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Risk Management and Patient Safety Lessons Learned from the U.K.

by Lisa Droppo, MHSc, CHE

Introduction

Beginning in August 2001, I had the privilege of working and living in South West England for one year. Having worked in healthcare administration in Ontario for 12 years, this seemed a great opportunity to work in a different healthcare system. Given that my areas of expertise were quality, risk management and patient relations, when a contract opportunity arose for a Risk Management Projects Manager at the local acute care Trust (hospital), a natural relationship was established. In this article, I will reflect on my experience in the U.K. and will offer some key learnings and potential applications for risk management in Canada.

Upon joining the Royal Devon and Exeter NHS (National Health Service) Trust (http://www.rdehospital.nhs.uk), I was quickly assigned three projects to last my 10-month tenure. They were to:

• Coordinate the preparation and external review process for the Clinical Negligence Scheme for Trusts and in particular to assist the Trust in achieving a higher level of award recognition
• Lead the Trust's participation as one of the National Patient Safety Agency's 28 pilot sites
• Develop a process to select and implement an IT solution for management of clinical governance

Although not part of my initial mandate, I sought to propose and implement a strengthened organizational structure and roles for the ongoing management of clinical governance. As I oriented myself to the Trust and more specifically to the goals and objectives of the assigned projects, the interrelationships became readily apparent.

I was surprised by the many similarities and few differences between the U.K. and Canadian healthcare systems. Both are primarily national healthcare systems where all residents have access to healthcare services. The U.K. has a more substantial private healthcare system used primarily by U.K. residents to decrease waiting times for service. Interestingly, I noted that the same physicians worked in both the public and private healthcare systems. In the U.K., all hospital-based physicians are employed by the NHS. This is different than in Canada where only a limited number of physician groups (e.g. hospitalists, pathologists, etc.) are directly employed by the hospitals and all others are self-employed and undergo a credentialing process to receive privileges to provide service in the hospitals. I expected that this difference in employment arrangement would increase the capacity and desire for NHS physicians to participate in hospital administrative activities, although this was not my experience. On a broader note, I was struck by the fact that NHS organizations were experiencing many of the same challenges faced by Canadian healthcare organizations. Specifically, both are focussed on strategies to decrease waiting

times for service, struggle to fill positions in particular healthcare disciplines including nursing, pharmacy and speech-language pathology, and continue to explore different models of healthcare delivery both regionally and within organizations.

In the U.K., risk management falls under an umbrella known as Clinical Governance. Clinical Governance is defined as "a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish." (Scally and Donaldson, 1998; http://www.cgsupport.nhs.uk). This definition applies to all NHS organizations and in fact is part of an overall accountability framework which requires the Chief Executive to annually sign an accountability statement. I believe that this centralized governmental policy development clearly defines expectations of organizations within the public healthcare system and allows organizations to quickly adopt the framework and then invest time in operationalizing core processes.

Clinical Negligence Scheme for Trusts

The Clinical Negligence Scheme for Trusts (CNST) was established in 1994 to fund the cost of clinical negligence litigation in NHS trusts and to encourage and support effective management of claims and risk (www.nhsla.com). CNST membership and claims issues are administered by the NHS Litigation Authority (NHSLA), a Special Health Authority. Risk management matters are dealt with by the CNST assessment team at Willis Limited, an international risk management and insurance intermediary (www.willis.com), working closely with and overseen by the NHSLA. Individual trust contributions are calculated on an annual basis and can be reduced if the trust meets certain risk management criteria. It is this risk management assessment process in which I was involved.

Derived from claims history, CNST includes seven core and three specialty area risk management standards for organizations to assess themselves against and in turn be assessed by an external assessor (see Table 1). Recently, completely separate standards have been developed for Maternal Care due to its high risk nature. There are three standard levels. Organizations must begin at Level 1 and may then progress through levels two and three assuming they have been successful at the preceding level. Successful recognition at any level results in a premium reduction for up to a period of two years. Increasing levels result in a higher premium reduction. Successful achievement of levels 2 and 3 also contribute to enhanced recognition on other NHS Performance rating systems (www.chi.nhs.uk/ratings).

