Healthcare Quarterly

SPECIAL ISSUE Fifth in a Series

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hile improving patient safety remains a high priority in Canadian healthcare, organizations today face the new challenge of advancing patient safety and quality of care in an environment where budgets are flat or declining. Investments in patient safety thus compete with other efforts to improve services and to maintain operations. Both strategically and operationally, healthcare organizations need to assess their patient safety efforts through a critical lens and ask two related questions: How will these efforts reduce the risks of injury for patients in our care? What is their likely impact compared with other programs that may improve care and patient outcomes?

The articles in this fifth issue of Patient Safety Papers reflect on this challenge in differing ways. Here's a sample of what lies in this issue.

Better information on risks is a vital first step in comprehending where care needs to be safer. In an innovative analysis of influenza vaccine information on the Internet, Neil Seeman and his colleagues illustrate the value of understanding public perceptions of healthcare issues as a critical step in designing preventive health programs. Effective flu prevention cannot be achieved when a sizable population hold sceptical views on the safety of vaccines. Counter-marketing strategies are needed to provide assurances to those who shrug off the advice of public health leaders. Better information needs to guide action, an insight pursued by Roger Cheng and his coauthors in an assessment of medication safety indicators for acute care hospitals, and by Liudmila Husak and colleagues at the Canadian Institute for Health Information, who analyze the problems of sepsis and its impact on in-patient mortality in Canadian hospitals.

Safer care results only from the effective implementation of a safety solution. Karyn Popovich and her colleagues at North York General Hospital (NYGH) outline their approach to the prevention of pressure ulcers. Despite a growing evidence base of best practices, many organizations struggle to address this problem. By creating a comprehensive program, enlisting frontline staff and building competencies in wound care, NYGH reduced the incidence of skin pressure ulcers by 60%, allowing nursing resources to redirect their attention to other priorities. Investments in information systems have been a major lever for improving patient safety, but they can also introduce new sources of error. Elizabeth Borycki and Elizabeth Keay review the evidence on how healthcare information systems can contribute to increased errors, and these authors provide advice on a range of methods for improving the performance of these systems: strengthening procurement processes, guiding implementation and identifying technology-induced errors. Implementing safety solutions at the front line is rarely feasible if clinicians do not champion their use. Chris Hayes and colleagues from several Toronto area hospitals outline their experiences in creating physician leader positions for patient safety and building organizational support for this key role.

Organizations across Canada are engaged in patient safety projects. But undertakings can be insufficient in scale and often have only limited impact. Scaling up patient safety initiatives requires integrated approaches that link learning and practice changes across programs. Two leading examples from The Hospital for Sick Children (SickKids) and Hamilton Health Sciences offer organizational approaches that systematically address risks and identify improvements. Polly Stevens and her colleagues from SickKids review nine years of learning from critical occurrence reviews, while Rosanne Zimmerman and colleagues from Hamilton Health Sciences identify how they used death reviews to drill down on hospital standardized mortality ratio results in the pursuit of an audacious goal: reducing preventable deaths to zero.

Patient safety solutions are sustained when teamwork thrives and communication is effective. Anne Kearney and her colleagues at Memorial University of Newfoundland describe their implementation of inter-professional education on patient safety, building competencies across medical, nursing and pharmacy students. Angie Andreoli and a team at the Toronto Rehabilitation Institute used the Situation-Background-Assessment-Recommendation (SBAR) tool to strengthen team communication as part of a falls prevention and management initiative. They discovered that SBAR supports improved communication even in non-urgent situations. Physician handover is an important transition. Niraj Mistry et al. describe the development and implementation of a standardized protocol that improves the reliability of handovers at The Hospital for Sick Children.

Assessing and improving patient safety culture create a supportive context for change for the better. Madelyn Law et al. describe a new tool for patient safety culture and discuss how its results help leaders to address underlying issues. Michael Gardam and his co-authors illustrate how effective strategies often rest on both scientific evidence and local adaptations. Their insights on "positive deviance" approaches suggest that complex problems such as infection control need to be understood as behaviour changes that can only be effective if we understand what tactics work in specific settings.

The rich array of experiences and insights detailed in these articles and the others in this collection provide ongoing testimony to the continued efforts across Canada to improve patient safety. I welcome your feedback on these findings.

My thanks go to our editorial advisory board for their continuing guidance. In addition, this year we asked a number of patient safety experts to serve as associate editors of the journal, to review manuscripts and provide feedback in selecting the articles for this special issue. My thanks to all of them for their excellent work and support.

- G. Ross Baker, PhD

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Patient Safety and Health Care Progress Go Hand-in-Hand

Drug Safety and Effectiveness paper coming November 2010.



RT @CPSI_ISPC: The launch of Canadian Patient Safety Week today in St. John's, NL. http://tinyurl.com/yl7jr9g 4:55 PM Oct 29th, 2009 via web



The Ontario Telemedicine Network's Telehomecare program is helping many Canadians better manage their chronic conditions from home through daily electronic communication with health care teams.

Dr. Ed Brown, CEO of the Ontario Telemedicine Network



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Canadian Patient Safety Institute

The Canadian Patient Safety Institute (CPSI) is proud to sponsor this special issue of Healthcare Quarterly, the fifth issue of Patient Safety Papers, along with the Health Council of Canada and Accreditation Canada. CPSI's role is to support the healthcare system in becoming safer. We currently navigate an environment with the following characteristics:

- The safety landscape is crowded, with many players. This is both a strength - with more interest and participation in safety - and a challenge - sorting out roles, relationships and partnerships.
- The resounding "message from the field" is that organizations are overwhelmed with new expectations and activities coming at them from all directions, a situation that creates an absorption challenge.
- So far, the focus of the quality and safety movements in Canada has been at the ground level, with incremental improvement built on voluntary participation and incentives. Some progress is accelerated by the policies and requirements of agencies such as Accreditation Canada; but, by and large, spread has been difficult.
- The challenge with healthcare budgets involves whether organizations view spending on safety initiatives as even more vital in an era of restraint or as a discretionary investment that can be deferred until their budgetary outlook improves.

The achievement of our healthcare system is our barometer of success. At CPSI, patient safety is not considered "our" issue; it is ultimately that of the public. Our funder, partner agencies, researchers and healthcare organizations recognize our contributions and our value as patient safety improves. At times, our role and profile will be prominent, particularly as we launch new initiatives. But we accomplish most when we help others succeed. Our impact is greatest where we are able to mobilize others' resources and capacities.

We recognize the importance of research in improving patient safety to explore unchartered territory and to ask the difficult questions. This includes investigating solutions to known patient safety complexities. This issue of the journal speaks to the exciting work in patient safety research.

We look forward to continuing with you on this journey. HQ

- Hugh MacLeod, chief executive officer, Canadian Patient Safety Institute

Health Council of Canada

he Health Council of Canada is once again pleased to co-sponsor this special issue of Healthcare Quarterly - Patient Safety Papers, Fifth Edition. Patient safety measures throughout the healthcare system are important to Canadians, healthcare providers and governments, for in the absence of such measures, patients are at risk.

One topic we continue to pursue in our work is pharmaceuticals management and its relationship to patient safety. In the 2004 10-Year Plan to Strengthen Healthcare, first ministers directed ministers of health to establish a ministerial task force to develop and implement a national pharmaceuticals strategy. The strategy was to include actions to strengthen the evaluation of real-world drug safety and effectiveness, and to accelerate access to and reduce the costs of non-patented prescription drugs.

The Health Council has explored the issue of patient safety in many of our reports, including The National Pharmaceuticals Strategy (commentary plus status report) and Optimal Prescribing and Medication Use in Canada: Challenges and Opportunities. In June, we released a commissioned discussion paper, Generic Drug Pricing and Access in Canada: What Are the Implications? that presented options for governments who are seeking to reduce generic drug costs, thereby increasing access to required medications and improving patient compliance.

Our fall discussion paper on drug safety and effectiveness reveals what Canada is doing well, how other countries are approaching the monitoring and assessment of drugs that are entering or already on the market and what can be learned from one another. The paper suggests approaches for strengthening drug-surveillance activities. The Health Council sees the need for increasing the available evidence on drug safety and effectiveness and for improving the capacity to undertake highquality research on post-market drug safety and effectiveness. These steps are crucial to achieving four goals: improved patient safety, reduced adverse reactions to medications, better health outcomes and enhanced sustainability of our health system.

The Health Council further believes that effective chronic disease management and primary healthcare reforms – aided by electronic health records for all Canadians - are needed to deliver the safest, most effective and most efficient care to patients. Our Canadian Healthcare Matters bulletins and our recent commentary on a national dialogue on primary healthcare reform explore these issues further. All reports can be found on our website at www. healthcouncilcanada.ca. We hope you join in the discussion there.

Along with the Canadian Patient Safety Institute and Accreditation Canada, we remain committed to helping create a safer, more accessible, high-quality and sustainable healthcare system for all Canadians. HQ

- John G. Abbott, chief executive officer, Health Council of Canada

Accreditation Canada

ccreditation Canada is once again proud to co-sponsor, with the Canadian Patient Safety Institute (CPSI) and the Health Council of Canada, this special issue of *Healthcare Quarterly*, Patient Safety Papers (the fifth in this series).

As you know, the focus of accreditation is quality improvement through the application of standards and performance measures, subsequently verified through an on-site visit by the survey team. Safety is an inherent component of quality. If an action taken is unsafe, clearly quality is jeopardized. Within the focus on patient safety, the required organizational practices (ROPs) were introduced in 2005. Initially, 21 ROPs were identified; in the subsequent years, additional ROPs have been added such that currently there are 34. Some are sector specific. It is important for each organization to understand which ROPs are relevant.

We recognize that some of the ROPs are easier to implement than others. In the information provided to client organizations, while we identify *what* is required we are not as prescriptive about *how* it should be accomplished. Depending on factors such as the context of your healthcare organization and the nature of your patient population, the strategies that you implement to achieve the ROP might be quite different from those of another organization, and equally acceptable. We have worked to balance the pace of introduction of each ROP – following significant research and consultation – with the capacity of the system to manage the requirement. There was significant improvement in ROP compliance from 2008 to 2009.

Over the past few years, there has been an increasing number of organizations pursuing the patient safety and quality agenda. Collaboration with key partners across Canada is essential and fundamental to all aspects of our work. We are committed to continuing to work collaboratively and to align our work with the health quality councils, other provincial organizations, government and national organizations such as CPSI, the Health Council of Canada, the Institute for Safe Medication Practices Canada and the Canadian Institute for Health Information. Minimizing duplication and optimizing consistency are key. The accreditation process must add value and contribute to enabling your organization to achieve your priorities.

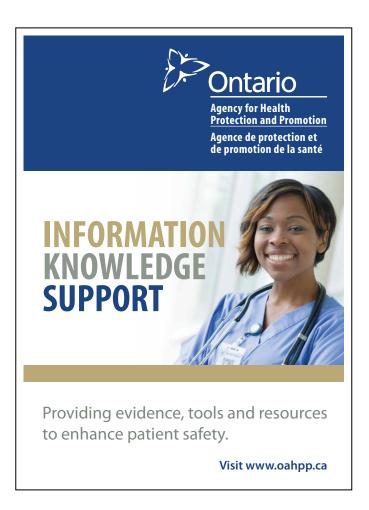
One important strategic direction of Accreditation Canada has been to strengthen our role in the area of sharing knowledge. The release of *Qmentum Quarterly* several years ago has contributed to that end. Secondly, we have redesigned the leading practices section on our website. You will find it much improved and searchable by key words. New leading practices will be added to the database as they are confirmed. An updated ROP

handbook dated April 2010 is posted on our website. We continue to add content to improve communication and guidelines regarding each ROP. Your feedback regarding *Qmentum Quarterly*, leading practices, the ROP guidelines and any product or initiative from Accreditation Canada is welcome.

Given the introduction of Qmentum in 2008 and the three-year accreditation cycle, by the end of 2010, the majority of the Accreditation Canada client organizations will have experienced Qmentum. Early in 2011, we will conduct a thorough analysis of accreditation data (de-identified) and determine the trends, areas of strength and matters for improvement across Canada. This information will be shared with you and enable you to benchmark your own organization against this three-year national picture.

We send a sincere thank you to all of the authors who have contributed to this issue. It is within the application of this knowledge that the true value and impact will be realized. HQ

 Wendy Nicklin, president and chief executive officer, Accreditation Canada



Assessing and Responding in Real Time to Online Anti-vaccine Sentiment during a Flu Pandemic

Neil Seeman, Alton Ing and Carlos Rizo

Abstract

The perceived safety of vaccination is an important explanatory factor for vaccine uptake and, consequently, for rates of illness and death. The objectives of this study were (1) to evaluate Canadian attitudes around the safety of the H1N1 vaccine during the fall 2009 influenza pandemic and (2) to consider how public health communications can leverage the Internet to counteract, in real time, anti-vaccine sentiment.

We surveyed a random sample of 175,257 Canadian web users from October 27 to November 19, 2009, about their perceptions of the safety of the HINI vaccine. In an independent analysis, we also assessed the popularity of online flu vaccine-related information using a tool developed for this purpose. A total of 27,382 unique online participants answered the survey (15.6% response rate). Of the respondents, 23.4% considered the vaccine safe, 41.4% thought it was unsafe and 35.2% reported ambivalence over its safety. Websites and blog posts with anti-vaccine sentiment remained popular during the course of the pandemic.

Current public health communication and education strategies about the flu vaccine can be complemented by web analytics that identify, track and neutralize anti-vaccine sentiment on the Internet, thus increasing perceived vaccine safety. Counter-marketing strategies can be transparent and collaborative, engaging online "influencers" who spread misinformation.

rior to the 2009 influenza A (H1N1) pandemic, public health experts recognized that communities throughout the globe were deficient in pandemic planning (Mareinniss et al. 2009) and could benefit from strategies to increase vaccination rates. In any epidemic, high vaccination uptake is essential in order to limit transmission, protect groups at high risk, reduce the number of severe outcomes and prevent an overload of health services use. Inadequate information about the protective effects of a demonstrably safe flu vaccine reduces immunization rates, contributing to a more rapid spread and wider distribution of an epidemic. Healthcare workers are at particular risk, and, accordingly, in some jurisdictions such as Ontario, it is a hospital board-level responsibility to ensure rapid-response emergency preparedness plans are in place to protect the safety of hospital workers in the event of an infectious outbreak (Seeman et al. 2008).

Systematic reviews show that vaccines prevent infection, complication and death, especially when provided to groups at high risk (Jefferson et al. 2008). Why, then, do many people choose not to be vaccinated? Reasons include a lack of familiarity with the epidemiological facts, a lack of support or notification from the healthcare system and unfounded fears about vaccine safety (Baeyens 2010; Maurer et al. 2010). Common fears are that a new vaccine has been rushed to production with insufficient prior research, that it has not been adequately tested and that long-term studies are needed (Seale et al. 2010). General

anti-vaccination sentiment has been growing worldwide due to the well-publicized but unsubstantiated link between flu immunization and autism; between hepatitis B vaccination and multiple sclerosis in France; and between convulsions and sudden death and human papillomavirus immunization in Austria, Germany and Spain (Alvarez-Pasquin et al. 2009).

Efforts to offset the arguments of the anti-vaccine movement, to calm public fears and to provide accurate information require sustained, effective public health communication. Concerns about safety and side effects need to be addressed; as well, transparency is required about the vaccine development process. Was this successfully accomplished in Canada? A poll conducted between October 1 and 5, 2009, by Harris-Decima revealed that only a third of Canadians intended to get vaccinated, 11% described themselves as very concerned about H1N1 and 25% reported being somewhat concerned (Harris-Decima 2009). The federal health minister noted that the biggest challenge to preventing the spread of the virus was communicating the need for vaccination. Health Canada's information about vaccine safety was broadly disseminated on posters, on buses and subways, in multi-language newspapers and on social media such as Facebook. The information was posted on government and hospital websites across Canada, and Health Canada's website was prominently hyper-linked via mainstream Canadian media news sites. This seemed like a logical communications strategy given that the news media have been a leading source of public health information (Gollust and Lantz 2009).

The challenge with social risk communication in the age of the Internet is the increasing fragmentation of media (Sunstein 2007). Today, Canadians access health information not through print newspapers, radio or cable television but predominantly through the Internet. For at least five years, the first place people seek health-related information has been the web (Hesse et al. 2005). Unfortunately, some Internet sites and postings, light on facts and packed with emotionally laden anecdotes, worsen concerns regarding vaccination safety (Maurer et al. 2010; Wolfe et al. 2002).

Given the degree to which the public accesses vaccine-related information online, we wanted to track whether online postings about the H1N1 flu vaccine were undermining ongoing communications efforts by public health authorities during the fall of 2009. We also wanted to know whether anti-vaccine sentiment escalated after Health Canada's approval of the vaccine and, if so, to suggest Internet communications strategies (Rizo et al. 2005) at the national, regional and hospital levels that could assess, monitor and, ideally, counteract such sentiment.

Methodology

Two parallel, independent steps were initiated to address our objectives. In step A, we surveyed a random sample of Canadian web users from October 27 to November 19, 2009, about their

perceptions of the safety of the H1NI vaccine after Health Canada approved the vaccine. In step B, we determined which vaccine safety Internet sites were most trusted by the public by deploying a dynamic "Internet robot" that informed us about (1) which uniform resource locators (URLs) regarding "myths and facts" about the H1N1 vaccine were being most widely shared and discussed among English-language Internet users and (2) which websites, blogs and links were being shared on social media sites. Both step A (the survey) and step B (the Internet robot) were independent, and the results should be interpreted as such. Both steps of our process are described below.

Step A: Random Online Survey of Internet Users' Perceptions of Vaccine Safety

For the survey of Internet users' perceptions of vaccine safety, we used the RIWI Time Trender service (http://riwi.com), which applies a patent-pending Internet intercept method that provides access to immediate respondent data based on a random sampling of Internet users. Response to the survey was randomized by accessing thousands of "nonsense" domain names (URLs) that reach hundreds of thousands of random Internet users. A nonsense domain is a URL that has no English-language meaning (e.g., www.jhwje.ca) and is not being used for commercial or other purposes. Thus, the method captures potential respondents navigating the Internet who type in nonsense domains by random accident (i.e., mistypes). The Internet intercept method is not like email spam; it is more akin to an online "random digit dialing" survey since all Internet users have a relatively equal probability of inadvertently landing on the web page where the survey is posted. Only Canadian Internet users were able to respond (geographically identified, anonymously, by their Internet protocol, or IP, address).

The survey asked, "Is the H1N1 flu vaccine safe?" Answer options were limited to "yes," "no," "don't know" and "skip." Respondents were also asked their age (under 18, 18–29, 30–49, 50–64 and over 64) and their sex. They were able to answer only once, either in English or French. The survey contained a privacy policy explaining that collected information would not identify individuals, businesses or households. Respondents were advised that information would be kept anonymous and that they had the choice not to respond.

Step B: H1N1 Myth and Fact Internet Aggregator

At the same time that we initiated the survey (October 27, 2009), we launched a software tool to count how often flu vaccine–related information websites were being shared on blogs and social media sites such as Digg, YouTube, Facebook and Twitter. We wanted to identify which websites containing information on myths and facts about the H1N1 vaccine were the most viewed, read and shared on the web. We used standardized English search strings to identify which websites were discussing

the safety of the vaccine. Using a structured algorithm, we were able to track, on a daily basis, which of these websites were rising in popularity (i.e., were being shared with increasing frequency among web users). This is different from counting website "hits," which do not track whether the individuals visiting the site take the additional steps of creating a short form of the URL (i.e., by using popular website "shorteners" such as http://www.tinyurl. com or http://www.bit.ly) and then emailing, texting or otherwise sharing the shortened link (e.g., via Facebook or Twitter) with others. We aggregated and displayed this information in real time on a publicly accessible area called the Flu Chat Lab at http://www.myhealthinnovation.com. The dynamic aggregation of this Flu Chat Lab content is now accessible and ongoing at http://lab.innovationcell.com (Figure 1).

The computer-programmed Flu Chat Lab aggregation technique involved the following five steps:

1. 'Chatter' collection. We built a selection of relevant Englishlanguage search strings (available upon request). The goal of the search strings was to identify postings on the web that contained self-reports about the perceived truth or falsity of information concerning the H1N1 flu vaccine.

2. Data collection. All the search string queries were submitted

- on a daily basis into Google Search, and search results were collected in a database, with duplicate URLs removed. The
 - first 64 top-ranked search results (for each search string) were collected daily.
- 3. Scoring. Each unique search result was measured for "mentions" - that is, the degree to which the URL was shared by global Internet users across the web - to establish a "chat level" in "decibels" (dB). The aggregator tool counted the number of mentions of every search result in the database and assigned it a chat level. The chat level was calculated in units of decibels (dB) as 20 LOG10 (9 + Mentions). This method of measuring chat level is analogous to the measurement by audio engineers of intensity, loudness and power. The logarithmic scale allowed us to visualize mentions as "audio intensity" on a linear scale.

- 4. Categorization of chat level. The chat level for each search result was categorized into one of four levels: high (60 dB and above), medium (40-59 dB), low (20-39 dB) and none (below 20 dB).
- 5. Daily dynamic scoring. The change in chat level (over 24 hours) was calculated in order to rank "trending" search results. On a daily basis, the chat levels for new and existing search results were updated. In this manner, we visualized the change in chat level for each search result.

Results

Step A Findings: Daily Tracking Survey of Canadian Web Users about Perceived Vaccine Safety

There were 27,382 unique respondents (i.e., from unique computing devices) who completed the survey, out of 175,257 separate Canadians exposed to the survey. This translated to a response rate of 15.6%. The remainder of the respondents (84.4%) chose to hit "skip" (signaling their unwillingness to complete the survey) or closed their web browsers. We verified that the target of our survey only covered Canadian IP addresses, across all provinces and territories. Each day, an average of 1,141 Canadian web users completed the survey.

Table 1 shows the relative response rate of Canadian Internet

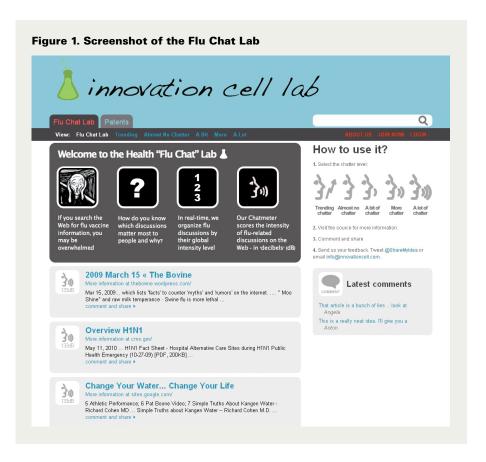


Table 1. Survey response by region compared with percentage of Canadian population

Region	Percentage from Each Region (N = 27,382)	Region Population as Percentage of Population*		
Alberta	12.3	10.9		
British Columbia	12.0	13.2		
Manitoba	3.4	3.6		
New Brunswick	2.0	2.2		
Newfoundland and Labrador	1.2	1.5		
Nova Scotia	3.4	2.7		
Northwest Territories	0.1	0.1		
Nunavut	0.1	0.1		
Ontario	41.2	38.7		
Prince Edward Island	0.5	0.4		
Quebec	20.4	23.2		
Saskatchewan	3.2	3.1		
Yukon	0.1	0.1		

^{*}Source: Statistics Canada (2009a).

Table 2. Survey response by sex compared to percentage of Internet users

Sex	Response Rate (%) (<i>N</i> = 27,382)	Sex as Percentage of Canadian Internet Users*
Male	38.8	50.2
Female	61.2	49.8

^{*}Source: comScore Networks Inc. (2008).

users to the survey, comparing the response rate in each jurisdiction to its proportion in the national population. Table 1 shows responses by region compared with the percentage of the Canadian population, and Table 2 shows responses by sex compared with the Canadian population. Table 3 shows the survey responses by age compared with the relative frequency of Internet use by age group (from the most comparable data source available).

Our survey findings, illustrated in Figure 2, show that an average of 23.4% of Canadians surveyed considered the vaccine safe, while 41.4% thought it was unsafe and 35.2% reported ambivalence over its safety. Over the 24 days surveyed, the percentage of those who said the vaccine was not safe peaked at 45.3% (on November 18, 2009). The general trend line for those who felt the vaccine was safe stayed relatively static, with a low of 21.0% (on November 17) and a high of 28.4% (on October 29), two days after Health Canada had approved the H1N1 vaccine and public health communications efforts were most visible in online and print media.

Step B Findings: Aggregating **Perceived**

Web-Posted Myths and Facts about the Flu Vaccine

Our Flu Chat Lab aggregator showed that, from October 27, 2009, to the date of analysis (April 6, 2010), websites containing anti-vaccine sentiment remained popular. The number of search results we collected as of the time of writing was 17,392. The distribution of search results about vaccine

safety by chat level is described in Table 4. Appendix 1 identifies the top 20 search results discussing the safety of the vaccine.

Twelve of the 20 URLs (60%) in Appendix 1 (http://www. longwoods.com/content/ 21923) contain anti-vaccine sentiment (numbers 1, 2, 3, 5, 7, 9, 10, 14, 15, 16, 17 and 19). Three of 20 (15%) are government sources (numbers 8, 12 and 20). Our methodology indicated that each of these 20 URLs had been shared and viewed over 1,300 times (i.e., passed from one Internet user to another via social networks such as Facebook, Twitter, YouTube or Digg). The top-ranked URL in

Table 3. Survey response by age compared to relative Internet usage

Age (y)	Response Rate (%) (<i>N</i> = 27,382)	Relative Internet Usage, from Most Comparable Data Source Available*
<18	41.3	23.8 (for ages 12–17)
18–29	37.8	22.3 (for ages 18–29)
30–49	13.7 21.8 (for ages 30–44)	
50-64	3.2	19.4 (for ages 45–59)
65+	3.9	12.7 (for ages 60+)

^{*}Source: Zamaria and Fletcher (2008)

Table 4. Distribution of URL postings about vaccine safety by "chat level"

Chat Level	Count	Percentage of Postings
High (60 dB)	55	0.32
Medium (40–59 dB)	475	2.73
Low (20–39 dB)	2,139	12.3
None/minimal (0–19 dB)	14,723	84.7
Total	17,392	100.1

URL = uniform resource locator

Appendix 1 was shared and then viewed by the person to whom the link was sent over 9,600 times, as of the time of this writing. As of April 6, 2009, the Flu Chat Lab showed that the video "Girl Gets 'Flu' Shot and Now Can Only Walk Backwards" (number 2) had been shared 8,773 times and viewed 2,386,817 times, as indicated by YouTube.

Discussion

For our daily tracking survey (step A), we attempted to obtain a random sample of Internet users. Based on Tables 1, 2 and 3, we feel we succeeded in approximating geographical representation across Canada, but Tables 2 and 3 reveal that our sample was not representative in terms of sex and age, which may limit the generalizability of our findings. The online nature of our survey skewed the response toward a younger demographic. Women were overrepresented, possibly due to the fact that women are usually the primary caregivers and would thus be more concerned about vaccine safety. One could question whether the universe of Internet users is representative of the popula-

tion; however, with Canadian Internet usage being 70% or over for ages 15-64 (over 80% for those 15-54 and 70% for those 55-64 and rising (Statistics Canada 2009b), our survey accessed at least as wide a net of potential respondents as computer-assisted telephone interviewing. A growing percentage of Canadians do not own a telephone landline or they block telemarketers and polling companies from contacting them. At 15.6%, the relatively low response rate could suggest important differences between those who responded and the majority who did not. For example, the respondents might have had more time available to complete the survey than non-respondents. However, the survey took only 10-60 seconds to complete. The large sample size (N =27,382) reduces concerns about coverage bias. A response rate of 15.6% is reflective of web surveys generally, response rate being a challenge for all online surveys, even when pre-recruited panels are used (Couper and Miller 2008). We tried to correct for a low response rate by using large, geographically representative, daily, random sampling.

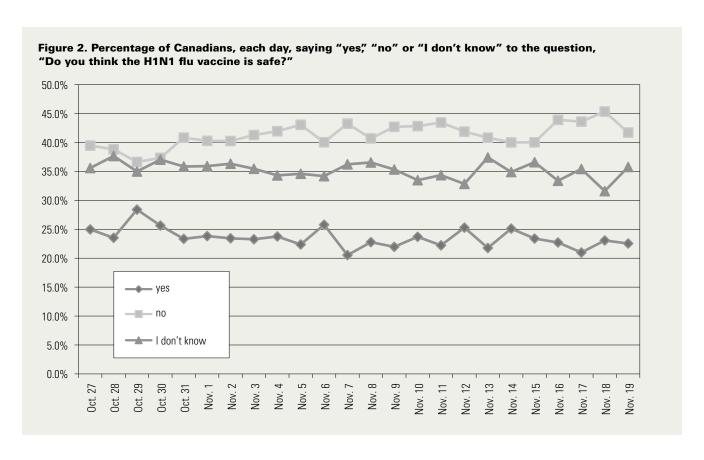
With regard to the findings of our Flu Chat Lab (step B), whose findings are independent and should not be correlated with those in step A, the dominant bias

is the English-language nature of the postings aggregated. We were limited by query limits imposed by Google Search in terms of the number of search results for each search string. Further, Google Search was the only search engine we used. However, Google Search is by far the most popular search engine in Canada, with the most number of web pages indexed compared with any other search engine in the world.

It is not always possible to interpret the meaning of numbers of mentions of websites since interest can be generated by stories that are amusing, celebrity-focused or popular for other reasons. Nevertheless, we did establish that anti-vaccine sites were generating wide interest among Canadians. There is no direct evidence that viewing anti-vaccine sites led to the perception shared by 41.4% of Canadians surveyed that the H1N1 vaccine was not safe.

Future Policy Directions

Prior research has suggested that health-related blogs with clinically relevant and accurate chronic illness information are



frequently the most viewed and, increasingly, the most trusted by Internet users (Seeman 2009). Nonetheless, our findings in step B show that sustained anti-vaccine sentiment continues to be viewed and shared actively on the web. Our findings from step A show that Canadian Internet users, even after the approval of the H1N1 vaccine in Canada, were skeptical, over the course of 24 days, about the vaccine's safety. This suggests that public health authorities may need to use "counter-marketing" strategies.

So-called counter-marketing is a growing social marketing strategy that has been effective in tobacco control (countering the messages of tobacco companies) (Evans and McCormack 2008). An effective counter-marketing strategy can proactively identify and expose misinformation and anecdotal evidence that "tugs at the heart strings" in near real time (Davies et al. 2002).

