

Denmark Launches Patient Safety Initiative

BY SUSAN RAEF, EDITOR

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Patient safety is an issue with no national borders. Medical and legal systems may vary from country to country, but the core issues of patient safety are the same virtually everywhere. NPSF is actively involved in gathering patient safety information and sharing ideas with health care professionals from many countries. This issue of Focus takes a look at patient safety from an international perspective.

In September, Danish OB-GYN Beth Lilja Pedersen, MD, traveled to Chicago from Copenhagen to meet with the National Patient Safety Foundation's staff. Focus interviewed Dr. Pedersen, a pioneer in Denmark's emerging patient safety movement.

"I work for Copenhagen Hospital Corporation, or H:S, a public health organization that owns and operates six hospitals serving 20% of the Danish health care system," says Beth Lilja Pedersen, MD. H:S is the largest hospital system in Denmark, a country with socialized medical care.

"H:S is the first health hospital system in Denmark to take up patient safety in a structure manner," Dr. Pedersen explains. There are two reasons:

1. In 2000, H:S took the initiative to launch the Danish Medical Practice Study, modeled after the Harvard Medical Practice Study. "The study was published at the end of September," says Dr. Pedersen. "It found that 40% of adverse medical events were preventable. This gave us documentation that we have a big patient-safety problem."
2. H:S is the first hospital system in Scandinavia that is being accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). "The Joint Commission has standards in patient care," says Dr. Pedersen, "although the international standards are not as explicit as the domestic ones."

Devoting full-time to patient safety

"Up until the first of September, I was an ordinary obstetrician," she explains, "but I have spent a lot of years researching various aspects of patient safety. I've worked from the legal

perspective. And for two years, I have been involved in a medical technology assessment study of clinical risk management at my delivery ward."

'On Dec. 10, 2001, we are having a general assembly to start a Danish National Patient Safety Foundation. We would like to know how we can unite our energies with the NPSF!'

**—Beth Lilja Pedersen, MD
Copenhagen Hospital Corp.**

"Last year I was taken from my clinical work to serve on a task force charged with developing a patient safety policy for this hospital corporation," says Dr. Pedersen. "The headquarters asked me to submit a report from the task force on what they should do about patient safety, and how they should do it. I finished that work in April, and they decided to make it their policy. This is why they established this patient safety department on the first of September."

The task force was chaired by the hospital's chief of medical affairs, Janne Lehman Knudsen, who visited the NPSF in October. "The CEO of H:S, Erik Juhl and the chief of medical affairs took the initiative to create this task force and have been supportive all the way," says Dr. Pedersen. "Leadership involvement is essential, and our leaders have been fully engaged in the patient safety initiative."

"We are starting out now," says Dr. Pedersen of her country's patient safety initiative. "We have to learn from what you did

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Beth Lilja Pedersen, MD, is an obstetrician-gynecologist in Copenhagen, Denmark who developed the first formal patient safety program for Copenhagen Hospital Corporation, Denmark's largest university hospital system.

As a patient safety pioneer in her country, Dr. Pedersen now devotes full-time to managing the patient safety program she designed, and is involved in launching Denmark's National Patient Safety Foundation.

for many years in the United States. That was one reason why I visited the National Patient Safety Foundation.”

“We also need to learn where to look for information, how the NPSF can help us, and what we can do that you would like to know more about,” says Dr. Pedersen. “On Dec. 10, 2001, we are having a general assembly to start a Danish National Patient Safety Foundation. We would like to know how we can unite our energies with the NPSF. Whatever we can learn, we need to learn from people who have thought about patient safety for longer than we have.”

Patient safety in Denmark's legal system

One of the biggest challenges to improving patient safety in the U.S. is the hesitance by some hospitals and health care professionals to disclose information about safety incidents for fear of how it might affect them in court.

“We don't have the problem of worrying about landing in court,” says Dr. Pedersen. “We have the same problem—fear of disclosure—but for other reasons. Our complaint system is a public, no-fault complaint system, so it's easy to overcome the problem there.”

