP ON PATIENT SAFETY

The High Level Group on Healthcare services and Medical care created in 2005 includes a Working Group on Patient Safety (chaired by Sir Liam Donaldson). This Member States and Commission working group accepted the participation of some stakeholders including HOPE, CPME and European Federation of Nurses.
A project proposal on Patient Safety Reporting, to encourage and support Member States in establishing effective Patient Safety reporting and learning systems, was discussed within the group in 2006. The project was prepared and submitted by Denmark—National Board of Health to the Call for proposal 2006, project was rejected. In the consensus conference the conference participants applauded the initiative of the High Level Group on Patient Safety to move to set up a patient safety network in Europe involving all Member States.

The discussion on Reporting within the Patient Safety working group continues. The Group is drafting Recommendation of the High Level Group on Improving Patient Safety in the EU. Among others, there is a recommendation to establish effective reporting and learning mechanisms.

(...)

- Establish effective reporting and learning systems on adverse events in health care in order to establish the extent of error and adverse events, monitor trends, develop effective interventions, observe changes following the introduction of those interventions and share learning on what interventions are effective (as well as those that are not). This must link to other work on adverse incident reporting, such as pharmacovigilance systems, already in operation.
- Establish a transparent, open and honest patient safety culture in health care by clarifying the legal situation on health professionals’ liability issues and creating an environment where it is easy and safe to report and there is an opportunity to learn from mistakes without fear of punishment. This needs to work alongside Member States’ disciplinary procedures for health care professionals, for example where negligence is proved.

Today the group is working on the project EUNetPaS (European Union Network for Patient Safety. Changing culture and reducing adverse drug events) to be submitted by HAS (French Haute Autorité de Santé) to Public Health programme 2007. In its proposal, one of its working packages is devoted to Incident Reporting System. It is proposed that this part of the project will be lead by Denmark.
DANISH HEALTH CARE - MAIN CHARACTERISTICS

Health care is a public task financed through taxes, with a very small private health sector. Hospital care and visits to general practitioners and practising specialists are free of charge. Total public and private expenditure represents around 8% of GNP.

The responsibility is decentralised and faced a recent change of organisation. With the local government reform implemented on 1st of January 2007, the 14 counties 5 new regions were established. The new regions are responsible for the health care sector, including the hospital sector, psychiatry and health insurance, general practitioners and specialists. The Danish hospital sector currently consists of 57 somatic hospitals - a number decreasing, with an average length of stay of 4.7 days. In addition there are 14 psychiatric hospitals.

LAW ON PATIENT SAFETY

Patient Safety in the Danish Health Care System is structured around an Act that came into force on the 1st of January 2004. This Act has been evaluated after 2 years.

The objective of the Act was to improve patient safety within the Danish health care system by ensuring the receiving and analysing of reports on adverse events, reporting of information to the National Board of Health and advising the health care system on patient safety. The system is mandatory, confidential and with no sanction.

The §6 in the Law on Patient Safety states that “A health care professional reporting an adverse event shall not as a result of such reporting be subjected to disciplinary investigation or measures by the employing authority, supervisory reactions by the National Board of Health or criminal sanctions by the courts.”

The process has been developed in different phases, starting by Phase 1: Hospitals (January 1st, 2004), Phase 2: Hospital-like clinics (2005) and further to Phase 3: Primary health care sector (2007) and finally Phase 4: Patients (2007).

The evaluation report published in August 2006 answered three main questions:

1. Do the staff have confidence to the Patient Safety System?
   - 63% have a high or very high trust in the Confidentiality of the system,
   - 27% do not have confidence to the Confidentiality of the system.

2. Do the staff fear sanctions, reprimand or shaming as a consequence of their reporting?
   - 70% do not fear any consequences of reporting,
   - 30% fear some form of consequences of reporting.
3. Do the staff report adverse events?
- 85% of the acknowledged adverse events are reported by the involved staff member,
- 15% of the acknowledged adverse events are not reported by the involved staff member.

The lessons learned so far is that the difficulties one encounters when establishing a patient safety incidents reporting system are primarily of a cultural nature. However at the same time, the staff is most likely more “Patient Safety Mature” than one can presume.