Our novel approaches to determining public attitudes to healthcare issues using real-time Internet data gathering can be applied more broadly to understand public sentiment, at low cost and with rapidity, on a broad range of policy issues. Step A, for example, has already been used to determine public attitudes among Canadians toward providing social supports (e.g., help with the laundry or other household chores) for chronically ill neighbours (Seeman and Brown in press). Step B can be used to determine the readiness with which people share online information with their peers about taboo subjects such as mental

health problems and needs. Highly shared information can help to guide the improved visual design, features and language formatting for online health tools that target subpopulations of interest. Applying both qualitative and quantitative analyses to blogs and exchanges on social networks can potentially tap into the perceptions of large numbers of people with respect to many health issues other than vaccinations (e.g., satisfaction with healthcare services, pathways to care and outcomes and overall experiences of care).

Using tools similar to the ones described here, hospitals, public health agencies, health regions and health ministries can learn about the extent and causes of the public's anti-vaccine sentiments and devise methods to effectively neutralize them. For example, an independent evaluation unit staffed with expert clinical reviewers and social media experts could create a running search string methodology (in both official languages and in other languages reflective of Canada's diverse population) akin to our approach in step B. This approach would identify, in real time, which websites were disseminating popular anti-vaccine-related information. Sites with anti-vaccine sentiment that were growing in intensity could be flagged. These findings could be stored in a secure database accessible by website editors working with public health officials at the national, provincial and local levels, and by web editors working with hospitals and health regions.

While we have not provided direct evidence that Internet viewing was responsible for the low uptake of the H1N1 vaccine, Betsch et al. (2010) have shown that accessing vaccinecritical websites for five to 10 minutes increases the perception of risk of vaccinating and decreases the perception of risk of not vaccinating. Intentions to vaccinate are diminished by such viewing. Vaccine-critical websites therefore potentially contribute to changes in risk perception, which, in turn, can affect the public's willingness to get vaccinated. Future research should validate the extent to which website information does, in fact, influence perceptions of vaccine safety, public willingness to get vaccinated and other areas of patient safety. Given the amount of resources that companies, charitable organizations and healthcare organizations are currently investing in viral advertising on the web, particularly on social networks, it is likely to have some impact (Seeman 2008); but the exact extent of this impact is hard to assess beyond traditional metrics such as website hits and trends in site usage (e.g., Alexa.com).

There is some literature suggesting that people seek out information that confirms their existing attitudes (Sunstein 2007); therefore, the impact of misinformation about the vaccine might be less than we think. Given the thousands of websites being created every second, competition for public attention online is extremely challenging. Therefore, measures of engagement of the target population, rather than simple website hits, are more valuable to assessing the impact of any online healthcare intervention or information tool. The degree to which the public shares websites (our process in step B), rather than website hits, is one such measure of engagement. Other measures of value include the degree to which potential users of a website can become aware of its existence. Such measures might include the Google "footprint" for the website of interest ("geo-located" to URLs for the target populations); "in-links" to the website; and the extent to which the site is visible on Google when the target populations actively search for related information (e.g., cancer and depressed for people suffering from these overlapping conditions).

Our Approach: Collaborative Counter-Marketing to Address Anti-vaccine Sentiment

What we call a "collaborative counter-marketing model" involves engaging in publicly viewable web discussions with the authors of the anti-vaccine postings. This could be accomplished through an independent evaluation unit's ongoing postings or annotations to the content posted by vaccine dissenters. This approach would show constructive, transparent engagement and provide demonstrable evidence that a counter-marketing strategy is meant to provoke dialogue, not shut down dissent. The public perception of shutting down dissent could, in itself, raise skepticism and anti-vaccine sentiment that could accumulate on blogs and online forums. Under our approach, each

region and hospital could engage in meaningful dialogue with locally influential dissenters. Those with disproportionate influence in a particular geographical region could be identified by the evaluation unit using detection methods geo-located to towns, cities and provinces. Local authorities could choose with whom to engage in dialogue in order to achieve maximum impact.

Conclusion

The web contains much flu-related anti-vaccine sentiment that is potentially dangerous to the perceptions of risk and a willingness to get vaccinated. This challenge, we feel, can potentially be mitigated using real-time web analytics. Current public health communication and education strategies can be complemented by web analytics that identify and track anti-vaccine sentiment on the Internet. A collaborative counter-marketing model can be supported by the type of real-time daily Internet tracking survey described in this article (i.e., step A), making it possible – at a community, city, province, region, or country level - to monitor the success of the collaborative counter-marketing strategy. When, in a future pandemic, scarce public health resources need to be shifted rapidly to regions where anti-vaccination sentiment runs high, a method of collaborative counter-marketing, as described here, can provide the public with accurate risk information, which should help to boost vaccination rates and thereby enhance public safety. HQ

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Community Pharmacy Incident Reporting: A New Tool for Community Pharmacies in Canada

Certina Ho, Patricia Hung, Gary Lee and Medina Kadija

Abstract

Incident reporting offers insight into a variety of intricate processes in healthcare. However, it has been found that medication incidents are under reported in the community pharmacy setting.

The Community Pharmacy Incident Reporting (CPhIR) program was created by the Institute for Safe Medication Practices Canada specifically for incident reporting in the community pharmacy setting in Canada. The initial development of key elements for CPhIR included several focusgroup teleconferences with pharmacists from Ontario and Nova Scotia. Throughout the development and release of the CPhIR pilot, feedback from pharmacists and pharmacy technicians was constantly incorporated into the reporting program. After several rounds of iterative feedback, testing and consultation with community pharmacy practitioners, a final version of the CPhIR program, together with selfdirected training materials, is now ready to launch.

The CPhIR program provides users with a one-stop platform to report and record medication incidents, export data for customized analysis and view comparisons of individual and aggregate data. These unique functions allow for a detailed analysis of underlying contributing factors in medication incidents. A communication piece for pharmacies to share their experiences is in the process of development. To ensure the success of the CPhIR program, a patient safety culture must be established.

By gaining a deeper understanding of possible causes of medication incidents, community pharmacies can implement system-based strategies for quality improvement and to prevent potential errors from occurring again in the future. This article highlights key features of the CPhIR program that will assist community pharmacies to improve their drug distribution system and, ultimately, enhance patient safety.

atient safety has become an increasingly significant aspect of healthcare. One method to improve patient safety is to learn from breakdowns in the healthcare system that lead to potential harm to patients (World Health Organization [WHO] 2005). To learn from these failures, these incidents need to be brought to light and reported. Incident reporting offers insight into a variety of intricate processes in healthcare. An incident typically occurs after multiple factors fail in a cascade of interconnected events, rather than a single factor at one point during the delivery of care to the patient. By reporting incidents, healthcare practitioners are able to investigate the root causes of the incident and learn by making changes in the system to prevent a future occurrence.

While other healthcare settings have an increased awareness about patient safety, community pharmacy seems to lag behind (MacKinnon 2006). In certain healthcare settings, including hospitals and long-term care facilities, a reporting system is a required organizational practice by Accreditation Canada, a national standard-setting organization (Accreditation Canada

2008). However, standards in community pharmacy are set by each individual provincial regulatory body, so community pharmacies throughout Canada may have different practices regarding incident reporting. Although there is a national reporting system, the Individual Practitioner Reporting by the Institute for Safe Medication Practices Canada (ISMP Canada; available at https://www.ismp-canada.org/err_report. htm), where any healthcare practitioner can report medication incidents, it has been found that medication incidents are underreported in the community pharmacy setting relative to other institutions (Cheng et al. 2010). This lack of reporting may be due to the uniqueness of the community pharmacy setting compared with other settings. In contrast to other healthcare institutions, the majority of patients at a community pharmacy are ambulatory and do not require medication administration or direct medical assistance. The main purpose of community pharmacies is to distribute medications and provide pharmaceutical care for patients. As most reporting systems available cater to hospitals or long-term care facilities, there is a need for an incident reporting system specific to the community pharmacy setting that allows the study of factors or work processes in a community/outpatient medication-distribution system.

Currently, some of the larger corporate pharmacies do have a reporting system in place. However, these systems are typically used for legal purposes. When a medication incident occurs, the pharmacist is required to report the incident to mitigate any liability. These systems are usually not anonymous, so pharmacists may feel intimidated to report incidents for fear of being reprimanded. Furthermore, these existing systems are rarely implemented to understand contributing factors of medication incidents, so many of the reported medication incidents at one location can potentially occur again at another location of the corporate pharmacy.

ISMP Canada developed the Community Pharmacy Incident Reporting (CPhIR) program, the first national incident reporting program made specifically for community pharmacies. This article discusses the development and highlights the key features of the CPhIR program that will assist community pharmacies to improve their drug distribution system and, ultimately, enhance patient safety.

Development

As a starting point for the development of a reporting program for community pharmacy, the data elements from ISMP Canada's Individual Practitioner Reporting form were used. These elements, listed in Table 1, were presented to a research team, SafetyNET-Rx (http://www.safetynetrx.ca), in Nova Scotia. Nova Scotia has recently passed new quality assurance standards, which include the need to report near misses and medication incidents (or quality related events) in community pharmacies. ISMP Canada worked collaboratively with

this research team to develop the initial key elements of the CPhIR program. The research team consisted of many stakeholders including community pharmacists, pharmacy technicians, members from the provincial regulatory body and researchers from academic institutions. After iterative discussion and teleconferences, data elements were finally customized for community pharmacy incident reporting. The elements from Table 1 were then narrowed down to those listed in Table 2 for the CPhIR program. Most data elements removed were typically used in an acute care setting and were hence irrelevant to community pharmacy incident reporting.

After several months of development, the CPhIR program was released as a pilot project. Thirteen community pharmacies that had participated in the SafetyNET-Rx phase I pilot project in 2008 were invited to test the CPhIR program by submitting mock-up medication incidents to the training/demonstration site of CPhIR (http://www.cphir.ca/training). Several Ontario pharmacies also had the opportunity to view and pilot-test the CPhIR program at the same time, including independent, grocery, mass merchandising and chain pharmacies. They provided feedback to the CPhIR development team and were invited to participate in future teleconferences.

In July 2009, two focus groups via teleconference, one from Ontario and one from Nova Scotia, were invited to test the reporting feature of the program (Figure 1). Individuals in these focus groups included pharmacists, managers from the corporate office of chain pharmacies, members of provincial pharmacy associations and researchers from academic institutions. Modifications of the Report an Incident interface took place based on recommendations from the focus group participants.

Subsequent teleconferences were arranged with pharmacy practitioners in Ontario and Nova Scotia in August 2009, December 2009 and March 2010, seeking their feedback and input to the Search, Stats and Account Management components of the CPhIR program, respectively (Figures 2–5). While the Search and Account Management components were released at once with minor feedback, the Stats function was released in four phases. The four phases included downloading the statistics within CPhIR to the user's local computer hard drive, exporting individual statistics into Microsoft Office Excel for internal and customized analysis, comparing individual and aggregate data in frequency tables within CPhIR and, finally, comparing individual and aggregate data in graphs within CPhIR. As each phase was released, feedback from pharmacists and pharmacy technicians was incorporated.

CPhIR continues to receive minor updates based on feedback from users of the program after they have tested the reporting system through the submission of mock-up medication incidents to the CPhIR training/demonstration website. Once all final updates are completed, ISMP Canada plans to allow users to become comfortable with the final product for a

Table 1. Individual practitioner reporting core data set

Individual Practition	ner Reporting Data Elements	Mandatory/Optional Indicator	Input Type
Incident	Date of incident	Optional	Pop-up calendar
	Time of incident	Optional	Text box
	Incident description/how discovered	Mandatory	Text box
	Stages involved	Mandatory	Check boxes
	Type of incident	Mandatory	Pull-down menu
	Discovered by	Mandatory	Pull-down menu
	Care area type	Mandatory	Pull-down menu
Outcome	Severity/outcome	Mandatory	Radio buttons
	Intervention	Optional	Text box
Medication(s)	Medication name	Mandatory	Text box
	Strength	Optional	Text box
	Route of administration	Optional	Text box
	Manufacturer	Optional	Text box
	Lot number	Optional	Text box
	Confusing drug name, label or packaging	Mandatory	Radio buttons
	Upload picture or PDF file	Optional	File input
Follow-Up	Action	Optional	Text box
	Comments/recommendations	Optional	Text box
	System improvement strategies implemented	Optional	Text box
Patient	Non-patient specific	Optional	Check box
	Age category	Optional	Pull-down menu
	Gender	Optional	Radio buttons
Reporter	Name	Optional	Text box
	Practice setting	Optional	Text box
	City	Optional	Text box
	Province	Optional	Pull-down menu
	Postal code	Optional	Text box
	Email	Optional	Text box
	Permission to contact reporter	Optional	Text box

Individual Practitioner	Reporting Data Elements	Mandatory/Optional Indicator	Input Type
Possible contributing factors	Critical patient information missing	Optional	Select menu
	Critical drug information missing	Optional	Select menu
	Miscommunication of drug order	Optional	Select menu
	Drug name, label or packaging problem	Optional	Select menu
	Drug storage or delivery problem	Optional	Select menu
	Drug delivery device problem	Optional	Select menu
	Environmental, staffing or workflow problem	Optional	Select menu
	Staff education problem	Optional	Select menu
	Patient education problem	Optional	Select menu
	Lack of quality control or independent check systems	Optional	Select menu

PDF = portable document format.

Source: Adapted from Canadian Medication Incident Reporting and Prevention System Core Data Set for Individual Practitioner Reporting, available at http://www.ismp-canada.org/cmirps.html.

Table 2. CPhIR Core Data Set

CPhIR Data Elements	Mandatory/ Optional Indicator	Input Type
Date incident occurred	Mandatory	Calendar
Time incident occurred	Optional	Pull-down menu
Type of incident	Mandatory	Radio buttons
Incident discovered by	Mandatory	Pull-down menu
Medication system stages involved in this incident	Mandatory	Check boxes
Medications	Mandatory	Text box
Patient's gender	Optional	Pull-down menu
Patient's age	Optional	Pull-down menu
Degree of harm to patient due to incident	Mandatory	Radio buttons
Incident description/how incident was discovered	Mandatory	Text box
Other incident info	Optional	Check boxes
Contributing factors of this incident	Optional	Check boxes
Actions at store level (Include action plan, person in charge, and target date for completion)	Optional	Text box
Shared learning for ISMP Canada to disseminate (What has been done to prevent a similar occurrence in the future)	Optional	Text box

CPhIR = Community Pharmacy Incident Reporting; ISMP Canada = Institute for Safe Medication Practices Canada.

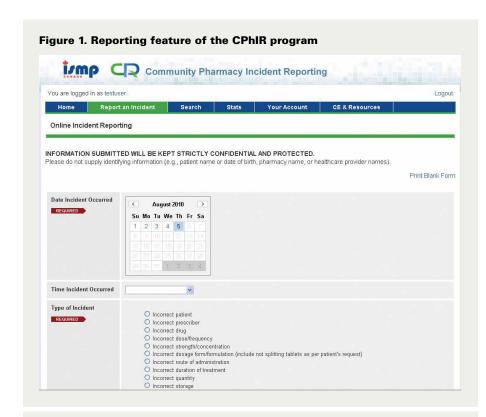


Figure 2. Search feature of the CPhIR program i/mp Community Pharmacy Incident Reporting Logout Search Reported Adverse Drug Events Start Date (YYYY-MM-DD) (YYYY-MM-DD) Type of Incident Incident Discovered By Medication System Stages Involved Prescribing Monitoring / Follow-up
 Not Applicable (Unable to determine one or more of the above medication system phases) Medication (free-text) Degree of Harm to Patient ☐ NO ERROR □ DEATH

few months before completing a formal extensive evaluation of the program. Although no formal evaluation has taken place,

many users from the 13 community pharmacies in Nova Scotia and the pharmacies in Ontario have deemed the program easy to use and have said that, in general, they are able to complete the data entry and submission of an incident report within approximately five minutes. In fact, the user-friendliness of the CPhIR program has allowed some of these users to switch from employing a paper-based reporting form to directly inputting the incident information online at the CPhIR website upon the occurrence and discovery of an incident.

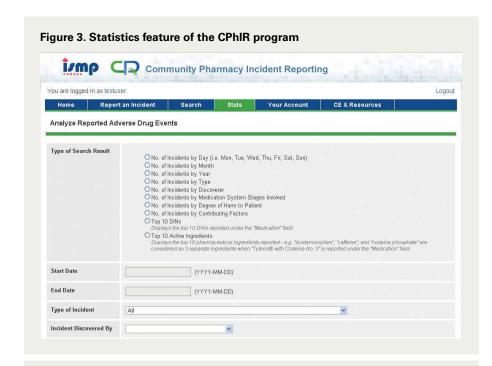
Implementation

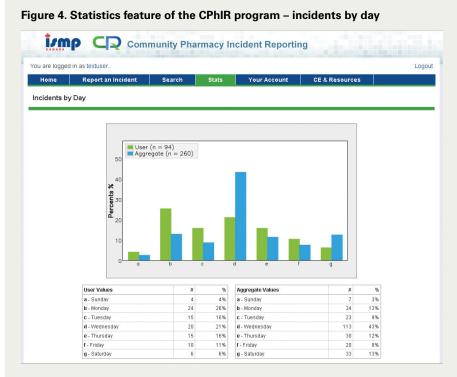
As of April 2010, the CPhIR program is available to community pharmacies at http://www.cphir. ca. An annual subscription fee is required for CPhIR that includes the use of the program, electronic access of ISMP Canada Safety Bulletins, SafeMedicationUse.ca Newsletter, and Medication Safety Alerts throughout the year. Since CPhIR is easily accessible from any location with an Internet connection, pharmacies in rural locations are also able to use the program. CPhIR is a one-stop platform with the following components - Report an Incident (see Figure 1), Search (see Figure 2), Stats (see Figures 3 and 4), Your Account (see Figure 5) and CE & Resources (Figure 6). Frequently asked questions (FAQs) (Figure 7) are also available online.

Registration

The registration function is an internal function used by ISMP Canada to register users. To complete registration, the pharmacy must complete a data sharing agreement, which states that the pharmacy agrees to share information regarding

reported medication incidents with ISMP Canada. The registration is completed by one designated employee at ISMP Canada





who does not have access to reported medication incidents. This individual assigns the pharmacy a unique username, which is only accessible by this individual. By delegating different tasks involved with CPhIR to different employees, medication incidents reported from pharmacies essentially remain anonymous.

Home

Currently, the home page of CPhIR lists open incidents as a reminder for users to close and submit these reports after they login. An open incident is similar to a draft report where the user has entered some information but has not submitted a final copy to ISMP Canada. This allows users to start entering information when an incident is discovered but to have more time to collect further details of the incident before entering all the information. Open incidents can be edited up to 90 days before they are automatically submitted to the ISMP Canada national incident database.

Report an Incident

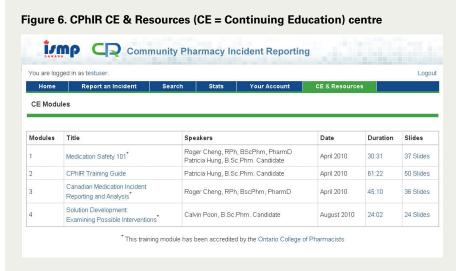
Table 2 displays the fields in the reporting interface of CPhIR. With a combination of check boxes, pulldown menus and radio buttons for selection, the form is relatively easy to use. Since the reporting process is not likely to be time consuming, pharmacy staff members are encouraged to fill out the form for both near misses and medication incidents upon the occurrence or discovery of the event.

Search

The Search function allows users to retrieve an individual or a series of incidents based on self-determined criteria. When the user retrieves a cluster of incidents, these can be exported to Microsoft Office Excel[®]. Once the data are exported, the user can then perform a customized analysis for the individual pharmacy. The user can employ

descriptive statistics to provide an analysis of any mandatory data elements listed in Table 2. This feature is particularly useful for pharmacies to analyze reported incidents and to determine possible contributing factors of these incidents. Once the causes





of medication incidents have been uncovered, system-based strategies can be implemented in the work environment to prevent the reoccurrence of similar events.

Statistics

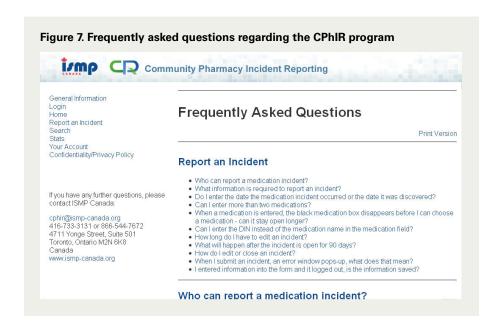
Although certain contributing factors can only be associated to an individual community pharmacy, other factors may be present in the distribution systems of all community pharmacies in general. The Stats function addresses this concern.

This function compares the statistics of medication incidents at the individual pharmacy level versus a national aggregate of all incidents reported through CPhIR from community pharmacies across Canada. This is valuable because users are able to identify trends and whether certain incidents are specific to a particular pharmacy setting or are generalized to all community pharmacies across the nation.

CE & Resources

The CE & Resources centre includes modules about patient safety. The first module provides an overview of medication safety consisting of the significance of medication incidents, human and environmental factors and the system approach to medication safety. This module should educate users about the importance of medication safety and help to shape an open culture toward reporting medication incidents for the purpose of shared learning. The second module is a tutorial that teaches users how to use the CPhIR program, including all functions described above. A third module provides a brief description on different methods to conduct meaningful medication incident analyses. A fourth module offers various error reduction strategies or solution development after identification of causes or contributing factors of medication incidents in a practice setting. Further CE training modules will be available as CPhIR continues to develop.

All reported near misses and medication incidents will be submitted to the ISMP Canada national incident database. which contributes to the Canadian Medication Incident Reporting and Prevention System (http://www.ismp-canada. org/cmirps.htm). ISMP Canada will analyze the medication incidents and provide recommendations for medication safety and continuous quality improvement in community pharmacy practice via the dissemination of safety bulletins or newsletters.



Quarterly updates are planned to be released to all CPhIR users providing information about medication incidents reported through CPhIR.

Next Steps

As more medication incidents are reported to ISMP Canada via the CPhIR Program, ISMP Canada intends to introduce a communication platform to CPhIR. Preliminary plans include weekly tips and quarterly newsletters regarding medication safety through learning from incidents submitted to CPhIR. By offering a communication channel, ISMP Canada would like to encourage open dialogue and shared learning among all community pharmacies in Canada for the common goal of enhancing patient safety.

To ensure the success of the program, a culture toward patient safety must be established in community pharmacy practices. Ashcroft et al. (2005) commented that pharmacists and pharmacy technicians do not report incidents because they feel the risks of being blamed outweigh the benefits of learning from the incident. Therefore, it is essential to establish an open culture where medications incidents are freely discussed and a system-based strategy is the focal point of discussion to learn, rather than a blame-and-shame approach, which is ineffective and meaningless toward patient safety.

Conclusion

The WHO Draft Guidelines for Adverse Event Reporting and Learning Systems describes four core concepts of a patient safety reporting system:

- The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health-care
- Reporting must be safe. Individuals who report incidents must not be punished or suffer other ill-effects from reporting.
- Reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis. Ideally, it also includes recommendations for changes in processes and systems of healthcare.
- · Meaningful analysis, learning, and dissemination of lessons learned require expertise and other human and financial resources. The agency

that receives reports must be capable of disseminating information, making recommendations for changes, and informing the development of solutions. (2005: 10)

The CPhIR program aligns with the above core concepts. CPhIR was built to learn from failures in the system processes of community pharmacies. It is a special program made to accommodate the unique setting of the community pharmacy. The second concept states that reporters must feel safe using a reporting program. In the CPhIR program, (1) data are transmitted to ISMP Canada securely and anonymously so that no blame can be associated to the reporter(s) at the community pharmacy; and (2) a no-blaming culture is encouraged internally at the community pharmacy so that no individual staff member is punished. The WHO guidelines suggest that a meaningful analysis must be completed to understand how errors occur and what recommendations can be made to improve the system. CPhIR includes features that can assist individual community pharmacy in these analyses by allowing the user to generate descriptive statistics (such as frequency tables and graphs) on the mandatory data elements listed in Table 2 via the Stats function (see Figure 4) when users login with their unique username and password. Finally, the "agency" referred in the WHO guidelines is ISMP Canada. All reported medication incidents will be transmitted to the ISMP Canada national incident database, where experts in the medication safety field can analyze the incidents, make recommendations and disseminate findings and learning to healthcare practitioners in Canada. The ISMP Canada Safety Bulletins (available at http://www.ismp-canada.org/ISMPCSafetyBulletins.

htm) and the anticipated communication platform in CPhIR will be the means to fulfill the notion of the dissemination of recommendations and development of solutions.

CPhIR is a brand new tool that will change the state of incident reporting in community pharmacies. By gaining a deeper understanding of possible causes of medication incidents, community pharmacies can implement system-based strategies for quality improvement and the prevention of potential errors from occurring again in the future, which will ultimately enhance patient safety. HQ

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(SafetyNET-Rx in Nova Scotia), funded by the Social Sciences and Humanities Research Council of Canada phase I pilot project 2008-2009), has been extremely helpful and is very much appreciated. CPhIR contributes to the Canadian Medication Incident Reporting and Prevention System.

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Providing evidence to help save lives

When reviewing HSMR data over the past five years, Southlake Regional Health Centre identified sepsis, a condition resulting from the body's response to severe infection, as a cause of death requiring further investigation. Recognizing the high mortality rates associated with sepsis nationally—three times as high as for heart attack patients—the centre is now focused on early identification and treatment of the condition and using the HSMR to monitor improvements over time.

"The HSMR was instrumental in providing us with a key starting point to assess our mortality rates."

— Barbara Kendrick, Director of Quality and Planning,

Southlake Regional Health Centre (Newmarket, Ontario)

difference data makes



Identification of Medication Safety Indicators in Acute Care Settings for Public Reporting in Ontario

Roger Cheng, Lindsay Yoo, Certina Ho and Medina Kadija

Abstract

In healthcare settings, indicators are useful tools to assess the structure, process and outcomes of care. Moreover, when used to report to the public, indicators ensure greater transparency for our healthcare system.

The purpose of this study was to identify in acute care settings three medication safety indicators that are suitable for public reporting in Ontario. A multi-phase process was developed that included a literature review, compilation and evaluation of possible indicators and a consensus-generation process involving a focus group (modified nominal group technique) with Ontario healthcare experts from various disciplines.

More than 300 potential medication safety indicators were identified through the literature review. Two analysts, working independently and using a defined set of selection criteria, narrowed the focus to 49 and subsequently 12 candidate indicators. A focus group of leading experts across the healthcare fields in Ontario was convened and reached consensus on three indicators. These three indicators focused on the areas of venous thromboembolism prevention, acute myocardial infarction discharge medications and medication reconciliation.

This report describes a multi-phase process undertaken by the Institute for Safe Medication Practices Canada to identify in acute care settings three medication safety indicators suitable for public reporting in Ontario. These indicators point to important areas in medication safety at which deficiencies can result in significant patient harm. There is a potential for these indicators to provide hospitals and healthcare providers with tangible and realistic mechanisms for measuring performance and, ultimately, improving the quality of care.

ndicators are measures that describe particular aspects of a system. They can be used to assess what happens to patients as a result of how well clinicians and organizational systems function to address the needs of patients. Monitoring performance over time, benchmarking and prioritization of activities are some of the ways that indicators allow for continuous quality improvement (Mainz 2003).

Indicators also serve as accountability tools to stakeholders; when used to report to the public, indicators can contribute to greater transparency in healthcare. Although indicators are critical to improving the quality and appropriateness of care, they are not direct measures of quality and are not meant to be definitive or diagnostic of a system. They do not necessarily encompass every aspect of the system they measure, which necessitates the need for investigation and analysis of the results in order to understand the context of the particular indicator within the institution's system. However, indicators can act as an initial step in improving quality of care by shedding light on general areas that warrant additional attention (Pencheon et al. 2008).

This article describes the process used by the Institute for Safe Medication Practices Canada (ISMP Canada) to identify

medication safety indicators in acute care settings for public reporting to be recommended to the Ontario Ministry of Health and Long-Term Care (MOHLTC). In 2002, ISMP Canada and MOHLTC collaborated to create the Medication Safety Support Service (MSSS), a multidisciplinary advisory committee of representatives from the provincial professional colleges and association of medicine, nursing and pharmacy, as well as the Ontario Hospital Association. Since its formation, MSSS has undertaken a number of medication safety projects and has made recommendations for systems-based enhancements in the handling of concentrated electrolytes, opioids and anticoagulants. The development of medication safety indicators is therefore, in many respects, a natural outgrowth of the expertise and mandate of MSSS.

Medication Safety Indicators

Indicators of medication safety are an important subset of healthcare indicators. In the context of this project, medication safety refers to two aspects: The first is to ensure that patients are ordered the most appropriate pharmacological treatment plan based on the best available evidence. The second is to ensure that the treatment plan is carried out as ordered. This is consistent with the position that "achieving safer care has three agendas, all of which are necessary for success: identifying what works (efficacy), ensuring that the patient receives it (appropriate use), and delivering it flawlessly (no errors)" (Leape 2002: 504). Deficiencies in the first aspect of medication safety, such as the low rate of venous thromboembolism prophylaxis, have been the focus of both national and international patient safety initiatives and reports (Safer Healthcare Now! 2008; Shojania 2001). Likewise, deficiencies of the second aspect of medication safety, such as administration of a medication to the incorrect patient, are commonly known as medication errors and considered a key aspect of medication safety. The medication safety indicators selected in this project cover both aspects. They may be used to monitor and evaluate management, clinical and support functions that affect how safely and effectively medications are being used in our healthcare system (MacKinnon and McCaffrey 2004).

Like other aspects of healthcare, medication systems can be viewed as consisting of three factors: structures, processes and outcomes (Donabedian 2005). Monitoring these different aspects requires various types of indicators. Thus, the project focused upon developing the following:

Structure indicators or measures of the environment such as the hospital infrastructure or systems that impact medication use and safety. Such indicators are not directly linked to outcomes but can be helpful in guiding system improvements. They provide a snapshot of the organizational structure and the status of the organization's activities in a

- particular area of interest, such as whether or not an organization has a process for medication error reporting and analysis (New South Wales Therapeutic Advisory Group 2007).
- Process indicators or measures of compliance with processes of care – these have been shown to improve health outcomes. Process indicators may be directly linked to outcomes (e.g., pre-surgical antibiotic or anticoagulation prophylaxis) and can be helpful in guiding system-based improvements.
- Outcome indicators or data related to the outcomes of care or health system performance - such as the proportion of medication incidents that result in harm or death. Outcome indicators may be easy for the general public to understand but may not provide information that is sufficiently specific to guide system-based improvements.