“But we also have a legal complaint system where, if you file a complaint, a committee will look at it and blame the individual responsible for the treatment,” she explains. “Health professionals are held personally responsible for the care they provide. If the committee finds you responsible for some failure, you will be held accountable. That's a very humiliating thing,” Dr. Pedersen says, although it does not have economic consequences.

“When you have socialized medicine, doctors don't get paid as much as American doctors,” she explains. “The consequences of being held accountable by the committee have a lot to do with your integrity, about how you feel about yourself.”

“Sometimes you don't want to disclose information because you're afraid it's going to be used against you by the committee,” she says. “And of course, there has to be some kind of system where you're held responsible. Patients have to be able to voice their complaints if there were problems with their treatment. All of this affects patient safety.”

Training physicians in root-cause analysis

Despite the differences in the medical and legal systems, Dr. Pedersen feels that the patient safety principles developed in the US would work in Denmark's system. “In December, I'm going to have the first course in patient safety where we'll educate 33 individuals to do root-cause analysis,” she says.

‘We don't have the problem of worrying about landing in court. We have the same problem—fear of disclosure—but for other reasons.’

“Root-cause analysis has never been done in the Danish health care system before,” says Dr. Pedersen. “We are not used to looking at what we did and how we could have done it differently in any systematic manner. I think we can learn a lot from that, and from the sort of questioning that has developed in the U.S.—like asking ‘What happened?’ instead of ‘Who did it?’”

Danish physicians respond favorably

Dr. Pedersen says Denmark's health care professionals have been very receptive to the patient safety initiative. “I went on a TV show for half an hour to talk about patient safety, and afterward, everyone was asking me, ‘What do your colleagues say about this?’ Actually, my colleagues are extremely positive because finally, someone is going to learn from medical incidents instead of just finding somebody to blame. Doctors are very interested in trying to set up a patient safety system and support it.”

What's ahead for Denmark's patient safety initiative?

Dr. Pedersen says health care professionals in all of Denmark's 13 counties are asking, “What can we do? Should we use the same safety program as Copenhagen Hospital Corporation or should we develop our own?”

“I'm sure that in the next two years, there will be a policy for patient safety in all the counties,” says Dr. Pedersen. “The minister of health care wants to implement something on a national basis.”

Dr. Pedersen recently attended the Salzburg Seminar on Patient Safety in Austria, where 70 patient safety professionals from around the world convened—including NPSF Distinguished Advisors Lucian Leape, MD and Donald Berwick, MD.

“There were 15 Europeans at the conference, and we discussed the possibility of creating a European patient safety society,” Dr. Pedersen recalls. “We have already met with people from Norway, Sweden and Denmark. I think it's extremely important to have this kind of international relationships.” **NPSF**

NPSF Research Grant Results

Evaluating the Role of Auditory Warning Signals in Critical Care Settings

BY YAN XIAO, PhD AND COLLEAGUES

Each year, the NPSF awards a number of patient safety research grants. Following is a summary of the results of an NPSF-funded study conducted by Yan Xiao, PhD, Frank Jacob Seagull, PhD and Colin Mackenzie, MD, of the University of Maryland School of Medicine; Christopher Wickens, PhD, of the University of Illinois Institute of Aviation; and Darin K. Via, MD, of the Uniformed Services University of Health Sciences.

How effective are auditory warning signals in critical care?

This project aimed to demonstrate the value of cognitive engineering in understanding safety-enhancing technology, and to clarify the role of auditory alarms in patient monitoring. The project had three specific goals:

1. To determine patterns of information use during real and simulated anesthesia;
2. To develop a general framework depicting the role of and need for auditory warning signals for alerting as well as auditory "updating" signals in patient monitoring; and
3. To produce a set of tentative design principles for auditory monitoring signals in critical care.

Tracking eye-gazing data during patient care

The key innovative method developed and used in this project was an ambulatory eye-tracking device that captured eye-gaze data during real and simulated patient care.

Two complementary studies were conducted on the informational value of a user responses to auditory warning signals in critical care settings:

1. A prospective, comprehensive (video-based with ambulatory eye-tracking devices) data collection in real patient care (anesthesia induction and airway management); and
2. A set of experiments in a high-fidelity environment, also using eye-tracking devices.