Table 1. CNST Standards
Standard 1: Learning from Experience
Standard 2: Response to Major Clinical Incidents
Standard 3: Advice and Consent
Standard 4 : Health Records
Standard 5: Induction, Training and Competence
Standard 6: Implementation of Clinical Risk Management
Standard 7: Clinical Care
Standard 8: The Management of Care in Trusts Providing Mental Health Services
Standard 9: Ambulance Service
Standard 10: Maternity Care
Source: CNST Clinical Risk Management Standards. www.nhsla.com/docs/CNST%20General%20Manual%20August%202003.pdf

The standards are clearly defined and include a description of the evidence that must be provided. Each organization works with their assessor who provides coaching and guidance throughout the process. Organizations submit documentation to their assessor who visits the Trust to validate the processes and outcomes described in the documentation. The assessment visit agenda is developed in advance and involves numerous small meetings to focus on important core processes and high risk areas. These include risk management strategy and structures, patient complaints, health record management, staff and medical staff orientation, blood transfusion, infection control and maternal care.

I was involved in preparing my Trust for a Level 2 reassessment where the Level 2 standards had been modified substantially since the previous assessment. Particularly challenging standards were related to processes to ensure that staff involved in the blood transfusion process (including transportation) were properly trained to fulfill their role. This involved the development of curricula for a variety of audiences and an intensive education plan to transfer knowledge and skills and document same within a few months. A second new standard area was related to the requirement that all staff using diagnostic and therapeutic equipment were properly trained to do so. This required a complete inventory of all diagnostic and therapeutic equipment as per the Medical Devices Agency (now known as the Medicines and Healthcare Products Regulatory Agency, www.mhra.gov.uk) definition and the development of a process to determine which devices would require staff to have specialized training. Using a modified version of a risk matrix, each device was assessed for likelihood of causing harm and the consequence/impact should harm occur. Devices were then sorted into low, medium and high risk severity and the Trust focussed on training programs and delivery for all high

risk devices as the first phase. This was an extremely ambitious task which was successfully accomplished over three months. Following a two-day assessment visit, the Trust was awarded Level 2 recognition under the new standards, a tremendous accomplishment.

Incident Reporting Pilot Test

The National Patient Safety Agency (NPSA) is a Special Health Authority established in July 2001 to co-ordinate the efforts of all those involved in healthcare, and more importantly to learn from patient safety incidents occurring in the NHS (www.npsa.nhs.uk). As part of their mandate, the NPSA tries to promote an open and fair culture in the NHS, changing the emphasis from the "who" to the "how." The NPSA arose from a recommendation in an important report called, An Organisation with a Memory (www.doh.gov.uk/orgmemreport).

Beginning in September 2001, as a pilot site organization, the Trust was expected to participate in a pilot test of a centralized incident reporting system. Unidentifiable (anonymous) incident data was to be electronically transferred to a centralized database for national analysis and trending. In order to participate, pilot organizations needed to have an on-line incident reporting system which included risk assessment of every incident. Further, the reporting system vendors had to work with the NPSA to develop an interface to exchange incident data from the trusts, remove any identifying information about those involved in incidents or the Trust. Our Trust was using one of three common reporting systems in the NHS, but not the one selected as the primary partner with the NPSA. As a result, although the interface was eventually developed and implemented, there were challenges in meeting the project dates. Further, our Trust had not been previously assessing incident risk. This required the adoption of a framework provided to pilot Trusts, and risk assessment by a small team to risk assess incidents over the six month pilot. The risk assessment framework allowed for consideration of not only the harm that did result from the incident but also the potential for harm. This process encouraged the reporting and learning from near misses (www.npsa.nhs.uk/admin/publications/docs/npsa%20risk%20assessment%20tool.doc).

The second element of the pilot was to begin using root cause analysis to investigate and learn from incidents, including near misses. Teams from pilot sites were provided with a six-day educational program over a period of eight months which allowed participants to understand accident theory, human factors and a number of models and tools for root cause analysis. Pilot teams

applied the learning in their own Trusts and shared experiences with the other pilot sites for additional learning. The Trust was able to quickly incorporate this new approach which was received enthusiastically by staff and physicians.

During the pilot phase, NPSA also introduced important national patient safety projects including enhanced practices for the management of concentrated potassium chloride and more recently the introduction of common emergency codes.

Since my departure from the U.K., the NPSA has launched the National Reporting and Learning System (NRLP), a national reporting system to help the NHS improve patient safety. Further, the experience with root cause analysis has resulted in the development of more formal training programs including e-learning modules.

Integrated Risk Management System

Prior to my arrival at the Trust, a process had been initiated to identify an IT solution to support and integrate a number of clinical governance functions including incident reporting and management, feedback from patients and their families, claims management and a risk register. A number of separate systems, from a variety of vendors, were in place, some of which were quickly becoming redundant and no longer supported by the original vendors. The Trust had developed some specifications and invited a number of vendors to provide demonstrations almost a year earlier. Although there were two preferred products, no further selection was made following this process.