Methods

To identify medication safety indicators, ISMP Canada undertook a multi-phase research and development process consistent with indicator development processes described by both Canadian and international bodies (Agency for Healthcare Research and Quality 2006; Canadian Institute for Health Information 2003; New South Wales Therapeutic Advisory Group 2007). Phases consisted of the following:

- 1. Literature review
- 2. Development of a set of indicator-selection criteria
- 3. Extraction of medication safety indicators from the literature
- 4. Use of the selection criteria to, through two screening rounds, narrow down the list to 12 candidate indicators
- 5. By means of a focus group of experts, reaching consensus on the three most appropriate indicators to be recommended for public reporting

The results of this process were then communicated to the Ontario MOHLTC and the participants by means of a final report.

Phase One: Literature Review

Using a set of search terms, Medline, Embase and Google databases were searched for national and international work on the subject of medication safety indicators. In addition, the reference sections of articles were manually reviewed and a number of healthcare and patient safety organizations (e.g., the Institute for Health Improvement, Accreditation Canada, the Canadian Institute for Health Information and the Canadian Patient Safety Institute) were consulted for reports and grey literature. Indicator manuals from other institutions were also included in the literature review, such as those from the New South Wales Therapeutic Advisory Group.

The search retrieved more than 100 domestic and international journal articles, studies and reports. All resources were printed and compiled for extraction of medication safety indicators.

Phase Two: Development of Selection Criteria

Selection criteria previously used in the development of medication safety indicators were consulted (Agency for Healthcare Research and Quality 2006; Canadian Institute for Health Information 2003; MOHLTC 2009; New South Wales Therapeutic Advisory Group 2007). Selection criteria that were developed were as follows:

- The indicator aligns with current or emerging medication and patient safety initiatives in Ontario and/or Canada (e.g., Accreditation Canada 2009; Safer Healthcare Now! 2007a, 2007b, 2007c, 2008).
- The data required for the indicator are readily available for the settings and time periods required, with no unreasonable obstacles or constraints on access, and the information can be used without restrictions.
- The indicator appears to measure what is intended (i.e., it has face validity), is accepted by the healthcare community, covers relevant content or domains and has predictive power.
- The information being collected can be used to inform and influence policy or funding or alter the behaviour of health services providers.
- The indicator can be readily interpreted, and the intended audience (in this case, the general public) can generally understand the implications if the value changes.
- There is evidence that the highlighted practice can result in improved outcomes (i.e., the indicator is evidence based).

Phase Three: Extraction of Indicators from the Literature

Two analysts independently extracted medication safety indicators from the retrieved literature; as well, a small number of indicators were created by the analysts to reflect important aspects of medication safety. More than 300 potential indicators were identified and, using the above selection criteria, submitted to two rounds of analysis and screening.

Phase Four: Narrowing Down to 12 Candidate Indicators

In the first round of screening, the goal was to reduce the list of indicators by quickly excluding those that clearly did not meet the selection criteria. The two analysts worked independently and, when finished, compared results and discussed and resolved discrepancies. Through this process, the list was reduced to 49 indicators. The 49 indicators were subjected to a second round of evaluation by the analysts, at the end of which 12 (four each for structure, process and outcome) indicators were identified as the most promising. Table 1 summarizes the

12 candidate indicators and shows the rationale for including them, how they align with other medication safety indicators or recommendations and their limitations.

The four structural candidate indicators looked at whether organizations had adopted policies or procedures to reduce the risk of harm from two classes of high-risk medications -concentrated electrolytes and narcotics; had a policy and process for reporting and analyzing medication incidents; and had conducted at least one medication safety-related analysis per year. All four of these indicators were essentially dichotomous (yes/no), although it was also possible to determine the percentage of units in a facility in which concentrated electrolyte (i.e., concentrated potassium) vials were available.

The four process indicators were as follows:

- Proportion of patients with acute myocardial infarction (AMI) discharged with appropriate (secondary prevention) medications
- Proportion of patients for whom medication reconciliation was conducted upon admission to hospital
- Proportion of selected surgical patients who were given antibiotic prophylaxis
- Proportion of selected surgical patients who were given prophylaxis anticoagulation to prevent venous thromboembolism (VTE)

The four outcome indicators were as follows:

- A list of the 10 medications most frequently associated with harm or death medication incidents (as previously reported by ISMP Canada [2006])
- A breakdown of the frequency of different types of medication incidents, such as incidents resulting in harm or in death (as previously reported by the Ontario Health Quality Council [2009])
- The proportion of medication incidents that result in harm or death per days of patient care
- The proportion of total deaths in Ontario associated with medication incidents, suggested by data from the Office of the Chief Coroner for Ontario

Phase Five: Generating Consensus on Three **Indicators for Public Reporting**

An expert focus group of 17 individuals was created consisting of representatives from MOHLTC, the Ontario Health Quality Council, hospitals from across the province and community pharmacy. The individuals of this group are familiar with the mandate of ISMP Canada and had attended at least one medication safety workshop or seminar held by ISMP Canada; as such, they were consulted for their participation in this endeavour. Table 2 provides a more detailed summary of the membership of this expert focus group. Using a modified nominal group

Table 1. Twelve candidate medication safety indicators

Type of Indicator	Indicator	Description	Rationale	Alignment	Limitations
Structure	Concentrated electrolytes	Concentrated electrolytes (concentrated potassium chloride, potassium phosphate and sodium chloride >0.9%) are removed from patient care areas (yes/no) (percentage of patient care areas where concentrated potassium vials are available)	Numerous case reports worldwide of patient deaths from accidental intravenous administration of concentrated potassium chloride (Joint Commission 1998)	Accreditation Canada (2009) ROP WHO Joint Commission (2009) NSW Therapeutic Advisory Group (2007)	Evidence from case reports only
Structure	Narcotic safety	Three criteria: 1. Removal of hydromorphone ampoules or vials with concentration >2 mg/mL (except palliative care) (yes/no) 2. Removal of morphine ampoules or vials with concentrations >15 mg/ mL (yes/no) 3. Standardization and limitation of the number of parenteral narcotic (opioid) concentrations available (yes/no)	Case reports of patient harm and death from narcotic (opioid) medication mix-ups (ISMP Canada 2006)	Accreditation Canada (2009) ROP	Evidence from case reports only
Structure	Incident reporting and analysis	Organization has a policy and process for reporting and analyzing medication incidents (yes/no)	Growing realization that most healthcare errors reflect systemic weaknesses and often have root causes that can be generalized and corrected (World Alliance for Patient Safety 2005); learning from other high-performance industries such as aviation	Accreditation Canada (2009) WHO (World Alliance for Patient Safety 2005)	Does not measure the quality of the reporting and analysis process
Structure	Prospective medication safety analysis	Organization conducts at least one medication safety- related analysis per year (yes/no)	Prospective analysis helps to create a culture of safety by ensuring proactive reviews and improvements to prevent the occurrence of an adverse event (Accreditation Canada 2009)	Accreditation Canada (2009) ROP	Does not measure the quality of an analysis
Process	AMI discharge medications	Proportion of patients with AMI who are discharged with appropriate medications (defined as ASA, beta-blocker, ACEI or ARB anti-hypertensive, and statin)	Multiple randomized controlled trials have established the efficacy of ASA, beta-blockers, ACEIs/ARBs and statins for secondary prevention of AMI; yet, many patients with AMI are not discharged on appropriate medications (Safer Healthcare Now! 2007a)	Safer Healthcare Now! (2007a) IHI (n.d.) NSW Therapeutic Advisory Group (2007)	Only appropriate for acute care hospitals; does not apply to long-term care

Type of Indicator	Indicator	Description	Rationale	Alignment	Limitations
Process	Medication reconciliation	Proportion of patients who are subject to medication reconciliation upon admission	Errors at patient transition points have been identified as a significant source of medication incidents; multiple studies have shown that medication reconciliation reduces unintended medication discrepancies with potential for harm (Kwan et al. 2007; Nigram et al. 2008; Safer Healthcare Now! 2007b)	Safer Healthcare Now! (2007b) IHI (n.d.) NSW Therapeutic Advisory Group (2007) WHO Joint Commission Canadian safety indicators for medication use (Nigram et al. 2008)	Does not provide information regarding quality of the best possible medication history and medication reconciliation
Process	Antibiotic prophylaxis for surgery	Proportion of select surgical patients (coronary artery bypass graft, cardiac surgery, hip arthroplasty, knee arthroplasty, hysterectomy and vascular surgery) who receive prophylactic antibiotics	Surgical-site infections are the second most common type of adverse events occurring among hospitalized patients in the United States; extensive clinical evidence supporting the use of antibiotic prophylaxis administered in a timely manner for the prevention of surgical-site infections (Safer Healthcare Now! 2007c)	Safer Healthcare Now! (2007c) IHI (n.d.) NSW Therapeutic Advisory Group (2007) WHO Surgical Safety Checklist (2009)	Does not measure the appropriateness of the antibiotic selected Is not applicable to longterm care settings
Process	VTE prevention	Proportion of at-risk or eligible patients (undergoing major general or hip fracture surgery) who receive thromboprophylaxis (Safer Healthcare Now! 2008)	Thromboprophylaxis has been shown to reduce symptomatic and fatal VTE, as well as reducing all-cause mortality, while at the same time decreasing healthcare costs; e.g., comprehensive analysis of patient safety practices by the Agency for Health Research and Quality considered the appropriate use of thromboprophylaxis the highest-ranked patient safety practice for hospitals (Shojania et al. 2001)	Safer Healthcare Now! (2008) IHI (n.d.) NSW Therapeutic Advisory Group (2007) ISMP Canada anticoagulant project (2007)	Not applicable to long- term care settings
Outcome	Top 10 medications	List of top 10 medications associated with harm or death medication incidents	Informs the public about the medications most frequently associated with reported medication incidents with harm or death (ISMP Canada 2006)	Ontario Health Quality Council (2009) Reports from major US and UK patient safety organizations (Medmarx 2010; National Patient Safety Agency 2008)	Ouantitative data based on voluntary reporting, so cannot establish data reliability or validity Frequency of medication incidents may be related to how often or commonly a medication is used
Outcome	Medication incident types – harm or death incidents	Frequency of medication incidents resulting in harm or death, categorized according to the type of incident (e.g., incorrect dose, incorrect medication, incorrect patient etc.)	Informs the public about the types of medications and medication incidents most frequently associated with harm or death	Ontario Health Quality Council (2009) Reports from patient safety organizations such as National Patient Safety Agency (2008) and Medmarx (2010)	Ouantitative data based on voluntary reporting, so cannot establish data reliability or validity Frequency of incident types may be related to different reporting practices among different healthcare disciplines

Type of Indicator	Indicator	Description	Rationale	Alignment	Limitations
Outcome	Medication incident rates – harm or death incidents	Proportion of medication incidents that result in harm or death per days of patient care	Direct medication safety outcome measure and one that is easy for the public to understand	IHI (n.d.)	May lead to comparison of voluntary reporting incident rates, a step that is not supported by ISMP Canada because of data quality issues inherent to voluntary systems Definition of harm may differ between hospitals. and there is no means of establishing reliability or validity of quantitative data; such an indicator could be more feasible if there were a province-wide, standardized mandatory medication incident reporting system
Outcome	Deaths associated with medication incidents	Proportion of total deaths in Ontario that are associated with medication incidents	Derived from reliable quantitative data, as opposed to voluntary reporting, and is independent of hospital safety culture and incident reporting systems Informs the public about the number of deaths associated with medication incidents in relation to common causes of death; can be easy for the public to understand: a landmark Institute of Medicine report compared the estimated annual deaths due to preventable medical mistakes with other common causes of death (breast cancer, car accidents, HIV infections) (Kohn et al. 1999)	Institute of Medicine (n.d.)	Does not provide information about medication incidents of lesser severity (e.g., harm or near misses) Implementation requires coordination with the Office of the Chief Corone for Ontario

ACEI = angiotensin-converting enzyme inhibitor; AMI = acute myocardial infarction; ARB = angiotensin receptor blocker; ASA = acetylsalicylic acid; HIV = human immunodeficiency virus; IHI = Institute for Healthcare Improvement; ISMP = Institute for Safe Medication Practices; NSW = New South Wales; ROP = required organizational practice; VTE = venous thromboembolism; WHO = World Health Organization.

technique (Jones and Hunter 1995), participants were provided with information about the 12 candidate indicators (detailed description, rationale, alignment with other indicators or measures and limitations) and then divided into seven small groups of two to three participants per group for discussion. Groups then voted for the three medication safety indicators of their choice, after which participants described the rationale of their selections; this was followed by further discussion and debate. A second round of voting was then held to make the final selection of three indicators. Focus group discussions were also recorded, transcribed and subjected to thematic analysis.

Results

By the end of the second round of voting, the indicators that received the most votes were all process indicators: AMI discharge medications and VTE prophylaxis were unanimously selected by all seven small groups, and medication reconciliation was selected by five groups. The expert panel also supported to a lesser extent the outcome indicator of the number of deaths associated with medication incidents, but due to the low level of support (two votes) it was not included in the final list of three medication safety indicators.

Thematic analysis of the focus group discussion notes revealed

Table 2. Demographics of the expert focus group participants

Characteristic	Directors of Pharmacy n = 9 (%)	Medication Safety Specialists n = 3 (%)	Health Policy, Research and Analysis n = 4 (%)	Pharmacy Marketing and Management n = 1 (%)	Total N = 17 (%)
Gender					
Male	2 (22)	_	1 (25)	1 (100)	4 (24)
Female	7 (78)	3 (100)	3 (75)	_	13 (76)
Practice setting					
Hospital	9 (100)	3 (100)	_	_	12 (70)
Provincial Ministry of Health and Long-Term Care	-	_	3 (75)	_	3 (18)
Provincial Health Quality Organization	-	-	1 (25)	_	1 (6)
Community pharmacy	-	-	-	1 (100)	1 (6)

some of the issues that shaped the final selections. First, there was considerable discussion about the fundamental objective of the indicators: whether they should be designed to promote healthcare system accountability or to increase public awareness of medication safety. The group's decision was that indicators should be developed that primarily support healthcare accountability, although consideration should also be given to their suitability for sharing with the public (that is, public reporting).

In the case of the process indicators (AMI discharge medications, pre-surgical antibiotic and anticoagulant prophylaxis and medication reconciliation), it was clear from the comments of the panel members that considerable clinical evidence of effectiveness gave the indicators not only validity but also perceived potential to promote beneficial change. Moreover, as many institutions are already tracking some of these indicators (e.g., pre-surgical anticoagulant prophylaxis), gathering data for public reporting was seen as highly feasible. At the same time, one group felt that, at least in the case of surgical prophylaxis, the interventions were already largely integrated into standard practices and so the potential for change would be limited. This group argued that there might be greater benefit if indicators focused upon areas where there is less adaptation of best practices and therefore a greater need for improvement.

Medication reconciliation was recognized to be somewhat different from the other three process indicators in that it addresses overall system integration as opposed to a specific clinical practice. Its relationship to system integration was

considered a significant challenge in healthcare by some participants. Other participants, however, felt that although medication reconciliation is important, it may not be as strongly linked to patient outcomes or impact compared with the other three process indicators (in the short list of 12 indicators).

There are also methodological challenges in creating a medication reconciliation indicator. Clear and feasible definitions must be created for both the numerator and denominator. and data need to be captured in a consistent manner. Ensuring comparability in medication reconciliation rates between hospitals could be difficult as different institutions may have varying criteria for determining which patients are appropriate candidates or how reconciliation is conducted. As a result, some participants suggested that medication reconciliation should be considered a "stretch goal" that healthcare could work toward and that could be used to dialogue with the public.

Although there was a general consensus in the group that the four candidate structure indicators (removal of concentrated electrolytes, narcotic safety, incident reporting system and prospective analysis) were important in terms of patient safety and accountability, participants were uncertain as to whether they would be appropriate for public reporting. The challenge for these indicators is that their significance may not be readily apparent to the public. For instance, the indicator of removing concentrated electrolytes would require explanations of what is meant by "concentrated electrolytes," what sort of risk they pose and how their removal from some settings can address patient safety.

A second issue raised by the structural indicators concerned the ability of the dichotomous structure indicators (yes/no) to track improvement in individual hospitals over time. In other words, if an institution was able to answer "yes" to an indicator, would there be benefit in repeating the question? One suggestion was to create a composite indicator so that the progress of individual hospitals in meeting all four indicators could be tracked over time.

The outcome indicators identified through the literature search and analysis (list of top 10 medications associated with medication incidents resulting in harm or death, types and rates of medication incidents and deaths associated with medication errors) were seen as having the advantage of being easy for the general public to understand. However, methodological and data limitations (see Table 1) were seen as potential challenges, particularly those limitations associated with voluntary medication incident reporting systems.

Discussion

Our review of literature identified more than 100 journal articles from which more than 300 potential medication safety indicators were extracted. This indicates a substantial body of work already done in this area. However, although most of the articles provided a final list of indicators, very few of them provided information regarding the rationale for their selection and the discussions involved in making these selections. By presenting the final indicators that were chosen as well as a thematic analysis of the focus group discussion, the results of this project provide insight to the rationale for each indicator selection, as well as some of the anticipated difficulties and challenges toward their implementation in healthcare organizations.

A limitation of the methodology used in this project expressed by a number of focus group members was that they were presented with only 12 candidate indicators (out of over 300) for consideration, and that there were no modifications to or addition of indicators after the first round of voting. Some members wondered if there were other suitable indicators beyond the 12 candidate indicators, especially from the 49 indicators after round one of screening. Some suggested that it would have been beneficial to have had an additional focus group meeting at an earlier stage of screening. To address this limitation, the list of 49 candidate indicators was subsequently provided to each of the focus group members after the meeting. Further feedback was then obtained, and it was clear that the final selections remained the same. Although the objective of this initiative was to identify three medication safety indicators for public reporting, the value of the 12 candidate indicators that were initially presented to the focus group should not be overlooked. Many of the experts within the focus group had recognized their role and importance within the healthcare system, and it was only after extensive deliberations that

consensus on the three indicators was achieved. These additional indicators merit further analysis and may provide the basis for subsequent research opportunities.

Conclusion

This report describes a multi-phase process undertaken by ISMP Canada to identify a small number of indicators of medication safety for Ontario that would be informative, aligned with current patient safety initiatives, of acceptable quality (valid and reliable), actionable, understandable by the intended audience including the general public, evidence based and feasible for data collection. The indicators that were selected (AMI discharge medications, VTE prophylaxis and medication reconciliation) are evidence based and can be derived from existing and reliable hospital data. They point to important areas in the healthcare system in which deficiencies can result in significant patient harm, and they thus have the potential to provide hospitals and healthcare providers with tangible and realistic mechanisms for measuring performance and improving the quality of care. Moreover, if clearly defined and communicated with appropriate explanations, they should be understandable by the public, thereby increasing public awareness of the importance of medication safety. HQ

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National Analysis of Sepsis Hospitalizations and Factors Contributing to Sepsis In-Hospital Mortality in Canada

Liudmila Husak, Annette Marcuzzi, Jeremy Herring, Eugene Wen, Ling Yin, Dragos Daniel Capan and Geta Cernat

Abstract

Sepsis is one of the leading causes of in-hospital mortality in Canada. Patient safety is an important component of sepsis prevention and control. The Canadian Institute for Health Information recently released a report that examines a national picture of sepsis hospitalizations and mortality. This article highlights and expands some of the key findings from this report. Specifically, we look here more closely at patients admitted through the emergency departments (ED) in order to determine if earlier recognition of sepsis in the ED would lead to improved patient outcomes.

epsis is a leading cause of mortality; at 30–50%, the mortality rate associated with sepsis is markedly high (Surviving Sepsis Campaign 2008). A prospective observational study of 12 Canadian community and teaching hospital critical care units found that mortality for patients with severe sepsis was slightly over 38% (Martin et al. 2009). Additionally, the personal and economic costs associated with sepsis are high. With more than 18 million cases of severe sepsis worldwide each year, the disease is linked to increased hospital resource use and prolonged stays in intensive care units (ICUs) (Angus et al. 2001; Surviving Sepsis Campaign 2008).

Sepsis is a complex syndrome that is difficult to define. It is also difficult to diagnose because there is no "typical presen-

tation"; the signs and symptoms are highly variable. In the medical community, definitions of sepsis have been developed and subsequently rethought due to both advances in the understanding of the condition and the introduction of potential new therapies (Levy et al. 2003; Members of the American College of Chest Physicians et al. 1992).

So, what is sepsis? It is the clinical syndrome defined by the presence of both whole-body infection and a systemic inflammatory response (Levy et al. 2003). When sepsis is complicated by organ dysfunction in at least one body system, it is referred to as severe sepsis. Septic shock occurs when severe sepsis is made worse by a state of acute circulatory failure. It is characterized by persistent arterial hypotension that is unexplained by other causes, and occurs despite adequate volume resuscitation.

A 2009 report by the Canadian Institute for Health Information (CIHI) provides a national picture of sepsis hospitalizations and mortality. This is the first time that the number of sepsis hospitalizations, mortality rate and characteristics of patients with sepsis have been captured for acute care hospitals at the national level. After the report was published, the scope of the sepsis study was expanded to look more closely at patients admitted through the emergency departments (EDs). Patients with sepsis were tracked prior to their admission to hospital in order to determine if earlier recognition of sepsis in the ED would have led to improved patient outcomes.

Methods

CIHI's Discharge Abstract Database (DAD) was used to conduct data analyses. Hospitalizations with a discharge date between April 1, 2004, and March 31, 2009, were selected. Due to the differences in data collection, Quebec data were not included.

The unit of analysis was one hospitalization – that is, one episode of care. To account for transfers from one acute hospital to another, individual abstracts were combined to build episodes of care or hospitalizations. A transfer was assumed to have occurred if admission to an acute care institution occurred on the same day or prior to discharge from the preceding acute care institution.

Data on ED visits were extracted from the National Ambulatory Care Reporting System (NACRS) for the period from April 1, 2008, to March 31, 2009. This study was focused on Ontario emergency data from NACRS.

Patients with sepsis or severe sepsis were identified using specific codes from the International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Canada (ICD-10-CA), and the Canadian Classification of Health Interventions (CCI) (see Appendix 1). The number of pre-existing co-morbidities (having impact on patients' treatment and length of stay) was determined using the Charlson Index Score (Quan et al. 2005). The co-morbid conditions coded as type M, 1, W, X and Y (not type 2 on the same abstract) were used to calculate the Charlson Index Score for the first sepsis admission. Patients were considered admitted to an ICU if an ICU stay was recorded in the DAD at any time during the episode of care. Patients were considered directly admitted to an ICU from the ED if the discharge disposition on

Figure 1. Sepsis hospitalization rates, Canada 120 Age Standardized Rate per 100,000 Population 100 103.2 101.9 101.7 99.6 98.9 80 67.9 60 65.7 64.8 63.9 63.5 40 39.7 37.1 34.9 33.7 34.0 20 2004-2005 2005-2006 2006-2007 2007-2008 2008-2009 Sepsis Severe sepsis Non-severe sepsis Source: Discharge Abstract Database, Canadian Institute for Health Information

their NACRS record was recorded as 5. Specific criteria based on diagnosis typing were used to determine if sepsis occurred before or after admission to hospital (Canadian Institute for Health Information 2009: 14).

Results

Sepsis Hospitalizations and Characteristics of

In 2008–2009, a total of 30,587 sepsis hospitalizations were observed in Canada (outside Quebec), up from 26,803 hospitalizations in 2004–2005. In 4.0% of patients, sepsis occurred more than once in a year. Severe sepsis was observed in 39.4%, or 12,063, of all sepsis hospitalizations.

While hospitalization rates for all sepsis remained similar from 2004–2005 to 2008–2009 (p = .41), hospitalization rates for severe sepsis increased by 17.8% (p = .01), after population growth and aging were taken into consideration (Figure 1).

Older adults and young children accounted for the majority of sepsis cases. Patients who were 60 and older comprised 60.6% of all sepsis hospitalizations in 2008–2009. The median age of patients with sepsis was 66. Among patients with sepsis, there were more men than women: 54.6% of patients were men.

Patients with sepsis tended to have more pre-existing co-morbidities than did patients hospitalized for other reasons (Table 1). At least one pre-existing co-morbidity was recorded in 44.5% of patients with sepsis, as opposed to 23.1% of other patients. The most frequent co-morbidities in patients with sepsis were diabetes and cancer.

The majority (79%) of patients with sepsis were admitted

via the EDs, while 12.4% were admitted directly, 6.6% were newborns and 2% came either from clinics or day-surgery centres of the reporting facilities. Most of patients who survived sepsis were discharged home (56.4%). About 21.1% of patients with sepsis were discharged to home settings with external support, and 15.8% went to continuing care facilities.

Among patients with severe sepsis, the majority (62.6%) had one system affected by organ dysfunction (Table 2). The respiratory system was the most commonly affected, followed by the renal and cardiovascular systems.

Sepsis Mortality

In 2008-2009, 9,320 patients with sepsis died in hospitals across Canada (outside Quebec), which represented 10.9% of all deaths occurring in hospitals. The crude mortality for all patients with sepsis was 30.5% in 2008-2009 (45.2% for patients with severe sepsis and 20.9% for patients whose sepsis did not progress to severe).

Table 1. Charlson Index Score, 2008-2009

Charlson Index Score	Among Patients with Sepsis (%)	Among All Other Hospitalizations (%)	
0	55.5	76.9	
1 or 2	30.4	18.4	
3 or more	14.1	4.7	

Source: Discharge Abstract Database, Canadian Institute for Health Information.

Table 2. Acute organ failure in patients with severe sepsis, 2008-2009

Number of Systems Failing	Percent Occurrence	Percent Mortality (95% CI)
1	62.6	39.1 (38.0–40.2)
2	27.1	52.8 (51.1–54.5)
3 or more	10.3	62.0 (59.3–64.7)
Organ System*	Percent Occurrence	Percent Mortality (95% CI)
Respiratory	54.5	48.3 (47.1–49.6)
Renal	51.6	49.9 (48.7–51.1)
Cardiovascular	19.8	45.8 (43.8–47.8)
Hepatic	4.9	70.0 (66.2–73.7)
Hematological	9.4	51.4 (48.5–54.3)
Central nervous	9.9	44.7 (41.9–47.5)

CI = confidence interval

Source: Discharge Abstract Database, Canadian Institute for Health Information.

Some patients with sepsis were more likely to die than others. Older age, female gender, the presence of pre-admission co-morbidities, severe sepsis and sepsis that occurred after admission to hospital were associated with significantly higher odds of dying in patients with sepsis (Table 3).

There were no significant changes in risk-adjusted sepsis mortality rates over the five years (p = .11; Figure 2). Rates were adjusted using a logistic regression model for age, gender, Charlson Index Score and sepsis occurring after admission as covariates.

Hospital Care

The median total length of hospital stay for patients with sepsis was 12 days in 2008–2009 - approximately nine days longer than the median length of stay due to other reasons (Table 4). Furthermore, patients with severe sepsis stayed in hospital about 11 days longer than patients whose sepsis was not severe.

About 45.1% of all patients with sepsis and about 57.3% of patients with sepsis who died had stayed in ICUs (Table 5). The median length of an ICU stay for patients with sepsis in 2008-2009 was 6.3 days - about four days longer than the ICU stay of patients admitted for other reasons. Patients with severe sepsis were 2.6 times more likely to be admitted to the ICU and stayed there about six days longer than patients whose sepsis was not severe.

Early Recognition of Sepsis and Its Effect on Patient Outcomes: An **Analysis of Ontario ED Data**

Early recognition and consistent implementation of evidence-based bundles of care have been shown to improve outcomes for patients with sepsis (Levy et al. 2010). In this analysis of Ontario 2008-2009 NACRS data, the existing study cohort was tracked prior to in-hospital sepsis admission. Data on ED visits that occurred on the same day as in-hospital sepsis admission was used to determine if sepsis was recognized in the EDs and how it affected patient outcomes.

A total of 16,152 patients (52.8% of the existing sepsis cohort) were treated in Ontario acute care hospitals. Of these, 12,508 (77.4%) had an ED visit that took place on the same day prior to in-hospital admission. For the majority of patients (10,173 [81.3%]), sepsis was identified as occurring before admission to the hospital. These patients comprised a

cohort for further analyses as they may have already presented signs and symptoms of sepsis in the ED.

The majority of hospitalized patients with sepsis did not receive a sepsis diagnosis in the ED. Out of the cohort of 10,173 patients identified as having sepsis prior to admission, only 2,688 (26.4%) had sepsis identified and recorded on their ED chart during their ED visit. For patients where sepsis was not identified on the ED chart, various conditions were listed as main problems (Table 6).

Patients for whom sepsis was identified in the ED experi-

^{*}Each system was counted independently.

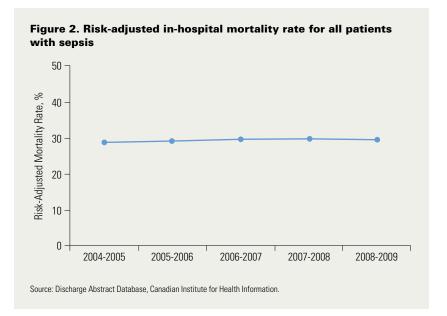


Table 3. Factors affecting sepsis mortality in hospital*

	Odds Ratio	95% CI
Age (each additional year)	1.034	1.033-1.034
Women compared with men	1.08	1.05–1.11
Charlson Index Score (compared with no Charlson Index co-morbidities)		
1 or 2	1.38	1.34–1.42
3 or more	2.28	2.20–2.36
Severe sepsis compared with non-severe	3.01	2.93–3.09
Sepsis occurring after admission compared with sepsis pre-admission	1.56	1.51–1.60

*For patients admitted to acute hospitals outside of Quebec between April 2004 and March 2009. Source: Discharge Abstract Database, Canadian Institute for Health Information.

enced lower crude mortality than did patients for whom sepsis was not identified (29.1% versus 32.8%, respectively). A logistic regression model was applied to estimate whether the presence of sepsis in the ED chart was a significant predictor of a lower mortality rate, after adjusting for the effects of sex, age and the Charlson Index score. After adjustment, patients for whom sepsis was identified in the ED had lower odds of dying compared with

patients for whom sepsis was not identified in the ED (odds ratio [OR] = 0.88, 95% confidence interval [CI] 0.80-0.97).