**ORGANISATION OF THE DANISH REPORTING SYSTEM**

From the sharp to the blunt end, the key factors of success are: a frontline person, a supporting work environment, communication, procedures, organization equipment, training and leadership.

The event report (intranet form) answers the following questions:

- When did it happen?
- Where did it happen?
- Who are you?
- What happened?
- Why did it happen?
- What were the consequences for the patient?
- How do you think we can prevent similar events in the future?

The handling staff for reporting and analysis of the report is made up of a Department Manager, a Patient Safety Manager and a Patient Safety Officer. The information is then sent to the Regional database and finally to the National database.

To prioritize the events a Safety Assessment Code (SAC) - Matrix has been designed differentiating events between: Remote, Uncommon, Occasional, Frequent, Severity and Catastrophic, Major, Moderate, or Minor. The Score given will influence the way it will be handled. The answer to Score 1 will be a local action, a Score 2 answer will result in an aggregated Root Cause Analysis and a Score 3 answer will result in a Root Cause Analysis. A Root Cause Analysis deals with the essential questions: what happened? Why did it happen? How do we prevent it from happening again? Without never asking who.

The analysis of Reporting shows that 6% is confidential while 94% is anonymous.
EXAMPLE OF AN EVENT

Delay of diagnosis and treatment

- Unconscious woman with history of cerebral aneurism arrives at hospital A (01.17)
- CT scanner out of order at hospital A
- Neurosurgical unit at hospital B refuses to receive patient (no spare beds)
- Problems with contacting doctor at hospital C (> 1 hour)
- CT scan performed at hospital C confirms cerebral hemorrhage
- Neurosurgical unit at hospital B refuses to receive patient
- Ambulance doctor brings the patient to trauma unit at hospital B
- Surgery (07.45)

Root Cause Analysis is done by a team made up of:

1. Medical Director
2. Chief Nurse
3. Head of Neurosurgery
4. Senior Doctor
5. Frontline nurse
6. Anesthesiologist, frontline
7. ICU nurse frontline I
8. ICU nurse frontline II
9. Cardiologist frontline
10. Patient Safety Officer

They proceed to the analysis: What happened? Why did it happen? How do we prevent it from happening again?

When calls are not immediately answered it increases the likelihood of delay etc. Furthermore it also increases the likelihood of delay when guidelines are not written with complex situations in mind.

Since the neurosurgical diagnosis were not confirmed the neurosurgical unit would not accept the patient because they had no available ICU beds. This also increases the likelihood of delay etc. The interpretation of the understanding of when there are empty ICU beds are not clear. This increases the likely about discussion between involved personal and therefore the likelihood of delay etc.
Solution

Within one month all hospitals will present a plan for how calls always will be answered.

Guidelines must protect the patient against transferal between more than two hospitals. A new guideline will be ready for approval within two months.

There should always be a plan for how to admit the next neurosurgical emergency patient. This includes involvement of other neurosurgical departments in other regions. A new agreement will be ready in two month.

Guidelines on how to count the numbers of ICU beds are revised. The revision will be ready in one month.

OTHER PATIENT SAFETY INITIATIVES AND TOOLS

A law on Reporting was not considered as enough. Health care staff needs education and concrete tools. Patients should be involved.

The Danish Society for Patient Safety was launched in 2001 as an independent, non profit organisation. The Secretariat has 10 employees, financed by membership fees, private funds and the hospital owners.

The Board consists of all major stakeholders: regional governments interest organisation (hospital owners); regional representatives; professions; patient organisations; pharmacists; industry; research.

The results until now are a consensus on the Danish Act on Patient Safety (National Reporting system); the development of Patient Safety tool kits and educational programmes (train the trainers); the patient empowerment tools: 10 tips, patient handbook; the fact that patient safety is continuously a high priority on the political agenda.

Several initiatives and tools besides the reporting system have been developed:

- Patient Safety Training has been developed with a master class in patient safety, seminars, a yearly conference and toolkits

- A “Safe Patient” project provide for example general information, cases, tools and includes patient involvement.