The eye-tracking device was packaged in a backpack and collected eye-gaze position data through a head-mounted camera and an infrared eye-position measuring mechanism. Video images from the head-mounted camera were recorded, providing a general field of view from the perspective of the device wearer. The eye-gaze positions were in the form of cross-hairs overlaid onto the video images of visual fields.

In the real and simulated settings of the two studies, the criteria settings of the alarm systems were manipulated to

either default settings ("control condition"), or to more strict settings, meaning alarms sounded when smaller deviations were detected ("strict condition"). These manipulations were carried out for four main vital signs: heart rate, blood pressure, oxygen saturation, and exhaled carbon dioxide level.

For the study in the real environment, data was collected on the anesthesia induction and airway management (intubation) of elective surgery cases. For the study in the simulated environment, two scenarios were designed surrounding similar tasks: anesthesia induction and airway management. Simulated patient care was conducted with a full-mission, hands-on, high-fidelity patient simulation environment in Uniformed Services University of Health Sciences.

The resulting videotapes were manually coded to extract information on the activities and eye fixations of the care provider. Eye fixations and activities were coded into three categories: looking at the patient or other care providers; looking at monitoring equipment; and manipulating the monitoring equipment (i.e., adjusting settings of any patient-monitoring or support device).

What did the eye-gaze data reveal?

The eye-gaze data from 16 real operating room cases and 30 simulated cases yielded the following research results:

- **It is feasible to deploy ambulatory eye-trackers in a clinical environment.** The ambulatory eye-tracking device was successfully used during the high-workload period of anesthesia induction and airway management. Differences in monitoring frequency by the anesthesia care providers were measured for various stages of anesthesia care.
- **Presence of auditory alarms correlated with the length of airway management.** When there were more alarms as the result of experimental manipulation, it took longer—54 seconds vs. 34 seconds—to accomplish laryngoscopy and intubation. The results demonstrate the negative impact of false alarms, and, combined with previous studies on auditory alarms, suggest that current auditory alarms could adversely affect patient care. Designers of alarming devices need to consider the negative impact of auditory alarms.
- **Care providers looked at different things in real operating rooms than during simulation.** Using an eye-

Yan Xiao, PhD, is associate professor of anesthesiology and information systems and a special member of faculty, School of Business, University of Maryland, College Park.

Frank Jacob Seagull, PhD, is a post-doctoral fellow in Human Factors and Technology Research at University of Maryland School of Medicine.

Colin F. Mackenzie, MD, is Professor of Anesthesiology and Director of the National Study Center for Trauma and Emergency Medical Services at University of Maryland, Baltimore.

Christopher Wickens, PhD, is a professor in the University of Illinois at Urbana-Champaign (UIUC) in the Department of Psychology, head of the UIUC Aviation Research Laboratory, and associate director of the Institute of Aviation at UIUC.

Darin Via, MD, is Assistant Professor of Anesthesiology, Uniformed Services University of Health Services, Bethesda, Maryland.

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tracker, we compared anesthesia care providers' visual scanning patterns during induction of anesthesia in real elective surgery with the patterns in simulated airway management. In simulation, care providers spent less time looking at the patient, and checked the monitoring equipment more frequently. The simulated patient seemed to be less informative and thus clinicians sought information from monitoring devices. This suggests potential limitations in evaluating care providers' monitoring behavior in a simulated environment.

'When there were more alarms as the result of experimental manipulation, it took longer—54 seconds vs. 34 seconds—to accomplish laryngoscopy and intubation.'

- **Care providers varied their monitoring behaviors during different phases of their tasks.** We attempted to compare how frequently the anesthesiologist looked at the vital signs monitors during the induction of anesthesia. Five time periods were selected for comparison: preparation for induction, induction, pre-oxygenation, intubation, and one minute post-intubation. The results show statistically different sampling rates in the five selected periods. There was a large increase of the sampling rate immediately after intubation, while during intubation the sampling rate was zero.

What is the impact on patient safety?

Is the environment in hospitals and clinics friendly to health care providers? Are devices designed to help improve patient safety? If not, how should we make the health care environment more user-friendly? This project examined these questions with auditory alarms as a case in point, using cognitive engineering methodologies.