There are several potential reasons for this finding. First, patients for whom sepsis was diagnosed in the ED were perhaps more promptly admitted – either to the hospital wards or to the ICU - because appropriate triage and disposition are key components of the sepsis treatment protocol (Nguyen et al. 2006). For example, an average length of stay in the ED for patients for whom sepsis was diagnosed in the ED was 5.6 hours, compared with 6.4 hours for patients for whom sepsis was not diagnosed. Furthermore, for patients admitted to an ICU directly who had sepsis on the ED chart, the ED length of stay was also shorter (5.0 hours compared with 5.4 hours for patients without sepsis on the ED chart).

Second, more patients for whom sepsis was diagnosed in the ED were admitted to the ICU directly: 29.2% versus 17.3% of patients for whom sepsis was not diagnosed (OR 2.02, 95% CI 1.82-2.24, after adjusting for age, sex and Charlson Index Score). Among patients admitted directly to an ICU, those for whom sepsis was recognized in the ED also experienced lower mortality (crude rates 33.8% versus 43.5%; OR 0.66, 95% CI 0.54-0.80).

Third, although administrative data do not capture the time between assessment and treatment, it is likely that if sepsis were recognized in the ED, then the appropriate management and treatment would start earlier (Nguyen et al. 2006). Implementation of the 2004 Surviving Sepsis Campaign guidelines have led hospitals to develop standardized ED protocols to prevent ICU admissions, if possible, and to improve outcomes of patients with sepsis in the ICU (Canadian Institute for Health Information 2009). Thus, subject to the accuracy of sepsis documentation in the ED, this study confirms that timely recognition and appropriate management of sepsis in the ED lead to improved patient outcomes.

Limitations

This study is subject to the limitations of the administrative database. First, the use of ICD-10-CA codes to identify sepsis cases is subject to the accuracy of documentation and coding. However, the codes selected to identify sepsis and severe sepsis in our study were used previously in the other sepsis studies that included administrative data (Angus et al. 2001; Dombrovskiy

Table 4. Median and mean total LOSs, 2008-2009

	Median LOS, Days (Mean)
All hospitalizations (excluding sepsis)	3 (6.80)
All sepsis	12 (25.9)
Severe sepsis	20 (37.6)
Non-severe sepsis	9 (18.3)

LOS = length of stay.

Source: Discharge Abstract Database, Canadian Institute for Health Information.

Table 5. ICU care, 2008-2009

	Percent Staying in the ICU	Median ICU LOS, Days (Mean)
All hospitalizations (excluding sepsis)	8.5	2.3 (4.7)
All sepsis	45.1	6.3 (14.2)
Severe sepsis	72.4	9.5 (18.2)
Non-severe sepsis	27.4	3.5 (7.5)

ICU = intensive care unit; LOS = length of stay.

Source: Discharge Abstract Database, Canadian Institute for Health Information.

et al. 2007; Martin et al. 2003). Martin et al. (2003) found, in the validation study, that using the codes from administrative databases to define sepsis resulted in acceptable predictive values. In addition, the distribution of the codes in our study did not substantially change over the study period (see Appendix 1, Table A1). Second, the DAD lacks data regarding the time of onset of specific conditions. Therefore, we could not determine whether the organ dysfunctions used to define severe sepsis occurred before or after an episode of sepsis. Despite these limitations, this study has the important advantage of being able to capture sepsis hospitalizations at the national level using a consistent approach.

Conclusion

Sepsis is an important contributor to in-hospital mortality and morbidity in Canada. Heightening the general awareness and understanding of national sepsis hospitalization and mortality rates is a key starting point. Sepsis care is clearly an important area for quality improvement efforts.

Lowering the numbers of those succumbing to this medical

Table 6. Top 10 conditions recorded as main problems

Main Problem	Number (%*)
Other disorders of urinary system	782 (10.4)
Pneumonia, organism unspecified	780 (10.4)
Fever of other and unknown origin	510 (6.8)
Abdominal and pelvic pain	230 (3.1)
Cellulitis	171 (2.3)
Other symptoms and signs involving cognitive functions and awareness	152 (2.0)
Heart failure	145 (1.9)
Malaise and fatigue	142 (1.9)
Other non-infective gastroenteritis and colitis	137 (1.8)
Acute renal failure	135 (1.8)
All other diagnoses	4,301 (57.5)

*Percentage of total number of patients in sepsis cohort without sepsis on emergency department chart.

Source: National Ambulatory Care Reporting System, Canadian Institute for Health Information.

condition can be a challenge as sepsis is difficult to diagnose and treat. But with early recognition of the signs and symptoms of sepsis, together with a more consistent implementation of care guidelines, the high mortality associated with sepsis can be reduced and lives can be saved. HQ

Appendix 1: Algorithms Used To Identify Patients with Sepsis and Severe Sepsis in the DAD

Patients with *sepsis* were identified in the DAD by using the ICD-10-CA codes presented in Table A1. The codes were selected based on the previous studies (Martin et al. 2003; Dombrovskiy et al. 2007), with input from classification specialists. The equivalent International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes were previously validated by Martin et al. (2003). The distribution of the codes was stable over the study period (see Table A1). Diagnosis types M, 1, 2, W, X or Y were used. Diagnosis type 3 (excluding cases where sepsis was one of the P.- codes) was only used if the following diagnoses were present on the same abstract as types M, 1, 2, W, X or Y: T80.2, T81.4, T88.0,

Table A1. ICD-10-CA codes used to identify patients with sepsis in the Discharge Abstract Database

ICD 10 CA	ICD-10-CA Codes* Description		Percentage of Codes among Sepsis Cases				
100 100			2005–2006	2006–2007	2007–2008	2008–2009	
A03.9	Shigellosis, unspecified	0.05	0.07	0.04	0.07	0.08	
A02.1	Salmonella septicaemia	0.23	0.31	0.27	0.23	0.28	
A28.0	Pasteurellosis	0.06	0.08	0.07	0.04	0.05	
A32.7	Listerial septicaemia	0.09	0.10	0.11	0.07	0.22	
A39.2	Acute meningococcaemia	0.08	0.10	0.04	0.07	0.08	
A39.4	Meningococcaemia, unspecified	0.12	0.08	0.08	0.06	0.06	
A40	Streptococcal septicaemia	7.62	8.18	8.33	8.37	8.39	
A41.0	Septicaemia due to Staphylococcus aureus	9.07	9.08	8.95	9.13	9.05	
A41.1	Septicaemia due to other specified staphylococcus	5.41	5.28	4.64	4.54	4.31	
A41.2	Septicaemia due to unspecified staphylococcus	0.97	0.87	0.79	0.83	0.72	
A41.3	Septicaemia due to Haemophilus influenzae	0.31	0.36	0.32	0.31	0.30	
A41.4	Septicaemia due to anaerobes	0.55	0.47	0.44	0.50	0.49	
A41.50	Septicaemia due to Escherichia coli	9.99	10.56	10.16	10.52	10.84	
A41.51	Septicaemia due to <i>Pseudomonas</i>	1.68	1.89	1.92	1.66	1.85	
A41.52	Septicaemia due to Serratia	0.34	0.41	0.30	0.26	0.28	
A41.58	Septicaemia due to other gram-negative organisms	3.87	3.99	3.94	3.88	3.82	
A41.80	Septicaemia due to Enterococcus	2.70	2.65	2.50	2.53	2.78	
A41.88	Other specified septicaemia	4.56	4.64	4.48	4.26	4.26	
A41.9	Septicaemia, unspecified	40.64	40.26	42.17	42.93	43.36	
B00.7	Disseminated herpesviral disease	0.05	0.04	0.04	0.07	0.03	
B37.7	Candidal septicaemia	1.18	1.15	1.12	1.06	1.11	
P36	Bacterial sepsis of newborn	9.63	8.68	8.45	7.97	6.92	
P35.2	Congenital herpesviral [herpes simplex] infection	0.08	0.08	0.09	0.07	0.12	
P37.5	Neonatal candidiasis	0.7	0.6	0.66	0.52	0.55	

ICD-10-CA = International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Canada.

Source: Discharge Abstract Database, Canadian Institute for Health Information.

T82.6, T82.7, T83.5, T83.6, T84.5, T84.6, T84.7, T85.7, O03.0, O03.5, O04.0, O04.5, O05.0, O05.5, O07.3, O08.0, O75.3, O85.-, O98.2, O98.5 and O98.8; and type 9: Y60.- to Y89.-. In the analysis of NACRS data, patients were considered to have sepsis if the diagnosis codes in the Table A1 were coded as "main" or "other problems."

Severe sepsis (including septic shock) was defined as sepsis complicated by organ dysfunction in at least one of the six organ systems (Table A2). The codes were selected based on the previous studies (Angus et al. 2001; Dombrovskiy et al. 2007; Martin et al. 2003) and input from classification specialists. The ICD-10-CA codes, typed as M, 1, 2, W, X and Y, and CCI (with extent attribute = "EX") codes presented in Table A2 were used.

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^{*}Other ICD-10-CA codes that were included (A21.7, A22.7, A23.9, A24.1, A26.7, A28.2, A39.3, A42.7, P37.2) had less than five cases in a year and are therefore not presented. These cases comprised <0.1% of all sensis cases

Table A2. ICD-10-CA and CCI codes used to identify patients with severe sepsis in the Discharge Abstract **Database**

System	ICD-10-CA and CCI Codes	Description
Respiratory	J96.0 J96.9 J80 R09.2 1.GZ.31.CA-ND, 1.GZ.31.CR-ND, 1.GZ.31. GP-ND	Acute respiratory failure Respiratory failure, unspecified Adult respiratory distress syndrome Respiratory arrest Mechanical ventilation
Cardiovascular	R57 195.1 195.8 195.9	Shock Orthostatic hypotension Other hypotension Hypotension, unspecified
Renal	N17	Acute renal failure
Hepatic	K72.0 K72.9 K76.3	Acute and subacute hepatic failure Hepatic failure, unspecified Infarction of liver
Neurological	F05.0 F05.9 G93.1 G93.4 G93.80	Delirium not superimposed on dementia Delirium, unspecified Anoxic brain damage Encephalopathy, unspecified Metabolic encephalopathy
Hematological	D69.5 D69.6 D65	Secondary thrombocytopenia Thrombocytopenia, unspecified Disseminated intravascular coagulation

CCI = Canadian Classification of Health Interventions: ICD-10-CA = International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Canada

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Skin and Wound Care Excellence: Integrating Best-Practice Evidence

Karyn Popovich, Paula Tohm and Theresa Hurd

Abstract

North York General Hospital (NYGH), in collaboration with Nursing Practice Solutions, Smith & Nephew and the Central Community Care Access Centre, implemented a program in skin and wound care that has made best-practice. evidenced-based wound care management possible, affordable and sustainable. Focused action using advanced wound care products and proven clinical approaches has dramatically improved the identification, protection and support of skin integrity.

Wound prevention and management are among the most direct and cost-effective measures a healthcare organization can take to improve patient safety and quality of life, and they allow for the reduction of expenditures and re-allocation of funds into other important areas. The Skin and Wound Care Program was designed to create and maintain resources within NYGH to ensure the delivery of consistent, best-practice wound prevention and management. The program has successfully sustained a significant reduction in the prevalence of pressure ulcers. Benefits of the program include improved patient safety, health and quality of life.

The Skin and Wound Care Program has seen the transfer of knowledge and evidence-based best practices to both the bedside and the community. Extending the collaborative effort beyond the walls of NYGH has helped the hospital gain further insight into and experience with our community

partners to spread skin and wound best practices across the healthcare continuum. Lessons learned have been shared with other healthcare organizations in forums such as the Congress of the World Union of Wound Healing Societies, thus contributing to the advancement of continuous improvement in healthcare.

ressure ulcers, defined as ulcerations of the skin and/ or deeper tissues due to unrelieved pressure, currently affect one in four patients in Canadian healthcare organizations. Given this high prevalence rate, the prevention and proper treatment of pressure ulcers are of critical importance to the Canadian medical community. In addition, pressure ulcers represent a serious risk to patient safety and a growing litigation risk for healthcare workers. Chronic and debilitating wounds are common across all sectors of Canadian healthcare. For example, the prevalence of pressure ulcers is 26-31% in acute care, 28-31% in long-term care and 15% in the community (Woodbury and Houghton 2004).

As a multi-site teaching hospital, North York General Hospital (NYGH) continually strives to improve safety, quality of care and the overall patient experience through the use of evidence-based best practices. NYGH has collaborated with Nursing Practice Solutions – advanced practice nurses with wound experience and proficiency - Smith & Nephew and the Central Community Care Access Centre (Central CCAC) to implement a program in skin and wound care that has made best-practice, evidenced-based wound care prevention and management possible, affordable and sustainable.

The majority of pressure ulcers develop in patients in acute care centres; but regardless of whether these ulcers develop in patients in acute care, chronic care or at home, they have an impact. Along with estimated costs of over \$10 billion annually throughout North America (Swanson 1999), pressure ulcers represent a drain on healthcare resources and a major burden in terms of morbidity and reduced quality of life for patients of all ages. Discomfort, low self-esteem and poor body image can cause personal suffering. Osteomyelitis and life-threatening sepsis are associated major complications (Culley 1998). Pain, loss of function and mobility, amputations and death are further consequences of pressure ulcers (Lee 2005).

Currently, healthcare organizations in Ontario and other regions of Canada are under unremitting pressure to match available financial resources with the growing demands of healthcare. Similar to healthcare centres throughout Canada, at NYGH care requirements combined with persistent shortages of qualified clinical staff place an overriding constraint on the usage and allocation of hospital beds.

The increasing complexity and acuity of hospitalized patients, coupled with the aging population and the escalating incidence of chronic diseases, result in a continual escalation in healthcare challenges. Although often hidden and misunderstood, the human and financial costs of wound care, both to patients and healthcare organizations as a whole, are exorbitant. In spite of this, the assessment, protection and support of skin integrity are lost among the many priorities managed by healthcare providers. Skin care becomes a top concern only when the impact of wounds is considered with respect to infections, morality rates, quality of life, limb amputations, pain and healthcare costs. Hospital-acquired pressure ulceration represents a major failure in systems to secure patient safety and quality of care. A high proportion of pressure ulcers are avoidable with adequate risk assessment and pressure-relieving interventions such as regular turning.

A Southern Ontario Acute Care case study demonstrated that stage III pressure ulcers result in an average length of stay (LOS) of 18.8 days and a total cost of \$19,213. stage IV pressure ulcers necessitate an average LOS of 27.7 days and \$29,208 and stage X ulcers with bone and necrotic tissue involvement result in an average LOS of 73.1 days with a total cost of \$85,436 (Hurd et al. 2008).

The Situation at NYGH

A pressure ulcer prevalence study completed in May 2007 indicated that pressure ulcers were the most prevalent wound at NYGH, at 21%. In comparison, the national pressure ulcer prevalence rate in acute care was 24% (Woodbury 2004). A

2004 survey of available Canadian data found that pressure ulcer prevalence rates averaged 24-26% (Woodbury and Houghton 2005). Of these ulcers at NYGH, 89% were stage I or II. The 2007 audit also found seven pressure ulcers at stage III; the potential cost to manage these seven patients was estimated at \$277,400 and 249 excess bed days.

NYGH set a project benchmark for pressure ulcer prevalence at 10.5%, to achieve a 50% reduction in the first year. The project benchmark was tempered by comparisons with international data from Japan, which has a benchmark of 5.8% (Sanada et al. 2004), the United States, whose benchmark is 8% (Cuddigan et al. 2001), and Australia, which has a benchmark of 16% (European Pressure Ulcer Advisory Panel Prevalence Working Group 2002).

Given the detrimental impact of pressure ulcers, it is important to determine where these wounds originate. The 2007 prevalence study demonstrated that 82% of pressure ulcers seen at NYGH originated in our hospital. This is a key finding since many hospital-acquired pressure ulcers can be prevented through a consistent and rigorous application of best-practice standards. The proven effectiveness of prevention strategies, combined with the large number of preventable wounds at NYGH, suggested that a continued decrease in the overall wound prevalence rate was achievable.

At NYGH, the percentage of pressure ulcers that were infected was 7% and of surgical wound infections was 13%. The cost to treat these infections with antibiotics was averaged \$169 per patient for a 10-day regimen. The case-cost data from Southern Ontario identified the cost of treating resistant infections such as methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant enterococci (VRE): an MRSA infection has an LOS of 28.8 days with a cost per case of \$43,487, and a VRE infection has an LOS of 44.9 days with a total cost per case of \$85,435.

Another cost related to pressure ulcers involves the daily changing of dressings. At least 48 patients at NYGH had dressings changed daily. This amounted to 56 hours of nursing time per week or 1.4 full-time nurses per week. Reducing this to three times weekly saves 33 hours of nursing time per week, equal to 0.9 full-time nurses. Only 100 patient wounds treated with non-advanced dressings (gauze) can be treated in the same time as 230 patient wounds with advanced dressings.

It was also noted in the audit that there was no standardization in the prevention, assessment and treatment of skin and wounds. Nurses expressed minimal comfort with respect to their knowledge and abilities to direct skin and wound care. A clinical nurse specialist (CNS) was assigned to wound care, and there was a Skin and Wound Care Committee, with a nurse champion from each unit. However, the role of the CNS included the management of wounds and dressings or assisting nurses in dressing changes – little education was provided on skin and wound care. When surveyed, 100% of clinicians stated that they would benefit from training in wound care.

As a result of this baseline prevalence data, skin and wound care became patient safety and corporate priorities. NYGH, in a collaborative partnership with Nursing Practice Solutions, Smith & Nephew and the Central CCAC, implemented a system of innovation in skin and wound care that has made best-practice, evidenced-based wound care management possible, affordable and sustainable.

Implementation into Practice

The Skin and Wound Care Program was initiated to make the environment of care safer by developing and implementing a comprehensive and competency-based pressure ulcer prevention and management program using evidenced-based best practices. The application of best practices included protocols/procedures, decision supports, education, enhancing organizational culture, building effective teamwork and improving communication.

Securing the commitment and engagement of staff were critical for success. These were accomplished by concentrating on the need to enhance the overall quality and safety of the patient care experience. By applying Lean methodology, a vertical value stream was completed. Dedicated inter-professional clinicians, physicians and those who influence the process collaborated to use their collective knowledge to develop a project plan.

The necessity of patient safety improvements surrounding a common goal provides an opportunity for teamwork and cohesion across systems and organizations. Collaborative teamwork in healthcare delivery ensures that healthcare professionals and providers are used effectively to deliver the best treatment possible. Team members include inter-professional and cross-functional staff so that the solutions developed go beyond the barriers of traditional silos, departmental boundaries and hospital borders.

A pilot study was completed on one medical unit. This included delivering competency-based unit and classroom education. Unit delivery training, a component of the training program, addressed the application of chronic wound theory and documentation to actual patient care. With this background, learners were able to identify and stage pressure ulcers and formulate the appropriate plan of care.

Following this positive experience, it was critical that the organization capitalize on the momentum and broaden the success enterprise wide. Improvement and enhancement have been leveraged throughout the rest of the program through staff awareness and education, product availability, clear accountabilities and expectations for performance. In order to improve the practice of wound care, training and education were provided to the point-of-care clinicians. Nursing Practice Solutions provided a complete package of professional wound care training and resource materials. Competency-based unit

delivery training addressed the application of chronic wound theory and documentation to actual patient care in the patient setting. Education was divided into modules that addressed the prevention, identification, management and documentation (e.g., pathways and assessment tools) for each type of wound (pressure ulcers, diabetic foot ulcers, lower extremity ulcers and surgical wound. The acronym T.I.M.E was integrated as a framework into the education to assist nurses with the assessment and management of wounds. Each module continued to reinforce both the assessment and management based on T-tissue (type of tissue for both assessment and management); I-represented infection (identification and management of infection in a wound); M-identified moisture (the amount of moisture in a wound; the assessment and management of a wound with a great deal or small amount of moisture); and finally E-for edge of wound which integrated the peri-wound area, tunnels and or undermining of a wound as well as the evaluation of the edge of the wound for healing purposes.

The focus of these real-life modules was to assist learners in the transfer of knowledge from books to the bedside. With this background, learners are able to identify patients at risk, formulate prevention strategies, identify and stage pressure ulcers and formulate appropriate plans of care. This competency-based education process was designed not only to assist clinicians in transferring knowledge into practice but also to build organizational capacity. As a result of the Skin and Wound Care Program, clinical staff members are informed and prepared to implement best-practice wound care, including proven techniques and the appropriate use of the best available products and technologies.

Clinical nurse educators participated in a train-the-trainer workshop to develop their own skills and learn to assist in knowledge transfer to the bedside nurses. Clinical nurse educators have a more involved role in wound care consultations and help to resolve clinical issues.

The product formulary was standardized, and now advanced dressings are used to decrease the frequency of dressing changes and the amount of nursing time spent performing dressing changes. More importantly, the use of advanced practice dressings improves wound granulation, expedites healing and significantly reduces the pain associated with frequent dressing changes. Clinical nurse educators support clinicians with complex wound care, and they reinforce best practices to sustain the program.

A wound assessment form was developed and implemented. Standardized patient plans were created from prevention to the management of stage IV pressure ulcers. Organization-wide skin and wound policies were revised. Wound care principles were initiated to establish proper wound care management. Assessment and documentation tools were streamlined with other corporate initiatives such as eCare (online documentation).

Nurses and other clinicians at NYGH use clinical pathways to support consistent, evidence-based, best-practice wound care. Clinical pathways are based on current regulations and accrediting standards, as well as the most recent research. All care plans and clinical pathways were developed in consultation with the advanced practice nurses and clinical staff and were tested in the field for ease of use.

It is important to note that with electronic patient documentation in place, clinicians have tools readily available to guide the delivery of best-practice wound care. Clinical outcomes for healthcare organizations where best practice guidelines have been established have confirmed that the prevalence of pressure ulcers can be reduced with the implementation of risk assessments linked to consistent prevention clinical pathways.

The Skin and Wound Care Program has verified the transfer of knowledge and evidence-based best practices to both the bedside and the community. A partnership has been formed with the Central CCAC, resulting in consistent product use and best-practice wound care. The strategies used in this project have been spread internally from the units where the project was initially piloted externally to the community. The importance of developing methodologies for continuous improvement from a systems perspective has been reinforced by the successful implementation of the program by our community partners in the Central CCAC. Successes have been shared with other healthcare organizations through various venues such as lectures, conferences (i.e., the Third Congress of the World Union of Wound Healing Societies) and on-site visits. Extending the collaborative effort beyond NYGH has demonstrated the program's broad applicability and transferability across different settings and segments of the healthcare system.

This innovation was designed in such a way that it could be shared, adapted and implemented effectively to improve health-care and foster system improvements. The Skin and Wound Care Program established the capabilities and resources within NYGH to deliver consistent, best-practice wound care, thereby, improving patient outcomes and reducing costs. The partner-ship with Nursing Practice Solutions and Smith & Nephew was focused and practical. It put proven tools in the hands of health-care professionals who work daily with patients who require wound care, and it addressed the specific needs and priorities of NYGH. The program was intended to reduce the incidence and prevalence of pressure ulcers, as well as reduce healing times, with all of the accompanying benefits for patient health and quality of life. The Skin and Wound Care Program includes assessment, prevention, education and best practices for wound care.

Evaluation Methodology

The data-collection survey tool was developed and provided by the advanced practice nurses. This form captures data on specific clinical indicators, such as prevalence of pressure ulcers and other types of wounds (i.e., percentage of pressure ulcers in hospitals, long-term care facilities and community care programs); patient safety information such as restraint use and falls; prevalence of wound infections; educational needs of the nurses; and patients with wounds who experience pain. To promote consistency in data collection, four advanced practice nurses who have had training and education both on the data-collection form, process and wounds collaborated with NYGH to collect data. Data were collected in May 2007, May 2008, January and November 2009.

Outcomes

Nurses have reported and demonstrated empowerment and autonomy in delivering wound care according to best practices. Positive partnerships have developed with both internal and external stakeholders. Physicians and surgeons have participated in and continue to lead wound steering committee meetings and educational sessions in collaboration with the advanced practice nurses. Unique to this program has been the successful spread into the community – the Central CCAC has identified an 85% decrease in patients discharged with hospital-acquired pressure ulcers. NYGH has provided education sessions for interdisciplinary students both in the classroom and at the bedside for partnering universities.

NYGH has not only met but exceeded its benchmark for the decrease of the prevalence of pressure ulcers (Figure 1). The pressure ulcers that are seen are predominantly stage I and stage II, with a steady reduction in the percentage of ulcers that reach stage III or greater (Figure 2). Advanced dressings are now being used on all chronic wounds, resulting in a drop in daily dressing changes from 40% in 2008 to 0% by the end of 2009 (Figure 3). The utilization of nursing resources, which can be represented in actual nursing hours (extrapolated from database), have been reduced or reallocated to other patient care areas through the direct reduction of the task of daily dressing changes (changing from daily dressings to every 3-7 days) and caring for patients with pressure ulcers. This has been extrapolated from the original database (based on average of 10 minutes per dressing change) and would represent a total of 119.9 hours (45.5 hours for reduction of pressure ulcers and 74.4 hours for reduction in daily dressing changes) or 2.9 FTE.

Continuing audits have revealed an increase in documentation compliance of completion of patient plans/pathways from original of 28% of documented patient plans to 100% documentation of patient plans/pathways. Feedback from staff has resulted in revisions to documentation to ensure compliance and ease of documentation.

Sustainability

Regardless of the project or the priority, sustaining change over time is a long-term endeavour. Adding resources or skills to a poor process may be a quick fix but is not necessarily the best solution to enhance the sustainability of a project. The challenge for healthcare is that quick fixes will continue to surface until the

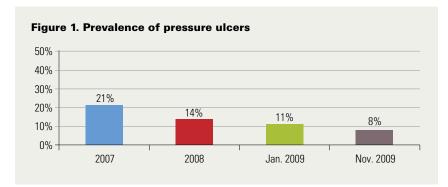


Figure 2. Percentage of hospital-acquired pressure ulcers at stage III or greater

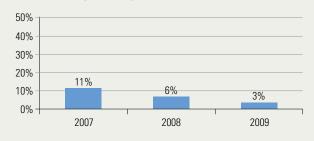
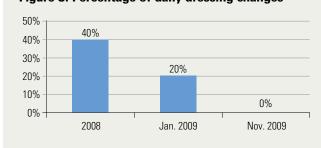


Figure 3. Percentage of daily dressing changes



culture of an organization shifts to that of continuous improvement. In a culture of continuous improvement, point-of-care staff comprehend the importance of their collective wisdom driving the changes. Subsequently, they realize that it is their responsibility to inspire, implement and sustain momentum to close the quality gaps.

The collaborative approach ensures that the views and opinions of those most affected by a process are accepted and legitimized. The collective wisdom of the team gained through their years of experience is applied to diagnose problems and develop solutions. Stakeholders not participating on the team are engaged at all times as their feedback is solicited on any proposed changes. The probability for long-term sustainability of improvements is far greater when the changes are made collaboratively rather than imposed on care providers.

The staff at NYGH continue to receive ongoing wound care education to enhance their knowledge of the prevention and management of wounds. Nursing orientation has been modified to include an overview of the Skin and Wound Care Program to new employees. Staff members are also familiarized through ongoing educational opportunities, including e-based learning from the Global Wound Academy.

The sustainability plan for skin and wound care includes a hospital-wide knowledge transfer strategy, a bi-annual prevalence study, on-unit support by clinical nurse educators, the involvement of advanced practice nurses for five years, an inter-professional approach and inter-organizational collaboration with community partners. HQ

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Methods to Assess the Safety of Health Information Systems

Elizabeth Borycki and Elizabeth Keay

Abstract

Research has shown that the introduction of health information systems (HISs) can reduce the likelihood of medical errors. However, there is a growing body of evidence that suggests that if it is not designed or implemented properly, a HIS can actually cause or induce health professionals to make medical errors (i.e., technology-induced errors). In order to maximize the benefits of HISs while decreasing the likelihood of such inadvertent technology-induced error, it is important that we understand the range of methods that can be used to ensure the safety of our systems. In this article, we report the results of a review of the literature related to the methods used in predicting, preventing and evaluating the potential for a HIS to cause technology-induced error. These methods can be classified in terms of their application, including before a HIS is implemented, after a HIS has been implemented and after a technology-induced error has occurred.

n the early 1990s, the first studies were published that demonstrated that health information systems (HISs) could improve patient safety, leading the Institute of Medicine (1992) to conclude that some HISs, such as computerized physician order entry systems and decision support systems, can reduce medical errors. In the mid-2000s, there emerged research that documented the potential of some HIS features, functions and emergent workflows to introduce new types of medical

errors into the clinical setting (Ash et al. 2007a; Ash et. al. 2007b; Borycki and Kushniruk 2008; Horsky et al. 2005; Koppel et al. 2005; Kushniruk et al. 2005). Work by these researchers and others led some government agencies to ask healthcare organizations to proceed cautiously when implementing a HIS (e.g., Joint Commission 2008) and in other cases to implement new testing and certification procedures (e.g., Health Canada 2009). These publications signalled the need to develop new methods, approaches or techniques to: (1) detect technology-induced errors before a system is implemented and (2) identify the circumstances that contributed to a technology-induced error involving a HIS both during and after system implementation. Researchers developed these approaches in order to prevent any future technology-induced errors involving a HIS (Borycki et al. 2009). In this article, we review the current state of knowledge involving the key methods, approaches and techniques that can be used by healthcare administrators (e.g., chief information officers, chief executive officers, medical and nursing directors) to assess the safety of a HIS and its associated devices prior to their implementation in a healthcare organization.