It became evident as a result of the Trust's participation in the NPSA pilot that a decision needed to be made whether to continue with one or more of the current systems or to look for the best integrated solution to meet all of the needs. The two vendors previously identified as potentially meeting the organization's needs were once again contacted. The specifications were reviewed and updated, and a second demonstration process was organized. An evaluation of the two vendors' products was undertaken against the specifications and those attending the demonstrations were asked to complete an evaluation form. Following the demonstrations, a new vendor was selected to meet all the needs. A contracting process and the customization of the database contents to meet the Trust's needs were initiated. Each team overseeing a unique component of clinical and non-clinical governance actively participated in designing their pick-lists. A project manager for the implementation was identified as my tenure came to a close following the contracting and customization processes.

Top 10 Patient Safety Myths

by Brian Shea, Patient Safety Leader, Cap Gemini Ernst & Young Health

Many provider CIOs are reevaluating their institutions' processes for insuring patient safety. Some are seeking counsel to help break through the noise of the HIM marketplace. With that in mind, Cap Gemini Ernst & Young Health has compiled the following list of the most dominant patient safety myths, along with tips on how healthcare leaders can counter them.

1. MYTH: CPOE alone can improve patient safety.

While Computerized Physician Order Entry (CPOE) has been helpful minimizing errors associated with medication orders, it is only one piece of the overall patient safety solution. Healthcare executives should consider how their technology supports safety across the entire enterprise and realize that anytime you add new technology, change a process, or both, you can 1) enhance safety and reduce certain errors, 2) introduce new errors into the system, and 3) make some errors - either new or existing - harder to detect. Executives must build a quality program around any project that affects their IT and/or care processes.

2. MYTH: My vendor understands patient safety.

Patient safety is a relatively new discipline. Unfortunately there are very few individuals who understand patient safety's key issues and approaches, and can match that with experience to make it relevant for you and your health system. It is important to note that, to date, HIM vendors have had limited success with physician adoption of CPOE and nurse usage of clinical documentation systems. Therefore, while vendors may know their systems' capabilities, they do not have much experience with how the technology is actually used and the implications for patient outcomes. It is important to 'do your homework' and learn as much as you possibly can before entering into a vendor partnership.

3. MYTH: Return-on-investment is the reason to address patient safety.

Don't build your ROI based on safety alone. Common folklore aside, it is impossible to directly measure any financial benefit from patient safety initiatives. Instead, consider investing in technology as a way to improve on patient safety while it improves your bottom line in other ways, such as decreasing lengths of stay or providing less expensive formulary medication choices.

4. MYTH: Implementing an advanced clinical system will mean layoffs.

Beware the vendor story that "our system will provide you enough rules and alerts that you can reduce or remove certain people from your processes." No clinical system contains enough current information to replace human decision-making, nor will these systems reach that level of functionality in the span of their product lifetimes.

5. MYTH: If we build it, they will come.

Trying to bring physicians on board after a clinical system has been selected and implemented is a common, and quite often, costly mistake. Do not expect anyone to "heal your pain" if you take a step that affects your medical and nursing staffs without their involvement and participation upfront. At the start of the process, pull together an interdisciplinary team of clinicians to help you choose the best solution that will support their work as well as create a patient safety environment.

6. MYTH: Everyone else has a patient safety problem - except us.

When surveyed, most healthcare leaders believe that patient safety is a major issue in the United States - but not at their facility. If you can imagine an error occurring when reflecting on how your organization delivers care, it can, probably will or even has already happened. A good way to begin the journey is to start with a realistic expectation - that your system has much work to do to improve reporting and enhance safety.

7. MYTH: Benchmarking will define where we should start improving safety.

We are still early in our development of advanced reporting systems for capturing medical errors. Until we have mature reporting systems and fully institute a culture where reporting errors is less threatening, we can't really get the full picture of where medical errors may and have occurred. If you rely on existing and incomplete benchmarketing data, it may hurt - and not help - your efforts.

8. MYTH: Patient safety requires a new corporate department.

If you want to make lasting change in your organization, patient safety should be part of the organizational "genome." Instead of creating another large "siloed" department with new positions that focus solely on safety, let patient safety become an integral part of all processes - part of the organizational fabric in everything you do. Consider the benefits here every employee is connected with a "Safety First" corporate culture.

Governance Structures and Roles

Throughout my work on the above three projects, I became increasingly familiar with all of the clinical and non-clinical governance processes in the Trust. Although the processes each had many strengths, the opportunity to maximize the learning and improvement was hampered by a complex structure. Each of the component functions reported to a separate senior manager and although these individuals and performance reports came forward to a centralized Risk Management Committee, the analysis was occurring at a very high level, limiting the likelihood of identifying important trends or opportunities across the organization.