- Toolkits which typically consists of a Compendium that gives a detailed description and explains the method to implement it. It contains elements on: Root Cause Analysis, Health Failure Mode Effect Analysis, Human
Factor, Legal aspects of patient safety work, Medication Reconciliation, Aggregated Root Cause Analysis, How Patient Organizations can reduce harm, Patient Safety Walk rounds. It includes also a power point presentation (including explaining notes) so that patient safety manager can easily educate others to use the method. Furthermore it contains relevant forms, charts, checklists and diagrams, a handbook and a CD with all the material.

**Initiatives for the patients**

Patients’ experiences with medical errors were surveyed with a response rate 49% for 26,300 questionnaires. 18% of patients answering the questionnaire had experienced errors.

Communication is organized with the “Ten tips for patients” concept:

1. Speak up if you have any questions or concerns
2. Let us know about your habits
3. Take notes during your stay
4. More ears listen better
5. You can let somebody else handle your consultation
6. Check your personal data
7. Ask about your operation
8. Tell us if it hurts
9. Before you are discharged – ask how your care shall continue
10. Know the medicines you are taking

A “Patients’ Guide to Safer Health Care” has been published with a “Travellers” guide for patients “when entering the unknown culture called the health care sector.”

The emphasis is also placed on “Patients for Patient Safety”
- A toolkit on Patient Safety targeted at patient organizations has been designed
- A seminar were held in November 2006 for patient organizations, including presentation of toolkit
- In April 2007 a national “Patients for Patient Safety Seminar” will take place

**THE NATIONAL CAMPAIGN – OPERATION LIFE**

The primary tasks for the Danish Society for Patient Safety in 2007 are the following: Patient empowerment activities with Patients for Patient Safety (WHO-workshop); Safe Team Communication; Patient Safety in the Primary Sector; and Operation Life, a national campaign for patient safety.

This national campaign is built upon the work of: 100k Lives Campaign (USA), Safer Patients Initiative (UK), Safer Healthcare Now! (Canada). It is financed by TrygFonden.
A stakeholders’ process was put in place:

- April-September 2006: Stakeholder group recommendations for a Danish campaign;
- June-August 2006: Danish Medical expert evaluation of interventions;
- August 2006: Regions support a campaign;
- November 2006: First meeting in the steering committee;
- November 2006: The Board of Danish Society for Patient Safety approved campaign.

The steering committee for Operation Life has representatives from: each of the five Danish Regions, the Danish Regions Association, the Danish Medical Association, the Danish Nurses Organisation, the Danish Rheumatism Association, the TrygFonden (SafeFoundation), the National Board of Health and the Danish Society for Patient Safety.

Operation Life will support the implementation of the coming Danish accreditation of hospitals “The Danish Quality Model.” It sets a professional focus in the present fusion of counties and hospitals into the Regions. It gives a possibility to brand the Regions as pro-active.

A campaign was considered relevant in Denmark and the Medical Scientific Committee estimates that it will have an effect. The 6 interventions suggested by IHI are relevant in Denmark with a few adjustments since these interventions are not yet sufficiently implemented in Denmark.

Correct treatment of AMI

- Early administration of aspirin
- Aspirin at discharge
- Early administration of beta-blocker
- Beta-blocker at discharge
- ACE-inhibitor or angiotensin receptor blockers at discharge for patients with systolic dysfunction
- Timely initiation of reperfusion (percutaneous intervention)
- Smoking cessation counseling

Prevention of Surgical Site Infection

- Appropriate use of antibiotics
- Appropriate hair removal (no shavers)
- Perioperative glucose control
- Perioperative control of temperature
Prevention of Central Line-Associated blood stream infection

- Hand hygiene
- Maximal barrier precautions (sterile clothing of staff and sterile cover for patient)
- Optimal catheter site selection
- Daily review of line necessity with prompt removal of unnecessary lines

Prevention of Ventilator-Associated Pneumonia

- Elevation of head of the bed to between 30 and 40 degrees
- Daily “sedation vacation” and daily assessment of readiness to extubate
- Deep vein thrombosis prophylaxis
- Peptic ulcer disease prophylaxis
- Mechanical (physiotherapy) prevention of vein thrombosis

Medication Reconciliation

- The patient’s current medicine list is compared to the doctors prescriptions in connection with admission, transfers and discharge from hospital
  1. The patient’s current medicine is registered as completely as possible
  2. The list is compared with the doctors prescriptions
  3. By “misfits” the prescriptions are reevaluated
  4. All changes are documented