For many years, designers have attached various types of alarms to displays and devices. This practice is well-intentioned; it aims at well-known limitations in human

performance, such as limited attention spans and difficulties in tracking many parameters. Control room operators can be warned of leaking valves; anesthesiologists can be warned of disconnected circuits; pilots can be warned of low fuel levels; train operators can be warned of overheated engines. On the flip side, however, in almost every work setting in which alarms are deployed, there are reports of inappropriate alarms.

During patient care, an anesthesiologist gathers information from a variety of sources to ensure the patient's safety. Much of the information is visual. Knowing where an anesthesiologist looks can thus provide a basis for estimating what information is needed, and help determine the best way to present that information.

Measuring eye-gazes while an anesthesiologist cares for a patient is a direct, objective way of studying an anesthesiologist's visual scanning patterns. However, technical difficulties abound for deploying such methods. We tested a commercial ambulatory eye-tracking device during the induction of anesthesia for elective surgery. The collected eye-gaze data were used to analyze how frequently anesthesiologists looked at various patient monitors.

The study established the feasibility of using an ambulatory eye-tracking device in the operating rooms. While the findings of the analysis were not unexpected, they provided an objective basis of quantifying the anesthesiologist's information-gathering patterns.

Could repositioning monitors improve safety?

During induction of anesthesia, the anesthesiologist has a high workload and effective means are needed to provide patient status information. Currently the vital signs monitors are scattered around the patient, making it difficult to gather information. For example, during intubation—during which the sample rate was zero in this study—well-positioned patient monitors could make it possible for the anesthesiologist to detect problems early.

There are many potential uses of eye-gaze data. Further analysis of the data from this study will establish the feasibility of discerning which parameter the anesthesiologist looks at and when. Ambulatory eye-tracking devices could also be used in comparing different designs of patient monitors, evaluating monitoring strategies that

may be used by the anesthesiologist, and determining the best allocation of patient monitors.

Data from eye-tracking devices may be analyzed to guide the design of innovative auditory “displays”—presenting patient status information through sound. Eye-gaze data could then demonstrate whether the anesthesiologist spends more time looking at the patient when auditory displays are used.

Patient safety can be improved substantially if cognitive engineering is routinely used in designing critical safety devices. This can lead to groundbreaking advances in providing information for monitoring and safeguarding the patient.

This project represents a new approach to understanding the informational value of auditory alarms. Problems with alarms have been a high-profile topic for many reasons. Various auditory alarm mechanisms have been introduced to improve patient safety, yet study after study has shown that alarms in a clinical environment are confusing, obtrusive and uninformative. Instead of safeguarding the patient, alarms often increase workload, make communications difficult, and produce a hostile work environment.

Visit the project Web site: <http://hfrp.umm.edu/alarms>

A Web site is now available to share knowledge and information acquired during the project. This site contains materials related to general alarm problems in patient monitoring, suggestions to clinicians and purchasers, publications and presentations related to the project, and resources such as bibliographies collected during our research on alarms.

Two journal paper manuscripts are being prepared to publish the research efforts. We also are actively involved in the University of Maryland Medical Center's efforts in patient safety, which include identification of patient monitor-related problems.

Providing a basis for further research

The eye-tracking data collected during this project is an important source for understanding monitoring behaviors of clinicians. We will further analyze the data to model monitoring behaviors. We also plan to extend the experiments conducted in controlled laboratory settings to understand how auditory displays can improve patient safety.

NPSF grant leads to further research funding

Since being awarded the NPSF grant, our research group has received a grant from the Agency for Healthcare Research and Quality to study chest-tube placement through video recording, two grants from the National Science Foundation to study coordination in trauma care, and a grant from the Army Research Institute to study team performance and leadership during trauma care.

‘Patient safety can be improved substantially if cognitive engineering is routinely used in designing critical safety devices. This can lead to groundbreaking advances in providing information for monitoring and safeguarding the patient.’

The NPSF funding has been instrumental in obtaining these multi-year grants that support research examining various aspects of patient safety.

The research supported by the NPSF grant has produced a number of publications in which the support from NPSF was acknowledged. One abstract presented at the 1998 annual meeting of the American Society of Anesthesiologists was selected as one of the 15 abstracts out of more than 1,400 to be featured as press releases. The abstract presented at a meeting sponsored by the Society of Technology in Anesthesia received an award for the best research abstract.