An external scan was conducted of other organizations and an emerging trend of Clinical Governance or Governance teams was identified. It was proposed and accepted that a Governance Manager position be established to oversee the risk management, patient relations, patient advocacy and liaison service, clinical audit and health and safety reporting. An external individual was recruited to this role to lead the organization through this integrating transition.

Reflections and Conclusions

As I reflect on this wonderful professional experience, I believe that there are some useful lessons for Canadian healthcare organizations, government and others:

- There are some advantages to governmental accountability frameworks that allow organizations to focus on implementation rather than design and perhaps prevent organizations from re-inventing the wheel.
- External reviews and assessments are useful and I believe can be strengthened in Canada through the addition of a requirement to demonstrate through substantive evidence successful achievement.
- The development of a national incident reporting system is an ambitious and challenging task. While I believe that there was tremendous value in developing a risk assessment framework, in practice it was challenging to implement and teach to others. Standardizing data entry to ensure that incidents are de-identified (anonymous) is also challenging. The potential advantages of such a national system would certainly be worthy of further investigation in Canada.
- Root cause analysis is a useful process for investigating and learning from incidents. It actively engages those most closely involved in the incident and takes a systems approach. Many of the tools and techniques are similar to those used for quality improvement and as a result I believe that Canadian organizations may have more experience to incorporate this process.

- Integrated risk management systems have tremendous capacity to assist in coordinating a number of related risk management activities (e.g. patient feedback, incident reporting and claims management). The development of such integrated systems is beginning in Canada and should be further pursued to support an enterprise risk management approach.
- I was introduced to the risk register; a tool for capturing identified risks that may not be the result of incidents, assessing their risk and monitoring action plan status. This proactive management of risks often identified through risk assessment processes offers an organization a strategic risk management approach which could easily be adopted in Canada.
- The U.K. healthcare system has a number of defining structural issues that make it different than the Canadian healthcare system. All those working in Trusts are employees of the Trust and as such are accountable for their participation and performance. In 1995 there was a change to claims management with the introduction of the NHSLA. This new process eliminated the capacity for an individual professional to be sued but rather only the organization. This ability to function under a single risk roof is very supportive to all Trust employees and also seemed to result in timely resolution of claims. There was no doubt that this integrated approach to claims seemed to overcome some of the challenges faced by Canadian healthcare organizations, their staff, and physicians.

I was truly privileged to have the opportunity described in this article. The enormous personal learning and growth from this experience has undoubtedly supported my career endeavours and has allowed me to recognize my transferable knowledge, behaviours and skills.

Acknowledgements

Reference

Scally, G. and L. J. Donaldson. 1998. "Clinical governance and the drive for quality improvement in the new NHS in England" *British Medical Journal* 317: 61-65

About the Author
Lisa Droppo, MHSc, CHE has worked in a variety of healthcare administrative roles for 14 years. In this article she refers to her experience as Risk Management Projects Manager at the Royal Devon and Exeter Healthcare NHS Trust in Exeter, England. Lisa is currently Director, Patient Safety at Trillium Health Centre in Mississauga, Ontario.

9. MYTH: It's okay to store almost all of our patient data on an outpatient system because that is how most receive care.
Since there are no standards to carry "hard coded" critical system messages between vendor systems, the usefulness of "best of breed" systems is limited. Though a patient experiences the majority of their care as an outpatient, storing rich patient data on an outpatient system that can not be extended into an inpatient or long-term care system creates a major gap through which safety issues can likely arise.

10. MYTH: Most medication errors occur at the order writing stage of the process.
Are you positive that none of your errors are occurring when medication is dispensed? Or during its administration? Before implementing a CPOE system, which requires a financial investment and change in established processes, you must undergo a careful study of your existing system.

About the Author
Dr. Brian Shea was project manager of CGE&Y's patient safety project and has dedicated his entire career to improving the materials and standards applied by the pharmacy and physician communities to improve a patient's safety. He has served as the Secretary of the Pharmacy and Therapeutics Committee at Brigham and Women's Hospital and as a member of the Harvard ADE Prevention Study Group. Elected a fellow of the American College of Clinical Pharmacy in 1997, Dr. Shea has published various articles on safety throughout his career, including co-authored studies on medication errors that appeared in Journal of the American Medical Association, and articles on patient safety in Advance for Health Information Executives and Healthcare Informatics (upcoming).

Newsworthy

US healthcare lobbyists outspend other pressure groups

According to the American Journal of Medicine healthcare lobbyists spent $237m, more than any other industry, to influence US senators and representatives, the White House, and federal agencies in 2000.