Defining and Understanding Technology-Induced Errors

Technology-induced errors can be defined as those sources of error that may "arise from: (a) the design and development of a technology, (b) the implementation and customization of

a technology, and/or (c) the interactions between the operation of a new technology and the new work processes that arise from a technology's use" (Borycki and Kushniruk 2008: 154). Technology-induced errors have been referred to by some researchers as "e-iatrogenesis" (Sittig 2008) and by others as one type of "unintended consequence" (Ash et al., 2007a; Ash et al., 2007b; Borycki et al. 2010, September). They differ from medical errors and adverse events as described by Classen and others (e.g., Classen and Metzger 2003; Kilbridge and Classen 2001). Medical errors can be defined as "failures in the process of medical management ... that have potential to harm the patient," and adverse events can be defined as those events arising from medical management that lead to patient harm or injury (Classen and Metzger, 2003: 42). Technology-induced errors have their origins in the technology itself and technologyhuman interactions, rather than the entire medical management process. Therefore, technology-induced errors may be considered one type of unintended consequence or error arising from the design, development, implementation and customization of technology and from the new workflows and interactions between technology and health professionals that emerge from a technology's use during the process of providing healthcare (Borycki et al. 2010, September).

the safety of a HIS during its design, development and procurement, prior to its implementation.

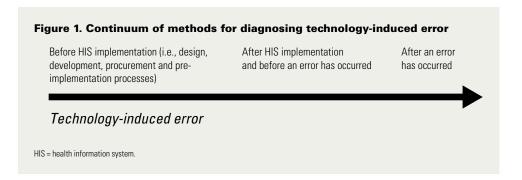
Here we describe and discuss these methods, approaches and techniques in terms of their relevance to healthcare administrators as part of an organization's risk management strategy. The methods are discussed in terms of a continuum that can be used by healthcare administrators from HIS software development (testing software and devices during the software design, development, procurement and pre-implementation processes) through to implementation and maintenance in clinical settings (Figure 1). In addition, each of these methods is described and reviewed in terms of its potential use in healthcare organizations (e.g., software vendors, hospitals and regional health authorities) as part of an organizational risk management strategy.

Before HIS Implementation: Design, **Development, Procurement and Pre-implementation Processes Safety Heuristics**

The use of evidence-based heuristics to evaluate the safety of software is a relatively new phenomenon. Historically, heuristics were developed and used to evaluate the usability of a HIS interface design (Kushniruk and Patel 2004). More recently,

> Carvalho and colleagues (2009) developed a list of evidence-based heuristics (i.e., guidelines regarding safe design) that could be used to evaluate the safety of HIS interface features, functions and emergent workflows during the software procurement process. These safety heuristics were developed and tested in three phases. In phase one, the researchers conducted a systematic review

of the published literature on technology-induced error. In phase two, three health informatics experts generated a set of heuristics during a round-table discussion after reviewing the evidence-based literature. The round-table discussion identified heuristics, which were classified into four safety domains: content, functions, workflows and safeguards. In phase three, the safety heuristics were applied to a demonstration version of the Veterans Affairs Computerized Patient Record System. This involved an analyst comparing features of the system and user interface against the set of heuristics and noting conformance or violation of the heuristics, as could be done by an analyst evaluating a system being considered for purchase by a regional health authority. The researchers found that 12 of the developed heuristics could be readily applied by an analyst conducting



To develop a comprehensive review of the current methods, approaches and techniques used to diagnose technologyinduced error, we conducted a search of Medline using the following key search terms: technology induced error and method, technology induced error and technique, technology induced error and approach, unintended consequences and method, unintended consequences and technique, unintended consequences and approach, e-iatrogenesis and method, e-iatrogenesis and technique, and e-iatrogenesis and approach. In our search of Medline, we identified 174 publications of which 13 abstracts described methods, techniques and approaches that could be used to identify potential and actual sources of technology-induced error in healthcare. There exist a number of methods published in the health informatics literature that can be used to determine

this type of evaluation. However, the researchers suggested that the remaining heuristics could be applied in conjunction with clinical simulation testing (Carvalho et al. 2009).

Use of Clinical Simulations

Several researchers have explored the use of clinical simulations as a methodology for identifying potential sources of technology-induced error arising from human-computer interaction. Clinical simulations typically involve observing health professionals interacting with the system (e.g., an electronic health record system or medication administration systems) using representative devices (e.g., a workstation or wireless cart) in a typical workplace (e.g., a hospital room) while they carry out representative real-world tasks (e.g., entering medication orders or performing medication administration) (Kushniruk et al. 2005, 2006).

Clinical simulations involve analysts video recording health professionals' interactions with a HIS and its associated devices. Computer screen recordings are also made to observe how the health professionals perform work-related tasks using the HIS. Subsequently, the analyst interviews the health professionals about the difficulties they may have experienced in using the software and hardware. The analyst then reviews the interview, video and audio data to identify instances of technology-induced errors (i.e., mistakes) and near misses (i.e., slips) (Kushniruk et al. 2005). This information is used to make modifications to the HIS, the types of devices that are used and the organization's policies, procedures and training to prevent any future occurrence of technology-induced errors or near misses (Kushniruk et al. 2006; Kuwata et al. 2006). It is worthwhile to note that these types of simulations, that is, those focused on technologyinduced errors, differ from those simulations conducted to determine the ability of a HIS to detect human data-entry errors, such as the simulations used to certify computerized physician order entry (CPOE) systems. Simulations that are used to certify CPOE systems involve simulated patients and orders to assess the ability of a CPOE system to detect adverse events and errors made by the health professionals entering the orders (e.g., physicians, nurse practitioners) (Classen et al. 2007). The focus of this latter type of simulation is on human error detection, such as assessing the ability of a system to notice human errors in prescribing (Classen et al. 2007), rather than on the error-inducing qualities of the HIS (Borycki et al. 2010, September; Kushniruk et al. 2005).

A Japanese and a US healthcare organization used clinical simulations to identify potential sources of technology-induced error before implementing a medication administration system and physician order entry system on a large scale (see Kushniruk et al. 2005; Kuwata et al. 2006). These clinical simulations provided HIS and device implementers in these hospital settings with system-specific feedback to prevent the occurrence of errors.

Clinical plus Computer-Based Simulations

More recently, clinical simulation work has been extended to include the use of computer-based simulations involving computer modelling to provide healthcare decision-makers with information about the potential impact of a HIS and its associated devices where technology-induced errors are concerned at a regional health authority level (Borycki et al. 2009). Data from clinical simulations were used as input parameters to a computer-based simulation model and extended to provide decision-makers with information about the impact of these technology-induced errors upon organizational medication error rates (i.e., physicians making prescribing errors as a result of interface design features) over time, such as over a year. In this work, the researchers have shown that if left unaddressed, technology-induced errors may have a significant impact upon organizational error rates. Such information may help decisionmakers to identify those technology-induced errors that might have the greatest impact upon the organization and enable them to develop a risk management strategy that includes interventions aimed at preventing the likelihood of an error occurring, such as redesigning some aspects of the HIS interface features and functions, selecting another device that better supports health professional work or altering the content of health professional training to ensure that health professionals are aware of how the system works (Borycki et al. 2009).

After HIS Software Implementation: Ethnography

A number of studies (e.g., Koppel et al. 2005) have documented the utility of ethnographic approaches such as interviews, focus groups, surveys and observations of health professionals using HIS in the study of technology-induced error after HIS implementation. Ethnographers have used varying combinations of these data-collection methods to document potential sources of technology-induced error (e.g., Ash et al., 2007a; Ash et al., 2007b; Koppel et al. 2005). Interview and focus group data gathered from physicians and nurses have been used to identify many instances where a HIS could lead to an error. The findings from these studies were significant; they suggest that health professionals could identify potential error-facilitating properties of a HIS or device while working in a clinical setting. These studies also signalled a need for governments and regional health authorities to develop error-reporting systems that allow health professionals to provide details about their real-world near-miss and error experiences involving HISs and devices.

Although ethnographic approaches can help to identify technology-induced errors, other research has found that health professionals may not be aware of the error-inducing aspects of a HIS and are therefore unable to report their occurrence (see Kushniruk et al. 2005). This research suggests that ethnographic approaches may have value in detecting some types of errors but that a group of technology-induced errors may go undetected by both the health professionals who are involved in near misses and errors and the ethnographers who are gathering data from health professionals using these systems (Borycki and Kushniruk 2008; Kushniruk et al. 2005). Health professionals may not be able to recall the instances where a potential or actual error may have occurred or the events that led to that error (i.e., recall bias) (Jackson and Verberg 2007). Furthermore, in cases where there is an external observer (such as an ethnographer), sometimes not all the technology-induced errors are recorded (i.e., ethnographers are sometimes physically unable to record all of the relevant data from health professional interactions with HISs) or the observers focus on only the activities they identified as relevant at the outset of their work (i.e., recording bias) (Jackson and Verberg 2007).

Costs associated with making

modifications to the system, re-implementation and re-training health professionals would be significantly reduced if changes were made to the system prior to implementation.

Another weakness of using ethnography after a system is in use in a clinical setting is the amount of time required to collect the data (e.g., several months of intensive work; Ash et al. 2007a; Ash et al., 2007b). Some researchers have attempted to reduce the amount of time needed to collect data about a HIS – as a result, a modified version of ethnography known as Rapid Assessment of Clinical System Interventions (RACSI) has been developed (Ash et al. 2008, November 6). Like ethnography, RACSI utilizes interviews, surveys and observations of health professionals using a HIS. Data collection and analysis take up to one month to complete (Ash et al. 2008, November 6). Although this is an improvement over traditional ethnographic approaches, errors may occur during the one-month period of data collection and analysis. Lastly, ethnographic and RACSI approaches to identifying technology-induced errors may lead to increased costs for regional health authorities, such as those associated with making modifications to the system, re-implementation and re-training health professionals. These costs would be significantly reduced if changes were made to the system prior to implementation (Kaner et al. 1999; Patton 2001).

After an Error Has Occurred

A case study approach has been used by a group of cognitive experts at a large teaching hospital in the United States to determine the root causes of errors and to identify any potential causes of errors involving "failures in the interaction between humans and information systems" (Horsky et al. 2005: 377). Cognitive experts investigated an error that resulted in a patient being found severely hyperkalemic; they first developed a timeline for events that led to the error using computer log data, performed an expert review of computer order entry, transfer and sign-out notes screens and then interviewed the two physicians involved in the error. The outcomes of the review were significant. The experts were able to identify the factors that contributed to the errors such as "errors by physicians in the use of the clinical information system, the absence of automated safeguards that help prevent errors, and uncertainty on the part of physicians about how to manage unusual ordering scenarios" (Horsky et al. 2005:308). The experts made several recommendations that could be implemented at vendor and organizational levels for error prevention, including (1) some modifications to the computer screen designs, (2) the introduction of alerts to inform users if the patient is already receiving the medication and if an order for a medication requires a review of more recent laboratory tests results and (3) further training for clinicians (Horsky et al. 2005).

Lessons Learned

In our work, we have identified several approaches to identifying technology-induced error from HIS development though to implementation. In our search of Medline, there emerged a number of methods that may be used to test for or diagnose potential causes of technology-induced error. These include (1) the use of evidence-based heuristics to evaluate the safety of a HIS, (2) the use of clinical simulations to identify technologyinduced error interactions between a HIS/devices, health professionals and patients, (3) an extension of clinical simulations to include computer-based simulations to observe long-term organizational implications of errors if uncorrected, (4) the use of ethnography after a HIS has been implemented, (5) an extension of ethnography referred to as rapid assessment and (6) the use of case studies after a technology-induced error has occurred. It is worthy to note that a failure modes and effects analysis (FMEA) was not reported from the literature search as being employed by health informatics researchers to identify potential technology-induced errors, nor was the method reported in the literature as being used to determine the factors that contributed to a technology-induced error that has occurred. To better understand the possible underlying reasons for this, one must consult the FMEA and healthcare FMEA literature.

FMEA was developed by reliability engineers to predict system reliability to establish the overall probability that a system will operate for a specific length of time without a component failure (Leveson 1995). In engineering, FMEA does not consider the effects of multiple failures and human error in operating procedures - that is, each failure is reviewed as an independent event, so this technique does not capture the interrelationships among system elements (Leveson 1995). FMEA

is used in safety analysis because it looks at the end effects of failure; but not all failures result in accidents, so FMEA can be inefficient (Leveson 1995). In healthcare, FMEA is used as a risk management tool to identify and control risks beyond the HIS. Healthcare FMEA is considered to be a proactive and thorough risk-control tool that allows for the examination of a process to determine what could go wrong. Healthcare FMEA uses the following steps (Leigh and Lagorio 2006):

- 1. Select a high-risk process to study.
- 2. Assemble an interdisciplinary team.
- 3. Diagram and describe the processes and sub-processes.
- 4. Brainstorm to identify all the failure points.
- 5. Identify the causes of failure using brainstorming and incident reports, their probability and severity to create a risk matrix.
- 6. Develop and implement actions with a responsible person.
- 7. Assess to ensure no new failure modes have been created.

These risk reduction actions must accomplish at least one of the following three objectives in order to be considered effective and to avoid future iterations of the FMEA process: (1) remove a single-point weakness, (2) create one or more effective control measures or (3) make the hazard so obvious that control measures are not needed (Grout 2007). FMEA can also be used to assess new programs, services or departments (Cohen and Tuohy 2006).

This review of the literature revealed that FMEA and healthcare FMEA were not specifically used by health informatics researchers to predict or prevent technology-induced errors, despite the fact that FMEA is used in safety analysis in healthcare (Leveson 1995). There may be a number of reasons for this. According to Classen and Metzger (2003), in healthcare, FMEA is primarily used to study sentinel adverse events, which differ from technology-induced errors (i.e., learning about the factors or flaws in a healthcare system that lead to an adverse event during medical management versus learning about how technology induces an error). The advantages of FMEA are its systematic approach, ability to build teams and promote teamwork, act as a visibility tool for managers, identify potential concerns and improve user satisfaction (Dhillon 2008; Leveson 1995). Its disadvantages include the time and costs involved in its use (Grout 2007; Levenson 1995). As well, FMEA, when applied to understanding adverse events in healthcare, does not provide sufficient information about the frequency of an adverse event, describe the relative contribution of differing factors or flaws in the HIS that lead to an adverse event or provide explicit prescriptive information about what action to take (Grout 2007; Leveson 1995). Instead, FMEA focuses on rare events and identifies a list of flaws with the current healthcare system (Classen and Metzger 2003).

Modifications to a HIS can be costly (especially after it has been fully developed or implemented) (Kaner et al. 1999; Patton 2001). Identifying technology-induced errors, understanding the frequency of their occurrence and the relative contributions of specific aspects of the design, development and implementation of a HIS that contribute to technology-induced errors will allow decision-makers to determine the system's impacts on healthcare (Borycki and Kushniruk 2008; Borycki et al. 2009). Such information, made available prior to full-scale system deployment, is necessary for decision-makers to assess risks and determine if fundamental changes to the software are necessary. FMEA (as has been applied in this area of healthcare) does not provide this information, whereas approaches in the literature regarding technology-induced errors do provide such information. For example, clinical simulations can be used to identify the types of technology-induced errors that are present and their relative frequency. Computer-based simulations can be used to determine the relative costs of addressing a technology-induced error versus the costs of patient injury and death over time at a healthcare system level (Borycki et al. 2009). Future research will need to investigate the utility of using FMEA in healthcare to manage risks associated with technology-induced error.

Summary

Regional health authorities are increasing their investment in HISs as a way of improving the effectiveness and efficiency of the healthcare system while at the same time reducing medical error rates. With the implementation of a HIS, new types of errors have been introduced into the healthcare system (i.e., technology-induced errors). These errors need to be addressed. In this article, we have presented a range of literaturedocumented methods, techniques and approaches to address technology-induced errors as part of a healthcare organizational risk management strategy. Healthcare administrators can use these methods in differing ways. Safety heuristics and clinical simulations can be used during the procurement process to identify systems for purchase according to their safety attributes. Clinical simulations can be used by healthcare organizations to identify potential technology-induced errors (near misses and mistakes) within the context of a safe simulated environment before implementation in the real world. Clinical simulations plus computer-based simulations can help healthcare administrators to identify those risk management activities involving a HIS (e.g., screen re-design, extra training for health professionals) they would like to undertake based on the HIS features and functions that may lead to error. Ethnography and RACSI allow health administrators to identify potential technologyinduced errors after a system has been implemented. Lastly, case studies can be effectively used to identify the factors that have led to an error, and provide healthcare administrators with recommendations that would prevent errors from occurring. In

summary, there are a number of methods that can be used by healthcare organizations to address technology-induced error as part of an organization's risk management strategy. HQ

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Increasing the Safety of Healthcare Information Systems through Improved Procurement: Toward a Framework for Selection of Safe Healthcare Systems

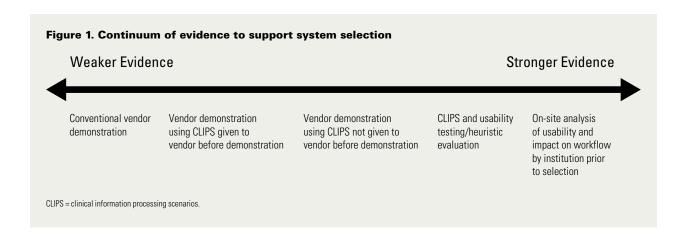
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Abstract

In this article, we describe a framework that we have developed for improving the effectiveness of critical decisionmaking in selecting information systems. In our framework, we consider system selection in terms of strength of evidence obtained from the testing of candidate systems in order to reduce risk and increase the likelihood of selection and implementation of an effective and safe system. Two case studies, one from a major North American hospital and one from a major European hospital, are presented to illustrate how methods such as usability testing can be applied to improve system selection as well as customization (through early identification of system-organization mismatches and error-prone system features). It is argued that technologyorganization fit and consideration of the potential for technology-induced error should be important selection criteria in the procurement process. Here, implications are discussed for the development of improved procurement processes to lead to safer healthcare systems.

The appropriate selection of health information technology (HIT; in particular, electronic health record [EHR] systems) is one of the most critical decisions in the journey toward streamlining healthcare and making it safer. Indeed, research has indicated that the selection of systems that match user and organizational

needs and effectively support work practices can lead to decreased medical error and increased patient safety (Borycki and Kushniruk 2008). However, there is also a growing body of literature indicating that systems that do not match the purchasing organization's needs and work practices may lead to safety hazards. Furthermore, specific features of health information systems and user interfaces have been shown to be highly related to the occurrence of medical error (Kushniruk et al. 2005). Along these lines, the literature now contains numerous examples of purchased systems that failed to meet user needs and that ultimately became safety issues. For example, work by Koppel and colleagues (2005) showed that the implementation of a commercially available electronic health system resulted in a range of errors, related both to gaps in interfacing of information and human factors issues, that created healthcare safety hazards (e.g., access to the wrong records by physicians, missing information and error-prone user-computer sequences). A subsequent study by Han et al. (2005) of a commercially available system indicated that deaths actually increased in a hospital unit after the implementation of the system. Furthermore, Kushniruk and colleagues (2005) have experimentally shown that specific features of a system's usability (e.g., how information is displayed to a user of a medication administration system, the style of human-computer interaction sequences etc.) are directly related to specific types of technology-induced error (e.g., errors in user interaction with a system that can lead to



incorrect entry of patient medication information by physicians). With this growing body of evidence that the selection of the wrong system can lead to serious safety issues, the question remains: what can be practically done to decrease the risk of selecting a system that does not fit with user needs and organizational structures and that may ultimately become a safety issue? In this article, we explore the use of rigorous clinical scenarios and the usability testing of candidate information systems to improve decision-making in purchasing expensive HIT and to lead to safer and more effective system implementations. Two case studies are described of organizations that have applied some of these approaches to their choice of effective and safe healthcare systems.

Toward a Framework for Improved System Selection and Safety

The appropriate selection of systems such as hospital-wide EHR systems represents a critical decision-making task. However, despite the potentially huge expenditure of money in purchasing large systems, decision-makers involved in the process are often allowed only very limited access to candidate systems prior to the system purchase (Kushniruk et al. 2009). Furthermore, the standard processes for health system procurement are unlikely to provide the decision-makers selecting systems with detailed information about the potential for system safety issues and hazards prior to purchase. In this section, we propose a framework for considering possible system selection methods in terms of the ability to get hands-on access to candidate systems to apply realistic test scenarios (customized to the purchasing organization) as well as to apply methods emerging from the area of usability testing to ensure that appropriate decisions are made regarding system safety. In subsequent sections, we describe two case studies, one from a major North American hospital and one from a major European hospital, where rigorous testing of systems prior to purchase have been conducted.

The framework we propose considers possible system selec-

tion methods in terms of a continuum (Figure 1) that ranges from weak evidence (simply involving a demonstration by the vendor to the selection committee) to strong evidence (involving hands-on analyses of the usability and impact of the system on hospital workflow within realistic or real settings prior to selection) to support decision-making regarding choosing from candidate systems. The continuum was developed based on an analysis of the literature and our experiences in consulting with and advising healthcare organizations in the use of new approaches to procurement (e.g., the application of usability testing and the use of low-cost methods for testing candidate EHR systems in situ, which are described below). This process involved convening an expert panel consisting of PhD-prepared experts in human factors and medical errors; these experts classified reported procurements along the continuum from weak to strong evidence for supporting the choice of a "safe" health information system. Decision-makers can use this continuum to support organizational decision-making in selecting from candidate systems.

In Figure 1, CLIPS refers to clinical information processing scenarios, which represent clinical situations that could be expected to occur within the local healthcare environment (Lincoln 1996). CLIPS can be used to test systems to determine if they respond appropriately to the situations described, and they should focus on special needs and unusual situations in addition to normal activities. In Figure 1, we can see that vendor demonstrations of products that do not include a rigorous set of CLIPS to guide testing can be seen as providing only weak evidence of how the system will respond to situations that might be error prone or lead to safety issues.

It should be noted that most current procurement processes can be located on the left-hand side of the continuum, with only a few published examples of procurements involving the collection of evidence at the far right of the continuum. It should also be noted that methods for analysis that have emerged from the field of usability engineering are located to

the right of the continuum. The two most popular usability engineering methods are usability testing and heuristic evaluation. Usability testing refers to observing representative users interacting with a system (typically involving video and screen recording of these interactions) while carrying out representative tasks. For example, this may involve observing health professionals (e.g., physicians or nurses) interacting with a health information system to enter or retrieve patient data (Kushniruk and Patel 2004). In contrast, heuristic evaluation involves an analyst systematically "stepping through" a user interface or system (i.e. examining the main screens of the interface or system in sequence) to identify violations of principles (or heuristics) associated with good design and usability (Nielsen 1993). Recent work by Carvalho et al. (2009) has extended this approach to the development and creation of a set of evidencebased heuristics that can be used by healthcare organizations to assess the safety of computerized physician order entry systems.

Case Study One: Procurement Involving Workflow-Based CLIPS Testing - Experiences at Mount Sinai Medical Center

The safety of healthcare information systems is directly related to their "fit" within the organization in which they are implemented (Borycki and Kushniruk 2008). This refers to the socio-technical aspects embodied in the system, such as how the system will respond to complex work sequences in the institution, how well the system responds to unusual or unique situations in the organization and how well the technical aspects of the system match and integrate seamlessly with the institution's technical infrastructure. In order to test candidate systems' fit with local practices in hospitals and ultimately their potential to be effective and safe systems, the development of realistic CLIPS is essential. To address this, Kannry and colleagues at Mount Sinai Medical Center in New York have worked to develop processes to create realistic CLIPS that can be used to test candidate systems not only on their basic functionality but also in terms of how well they respond to unusual situations and how well they integrate into the complex workflows and activities characteristic of large complex healthcare organizations.

In his previous work, Kannry has identified the unique challenge in HIT procurement - how to obtain user input in the procurement process (Kannry 2008; Kannry et al. 2006). Careful involvement of users during selection as well as implementation is critical and can be the difference between failure and success (Gray and Felkey 2004; Kannry 2007; McDowell et al. 2003). Yet, clinical users frequently have no prior education, training or experience to draw upon (Kannry 2007, 2008; Kannry et al. 2006). Users are frequently called upon to attend demonstrations as part of the selection process (McDowell et al. 2003) and asked to map the functionality demonstrated to their daily clinical needs. Many vendors prefer to demonstrate functionality and play to existing strengths while at the same time shying away from system and software weaknesses (Campbell et al. 1989; Einbinder et al. 1996). In addition, the workflow shown may not reflect that of the selection site as much as the workflow of the site at which the vendor developed the system. Vendor demonstrations are determined by the script, if any, that an institution supplies the vendor. Much like a film or television show, the script determines what is shown and in what order.

The approach taken at Mount Sinai Medical Center was to employ workflow-based scripting as opposed to functionalitybased scripting (Kannry et al. 2006); workflow-based scripting follows the clinical provider through typical patient care scenarios, whereas functionality-based scripting asks whether the system can do x and y and tries to follow a checklist organized by section. The workflow-based approach to scripting has been shown to more accurately represent users' preferences (Einbinder et al. 1996; Laerum and Faxvaag 2004).

Extensive scripts were created by a selection team member who is also a practising physician and were then reviewed by practitioners in multiple specialties. The focus of the scripting was on primary care because it accounts for the largest number of visits in the hospital-based practices. The scripts also emphasized the numerous hand-offs that occur, especially in an academic setting. The script and the evaluation form included six required scenarios and four optional scenarios that were used depending on audience composition. For example, the cardiology-specific scenario was only used when members of the Cardiology Unit attended demonstrations. The Sinai selection team then derived questions from the scripted clinical scenarios for an evaluation form, and showed early versions of the evaluation form to potential attendees to determine if the form could be realistically completed in terms of time and the length of the form.

Every demonstration of candidate systems at Mount Sinai Medical Center was monitored to ensure that vendors followed the script and represented the functionality that was live at an existing site. At the end of each scenario, users were encouraged to grade the scenario on an evaluation form. The form was designed to carefully follow the scripted workflow scenarios and result in an evaluation of the scripted demonstration. On the evaluation form, each clinical scenario was organized into sections; clinical users did not have to deal with "mysterious" section headers that used information technology terminology such as interfaces, screen design and security layer. Scenario sections were labelled to reflect the workflow and employed headings such as physician begins patient care, physician sees new patients and physician sees patient. Users were encouraged to provide additional comments.

When the scoring was completed, the earlier mapping of core functionality to workflow was employed to analyze the user responses along core functionality lines as well as in terms of workflow. For example, the scores could be analyzed in terms of how users graded the workflow "view list of previous notes from multiple specialties/providers" and in terms of core functionality such as "data retrieval and clinical documentation."

By applying the process described above, in conjunction with an analysis of published evidence on the safety of particular vendor products (described in Kannry et al. 2006), a single system was determined on all major categories to best match the needs at Mount Sinai and was since implemented with considerable buy-in at the institution at all levels, from clinical staff to management.

This case study would be placed at the left to mid-point of the continuum shown in Figure 1 as carefully crafted CLIPS were created (which were designed to tease out the impact of a system on workflow as well as test system functionality), however the scripts were given to the vendors prior to the product demonstrations.

Case Study Two: Procurement Involving Usability Testing and Usability Inspection - Experiences at Lille Regional University Hospital

As illustrated in Figure 1, one form of strong evidence for system choice involves usability testing of candidate systems. The approach has been described previously (Kushniruk and Patel 2004) and has typically been used to evaluate systems that are currently being designed or those that are about to be deployed (e.g., Borycki and Kushniruk 2005; Kushniruk et al. 2006) in order to determine if the system will lead to potential problems or safety issues. In addition, the approach can be applied within healthcare organizations at a low cost (see Kushniruk and Borycki 2006). The results of such study are typically fed back to either the redesign or customization of the system before its full release within the organization (e.g., hospital). The same methods have potentially huge impact if applied early in the system development life cycle, far before design or deployment phases, in particular within the actual system selection process itself (during the comparison of possible candidate vendor systems for selection).

There have been few reported applications of this type of usability-focused methodology for system selection (e.g., Graham and colleagues' work on the selection of infusion pumps is one exception; see Graham et al. [2004]) and fewer reported applications of usability testing inserted directly into the procurement process at a large hospital institution (see Beuscart-Zéphir et al. [2002]).

Lille Regional University Hospital in France is a large 3,000bed hospital that has begun to integrate a range of usability engineering methods directly into system procurement processes, including usability testing and related methods of usability inspection (Beuscart-Zéphir et al. 2001, 2005). In order to support the choice and acquisition process for a clinical information system in anesthesiology, several forms of evidence were collected to inform the decision-making (Beuscart-Zéphir et al. 2005). This included assessing the following three dimensions of candidate systems: (1) quality management, (2) usability and (3) performance (which focused on assessing the quality and exhaustiveness of documentation - including the percentage of relevant information made available to the anesthetist and the number of alerts generated). Of particular interest to this article is the work that was conducted around the assessment of quality management and usability to ensure that the product selected would both fit with the organizational workflow and lead to a system that was both effective and safe. The usability testing involved trained analysts observing and recording dialogues of users interacting with the candidate systems while these users carried out both simulated tasks (involving clinical information processing scenarios) and real tasks.

In this case, the usability tests included the study of actual end users (the anesthesiologists in the unit) and real patients, using a portable usability testing approach in which all the actions on the computer were video recorded to identify problems and issues during subsequent video review. The system testing took place in the real work environment where the selected system would ultimately be installed. By using this approach, software problems were identified and the impact of candidate systems on workflow could be compared directly in the real context of the hospital (Beuscart-Zéphir et al. 2005).

These data were used in conjunction with the results of a heuristic evaluation, which involved usability analysts stepping through and analyzing the candidate systems compared against a set of usability heuristics (guidelines that reflect good design practices - see Kushniruk and Patel [2004]). This approach demonstrated that one of the two candidate systems was shown to have a low score for adaptability, to consist of two different subproducts that were not fully integrated at the time of the test, and to contain some labels in a foreign language (as well as having other usability problems that could potentially lead to an unsafe system). Thus, the approach taken allowed for the assessment of vendor products regarding their potential to inadvertently cause technology-induced errors. Along these lines, recent work by Carvalho et al. (2009) has led to a set of heuristics to guide the usability inspection of commercial medication order entry systems; these heuristics can be used in the head-to-head comparison of commercial vendor-based HIT products.

A benefit of incorporating usability evaluation in the procurement process at Lille Hospital was that it allowed the hospital to select a usable and safe product (with the results of the analyses made by the usability analysts given to the vendor, who modified certain aspects of the product accordingly). This anesthesiology clinical information system is now installed and running routinely in all the anesthesiology departments of Lille Regional

Hospital (109 operating rooms, 118 post-operative beds and 110 consultation sites). In addition, an internal quality study of the anesthesiology records has shown a major improvement in terms of accessibility and reliability of medical information.