The NPSF research program, providing an effective framework for reporting while giving us latitude in planning and conducting research projects, is close to ideal. As the recipients of the first NPSF grants, we believe this is a remarkable achievement on the part of NPSF's research committee, and demonstrates NPSF's foresight. **NPSF**

How Can America's Patient Safety Community Help Britain's National Health Service? BY LYSE EDWARDS

In the summer of 2001, Lyse Edwards, a management trainee in Britain's National Health Service, served as an intern at NPSF's headquarters in Chicago. Focus invited Edwards to share her thoughts on patient safety.

As I left the British hospital at which I work on the 9th of February, 2001, I turned my car radio on to hear the news that a patient in another British hospital was in critical condition after a drug that should have been administered spinally was injected into a vein by mistake. The previous week, the big story in the news had been the death of 18-year-old Wayne Jowett following the cancer drug Vincristine being mistakenly injected into his spine rather than into a vein.

As a new manager in Britain's National Health Service (NHS), hearing these two stories in the space of a week shocked me into the realization that the service I had joined to help facilitate the best possible care for patients could harm the people it seeks to help.

I am participating in a two-year NHS post-graduate management training program that combines "real work" with academic study of health policy and management. Our introduction to the health service is by way of a three-month orientation period during which we immerse ourselves in the complexity of the NHS, spending time in a variety of clinical and non-clinical settings in both primary and secondary care. This is followed by real responsibility in a nine-month operational management role, usually in an acute hospital.

After this first year of the program, and before our final placement in a strategic role in primary care, we are given an elective period to explore any area of personal interest which will benefit the NHS as well as our own professional development. It seemed that an elective focusing on patient safety would be an interesting and informative experience, as my interest in patient safety had been sparked from my realization earlier in the year. The issue

was also high on the NHS agenda following the publication of the "Bristol Royal Infirmary Inquiry"¹ and "Building a Safer NHS for Patients,"² which sets out the British government's plans for implementing the recommendations of "An Organisation with a Memory."³

At the time I was searching for a host organization, there were no UK organizations focused purely on patient safety; however, one of my lecturers from the Health Services Management Centre at the University of Birmingham suggested the National Patient Safety Foundation.

'While at the NPSF, I had exposure to patient safety issues at the national, local, hospital and even individual level!'

Having looked at the NPSF Web site, it seemed the foundation would be an ideal organization to enhance my knowledge of the patient safety agenda, which seemed to be further developed in the US.

While at the NPSF, I had exposure to patient safety issues at the national, local, hospital and even individual level. I spent much of my time working in the Research Program, collating patient safety research from across the United States. It was interesting to see the broad range of topics being studied and observe the development a corpus of knowledge and experts in this relatively new field.

At the regional level, I attended the inaugural meeting of the Chicago Patient Safety Foundation and heard how local clinicians and managers are working together across

¹Kennedy, I., (2001), "Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995," London: HMSO

²Department of Health, (2001), "Building a Safer NHS for Patients," London: Department of Health

³Department of Health, (2000), "An Organisation With a Memory," London: Department of Health

⁴Vincent, C, Neale, G & Woloshynowych, M., (2001), "Adverse events in British hospitals: preliminary retrospective record review," *British Medical Journal*, Vol. 322, pp517-519

organizational boundaries to improve patient safety in the city. The examples of system failures and the issues we discussed—including the need for strong leadership in patient safety, the value of information technology in preventing error, the role of organizational culture and learning, and the best way to develop patient and community involvement—were not unfamiliar from my knowledge of the British experience. However, it was fascinating to compare how the same issues play out differently in various social, political and organizational environments.

At the hospital level, I visited a variety of organizations including Brigham and Women's Hospital and Massachusetts General in Boston, and Chicago's Cook County Hospital. I met clinicians and managers with responsibility for patient safety and explored how organizations manage the issues we had discussed at the Chicago Forum.