Drug companies and medical supply companies together spent $96m. Physicians and other health professionals, such as nurses, spent $46m, hospitals and nursing homes $40m, health insurance and managed care companies $31m, and disease advocacy and public health organizations spent $12m. During the study period, 1997-2000, spending on lobbying by health professionals grew by only 10% compared with 26% by other organizations.

The number of lobbying organizations grew by 50% between 1997 and 2000, when 1192 organizations filed about 40, 000 reports. (Source: *British Medical Journal*, Volume 328, Number 7444)

Study criticizes health insurance tax credit plan

Health insurance tax credits might not be the most cost-effective option to help the more than 40 million Americans without health insurance, says a recent analysis from the American Economic Association at Vanderbilt University in Tennessee.

According to the analysis, public health coverage for all adults up to 80% of the federal poverty level would cost $1.17 in federal spending for every dollar in health coverage for someone currently without health insurance. By comparison, the government would spend $3.32 for every dollar of new health coverage achieved through tax credits because many of the credits would go to people who already had health insurance. (Source: *American Medical News*, April 19, 2004)

Canadian Groups Call for Web Pharmacy Ban

Canadian healthcare advocacy groups have called on the government to ban web pharmacies because they could lead to drug shortages for Canadians. The groups said that cases of drug shortages were isolated, but they warned the government not to wait for a crisis to ban the industry.

Health Canada said it is monitoring the industry, but it has not found evidence that Canadians are facing drug shortages because of online pharmacies. (Source: *ihealthbeat*, March 31, 2004)

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Abstracts

Hospital Governance in a Crisis: Governance of Ontario Hospitals during SARS

by Lynne Golding and George Glover

The Ontario hospital system and, in particular, its management have been lauded for the manner in which they responded to the SARS epidemic that struck Ontario last Spring. Generally, the administrators of Ontario's hospitals – both administrators of hospitals that treated SARS patients and those that did not – are considered to have been quick in responding to the crisis, diligent in implementing applicable protocols, creative and scientifically sound in developing internal procedures where required and dedicated, beyond all conceivable expectations, to the support and safety of their patients and staff. **www.longwoods.com/hl/art.php?view=1&ID=98**

Hospitals and Government: A Relationship That Needs to Work by Bruce MacLellan

Effective government relations that create win-win situations begin with clear understanding of mutual objectives and concerns. The most obvious reason for this assertion is the simple fact that government is the main funding source for hospital operations. In addition, government health ministries set overall policy directions for the provision of health services, and hospitals are key implementers of such policies. Moreover, government influences the hospital's operating environment through legislation and regulations that affect governance, fundraising, human resources and other matters. **www.longwoods.com/hl/art.php?view=1&ID=85**

Knowledge Translation and the Duty of Care: A Medical-legal Analysis by Dr. Peggy J. Blair

Two major shifts have taken place in the medical-legal landscape in recent years. The first has been a shift towards "evidence-based" medicine. The second involves an enhanced focus on knowledge transfer, or "knowledge translation." Find out how knowledge translation is changing the medical-legal landscape and the liabilities that come with it. **www.longwoods.com/hl/art.php?ID=127&view=1**

A Primer on the Personal Information Protection and Electronic Documents Act ("PIPEDA") for Pharmaceutical and Medical Device/Technology Companies that Conduct Business in Canada by Megan Evans

On April 13, 2000 the Personal Information Protection and Electronic Documents Act ("PIPEDA") received royal assent making it the law across Canada. As the legislation itself states, PIPEDA establishes rules to govern the collection, use and disclosure of personal information in Canada in a manner that recognizes the right of privacy of individuals. **www.longwoods.com/hl/art.php?ID=88&view=1**

Conflict Resolution in Healthcare

by Pam Marshall and Rob Robson

In healthcare, the use of ADR has been slow to take hold; however there are some positive signs on the horizon. A number of programs and processes are in place and others will surely follow. Most healthcare facility risk management efforts adopt the classical "self-protective" stance encouraged by the insurance industry. However, this approach does not always work. This article outlines why ADR is well suited to resolve healthcare disputes, identify some of the unique characteristics of healthcare and review some of the current uses of ADR, emphasizing the Canadian context. **www.longwoods.com/hl/art.php?ID=112&view=1**

How much is enough? Patients' Right-to-Know v. Privacy Rights of Healthcare Providers by Cynthia Heinz

A physician may have a duty of care to disclose his or her own medical condition if that condition poses a material risk to the physician's patient. Find out how liability may arise in negligence from a physician's failure to meet this duty when harm is caused to the patient as a result. **www.longwoods.com/hl/art.php?ID=116&view=1**