There was also a commercial positive side effect for the company marketing the system. The good level of usability of this application, as demonstrated in the last round of usability evaluation during the procurement process, has been used by the vendor when responding to other calls for proposals. This argument, plus the company's successful implementation in a large hospital, has progressively led to additional market share for this particular vendor, which is now the leader in this specific healthcare domain for information systems in France. (In 2007, it won 100% of the calls for proposals in French hospitals.) Although usability was not the only factor in this successful procurement process (i.e., other factors such as cost, vendor reputation, support, standardization and capability for interoperability with existing systems were critical as well), it was a key factor when considering how to select a "safe" system and avoid risky choices that might lead to technology-induced errors (Kushniruk et al. 2005).

In Figure 1, we can see that hands-on testing of candidate systems within the actual clinical setting of potential use (i.e., high-fidelity usability testing, as described in Kushniruk and Borycki [2006]) prior to purchase has the potential to lead to a strong level of evidence regarding effectiveness and safety of systems within that particular organizational context. In the example of the procurement process at the Lille Regional University Hospital, this was taken to a further level by conducting both usability testing (involving real end users and patients "in situ", i.e., installed in the real working environment) and usability inspection of candidate systems installed within the hospital prior to making the system selection choice (Beuscart-Zéphir et al. 2005). This case study from France lies at the far right of the continuum shown in Figure 1 as it involves both heuristic evaluation and in situ usability testing of candidate systems installed and running in the actual clinical environment.

Lessons Learned

Lessons learned from our analyses to date include the following:

- It is not only possible but also feasible to increase the level of evidence available to decision-makers regarding the fit of candidate systems within their organization (as well as assessing the potential safety of those systems prior to implementation).
- The stronger the level of evidence obtained, the more confident the organization can be of a good system-organization fit.
- Major issues regarding system usability or safety that need to be addressed can be identified prior to signing contracts with the vendors involved, thereby allowing for the possibility of

- improvements to systems prior to installation.
- Some degree of knowledge of practices and processes involved in applying methods described in this article are needed to move to a stronger level of evidence.

Ultimately, the success of our investments in HIT (including the important aspect of ensuring system safety and effective healthcare) depend on how rigorous and accountable our system procurement practices are.

The stronger the level of evidence obtained, the more confident the organization can be of a good systemorganization fit.

Conclusions

The case studies above describe approaches to the testing of candidate systems that involve CLIPS and varied levels of system testing regarding the match to organizational workflow. There are many examples of procurement that could be considered to have applied a weak level of evidence to inform decisionmaking. This includes the "conventional" approach of rating candidate systems by a selection panel who passively watch vendor representatives demonstrate system features and capabilities. (For example, the author [A.K.] was an observer on a recent procurement made by a large regional health authority in which the final choice of a region-wide EHR system was based on such demonstrations made by two short-listed vendors.) An approach based on a further level of evidence is that of Kannry and colleagues (described in this article), which proposes that "evidence-based" system selection should include an analysis of reported experience with candidate systems to predict to how well a system responds to complex scenarios (Kannry et al. 2006). Current work to extend this further has involved usability testing methods (Beuscart-Zéphir et al. 2005) to allow for a stronger level of evidence than is typically currently undertaken, as exemplified by the case study of the system selection process at Lille Regional University Hospital. Usability testing applied during the procurement process ideally involves the installation of demonstration systems on site at an organization and observational analysis of representative users interacting with the system in testing. This permits systems to be tested in situ by the selection team (rather than demonstrated by the vendor). Along these lines, it can be argued that CLIPS ideally should not be a prearranged set of questions given to potential vendors in advance, in order to ensure that the vendor does not modify the demonstration system to appear to contain the desired functionality.

We are currently using the framework described in this article to analyze current approaches to system testing in

procurement and to assist in the development of new selection processes for use by hospitals, health authorities and regions in order to improve the chances of safe and successful HIT implementations. HQ

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Challenges of Hand Hygiene in Healthcare: The Development of a Tool Kit to Create Supportive Processes and Environments

Anjum Chagpar, Carleene Banez, Raquel Lopez and Joseph A. Cafazzo

Abstract

Hand hygiene compliance by healthcare providers has been difficult to achieve due to diverse environments, work culture, processes and task requirements. Because of this complexity, hand hygiene lends itself well to a human factors analysis in order to design a system that matches human cognitive and physical strengths and makes allowances for human limitations.

multi-phased user-centred approach was undertaken to explore barriers and enablers to hand hygiene in diverse environments (rehabilitation, family medicine, emergency and intensive care) for a number of healthcare workers (HCWs; physicians, nurses, allied health, housekeeping and patient support workers). Observational studies, interviews, focus groups and surveys were used to engage end users in solution development. Solutions were then validated through an environmental modification study, which sought to quantify the benefits of proposed solutions.

This research highlighted the need to take into consideration the differences between HCWs, their environments and the tools with which they are provided when recommending solutions to mitigate barriers. Context-specific recommendations resulting from this work have been formulated into a tool kit for dissemination by the Canadian Patient Safety Institute (CPSI).

Background

CPSI has partnered with provincial governments to encourage HCWs to adhere to the "four moments of hand hygiene":

- Before initial contact with a patient or patient's environment
- Before performing an aseptic procedure
- After the risk of body fluid exposure
- After contact with a patient or patient's environment

Compliance is a challenge, however. While it is well known that proper hand hygiene practices are the most effective method of reducing hospital-acquired infections (HAIs), the rate with which HCWs comply with best practice recommendations is still only approximately 40% (World Health Organization 2005). Low compliance is one reason that 5–10% of patients admitted into hospitals acquire at least one HAI (World Health Organization 2005).

There is no shortage of initiatives to address low compliance (Table 1). Best practice guidelines, education campaigns and guidance on auditing compliance are widespread. Yet existing recommendations around best practices often conflict, creating confusion for HCWs. For example, plain soap has been recommended because it is less likely to cause dermatitis (Jumaa 2005). Yet handwashing with plain soap does not remove pathogens, a fact that has resulted in recommendations to use antimicrobial

soaps and alcohol-based hand rubs (ABHRs). Similarly, because sink faucets can contaminate clean hands, guidelines recommend that sinks be sensor operated (Cochrane 2003). This is in conflict with reports that electronic faucets are more likely to harbour bacteria, which has resulted in a recommendation that sinks with manual faucets be employed (Merrer et al. 2005).

While there is support for the development of gold standards for hand hygiene (Elliott 2003; Farrington 2007; Larson 2003; Macias and Ponce-De-Leon 2005; Seal et al. 2005), some believe that it is necessary for providers to develop their own institution-appropriate guidelines (Held et al. 2001) and that 100% compliance may interfere with patient care (Storr and Clayton-Kent 2004).

Instead of focusing on education or auditing campaigns, or further developing and clarifying best practice guidelines, this project sought to identify barriers and enablers of hand hygiene in order to make environments and processes more supportive of hand hygiene activities. This human factors approach aims to optimize environments and processes that are natural and easy to use by matching them to human cognitive and physical strengths and making allowances for human limitations.

Methods

Five methods were used to identify barriers and enablers to performing hand hygiene, to design and validate potential solutions and to create a tool kit for healthcare institutions based on the project learnings:

- 1. A literature review to understand the current state with respect to barriers and enablers to hand hygiene
- 2. Heuristic evaluations of common hand hygiene products to identify features that positively or negatively influence performance and compliance
- 3. Field studies to determine the workflow of various HCWs so that barriers and enablers could be contextualized
- 4. Focus groups with HCWs to brainstorm and validate the potential of proposed solutions to the barriers identified using the previous three methods
- 5. An environment modification and validation study in which patterns of usage were monitored and qualitative findings from HCWs were sought through surveys

Table 1	. Best	practice	auidelines	and	campaigns

Organization or Country	Year Published	Title of Article
World Health Organization	2005	WHO Guidelines on Hand Hygiene in Health Care
Centers for Disease Control and Prevention – United States	2003	Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA
Ontario Ministry of Health and Long-Term Care	2008	Best Practices for Hand Hygiene In All Health Care Settings
Ireland	2001	Guidelines for Hand Hygiene in Irish Health Care Settings
National Institute for Clinical Excellence: United Kingdom	2003	Infection Control: Prevention of Healthcare-Associated Infection in Primary and Community Care
Australia	2004	Infection Control
Centers for Disease Control, Association for Professionals in Infection Control and Epidemiology, and Society for Healthcare Epidemiology of America	2006	How-to Guide: Improving Hand Hygiene
Public Health Agency of Canada	1998	Hand Washing, Cleaning, Disinfection and Sterilization in Health Care
Department of Health — England	2003	Winning Ways: Working together to reduce Healthcare Associated Infection in England
American Institute of Architects	2006	2006 Guidelines for Design and Construction of Hospital and Healthcare Facilities
National Health Service – United Kingdom	2008	Infection Control in the Built Environment: Design and Briefing

Literature Review

A literature search was performed using Medline, CINAHL and Embase databases. Separate searches were conducted for hand washing, hand disinfection, attitudes, devices and human factors.

Two additional restrictions were placed to help focus the search: only English articles and articles published since January 2000 were included. Using Medline, CINAHL and Embase, a total of 292, 163 and 306 articles were found, respectively. The titles and abstracts of the results from the three databases were examined. Bibliographical information from relevant articles was noted, and duplicates were eliminated. Finally, articles were excluded if they (1) were conducted in dental surgeries or (2) centred on surgical scrubbing and hand preparation. The remaining number of noted articles requiring further analysis was 111.

Heuristic Evaluation

Heuristic evaluation refers to the systematic inspection of a user-interface design for usability. Using a checklist of usability principles (or heuristics) as a guide, a product is evaluated according to how well it satisfies each principle. Common heuristics include accessibility, visibility, consistency, autonomy, efficiency, flexibility and error prevention (Zhang et al. 2003).

A heuristic evaluation was conducted to assess the hand hygiene products used in four clinical areas: the Medical Surgical Intensive Care Unit (MSICU), the Emergency Department (ED) and the Family Medicine Clinic at University Health Network, and the Medical Activation and Rehabilitation Unit at Bridgepoint Health Centre, in Toronto, Ontario. Between these four units, three types of sinks, four types of waste receptacles, four ABHRs, three brands of gloves, one lotion and two soap products were evaluated. The evaluations were conducted independently by two human factors specialists, who then came to consensus on identified issues through subsequent deliberation.

Field Studies

Field studies were conducted in the same four clinical units that were reviewed during the heuristic evaluations. A total of 110 hours of direct observation of members of the nursing, physician, allied health, patient support worker and housekeeping populations were conducted. Two human factors specialists concurrently observed HCWs so that significant findings could be discussed and consensus on barriers and enablers reached. Following the shadowing sessions, in-context interviews were used to further explore observations and understand decisionmaking rationale and context. Workflow maps were then developed to understand where hand hygiene should occur and to discover trends and root causes for poor compliance.

Focus Groups

A total of six focus groups were conducted with allied health professionals, rehabilitation HCWs, family medicine HCWs,

housekeeping staff, ED and MSICU nurses and ED and MSICU physicians. Where possible, groups consisted of only one profession in order to avoid potential inter-group effects and to encourage open dialogue around profession-specific barriers and enablers. Each session involved between six and eight participants who were asked to validate observed barriers and enablers and provide feedback on their generalizability and comprehensiveness. In addition, these sessions were used to brainstorm solutions that would then be selected for inclusion in the environmental modification and validation study.

Environment Modification and Validation Study

Following the design of potential solutions, an environment modification study was undertaken. In each of the four areas of study, two rooms were modified based on the results and recommendations of the literature review, heuristic evaluations, field studies and focus groups. These changes differed depending on the unit owing to the nature of their current physical environment. In all units, additional ABHR dispensers or bottles with redesigned labels were installed and additional products and accessories were relocated (regarding height, surface mounts etc.). Over a period of 18 days, data from digital dispensing counters were collected on the amount of product used. After the study period, these data were employed to determine which ABHRs were used most frequently. Post-modification surveys were also administered to all staff to assess their perceptions of the changes.

Findings

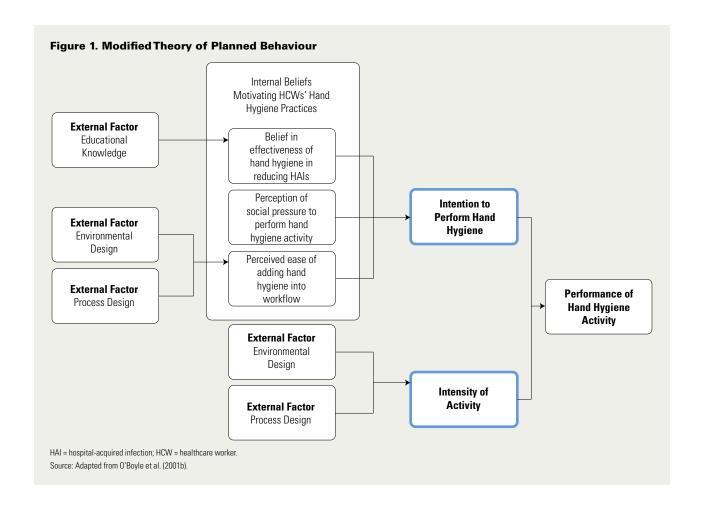
Literature Review

HCWs rightly view hand hygiene as a means of preventing the spread of infections to patients (Creedon 2006; O'Boyle et al. 2001a). In addition, they regard hand hygiene as a method of protecting themselves and their colleagues from acquiring infections (Creedon 2006; Lankford et al. 2003; O'Boyle et al. 2001a; Whitby et al. 2007). Still, compliance has been difficult to achieve.

O'Boyle et al. (2001b) used the Theory of Planned Behaviour to develop a model of the internal factors that motivate hand hygiene, including belief in the effectiveness of hand hygiene in reducing HAIs, the perception of social pressure to perform hand hygiene and the perceived ease of adding hand hygiene into workflow. These three factors influence the intention to perform hand hygiene. A fourth factor is the intensity of activity.

Extending O'Boyle et al.'s (2001b) model to infer external factors that influence hand hygiene performance, we hypothesized that factors such as the design of environments and processes could have an influence of the perceived ease of adding hand hygiene into the workflow as well as on the intensity of activity (Figure 1).

Suresh and Cahill (2007) and Cochrane (2003) used



human factors principles to investigate four of the environmental barriers: sinks, waste receptacles, ABHRs and gloves. No other studies were found that used human factors principles to assess and improve environments and processes related to hand hygiene.

Field Studies

Findings from direct observation sessions were in alignment with research reporting that healthcare professionals work in environments that do not support high-quality hand hygiene practices (Suresh and Cahill 2007). Thematic analysis of observational notes and in-context interview transcripts revealed three classes of barriers: environmental, attitudinal and process. Examples of each are described below.

Environmental Barriers

When exiting isolation rooms, HCWs remove personal protective equipment such as gowns, gloves and masks at the doorway. In accordance with recommended guidelines, once their equipment is removed, they are expected to perform hand hygiene.

This is difficult to do in many units as sinks are frequently located at the back of patients' rooms (Figure 2). Staff admitted that they re-enter the room to wash their hands or search for a sink in another location as a workaround. However, in their busy work environments, HCWs were often distracted on their way to find a sink and, as a result, started a new task without performing hand hygiene.

Attitudinal Barriers or Beliefs

In addition to environmental barriers, shadowing revealed several attitudinal barriers or beliefs about hand hygiene that prevented compliance with best practices. For example, it was observed that staff members were usually compliant with performing hand hygiene after glove removal. However, their compliance before donning gloves was much lower. Follow-up in-context interviews revealed that it is very difficult to don gloves when hands are damp, and HCWs rarely have enough time to wait for their hands to dry completely. Many perceived it to be more important to perform their patient care task quickly while wearing gloves than to perform hand hygiene

Figure 2. Poor access to sink located at the back of room, making it difficult to perform hand hygiene upon entering and exiting patient environment



Figure 3. Look-alike, unlabelled soap and ABHR dispensers



ARHR=alcohol-based band rub

before donning gloves to mitigate the risk of infection through small defects in the gloves.

Process Barriers

A third type of barrier identified was a process barrier - a routine put in place by a healthcare institution that discourages hand hygiene practices. For example, while in a patient's room, an HCW may take vital signs, check urine output and rotate the patient. According to the four moments of hand hygiene, hand cleansing should occur before entering the patient's environment, after the risk of exposure to body fluid and after exiting the patient's environment (Ontario Ministry of Health and Long-Term Care 2008). A policy requiring that gloves be worn made it tedious to perform hand hygiene for all the recommended moments as the gloves had to be removed and placed in a waste bin, hand hygiene products had to be located and used and new gloves needed to be donned before care could be continued. Many staff members were unable to comply with

the recommended guidelines because of the additional time it required to complete this process.

The three types of barriers identified were very much related. Environmental barriers often reinforce attitudinal and process barriers. Not having the appropriate hand hygiene products always available forces HCWs to use products that are inferior as a substitute or to omit hand-cleaning practices when they believe it is not essential (Lankford et al. 2003; Suresh and Cahill 2007). When products are placed in inconvenient locations, this increases the length of time it takes to perform the task (Cochrane 2003).

Heuristic Evaluation

Several significant findings that influenced the ease with which hand hygiene was performed were found. With respect to soap, ABHRs and lotions, all three types of dispensers were the same size, shape and colour and had the same actuation method (Figure 3). This made it easy for products to be mistaken for each other and thus be used inappropriately.

Products were to be identified by brand names (Purell and GoJo) instead of by product. Small windows made it difficult to determine the amount of product remaining.

Another significant problem with the dispensers was the inability to view the remaining liquid levels (see Figure 3). Although the dispensers had clear plastic windows, it was difficult

to see the transparent liquid through the small opening. In order to view the amount of product remaining, the dispenser had to be fully opened, which increased the time of the refilling process as well as the likelihood of cross-contamination when empty containers were actuated.

Examples of other issues found include the inconsistent mounting height of the alcohol-based hand sanitizers, sometimes as high as 145 cm (57 inches), and the lack of temperature and pressure control on hand-free sinks. In order to be accessible for the average adult population, dispensers should be mounted at a height of between 84 and 112 cm (33-44 inches). Hands-free sinks may discourage handwashing if the water is either too hot or too cold, or if the water pressure is too high or too low.

Focus Groups

Several focus groups were held with each of the user groups to validate findings, share learnings and brainstorm solutions. These member-checking sessions revealed insights into how potential barriers may be addressed. For example, during observational studies, users were seen to be spending more time on handwashing in bathrooms while observing their reflection in a mirror. Sharing this finding during the brainstorming sessions led to the idea to place mirrors above ABHRs. Focus groups with housekeeping staff resulted in the development of a pop-up "EMPTY" flag to be used by HCWs when they attempt to dispense a product from an empty container (Figure 4). This approach is meant to engage everyone in the environment in the maintenance of full dispensers by also providing a number to call for a refill.

Figure 4. Examples of solutions generated through focus group brainstorming sessions





Mirrors were added above dispensers of alcohol-based hand rub to incent use. "EMPTY" flags were added to the dispensers to involve all users in keeping them full.

Focus groups were also used to validate and refine the design of new labels for soap, ABHRs and lotions in order to make them easier to identify. While best practice graphic design and human factors guidelines (Smith 1979; Wiednbeck 1999; Woodson and Conover 1964) were applied to the design, the focus groups yielded important insights into the most intuitive colours for the labels: pink for soap, yellow for lotion and blue for ABHRs.

Environmental Modification and Validation Study

In all units modified, additional ABHR dispensers or bottles with redesigned labels were installed, and additional products and accessories were relocated (regarding heights, surface mounts etc.). Digital actuation counters were installed on these ABHRs so that the number of times they were used during the study period could be captured. These frequency data were then used to identify optimal locations (Figure 5).

The locations and numbers of additional products were not meant to be ideal. Instead, they were used to explore behaviour patterns in order to identify locations and products that were used most frequently.

Data from the ABHR actuation counters revealed that the ABHRs placed just outside the room were used the most frequently. There was less agreement on where the optimal locations were for products inside the rooms. Surveys indicated that, even within a particular unit, physicians and nurses

> disagreed as to their preferred location of products, likely due to their differing workflows. Different preferences were also seen across the various locations, although there was universal consensus that ABHRs be placed at specimen drop-off, pneumatic tube and blood analysis machine locations.

The product empty flags were not felt to be visible enough, and observations confirmed that these were rarely used. Mirrors placed above the ABHRs were also not found to affect the frequency of use. Qualitative survey data revealed this to be due to the lack of privacy with which to view oneself in a hallway or patient room as compared with a washroom.

To address the variability in requirements of locations as well as the shortcomings of some of the potential solutions, recommenda-

tions were iteratively developed with HCWs from each of the environments. For example, we learned of a method to engage HCWs in the optimal placement of products using stickers. Each HCW was given a set of coloured dot stickers, each colour representing a different hand hygiene product. For a period of two weeks, whenever a hand hygiene product was unavailable at a particular location, HCWs were asked to place a dot at their preferred location. After two weeks, the densest clusters of dots were identified and used to determine product placement. Data collected after the modifications revealed a high degree of satisfaction with the re-worked environment.

Discussion

This study found that some recommendations for hand hygiene environment and process optimization were universal:

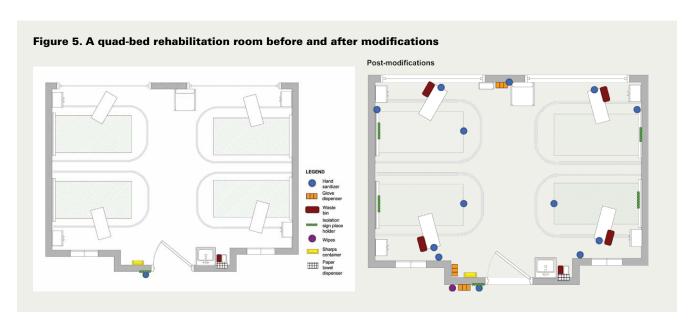
- At least one ABHR should be located within arm's reach of a patient room door.
- · Dispensers for different products should be distinctly different to avoid product confusion.
- Glove box containers should be mounted on vertical surfaces to increase accessibility and visibility.

It also highlighted that many recommendations are highly context dependent. To address this issue, a tool kit was developed to enable HCWs to apply universal recommendations as well as develop their own optimizations through the application of human factors principles. The development of the tool kit involved input from diverse stakeholders to ensure that its recommendations were sound and consistent with best practice guidelines. Ten infection prevention and control departments throughout Canada were sent content drafts and asked to provide feedback through a survey.

The resulting tool kit contains three sub-tools. The Environment Assessment Tool provides guidelines for creating environments that optimally support hand hygiene activities. Each recommendation in the guideline includes a human factors rationale and cites the usability principles (e.g., visibility, consistency, efficiency, flexibility etc.) that it meets. This context is provided to allow HCWs to adapt the recommendation if necessary, while maintaining the human factors and usability benefits. It is also intended to help alleviate confusion when guidelines may appear to conflict. For example, it may be sufficient to use manual sinks with long-lever faucets if they are in close proximity to paper towels and waste receptacles are appropriately located. Alternatively, if electronic sinks are used, they should have temperature and flow controls that are easily accessible, visible and understandable so that they can be changed according to individual preferences.

The Environment Assessment Tool also includes recommendations on how to engage front-line HCWs in the identification of ideal locations for products in their environments. Similarly, the Product Selection Tool provides guidance on how to engage HCWs in product procurement as well as label design, and the Maintenance Process Tool includes guidelines to collaboratively develop processes for ensuring the supply and maintenance of hand hygiene products.

The tools provided in the tool kit are consistent with the usercentred approach applied in this project to develop solutions. They aim to involve end users in the application of the recommendations according to their specific contexts as well as in the development of new solutions through focus groups and other collaborative activities. These approaches, along with the human factors and usability principles, applied to the optimiza-



tion of hand hygiene environments and processes may also be applied to other clinical processes and environments. By understanding the particular limitations and needs of end users and developing solutions collaboratively with them, human factors approaches result in user-validated customized solutions that better meet the needs of HCWs.

While the focus of this tool kit is on external factors that contribute to hand hygiene performance (see Figure 1), future work on further understanding and addressing the internal factors that influence hand hygiene is needed to fully address the issue of low compliance.

The tool kit was launched in April 2010 at Canada's Forum on Patient Safety and Quality Improvement. Copies are available from http://www.saferhealthcarenow.ca/EN/HandHygiene/ Pages/HumanFactorsToolKit.aspx. HQ

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Case Study of Physician Leaders in Quality and Patient Safety, and the Development of a Physician Leadership Network

Chris Hayes, Vandad Yousefi, Tamara Wallington and Amir Ginzburg

Abstract

There is increasing recognition of the need for physician leadership in quality and patient safety, and emerging evidence that physician leadership contributes to improved care. Hospitals are beginning to establish physician leader positions; however, there is little guidance on how to define these roles and the strategies physician leaders can use toward improving care. This case study examines the roles of four physician leaders, describes their contribution to the design and implementation of hospital quality and patient safety agendas and discusses the creation of a physician network to support these activities.

The positions were established between July 2006 and April 2009. All are corporate roles with varying reporting and accountability structures. The physician leads are involved in strategic planning, identifying and leading quality and safety initiatives, physician engagement and culture change. All have significantly contributed to the implementation of hospital improvement activities and are seen as influential among their peers as resources and mentors for local project success. Despite their accomplishments, these physician leads have been challenged by ambiguous role descriptions and difficulty identifying effective improvement strategies. As such, an expanding physician network was created with the goal of sharing approaches and tools and creating new strategies.

Physician leaders are an important factor in the improve-

ment of safety and quality within hospitals. This case study provides a template for the creation of such positions and highlights the importance of networking as an effective strategy for improving local care and advancing professional development of physician leaders in quality and patient safety.

here is increasing recognition of the need for physician leadership in quality and patient safety, and emerging evidence that high-performing organizations benefit from physician leadership in improving care (Baker et al. 2008; Pronovost et al. 2009; Reinertsen 1998). Whether it is referred to as physician engagement or by another term, it is generally accepted that the involvement of physicians in quality improvement projects is critical to the projects' success (Reinertsen et al. 2008). While experts acknowledge the importance of physician participation in quality improvement, the actual level of such participation continues to present challenges for quality and safety advocates. For example, one study revealed that most physicians did not routinely take part in clinical redesign initiatives, with only 34% of respondents participating in quality improvement efforts (Audet et al. 2005). Some cited reasons for this perceived lack of participation included the traditional consultant-based relationship between physicians and hospitals, strong physician autonomy and insufficient formalized training in quality improvement (Pronovost et al. 2009; Reinertsen et al. 2007). As a result, many healthcare institutions have developed formal physician leadership positions in quality and patient safety in an effort to address the above challenges and thus increase physician uptake of quality and safety efforts.

A recently published case report, based on the experience in the United States, has demonstrated the effectiveness of such formal physician positions in advancing and promoting quality improvement, among not only the medical staff but also the broader organization's healthcare professionals (Walsh et al. 2009). However, reports of similar experiences in Canada are lacking in the literature and, given the significant differences in the healthcare systems of the two countries, it is unclear if such experiences from the United States can be extrapolated to a Canadian context. This case study examines the roles of four physician leaders from hospitals in Ontario and describes their contribution to the design and implementation of hospital quality and patient safety agendas.

Physician Leader in Quality and Patient Safety: Role Descriptions Physician A

Physician A is an intensivist practising at a large urban university-affiliated hospital. Stemming from an academic interest in patient safety, this physician was appointed as director of patient safety for critical care in 2005. Physician A received patient safety training from the Institute for Healthcare Improvement and then, in alignment with the hospital's strategic vision, was appointed as medical director of quality and patient safety. In this role, physician A reported to the senior executive team under the supervision of the chief nursing officer. Initially, physician A was responsible for the implementation of patient safety initiatives including the Safer Healthcare Now! bundles and appointed as a member of the hospital's Quality of Care Committee and the Quality Committee of the board. As the role grew, physician A became more involved in strategic planning and increasing organizational capacity toward quality and patient safety. Physician A is a member of the Medical Advisory Council/ Committee (MAC) and in this role works to raise physician awareness of and participation in safety and quality initiatives.

Physician B

Physician B is a general internist with a hospital-based practice in a large community hospital known for its mature quality infrastructure and patient safety culture. Since entering independent practice in 2005, physician B participated in many front-line projects and committees and became chair of the Medical Quality of Care Committee in September 2008. Within that role, physician B supported critical incident reviews and was accountable to the MAC for physician-related system issues. Collaboration at the MAC advanced several physicianspecific quality and safety domains. Physician B informally expanded the role description to act as a physician resource

for many quality and safety projects. Broad inter-professional partnerships throughout the organization were required in this capacity. Quality and patient safety education for physicians, hospital staff and patients was also undertaken. The senior leadership team sanctioned formal training in patient safety and subsequently grew the role to include support of strategic planning for quality and safety, as well as regular engagement with the board. In the summer of 2010, the role was formally defined as Patient Safety and Medical Quality Officer. Physician B reports to the vice-president of patient services and quality, chief nursing officer and vice-president of medical and academic affairs, and remains an active member of the MAC.

Physician C

Physician C is a hospitalist at a large community hospital network and joined the organization in 2007, shortly after finishing his residency training. In 2008, the position of physician lead - quality was created as part of a renewed emphasis on quality and safety and a concomitant change in senior leadership. The physician lead in quality is a member of the MAC, with a direct reporting structure to both the MAC and the chief of staff. The roles and responsibilities of the physician lead include assisting the organization in its development of a culture of safety, helping physicians identify appropriate clinical quality indicators and develop initiatives, and providing regular progress reports to the MAC and the medical staff on the success of these efforts. In the first year, the physician lead performed various activities that were aimed at engaging the medical staff and building a capacity for an enhanced culture of safety and quality improvement among physicians. Physician C also participated in a clinical quality improvement initiative. In the second year of this position, the role has evolved to include participation in various committees and improvement activities in different capacities (resource, advisor or leader); as a result, the physician lead has been allocated 0.2 full-time equivalent (FTE) for quality improvement efforts.