I met with representatives from Dana Farber Cancer Institute's Patient and Family Advisory Council to see the role of this group in improving standards of quality and safety in the hospital. I also visited the Harvard Medical Simulation Center in Boston to see their innovative training for professionals to improve patient safety in the OR and to hear first-hand the early results of some NPSF-funded research based at the Center. It was fascinating to watch the medical simulations, and to see how interventions based on research into human factors can assist teams and individual practitioners in providing safer health care.

Now that I am back in the UK, it is interesting to see how the issues I explored in the US are being dealt with in Britain. Research in the UK suggests that about 10% of patients admitted to acute hospitals experience an adverse event, and that one-third of these events lead to moderate or greater impairment at great cost to the health service in terms of additional bed-days⁴

In response to these startling statistics, the British government has established an independent body, the National Patient Safety Agency. The role of this organization is to collect and analyze information on adverse events from NHS staff, patients and caregivers across Britain through a mandatory, confidential reporting system. The agency will then take the learning from these incidents and feed it back across the whole of the NHS. This system is currently being piloted, and will be implemented nationally in 2002.

'The examples of system failures and the issues we discussed ... were not unfamiliar from my knowledge of the British experience. However, it was fascinating to compare how the same issues play out differently in various social, political and organizational environments.'

The British government has set specific targets for reducing maladministered spinal injections; harm in obstetrics, gynecology and midwifery care; serious error in the use of medicines; and suicides by mental health patients as a result of hanging from non-collapsible bed or shower curtain rails. Like the NPSF, Britain's National Patient Safety Agency will seek to develop the patient safety research agenda and fund a program of research, as well as work with education and training bodies to promote patient safety education and to foster a culture of learning rather than one of blame.

This agency is in its early days, but given that the NHS is a public body and provides the majority of health care for citizens of the UK, it will be in a unique position to obtain a global picture of Britain's patient safety landscape and to disseminate lessons from which all our citizens can benefit. Similarly, it is early in my career in the NHS but I hope my experiences in the US will contribute not only to my personal development as a manager in the service but also to the organizational learning of the National Health Service.

As I am writing this, the headlines of today's national newspaper report that a woman is in a coma following an allergic reaction to an infusion of penicillin which her family claims that staff were warned about before they administered the drug. I hope that during my career, I will be able to contribute to the safety of our health service so that these headlines become a thing of the past. **NPSF**

Lyse Edwards is a management trainee in Britain's National Health Service in Birmingham, England.

In the summer of 2001, she served as an intern at the National Patient Safety Foundation's Chicago headquarters as part of her post graduate training program.

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The opinions expressed in this publication are not necessarily those of the National Patient Safety Foundation or of its Board of Directors.

To submit articles or publications for possible review in Focus, please direct materials to: Carrie Hennessy, Managing Editor, Focus on Patient Safety, National Patient Safety Foundation, 515 N. State Street, Chicago, Illinois 60610. Materials, inquiries and subscription requests for the publication will be accepted electronically at info@npsf.org or via fax at 312-464-4154.

Managing Editor: Carrie F. Hennessy
Editor: Susan Raef, WordPower Communications, Inc., Chicago

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NPSF Seeks Letters of Intent for Patient Safety Research and Development

The National Patient Safety Foundation seeks to stimulate new, innovative projects aimed at enhancing patient safety in the United States. The foundation's objective: to promote studies leading to preventing human errors, system errors and any form of preventable injury in health care and the adverse consequences to patients that may result.

Submit your letter of intent by March 15, 2002

In this first stage of a two-stage application process, NPSF is soliciting Letters of Intent (LOI) for research and development broadly related to identifying the causes of preventable injuries and errors and/or developing prevention strategies and methods to implement them. Finalists will be asked to prepare a formal proposal.

How many grants will be awarded?

The number of grants awarded will depend on the nature and quality of applications received and the total funds available. It is anticipated that at least \$400,000 will be allocated in the year 2002 application cycle.

A multidisciplinary team of experts will evaluate the LOIs. Investigators will be notified of the decision on their LOI no later than May 1, 2002.

More information available online

For complete details on the LOI submission process, please visit <http://www.npsf.org/html/rfp.html>.

National Patient Safety Foundation
515 North State Street, Suite 8350
Chicago, Illinois 60610