Rapid Response Team

- A “team” with one or more doctors and/or nurses with professional skills to evaluate and treat patients who appear acutely ill
- The team can be called by need for evaluation of critically ill patients
- The goal is to prevent heart failure/cardiac arrest outside intensive care

The campaign objective is to prevent 3000 deaths. All regions are represented in the campaign. 75% of the patients in somatic hospitals will be covered by the campaign (by the end of the campaign).
The numbers

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>Denmark</th>
<th>The Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>298 Mill.</td>
<td>5.4 Mill</td>
<td>2,211</td>
</tr>
<tr>
<td>Estimated preventable deaths</td>
<td>98,000</td>
<td>2,000</td>
<td>2,490</td>
</tr>
<tr>
<td>Deaths per year</td>
<td>2.5 Mill.</td>
<td>56,000</td>
<td>2,773</td>
</tr>
<tr>
<td>Admissions per year</td>
<td>37 Mill.</td>
<td>1.1 Mill.</td>
<td>3,778</td>
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For indicators, one mandatory indicator for each intervention is measured and a number of non-mandatory indicators are developed, that can be used for local monitoring of results and degree of implementation.

HSMR - the Danish version consists in tracking of individuals (personal id number), readmission/transfer accounted for, 30-days mortality, Terminal care accounted for, automatic data capture from existing databases (10 days delay).

Campaign participation is voluntary but there are obligations for participants: a minimum of one intervention should be implemented; mortality data maybe collected for each participating hospital; measuring one indicator per intervention ; engagement in site-visits.

Participating hospitals visit each other during campaign period. The culture in hospital-visits must be: encouraging; honest; curiousness towards others work and accomplishments; willingness to share and to learn from others.

The purpose is to spread knowledge about methods and results, to create networks, to create a feeling of ‘unity’ and create an incentive to reach results.

Events for campaign participants are organised to keep up enthusiasm, to get inspiration from international speakers, to encourage and create a feeling of “we can do this,” something to look forward to.

A Leadership Track was designed with a special session for CEOs and COOs as a part of the Events. Approximately 30-40 people attended in total. This might be inspired by “Get the Boards on Board”: activities for leaders to focus on Patient Safety and to improve quality in hospitals.
CONCLUSIONS OF THE STUDY TOUR

The aim was to understand the way the Danish reporting system had been designed and implemented as well as the way it works. This proved to be possible in one day.

Blame free reporting is part of a blame free culture. It is based on a strong law, with a mixture of local and national regulations. The strength is local but the benefit is visible on national level.

The system is mandatory but there are significant differences at regional level, due to the freedom to organise themselves. Ownership is very important, it was clearly understood that the system is not designed for a regulatory agency but for professionals. Its success is certainly a question of maturity of professional and patient organisations.

Structures are in place in each of the 5 Danish regions. The unit for patient safety of the capital region of Denmark was presented as an example of Danish reporting at local and regional level. Each hospital has organised itself with a PS officer per unit and PS manager at hospital level. Patient safety managers organise a yearly conference. There are 10 persons working in the Danish Society for Patient Safety. In Copenhagen there are 4 persons in the unit for a 2 million inhabitants.

30,000 reports were sent in the last two years, 25% by doctors and only 7% of them were anonymous. Doctors report catastrophic, nurses report issues with less impact. 2% of them are in the top class 1. It also picks near misses.

Toolkits are produced such as ten tips for patient safety, patient guide on a safer healthcare. The cases are also used for teaching.

All this requires a good information system.

Finally at the end of the meeting, there was a sense of frustration, that some countries are moving faster than others. What can be done to add and to support? The first element is that every country must have a system in place, but that this system has to fit within the national context of the individual countries. The second is to come together at European level and to find a way to learn from each others by exchanging information, experiences and best practise. An alternative to the network led by France, if it fails, would be to create a foundation/forum, set up by hospital federations and professional associations. This would provide a forum for the exchanging of knowledge and experiences regarding Patient Safety issues, and would ensure representation of all the relevant actors. Finally such a solution will be able to work much faster than in a European institution.