Physician D

Physician D is trained in both internal medicine and community medicine (public health). The position of physician lead - patient safety was formally created in April of 2009 to support the development of patient safety initiatives, promote leading practices and continue working toward a culture that is open to disclosure and committed to making changes that will ultimately improve patient care. This role works in collaboration with the senior vice-president for patient services, the vice-president of quality and professional practice, the chief of staff, all administrative program directors, medical directors and department chiefs. The leader is accountable and responsible for strategic leadership, program development, patient care and quality/risk management. Key areas of responsibility include

Table 1. Physician leaders in quality, safety and leadership network

Physician	Year Created	Position Title	Time Commitment	Reporting	Selected Committees	Selected Projects
A	2006	Medical director, quality and patient safety	Started as 0.2 FTE Now 0.3 FTE and 0.1 FTE for CPOE	Executive VP, chief nurse 2006— 2010 Now executive VP, chief medical officer	MAC Quality of Care Committee Quality Committee of the Board CPOE Advisory Committee Patient Care Council	VTE prophylaxis improvement HSMR reduction Quality liaison to all SHN bundle teams CPOE MAC BSC initiative SafetyNET (hospital-wide education and communication program for patient safety) Unit-based communication and teamwork training and safety project Strategic planning Stakeholder in corporate reorganization for safety Safety Week organization Lead for CLI team Director of CCRT Several QI/PS research projects
В	2008	Patient Safety and Medical Quality Officer	1 FTE clinical 0.3 FTE quality and patient safety	VP, patient services, quality; chief nursing officer; VP, medical and academic affairs MAC	MAC Medical Quality of Care Committee Quality and Patient Safety Committee (proposed) Board Quality Monitoring Committee Board Committee Clinical Operations Committee Order Set Committee	Board "big dot" indicators MAC quality scorecard IHI Global Trigger Tool Policy development (read-backs, physician consultations, disclosure, critical incident reviews) HSMR reduction CAUTI reduction Morbidity and mortality rounds "Do not use" abbreviations Patient safety education for patients, staff and physicians Emergency Department Process Improvement Program E-documentation
С	2008	Physician lead, quality	0.8 FTE clinical 0.2 FTE quality/ administrative	Chief of staff	MAC Management Quality Committee Project-specific committees (VTE, HSMR, BOOST)	VTE prophylaxis improvement HSMR reduction Mortality and morbidity rounds Sepsis BOOST Organizer of annual regional quality improvement conference
D	2009	Physician lead, patient safety	0.5 FTE safety 0.5 FTE clinical Ability to increase FTE contribution to safety initiatives as required	Chief of Staff; senior VP, patient services; chief nursing executive; VP, quality and professional practice	Pharmacy and Therapeutics Committee Corporate Clinical Quality of Care Committee Corporate IM/IT Steering Committee Best Practice Committee Cardiovascular Health System Redesign Safe Medication Practices Subcommittee Corporate Pandemic Planning Steering Committee Surge Surveillance Subcommittee Quality Information Network Patient Safety Committee (proposed)	SHN SSI SSC AMI Document management Physician reporting and results distribution Medication reconciliation (3-year project) Infant security on postpartum ward Review of reported adverse events

AMI = acute myocardial infarction; BOOST = Better Outcomes for Older Patients through Safer Transitions; CAUTI = catheter-associated urinary tract infection; CCRT = Critical Care Response Team; CLI = central line infection; CPOE = computerized physician order entry; CPSI = Canadian Patient Safety Institute; FTE = full-time equivalent; HSMR = hospital standardized mortality ratios; HI = Institute for Healthcare Improvement; IM/IT = information management/information technology; MAC = Medical Advisory Council/Committee; MAC BSC = MAC Balanced Scorecard; QI/PS = quality improvement/patient safety; SHN = Safer Healthcare Now!; SSC = surgical safety checklist; SSI = surgical site infection; VAP = ventilator-associated pneumonia; VP = vice-president; VTE = venous thromboembolism.

the following: facilitate physician participation in patient safety activities; educate physicians about their roles and responsibilities regarding patient safety; advocate for evidenced-based and leading practices to be the basis for clinical improvements; analyze patient safety indicators and make recommendations for improvements; promote a positive and non-punitive safety culture; and model and encourage open and honest communication between physicians and other members of the healthcare team. The physician leader serves as a resource to all departments on issues of patient safety.

Analysis of the Roles and Responsibilities

The physician quality leader roles described in this article are summarized in Table 1. They began in 2006 with the latest physician appointed in 2009. All the physicians are relatively early in their clinical careers, having completed postgraduate education between 2003 and 2006, and have participated in quality improvement or patient safety initiatives, research or educational activities prior to assuming their quality lead roles. They completed training in quality improvement or patient safety and regularly participate in related national and international conferences. In all cases, the positions were created from an alignment with hospital strategic plans and an identified interest in quality and patient safety among the physician quality leaders. The reporting structures among the physician quality roles vary, with some reporting to the chief of staff or through the MAC, while others report corporately to the executive team, usually to the chief nursing officer. Interestingly, all the physicians were trained as general internists or are practising as hospitalists.

There is much similarity in the activities and responsibilities of the described physician quality leaders. All are active members of several hospital-based committees such as pharmacy and therapeutics, quality of care and infection control and surveillance committees, and those aimed at implementing evidence-based best practices. All the physicians are members of the MAC, with the responsibility of raising awareness to and participation in hospital quality activities. Participating in quality improvement initiatives is a common responsibility of all the physician quality leaders, either as members of established initiatives or as leaders of both self- or hospital-initiated projects. For instance, most physicians were active participants in the Safer Healthcare Now! safety bundle implementation and also initiated and led projects such as early removal of urinary catheters, pandemic planning and improving venous thromboembolism (VTE) prophylaxis. Two of the physician quality leaders sit on hospital board quality committees and participate in hospital strategic quality planning and organizational redesign for quality. There appears to be a time-based trend in that the physician quality leaders have migrated from participants to leaders of initiatives and then to corporate objective planning activities as their positions evolve.

Successes

Within the above-described roles and activities, all the physician quality leaders felt that they had significant impact on advancing the hospital quality agenda by providing unique input and opportunities that were key to the success of quality and patient safety projects. These successes were appreciated (1) through initiatives led by the physicians, (2) through attitude and culture changes among hospital staff and peer physicians and (3) through altered corporate approaches or thinking around quality.

Examples of successful initiatives led by the physician quality leaders included efforts to improve hospital-wide VTE prophylaxis, spearheaded by two of the physicians. In one of these cases, the physician quality leader convinced the MAC to identify VTE prophylaxis as its own quality improvement initiative and be accountable for improved VTE care. One physician introduced and co-led an initiative to reduce catheter-associated urinary tract infections, which resulted in a 67% sustained reduction in the use of unnecessary catheters over one year. Successful attitudinal and culture change examples included a strategy developed by one physician to improve the delivery of evidence-based best care in a structured way through physician engagement. Two of the physician leads were also instrumental in changing the attitudes toward and process of conducting morbidity and mortality rounds, which has led to system improvement. At a corporate and strategic level, direct participation of the physician quality leaders is leading to the development of Balanced Scorecards for MAC, with quality indicators identified as important by hospital physician leadership. Additionally, the physicians have been successful at influencing the hospital boards on the importance and understanding of clinical indicators such as pressure ulcer prevalence and the importance of developing a pandemic plan in the event of widespread influenza.

The physician quality leaders felt that there were several factors key to the above successes. These included the ability to give clinical input into corporate initiatives by providing feedback regarding the clinical impact, feasibility and perceptions of frontline clinicians. This input led to modifications in implementation plans that resulted in greater improvement. The group felt that their participation in safety and quality initiatives gave greater credibility in the eyes of all health disciplines, leading to more accepted practice change among staff and physicians. Since all the roles are mostly consultative in nature with limited reporting accountabilities, the physicians believe they have an easier ability to influence across department structures and hierarchies. For instance, the physicians felt that they could suggest an improvement initiative to front-line clinicians, gain their input and then present it to senior management outside of traditional committees and meetings, thus speeding up improvement efforts.

Furthermore, the physician quality leaders were successful at increasing the involvement of their fellow physicians in the hospital quality agendas. For example, one physician quality leader was successful in recruiting physician champions for each of the Safer Healthcare Now! bundles. Another is developing a physician-based quality and safety committee composed of eight hospitalists, each motivated to lead individual quality and safety projects. Another was instrumental in recruiting physician champions into three large-scale projects including safer transitions of care, medication reconciliation and improved care in congestive heart failure. Strategies to achieve these successes included providing a constant dialogue aimed at aligning physicians' interests with corporate quality and safety objectives; delivering physician educational rounds on quality and patient safety topics; and engaging in individual conversations with front-line physicians and physician leaders to identify potential change agents. In each of the four organizations, these efforts led to improved physician participation in local quality and safety projects.

Challenges

Despite these early successes in advancing hospital quality and patient safety agendas, the physician quality leaders believe there are significant challenges that may limit the magnitude or chance of continued improvement. Although the positions came with much responsibility, there was often limited corporate positioning to make decisions and limited time, resources and support to translate ideas into sustained action. As compared with other physician leadership positions such as program and department medical directors, the physician quality leaders worked by influencing others as they had no direct reports, staff or budget to implement change. The physician quality leaders found it challenging to find reliable or available local data to demonstrate the need for change, particularly to other physicians. Where data were needed, they had difficulty obtaining appropriate resources for data collection.

The physician quality leaders face ongoing challenges in balancing their clinical work and corporate quality and safety portfolios, as they all generally put in more time than is allotted or remunerated by their corporate job descriptions. Furthermore, much of this time has been spent attending committee meetings, which has led to less direct project involvement or engagement in activities. In fact, as the physician quality leaders' roles evolved to include higher-level planning and project oversight, the group has become concerned that they are at risk of losing some credibility at the front lines over time.

The physician leaders also believe that additional professional development opportunities would be helpful yet are limited in availability, expensive and not offered through traditional continuing medical education channels. Finally, as each organization had only one formal physician quality leader, the physicians felt there was a lack of peer support internally, thereby restricting the ability to share ideas and develop successful improvement strategies.

Physician Quality Network

To address some of the challenges outlined above, the group has formed an external quality network of local physician quality leaders and other physicians interested in quality improvement and patient safety. At present, the network is growing and there are 20 members from various disciplines, representing academic and community organizations across Southern Ontario. The network meets both in person and online to discuss role descriptions and common challenges, and they share tools, resources and implementation strategies that have contributed to local successes. The initial meetings were mostly informal; however, more recently the group has added an educational component and invited external speakers. Members of the group are collaborating across organizations on quality improvement initiatives. Some examples include the generation of MAC quality scorecards and strategies to address the safety of hypotonic intravenous solutions. As the network grows, the members are discussing long-term goals such as carrying out larger-scale regional initiatives and bringing physician quality leader perspectives to the broader provincial quality agenda.

Discussion

Although the physician quality leaders described in this article have been in their positions for a relatively short period of time, they have each contributed to the local design, implementation and success of hospital-based safety and quality initiatives. Yet despite these positions being established independently, there are many commonalities in the roles and responsibilities, success factors and challenges. This group's collective experience is similar to that of a multi-site centre in the United States that created a new model of physician quality leadership (Walsh et al. 2009). In this US model, the centre moved from informal engagement of physicians in quality to the creation of formal titles with a joint reporting structure; physicians were involved in key corporate initiatives, set personal objectives and were given protected time and remuneration. Their success was seen through the increased participation in and completion of quality improvement initiatives and increased communication between practising clinicians and hospital administration (Walsh et al. 2009). Where this model differs from the Canadian experience described in this article, is that the US centre created and funded seven positions spanning multiple clinical areas within one organization. This clearly created more capacity for quality improvement by physicians in the organization and the opportunity for internal networking.

The physician quality leaders described in this article believe that their membership in the quality network has contributed to their enhanced knowledge of successful strategies, better peer support and improved leadership ability in quality and patient safety. This growing network has the potential to spread healthcare delivery improvement throughout the local region.

Using a network strategy to disseminate quality improvement through physicians has been described before. The Hospitalists as Emerging Leaders in Patient Safety (HELPS) consortium was a two-year program that brought together hospitalist leaders from nine healthcare organizations with the goal of sharing best practices in the implementation of quality and patient safety initiatives (Flanders et al. 2009). The consortium provided primer education to all participants, and at regular meetings focused on key patient safety and quality improvement topics. The barriers, success factors and quality improvement initiatives that they discussed were very similar to those experienced by the physicians in the Canadian experience outlined above (Flanders et al. 2009).

Conclusion

The four physician quality leaders discussed in this article feel that they have had a positive impact on local quality and patient safety agendas. Hospitals should consider creating physician quality leader roles to assist in physician engagement, quality improvement project success and strategic planning for quality and patient safety. This article may serve as a template for

organizations advancing their quality and safety agenda through the creation of physician quality leaders. However, it is important to recognize the challenges such physicians may face and the need for greater emphasis placed on corporate decision-making, resource allocation and support. Membership in the Physician Quality Network has further enabled these physicians to contribute to local change and potentially widespread improvement. Although the creation of the network has addressed many of the challenges that the physicians have faced in their roles, more widespread education and support are needed if physicians are to continue to play a major role in the improvement of healthcare delivery. HQ

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Building Safer Systems through Critical Occurrence Reviews: Nine Years of Learning

Polly Stevens, Lynn Urmson, Janice Campbell and Rita Damignani

t The Hospital for Sick Children (SickKids), the term critical occurrence was developed to describe any event that results in an actual or potential serious, undesirable and unexpected patient or staff outcome including death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition. It also includes a breach of legislation including the Personal Health Information Protection Act of Ontario. Although broader in its definition, the term aligns closely with critical incident as defined within the amendments to Regulation 965, under the *Public Hospitals Act* (Government of Ontario 1990). Critical occurrences may include (but are not limited to) potential or actual adverse outcomes (including death) associated with or resulting from medication errors; a wrong site, patient or procedure performed; contaminated drugs, devices or products; an equipment malfunction; an outbreak or unusual pattern/ type of nosocomial infection; employee actual or potentially serious injuries.

SickKids' Blueprint for Patient Safety includes the management of critical occurrences and disclosure as one component of a 10-item road map that has guided the hospital in its active transition to a culture of safety (Stevens et al. 2005; Matlow et al. 2008). An essential underpinning of the blueprint is the ongoing need to identify failures, examine their contributing factors and apply lessons learned and system redesign to prevent recurrences.

In 2001, The Hospital for Sick Children formally imple-

mented an innovative, systematic process for reviewing critical occurrences. This process was implemented following a series of inquests and in response to the Institute of Medicine's report challenging healthcare to learn from sentinel events in an effort to prevent harm (Kohn and Donaldson 2000). The review process was largely influenced by the work of the Clinical Risk Unit and the Association of Litigation and Risk Management (1999), which described a formal, practical protocol for investigating and analyzing clinical incidents. Subsequently, the London Protocol (Taylor-Adams and Vincent 2004) provided further support for a "systems analysis" that would identify a variety of contributing factors leading up to the eventual incident as well as taking into account all aspects of the healthcare system in question.

A systems approach to incident reviews recognizes that human performance is greatly influenced by environmental (or system) factors. These include factors related to the patient and family (e.g., complexity, ability to communicate), the task and technology (e.g., availability and use of protocols, decisionmaking aids), the individual (e.g., training, fatigue), the team (e.g., communication), the workplace (e.g., working conditions), the organization (e.g., priority setting) and regulatory and government agencies (e.g., rules, laws, regulations) (Reason 1995). When problems are identified, these broader aspects of the system are explored to determine whether they had an influence on the actions of caregivers and to decide what changes can be made to prevent similar events from occurring in the future.

At SickKids, critical occurrences are managed, documented and investigated promptly and consistently using a defined approach. The critical occurrence review (CO review) process is innovative in terms of the characteristics of the review team, which consists of a leadership "triad" of a senior administrator, senior physician (often a division head) and a representative from the Department of Quality and Risk Management (QRM). As well, the broad definition of a critical occurrence within our process is unique in that the definition goes beyond the criteria of actual patient harm to include potential-for-harm events with broader hospital systems issues.

CO Review Process

Despite our best efforts, unexpected harm as the result of care provided in hospital does occur, resulting in a significant impact on the patient, family, healthcare provider and institution. The first step in our CO review process is ensuring the needs of patients and families have been met as well as providing support for staff involved in events. Appendix 1 and 2 outline immediate priorities for the patient/family and staff as well as the investigation process for the management of critical occurrences at SickKids.

Reporting of an event leads to executive notification and agreement to launch a CO review, at which time the review team, the leadership triad, is established. The review team includes, at minimum, the administrative director for the area involved, the division head or department chief (a physician from within the area) and a representative from QRM. Other members may be added such as a senior staff member from another area also involved in the event. At this time, the decision is made whether to conduct the review under the guidelines of the Quality of Care Information Protection Act (QCIPA), which would protect the information from disclosure in legal and disciplinary proceedings (Government of Ontario 2004).

The review process begins with the creation of a chronological timeline of events to answer, "What happened?" This typically involves a review of the health record and any related documents (e.g., resuscitation records and staffing schedules). Review teams also interview individuals who may provide relevant facts or pertinent background information. The review determines "what was supposed to happen" (e.g., reference to relevant policies, procedures and/or protocols) as well as "what typically happens" (e.g., chart audit of similar cases, interviews with staff). The review process investigates why the event happened, determines recommendations to prevent recurrence and assigns responsibilities and establishes timelines for implementation to try and prevent it from happening again.

Recommendations are selected based on Eldridge's Hierarchy of Interventions framework (N. Eldridge, personal communication, June 6, 2008), which ranks interventions from weak to strong in terms of their effectiveness on impacting change and improvement (Table 1). Recommendations are specific,

Table 1. Hierarchy of effective interventions

Stronger	Architectural/physical change Engineering control or interlock (forcing functions) Simplification of the process Standardization Tangible involvement and action by leadership
Intermediate	Redundancy Increase in staffing/decrease in workload Eliminate/reduce distractions (sterile cockpit) Checklist/cognitive aid Read-back Enhanced documentation/communication
Weaker	Double-checks Warnings and labels New procedure/memorandum/policy Training Additional study/analysis

Courtesy of N. Eldridge, Department of Veterans Affairs.

actionable and measurable (e.g., via an audit) with associated timelines. If personal performance issues are identified within the review process, these are dealt with separately by the appropriate supervisor.

A summary report describing the facts of the case and the proposed recommendations to prevent a similar occurrence are presented for approval to the hospital's Quality Management Council (whose mandate is to ensure and promote a culture of quality improvement at SickKids). Following approval, the recommendations are presented to the Quality Committee of the SickKids Board.

The results of the review and, in particular, the recommendations for improvement are shared more broadly throughout the organization and with the patient and family. In the case of a QCIPA review, the hospital discloses to the patient and family the systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of similar critical incidents (Ontario Hospital Association 2008). Steps to the management of critical occurrences are outlined in Appendix 1 (Immediate Priorities) and Appendix 2 (Investigation).

Follow-up reports are prepared by QRM at appropriate intervals to assess progress toward the implementation of the endorsed recommendations.

Rationale

Best practices in highly reliable organizations support the investigation of critical occurrences. They can also be a strong impetus for change and are essential for the full and frank disclosure of harm related to adverse events to patients and families. The focus

of our work was to reflect on our methods for reviewing critical occurrences, evaluating their effectiveness and determining opportunities for improvement. Woloshynowych et al. (2005) completed a review of published and unpublished "techniques" on the investigation and analysis of critical incidents and adverse events in healthcare. Although much valuable work was identified in their review, the authors acknowledged that "there is considerable potential for further development of techniques, the utilization of a wider range of techniques and a need for validation and evaluation of existing methods which would make incident investigation more versatile and use limited resources more effectively" (Woloshynowych et al. 2005: 85).

Methods

In 2009, a retrospective analysis of all CO reviews completed over a nine-year period was undertaken by QRM. A database of all critical occurrence events was created and reviewed with the intention of identifying and trending these events. A "harm index" (Table 2) was used to identify events in terms of the extent and severity of harm occurring. Severity codes are often applied to safety and incident reports as a measure of the potential or actual outcome of the event and are used to highlight the event's seriousness and assist in the prioritization of system improvements. Events were analyzed and scored with respect to contributory factors using a "theme index" (Table 3). This index was created for and used in our safety reporting systems but is similar in nature to other "human error taxonomies" that have

Table 2. Harm index

- 1. Event did not reach anyone; potential minor harm
- 2. Event did not reach anyone; potential major harm
- 3. Event reached the person; minor or no harm resulted
- 4. Minor or no harm resulted; potential major harm
- 5. Event resulted in extra observation; monitoring
- 6. Event resulted in treatment or intervention
- 7. Event resulted in increased length of stay
- 8. Event may have contributed to permanent disability or death

Table 3. Theme index

- 1 Access
- 2. Care coordination
- 3 Communication
- 4. Documentation
- 5. Education/training
- 6. Environment
- 7. Equipment
- 8. Human resources
- 9. Infection control
- 10. Information technology
- 11. Leadership/culture
- 12. Medication management
- 13. Practice/protocol
- 14. Privacy
- 15. Transfer of care
- 16 Workflow
- 17. Evaluate/audit
- 18 Other

been produced to categorize error (Taylor-Adams 1996; Taylor-Adams and Vincent 2004).

This process was also an opportunity to update the "recommendations logbook" to identify changes that occurred as a result of the review process and to review the recommendations made by review teams. Recommendations are selected based on the Hierarchy of Interventions framework (see Table 1).

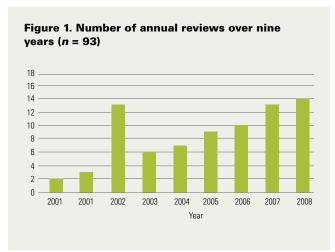
Descriptive statistics were used to analyze the findings.

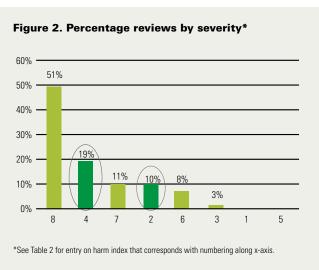
Results

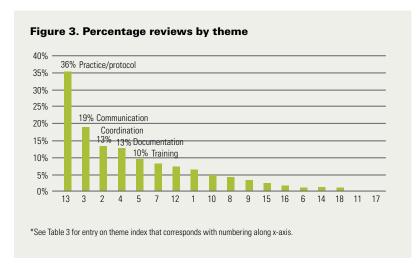
Between 2001 and 2009, 93 CO reviews were completed. Results of the study are summarized in Figures 1–5.

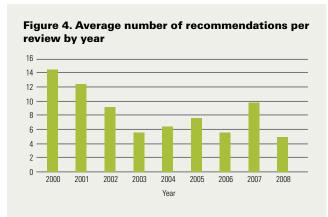
Discussion

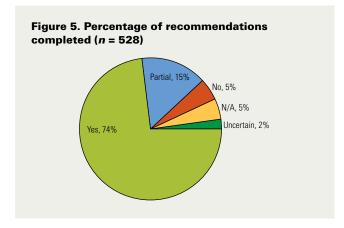
Our results identified several changes that occurred over the nine years since the implementation of the process for critical occurrences management. Increased reporting of critical occurrences and, subsequently, an increase in the number of CO reviews











undertaken annually were noted. Similar trends can be found in the literature, where a rise in the number of critical incidents being reported was attributed to an increased awareness among clinicians of the need to report, and a greater willingness to do so, rather than to any underlying change in the quality of care (Walshe and Dinneen 2001).

Thirty percent of these events were classified as potential-for-harm events with respect to the severity index (see Figure 2), suggesting a proactive approach to the prevention and mitigation of harm. Increased reporting and CO reviews are considered a positive trend in our facility, resulting from a trust that the process will lead to improvements.

Overarching themes contributing to critical occurrences were identified as practice and protocol, communication, coordination and documentation issues (See Table 3 for entry on theme index that corresponds with numbering along x-axis.). These findings are consistent with the patient safety literature (Joint Commission on Accreditation of Health Care Organizations

2004; Sutcliffe et al. 2004; Wilson et al. 1995). In the Lingard et al. study (2004) on communication failures in the operating room, communication failures occurred in approximately 30% of team exchanges. Communication breakdowns have long been cited as a root cause in almost every sentinel event reported to the Joint Commission's Sentinel Event Database and as the leading root cause in a majority of cases studied since 1996. Hierarchy differences, conflicting roles, ambiguity in responsibilities and power struggles can all lead to communication failures that compromise patient safety and quality of care.

Woloshynowych et al.'s report (2005) suggests that both researchers and investigation teams need to give more attention to recommendations for change and the implementation of changes. In our retrospective review, we identified a change in the number of recommendations from the review teams over the years (see Figure 4). Recommendations became increasingly focused and streamlined, with increased emphasis on the Hierarchy of Interventions framework (see Table 1), ranking weakest to strongest interventions in terms of their impact on "making it hard for people to do the wrong thing and easy for people to do the right thing."

Our analysis indicated that of 528 total recommendations over the nine years, 74% of recommendations were fully completed and 15% were partially completed (see Figure 5), resulting in significant system changes aimed at mitigating patient harm. The challenge of obtaining buy-in and action from management has been noted in many industries (Cronin 2006). Involvement of the leadership triad in our CO review process was thought to have a positive impact in terms of accountability with respect to following-up on recommendations.

Table 4 provides a summary of selected improvements that were implemented as a result of the CO review process over the years.

The absence of an inquest involving our facility was an additional unanticipated but significant outcome following

Table 4. Selected improvements as a result of critical occurrence reviews over nine years

Helicopter landing protocols

Quality control for rare laboratory tests

Pre-procedure safety checklists

Air-flow monitoring

Ambulatory referral system

Safe environment initiative

Communication of critical test results

Self-harm prevention (checklist)

Redesign of TPN order sheet

Osteopenia risk assessments

Widespread use of CCRT*

Improved documentation tools

Privacy and security practices

Building contractor sign-off/roof surveillance processes

CCRT = Critical Care Response Team; TPN = total parenteral nutrition.

*CCRTs are otherwise known as Medical Emergency Team or Rapid Response Team. CCRTs are composed of critical care specialists whose mandate is to provide rapid assistance to patients on the ward who have been identified as potentially at risk for deterioration.

the implementation of the CO review process. This suggests that our internal processes for the investigation and analysis of critical incidents are seen as effective in identifying and implementing changes that will reduce and potentially eliminate recurrences of similar events.

In recent years, new legislation has been enacted related to critical occurrences in our province. Amendments to Regulation 965 of the Public Hospitals Act (Ontario Regulation 423/07), which came into enforcement July 1, 2008, mandate the disclosure of critical incidents to the patient or substitute decisionmaker. Hospitals are required to disclose material facts of what occurred; consequences for the patient; and actions taken to address the consequences and systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents. Despite this new legislation, there has been relatively minimal impact to our facility as it has always been our practice to provide full and frank disclosure of events to patients and families, even for lower-risk events.

QCIPA has had an influence on our CO review process. QCIPA was enacted in 2004 as Schedule B of the Health Information Protection Act to encourage healthcare professionals to share information and hold open discussions to improve patient care without fear that the information will be used against them in legal proceedings (Government of Ontario 2004). Following a QCIPA review, a patient can be informed only of new facts identified in the review and system changes that have been made since the completion of the review.

Lessons Learned and Next Steps

In other high-risk industries, learning from accidents and nearmisses is a long-established practice. However, learning within healthcare has been described as "fragmentary, uncertain and usually confined to individuals or teams" (Woloshynowych et al. 2005: ix). Our review of critical occurrences over the past nine years has highlighted many positive changes that have resulted. It has also reinforced the need for continued efforts to improve the sharing of lessons learned and recommendations from critical incident reviews at an organizational level. Recently, pediatric grand rounds presentations have been introduced as a pilot initiative used to share organization-wide learnings from our CO reviews. Other opportunities exist, such as the Safety Learning Summaries circulated by the Winnipeg Regional Health Authorities to promote and share learnings from reviews of critical incidents (http://www.wrha.mb.ca/ healthinfo/patientsafety/criticalincidents/sls_all.php).

Although our findings suggest that the majority of recommendations from reviews were completed, it would be of value to enhance testing of their efficacy and to validate whether the suggested changes have led to the desired effect(s) on the system. This would help ensure that identified systemic problems have been addressed; recurrences have been reduced or eliminated; lessons have been learned and communicated; barriers to change have been unfrozen; and the "loop" has been closed to ensure organizational learning (Woloshynowych et al. 2005).

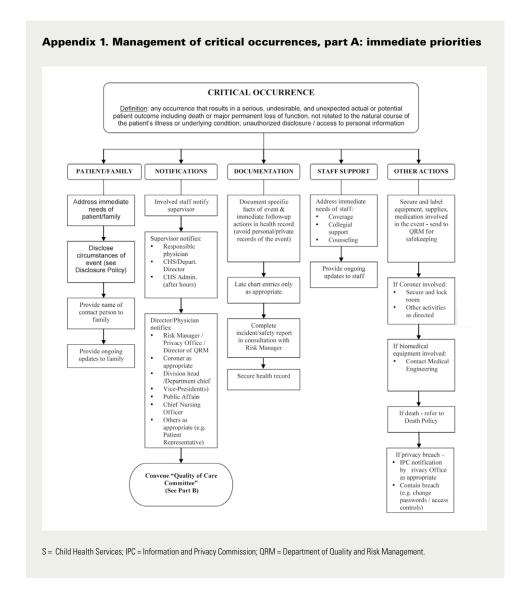
A variety of methods and approaches can and are being used to test the efficacy and sustainability of recommendations and improvement strategies. The observation of a ward/unit and auditing of a component of practice (e.g., removal of 0.3 NaCl with 3.3% dextrose intravenous solution from units) are effective checking mechanisms. Small research projects can also be implemented to assist in validating the success of improvement

Qualitative research (presently under way) aimed at exploring the experiences and perceptions of staff involved in these reviews will further inform the evaluation of our innovative "systems approach" to the management of critical occurrences. Regardless of the methods used, the presence of additional evaluation will ensure that learning from critical occurrences as well as nearmisses will continue to be a cornerstone of safety analysis and improvement in our organization. HQ

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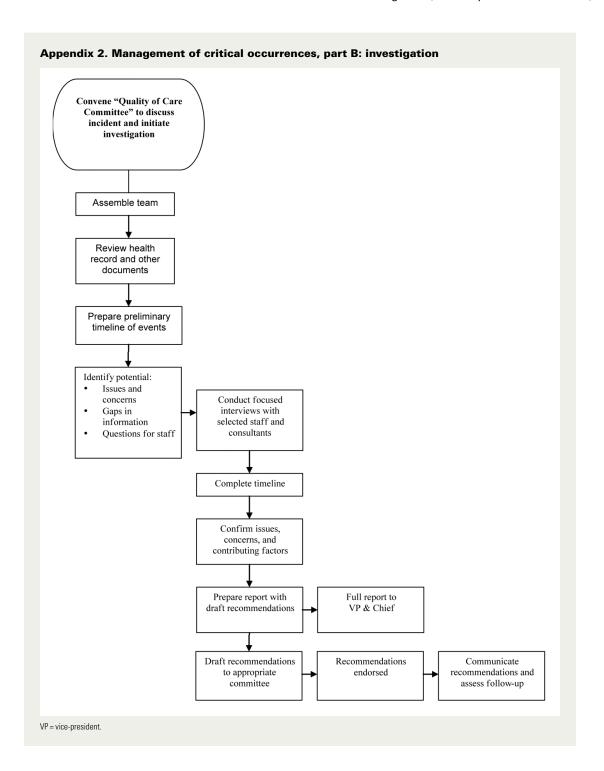
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Aiming for Zero Preventable Deaths: Using Death Review to Improve Care and Reduce Harm

Rosanne Zimmerman, Sharon Pierson, Richard McLean, Sue Anne McAlpine, Carole Caron, Beth Morris and Janie Lucas

Abstract

In 2005, our organization set a goal of zero preventable deaths by 2010 - notionally a sound goal but extremely challenging to measure, monitor and evaluate. The development of an interdisciplinary Death and Adverse Event Review process has provided a measure and framework for action to decrease adverse events (AEs) that cause harm.

Death and Adverse Event Review is a formal process in which trained reviewers consider patient deaths using a modified Global Trigger Tool to establish the presence of AEs or quality of care issues that may have potentially led to death or harm. When identified, these charts go to second-level review by a physician/interdisciplinary team to determine recommendations for actions to prevent future reoccurrences. Data have provided trending of system influences to patient safety. In 2008-2009, 1,817 deaths were reviewed and AE rates of 12.1% and 16.3% were identified. There were 422 AEs and 114 quality of care issues identified for follow-up. Of the 4.7% and 6.3% referred to the physician/interdisciplinary team for secondary review, 2.3% and 2.6% resulted in recommendations for improvement. In addition to local improvements, many system improvements have occurred as a result of the review, such as proposed minimum standards for physician documentation; a formal review of post-operative guidelines for patients with sleep apnea; and a working group to review nursing documentation, communication/follow-up of vital signs, fluid balance and pain management. The Death and Adverse Event Review process provides a new critical level of detail that supports continuous improvements to our care processes and ongoing progress toward our goal of zero preventable deaths.

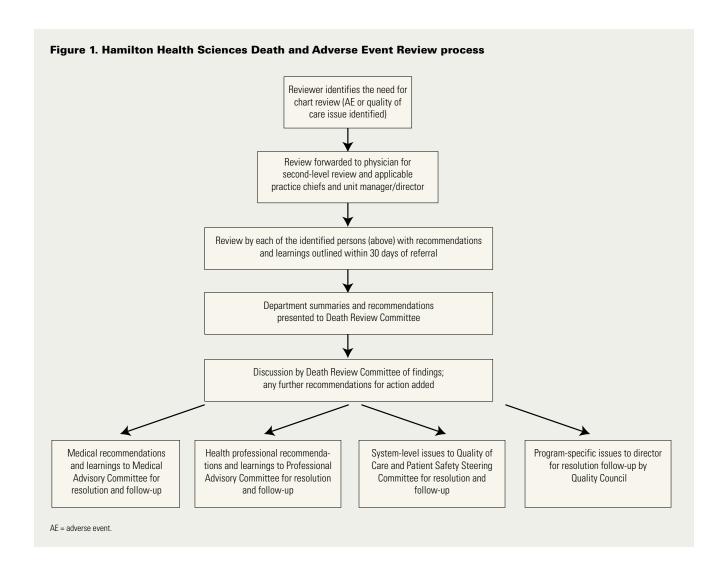
Ith the international focus on the measurement of hospital standardized mortality ratios (HSMRs), as well as the alarming frequency of adverse events (AEs) in hospitals, more and more hospitals are seeking strategies to understand the influences within the complexity of healthcare that may directly contribute to patient harm and death. As noted in the Canadian Adverse Events Study, 7.5% of Canadians may experience, as a result of healthcare management, an AE, which includes an unintended injury or complication that can lead to disability, prolonged hospital stay or death; this number rises to 10.9% of those receiving treatment in teaching hospitals (Baker et al. 2004). Measuring the prevention and reduction of AEs is challenging as it is an inherently complex and subjective process. Traditionally, patient safety events are identified and calculated according to voluntary, spontaneous reporting through occurrence reporting systems. However, studies have shown that only 10-20% of occurrences are actually reported and, of those, 90-95% cause no harm (Institute for Healthcare Improvement [IHI] 2009). Studies have also shown that medical record reviews (chart reviews) elicit significantly higher numbers of reports than does voluntary reporting. In a study by Levinson (2010) comparing multiple methods for identifying AEs, a review of medical records by nurses or physicians was found to be an effective way to identify AEs. Another study comparing chart review with occurrence reporting demonstrated that 83% of AEs were identified by chart review, whereas only 7% were identified by occurrence reporting (Baba-Akbari Sari et al. 2006).

As such, hospitals need effective methods to quantify and understand actual AE rates with a critical level of detail that allows for more confident and definitive decision-making. If hospitals do not have an accurate reflection of their true AE trends and rates, much effort can be focused on areas that may be reported frequently but are not an accurate reflection of highrisk areas of harm to patients. Critical analysis of significant harm events can expose actionable root causes versus responses

to trended occurrences. This paper outlines the interdisciplinary Death and Adverse Event Review process that has been developed at Hamilton Health Sciences (HHS) to more accurately measure and identify AEs that cause harm, and to provide a framework for action to decrease AEs that cause harm.

Death Review at HHS

HHS is a seven-site, 1,000-bed regional tertiary care facility composed of six hospitals and a cancer centre, and it has approximately 1,500 deaths per year. In 2005, HHS set a goal of zero preventable deaths by 2010. This was notionally a sound goal but practically a goal that was extremely challenging to measure, monitor and evaluate. HHS recognized that to be successful an effective and accurate means of identifying AEs would be required. This vision of zero preventable deaths, while arguably a stretch goal, has proven to be a driving force in engaging staff in the patient safety journey. Leape and Berwick (2005)



suggest that with sufficient will and leadership, we can aim for ambitious goals. The obstacles lie in beliefs, intentions, cultures and choices, all of which can change. While some may argue that zero preventable deaths is not truly attainable, this goal is aligned with our philosophy of continuous quality improvement, and truly no other goal would be acceptable to our staff or the patients and families we serve.

Prior to 2007, chart reviews were completed on all deceased patients; however, this process was fraught with challenges. The reviews occurred primarily at the physician level, and learning, communication and resolution of issues resided primarily within a particular department. There was no structured accountability, were few/limited forums for interdisciplinary discussion and was little corporate dissemination and sharing of findings. This reality, coupled with the literature findings, prompted HHS to reassess how it would successfully realize our goal of zero preventable deaths.

The new process has trained patient safety specialist reviewers (PSSRs) reviewing all adult patient deaths at HHS within 48-72 hours of death (whenever possible). The process is outlined in Figure 1. When an AE is found that may have potentially contributed to a patient's death it is referred for second level review by a physician reviewer. If the reviewer is in agreement, the chart is then reviewed by a multidisciplinary team for recommendations and follow-up which are forwarded to appropriate stakeholders. If not already completed, an Occurrence Report is initiated for any AEs in which there was moderate to severe harm noted by the PSSRs during the chart reviews and forwarded for follow-up and investigation. In addition, any "near miss" occurrences

or quality of care issues are flagged and forwarded to the respective stakeholder groups.

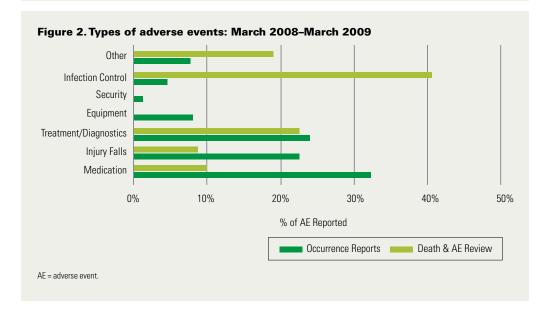
Methods

The chart review process uses a modified version of the Global Trigger Tool methodology developed by IHI. The IHI methodology involves a retrospective review of patient charts using "triggers" (clues) to identify possible AEs. The triggers are, in essence, clinical indicators thought to be predictive of the presence of an AE and to signal the need for further review of the situation in which they occur. HHS customized the IHI triggers to include screening tool criteria identified in the Canadian Adverse Events Study and criteria identified by HHS physicians and interdisciplinary practice chiefs.

During the review, details of all patient demographics are collected. Occurrences (AEs, near misses or quality of care

Table 1. Adverse events and referrals for second-level review

Adverse Events	Review (March 2008– August 2008)	Review (September 2008–March 2009)
Number of patient charts reviewed in total	840	977
Number of adverse events found	188	234
Number of patients (deaths) with adverse events	137 (16.3%)	118 (12.1%)
Number of charts referred to local Death Review Committee for second-level review	53 (6.3%)	46 (4.7%)
Number of charts accepted by local Death Review Committee	20 (2.4%)	26 (2.7%)



issues) are collected, quantified and categorized in a manner consistent with our organizational occurrence-reporting classifications and risk levels. This allows for comparisons of data from both sources. Every six months, the data are analyzed to understand trends and progress.

Results

Measurement of an Actual AE Rate

From March 2008 to March 2009, 1,817 deaths were reviewed and AE rates of 12.1% and 16.3% were identified. This represents 422 AEs and 114 quality of care issues that were identified for follow-up. Of the 1,817 deaths reviewed, only 4.7% and 6.3% were referred to the physician/interdisciplinary team for secondary review, of which only 2.3% and 2.6% resulted in recommendations for improvement (Table 1).

Of interest is the difference in AE trends revealed by the traditional HHS occurrence reporting and the Death and Adverse Event Review process. While occurrence reporting tends to highlight very visible harm (medication error, falls, proce-

Table 2. HHS Move Your Dot Matrix Data (March 2008-March 2009)

	ICU Admission	No ICU Admission
Comfort care only	"Box A": 50 deaths	"Box B": 190 deaths
Not comfort care only	"Box C": 500 deaths	"Box D": 1,077 deaths

HHS = Hamilton Health Sciences: ICLL = intensive care unit

dural/treatment errors), the Death and Adverse Event Review process seems to highlight less visible errors (infection control - hospital-acquired infections, procedural/treatment events and miscellaneous events such as self-extubations, aspirations and documentation issues that led to harm). These trends have allowed for focused targeted action to decrease AEs (Figure 2).

Move Your Dot Methodology

The Death and Adverse Event Review process also uses the IHI Move Your Dot strategy, which identifies how organizations might reduce mortality rates and consequently improve HSMR results. Using the model, deaths are categorized into four quadrants, which suggest where initiatives should be focused to impact mortality rates (Table 2). Results indicate that a focus is needed on box D (1,077 deaths), which further suggests that, since the outcome was death, these patients were in fact high risk but possibly not assessed as such. Work here might involve addressing core systems issues such as patient safety and specifically medication safety (IHI 2003). These results have

> fortuitously aligned with many current HHS initiatives implemented to date and support planning for future initiatives. Some examples of initiatives to date include the transfer of accountability guidelines, automated medication dispensing units and unit dose medication systems, rapid response teams and the communication of critical test results.

Table 3. Comparison of AE rates in the Canadian Adverse Events Study to Extrapolation of actual AE rates for HHS

Canadian Adverse Events Study*		Extrapolation of Canadian Adverse Events Study Results to HHS [†]	Death and Adverse Event Review Results [‡]
Number of admitted patients who will have one or more AE	10.3 per 100 admissions to teaching hospitals	4,120 admissions per year will experience an AE	12.3% of all patients who die experience an AE; if deaths could be compared to admission sample = 4,920/year§
Number of admitted patients who will experience one or more AE and die	1.6 per 100 admissions	640 admissions per year will experience one or more AE and die	202 deaths with one or more AE (0.5% of all admissions)

AE = adverse event; HHS = Hamilton Health Sciences.

Process Evaluation

Recently, a process evaluation was conducted with internally designed surveys with the 18 members of the Death Review Committee, including physicians, profession chiefs and members of the Quality and Patient Safety Team. The survey had a 61% response rate (11 members). As well, 48 stakeholders were also surveyed

^{*}Randomly selected chart reviews (admissions). Data from Baker et al. (2004).

[†]Based on 40,000 admissions annually.

^{*}September 2008-March 2009 annualized and assuming 40,000 admissions annually.

[§]Acuity/complexity of deaths would explain higher rate given not a comparable population.

including clinical managers and directors involved in the process and profession chiefs. There were 22 surveys returned (46%). Key highlights of the evaluation were as follows:

- Overall value of primary screening by reviewers was rated by 82% of respondents as very valuable to having excellent value.
- Death Review Committee members found the new process to be timely and an efficient use of time, and 82% noted the process to be an improvement.
- Impact of the Death and Adverse Event Review process to improving patient safety was rated as good to excellent by 82% of the Death Review Committee respondents and by 67% of the stakeholder respondents.
- · One area for improvement was improved sharing of the learnings from the death review; 67% of stakeholders identified this as an opportunity.

Discussion and Implications

To date there have been limited Canadian data available with respect to quantifying AE rates in hospitalized patients. The Canadian Adverse Events Study (Baker et al. 2004) found the overall incidence rate of AEs in patients at teaching hospitals was 10-11%. Other (non-Canadian) studies revealed that 2.3-16.6% of patents in acute care hospitals experienced one or more AEs (Baker et al. 2007). Most recently, an American study (Tolchin et al. 2007) found that 25% of patients who died had experienced an AE that may have contributed to their death. The significant disparity between the calculated/reported AE rates in the literature reflects the inherently complex and subjective nature of AE identification, measurement and reporting. This reality, coupled with the relative newness of patient safety research, makes identifying an expected AE rate or benchmark extremely difficult. Undoubtedly, it is very challenging for clinicians to distinguish the impact of an AE from other causes of poor outcomes, that is, determining whether a causal relationship actually exists between the AE and harm or death. Determining the preventability of AEs is equally difficult. That said, in an effort to identify potential AE rates at HHS, the results of the Canadian Adverse Events Study were extrapolated into "expected rates" for HHS; these and the actual AE rates from the Death and Adverse Event Reviews and are summarized in Table 3. Caution does need to be given to the extrapolation of these results given the differences in study groups (live and deceased patients), sample size and methodology.

AE Trends

The IHI (2009) notes that assessment of patient safety has traditionally relied on monitoring of systems and analyses of single or aggregate events. Continuous systematic monitoring of the frequency and nature of AEs has rarely been performed. This

has made it difficult for organizations to know definitively if the care they provide is becoming safer. Tracking AEs over time is a useful way to tell if changes being made are improving the safety of the care processes. The Death and Adverse Events Review enables us to focus on fixing faulty system processes to improve patient safety. As well, the process has focused the organization more on hidden harm system issues that may not have been addressed with the use of only occurrence reporting data.

Physician Engagement

The interdisciplinary approach has allowed for a better understanding of the whole system and the subsequent identification of system issues for improvement. Previously, deaths were reviewed by busy clinicians, something that happened with variable success depending on the department involved and the actual number of deaths combined with the lack of structured accountability. The use of nurse reviewers to screen charts prior to physician review has promoted physician engagement, allowing them to focus on events that have a defined question associated with them. Consequently, physicians are now able to complete the necessary reviews and assume an active role in improving system influences to patient safety.

Physicians are now able to complete the necessary reviews and assume an active role in improving system influences to patient safety.

There has been a notable increase in the number of charts that the physicians conducting second-level review have "accepted" from the PSSRs. In the first six-month period of review, only 15.4% of charts were accepted versus 57% of charts in the third review period. While there have been some minor modifications to the trigger tools and communication processes, the increase can in part be attributed to growing medical support for the process and the increasing expertise of the PSSRs. The culture of death review has also demonstrated significant change over the past year. The focus on interdisciplinary review, open discussion and challenging colleagues to make recommendations to ensure events do not happen again has become increasingly apparent, as have the refinement and attention to action.

Improved Death Review Processes

Many corporate and local level changes and initiatives have resulted from the Death and Adverse Event Review process. From a process perspective, all deaths at HHS are now reviewed within 72 hours whenever possible - a considerable and significant improvement from the previous experience of months required to complete some reviews. The use of a PSSR role and the application of trigger tools have considerably reduced the number of charts that are reviewed by physicians and the multidisciplinary teams. Only 4.7% and 6.3% of all deaths are forwarded by PSSRs for second-level review, thus allowing clinicians to focus on those charts with suspected issues versus a review of every patient death. In addition, there is continued evolution of the review processes: there is a growing interest in creating multidisciplinary teams for death review and a gradual shift away from reviews by the primary physicians.

All deaths are now reviewed within 72 hours whenever possible – a considerable improvement from the previous experience of months required to complete some reviews.

Improved Processes of Care

In addition to process improvements, many local and organizational improvement initiatives have resulted from the Death and Adverse Event Review process; a sample of some of these follow:

- A corporate Back to Basics initiative group has been formed to address an ongoing lack of documentation of fluid balance, weight and vital signs and/or critical follow-up of abnormal results to help prevent late rescues of patients.
- There has been a joint recommendation from the surgery and medicine departments to the Medical Advisory Committee to develop clear, basic minimum standards for physician documentation to better enable teams to follow consistent plans of care.
- There has been a recommendation for the chiefs of surgery and anesthesia to formally review the current guidelines for the monitoring and identification of patients with sleep apnea to allow for the identification of at-risk patients and appropriate planning for care.
- A hospital committee has been established to review the care of patients with a history of drug abuse who require intravenous or central lines to prevent harm resulting from selfinjections.
- A "transitional" transfer of accountability protocol for nurses was developed to make sure that appropriate and critical information is communicated when patients are transported "off units"; this will ensure that all areas are aware of risk issues for patients during transitional periods.

In addition, an extensive number of local level initiatives have been implemented following the review of referred cases.

Challenges and Lessons Learned

To date, significant progress has been made to refine and improve the Death and Adverse Event Review process. With this implementation, have come lessons in physician engagement and sustainability.

Physician Engagement

Significant engagement and support by key physician leaders including the vice-president of medicine and the Medical Advisory Committee (MAC) chair was essential to communicate the need for change and to assist with communication and support for process changes. Consistent attendance by the MAC chair to the HHS Death Review meetings was also instrumental in the ongoing development of a learning culture that is focused on opportunities to improve safety and clearly identified actions.

Sustainability

To ensure a sustainable and continually evolving process, multiple strategies were needed, including the following:

- Dedicated reviewers with significant training to continually improve and sustain the initiative
- An identified manager to provide oversight and operational management of the process
- Integrated inter- and intra-reviewer reliability auditing
- Clear accountability and reporting framework established with reports to the corporate Death Review Committee, corporate Quality Patient Safety Steering Committee and the MAC
- Continuous refinement of the process including a stakeholder evaluation completed in June 2009
- Integration of process with risk management practices
- Program- and unit-specific results presented biannually to management teams to share with front-line staff
- Integration of the trends and data into the quality and patient safety three-year plan

Conclusion

The purpose of the Death and Adverse Event Review process is to provide the detail required to lead to system-level improvements and to accelerate HHS to zero preventable harm and deaths. While the process has undoubtedly been challenging and complex, significant improvements and understanding of system issues have been gained as a result of its implementation. While many US hospitals employ a similar process or iteration, there are few Canadian hospitals that have adopted such a review process. To that end, HHS has relied on literature and internal expertise to guide our efforts; while there are a myriad of equally compelling and important initiatives that require attention and resources, HHS is committed to the Death and Adverse Event Review process. To sustain the current progress,

we continue to refine the process. As confidence is gained with the identification of trends and system issues that are contributing to AEs and potentially death, this process may evolve to a sampling approach. This would, in turn, create an opportunity to use resources to review patient populations at HHS other than the deceased. We believe we will continue to learn from the reviews and that the process is just one of many important tools that we are utilizing to understand patient safety issues at HHS. We are pleased that our efforts to date have resulted in many improvements to our care delivery system - improvements that will ensure that HHS delivers on its mission to be "leaders in exemplary care, innovation and academic excellence." HQ

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Enhancing Patient Safety through Undergraduate Inter-professional Health Education

Anne Kearney, Tanis Adey, Mary Bursey, Lynn Cooze, Carla Dillon, Juanita Barrett, Pam King-Jesso and Patricia McCarthy

The Context

Patient safety is a timely and important topic in Newfoundland and Labrador. In 2007, the provincial government established the Commission of Inquiry on Hormone Receptor Testing conducted by Justice Cameron – as a result of significant estrogen and progesterone receptor testing errors by the Eastern Health Regional Health Authority between 1997 and 2005. Among 60 recommendations outlined in her final report, Justice Cameron recommended the establishment of clear policies relating to adverse event disclosure, electronic occurrence reporting and senior leads for quality in all regional health authorities.

Also in 2007, the provincial government established the Task Force on Adverse Health Events with a mandate to "examine and evaluate how the health system identifies, evaluates, responds, and communicates" adverse events (2009: ix). The task force recommended that all regional health authorities and the provincial Department of Health and Community Services commit to a culture of patient safety. One of the 41 recommendations of the task force was that Memorial University of Newfoundland (MUN) consider implementing an inter-professional curriculum focused on patient safety and that the Canadian Patient Safety Institute (CPSI 2008) Safety Competencies Framework be used for guidance in the curriculum's development. This article describes the development, implementation and evaluation of an undergraduate inter-professional patient safety education module that resulted from this recommendation.

Enhancing a culture of patient safety begins with educating students of health professional programs about concepts such as the importance of working well as an inter-professional team. The ability to work collaboratively can enhance a culture of safety in the workplace and the effective management of adverse health events when they do occur. There is growing evidence that when healthcare professionals communicate effectively and know how to work as a team, the quality of patient care increases (Health Council of Canada 2009). Inter-professional education (IPE) – when two or more professions learn from and about each other (Centre for the Advancement of Interprofessional Education 1997) - is one way to improve communication and collaboration among members of a healthcare team.

In response to the provincial government task force's final report, the dean of medicine at MUN asked the Centre for Collaborative Health Professional Education to develop a proposal for the delivery of IPE concerning patient safety. This centre has a mandate to provide IPE to undergraduate and postgraduate students at MUN and practising healthcare professionals within the healthcare system.

IPE at Memorial University

IPE is well established at MUN. This is the 10th IPE module that students have participated in since 2005, when this university received one of 20 federally funded grants to enhance IPE in Canadian post-secondary institutions. Students from several

academic units have been involved, including those from clinical psychology, human kinetics and recreation, medicine, nursing (three sites), pharmacy and social work. The inclusion of police recruits and education students is planned for the future. Currently, the students also participate in four other undergraduate IPE modules related to mental health, professionalism, children's health and human immunodeficiency syndrome/acquired immunodeficiency syndrome.

Undergraduate IPE modules at MUN are integrated with existing courses, and all students are graded on their participation. The modules are based on a blended learning model whereby part of the learning is facilitated by an online learning management system - Desire2Learn (D2L) - while other learning activities occur face to face in small groups and plenary sessions. For most modules, the online component is two weeks in duration and involves inter-professional groups of students discussing issues related to a case study, such as how an interprofessional healthcare team can provide the best possible care. The face-to-face learning activities occur at the end of the online component. Standardized patient program role playing has been used in many of the face-to-face IPE learning activities to simulate patients or members of the healthcare team. Where possible, a former patient or inter-professional clinical team member is included in a plenary session to provide students with exposure to a real-world experience. Faculty members are recruited from applicable courses to participate in the development and implementation of the IPE modules. They facilitate both online and face-to-face learning activities and direct the development of the learning content and methods.

Patient Safety IPE Module

A committee, composed of the academic leads for undergraduate studies of all participating academic units, facilitates all IPE curriculum planning at MUN. At this level, it was decided that students in first-year medicine, third-year nursing (from both the main campus and west coast) and third-year pharmacy would be involved in the IPE Patient Safety module. Faculty members in the participating academic units were asked to volunteer to develop the module for launch within a six-month time frame. Experts from Eastern Health regional health authority joined the team, including the regional director for professional practice nursing and the assistant director of quality and risk management. The original curriculum team recruited additional members over this short planning period to ensure that sufficient expertise was present at all meetings. In the end, the faculty team was composed of 14 faculty, staff and community experts.

Details of the learning activities are presented below.

Online Component

The online component of the module involved a one-week,

case-based self-study. Students were assigned to one of 20 interprofessional groups to participate in online discussion through D2L. The curriculum team developed a case study based loosely on a documented event. It described a pediatric medication error resulting from both individual and system factors. In the case study, the physician, pharmacist and nurse all contributed in some way to the adverse event, so no one health professional was labelled as the cause. Students were asked to review the case and reflect on a series of questions designed to emphasize the importance of working together as a team and the competencies required to create a culture of safety within healthcare. Resources on D2L included the CPSI Safety Competency Framework and Canadian Disclosure Guidelines, the Situation-Background-Assessment-Recommendation (SBAR) communication tool developed by the Canadian Health Services Research Foundation and professional competencies for practising nurses, pharmacists and physicians related to patient safety. For example, the collaborator and manager roles within the CanMEDS Competency Framework were emphasized. Provincial resources included regional policies related to occurrence reporting and disclosure and the Adverse Event Management Framework developed by the task force. The curriculum team revised the case study many times to ensure it was not too complex for the level of the students involved. As well, faculty prepared a glossary of important terms and provided hyperlinks in the case study to additional explanatory information relevant to the medication error. There were also numerous hyperlinks for other resources such as key articles, websites, seminal reports, organizations concerned with patient safety, professional competency frameworks and professional associations' position statements related to patient safety. In preparation for their face-to-face learning activities, students were asked to reflect on all questions and were assigned to lead a discussion on one question within their group. All inter-professional student teams were facilitated by a faculty member from the participating academic units or a trained volunteer.

Face-to-Face Learning Activities

The face-to-face learning activities involved a 45-minute small-group meeting. Students located on the main campus in St. John's met in their inter-professional teams to discuss the assigned case study questions and to formulate questions for the expert panel in the ensuing plenary session. Nursing students on the west coast campus met in uni-professional groups. Each group consisted of nine or 10 students. Case study questions were developed to help the students learn that adverse events occur because of both system and individual issues and the importance of timely occurrence reporting and disclosure to the patient and family. The students were directed in some questions to review resources posted on D2L. The following questions were assigned to students:

- What errors were made by the inter-professional team and by the individual members?
- What CPSI safety competencies are most relevant to this case? [See the resource list.]
- What problems in the system might have led to the errors?
- How could the system be changed to prevent future errors?
- Should an "occurrence report" have been completed for this medication error? If so, who could have completed the form? Why are occurrence reports important? When should an occurrence report be completed? [See policies from Eastern Health and Western Health regarding "occurrence reporting."]
- Should the error have been disclosed to the patient's family? How should the disclosure of occurrences occur? [See policies from Eastern Health and Western Health regarding disclosure and the CPSI Canadian Disclosure Guidelines in the resource list.]
- Why do you think the inter-professional team members chose not to document this error?
- Use the SBAR tool to reflect on what happened in this situation. [See the website resource list.]
- Please review the professional competencies specific to your profession. [See the resource list.] Consider the competencies that might have prevented this occurrence.

The main role of the facilitator in the small-group meeting was to encourage discussion by all participants, promote respectful dialogue and maintain group focus on task in the short time allotted. Although facilitators were not expected to be a source of expertise related to the content matter or scope of practice of any health profession, they were familiar with the case and the background materials provided to the students. If contentious issues arose - for example, disagreement about the cause of the error - facilitators allowed the students to work through the discussion and come to a reasonable solution. When facilitators felt the students lacked some important information, this was imparted once the students concluded their discussion. By being non-directive, facilitators avoided sharing their opinions on issues such as scope of practice and treatment, thereby allowing students to critically reflect on these issues and come to their own conclusions. An answer key was created for each of the case study questions to provide support to the facilitators during the discussion.

Plenary Session

Students assembled in an auditorium for the 75-minute plenary session; nursing students from MUN's west coast campus participated by video-conference. An inter-professional panel led the discussion during the plenary. The panel was composed of a physician, a pharmacist and a nurse who is an organizational lead for quality and risk management. Standardized

Patient program members role-played the disclosure of an occurrence following a script developed from the case study. The roles within the simulation included the mother of the child who had received incorrect medication, the prescribing physician and the unit manager. There were two parts to the role-play. The first was a poor disclosure scenario in which the physician was evasive and defensive and the unit manager was not fully informed of the situation and was visibly frustrated. In this scenario, the mother became upset, indicating she would take further action. After the role-play, the panel members asked the students to discuss the disclosure, including how it could be improved. This step was followed by the enactment of a much more positive occurrence disclosure in which the physician clearly explained to the mother how the medication error occurred, the steps taken once the error was discovered, the subsequent care provided and current condition of her child. The mother's feelings were acknowledged, an apology was issued and the mother was encouraged to contact the unit manager if she had any further questions or concerns. This resulted in a more calm reaction from the mother. The students were again asked to reflect on this disclosure and to discuss how it supported a more positive patient safety environment. The panel members discussed various issues pertinent to patient safety, such as the importance of working together as a team to manage safety risks and clear institutional policy regarding occurrence reporting and disclosure. The plenary session ended with students posing questions to the panel regarding the case and the issue of patient safety in general.

Patient Safety Competencies

The CPSI Safety Competencies Framework identifies the knowledge, skills and attitudes required by health professionals to achieve a culture of safety in healthcare settings. CPSI recommends that competencies related to six domains be incorporated into health professional curricula at the pre- and post-licensure levels. While the students in the IPE module were required to reflect on all six patient safety competency domains, the curriculum team chose to emphasize two: (1) Work in Teams for Patient Safety - working within inter-professional teams to optimize both patient safety and quality of care - and (2) Manage Safety Risks - anticipating, recognizing and managing situations that place patients at risk.

The case study and associated questions were designed to encourage student reflection on key competences required for working in teams, including an understanding of the roles and responsibilities of each team member and protocols for the team's response to an adverse event. Similarly, competencies related to managing safety risks included the importance of recognizing that both individual and system factors contribute to adverse events and that standardized approaches and processes can increase patient safety.

Evaluation

Approval to administer the student assessment and program evaluation data collection tools was received from the research ethics board at MUN.

A total of 184 students from medicine, pharmacy and nursing (two sites) participated in the 2009 Interprofessional Patient Safety module (see Figure 1). Of these, 168 students completed an evaluation of the module (91.3%).

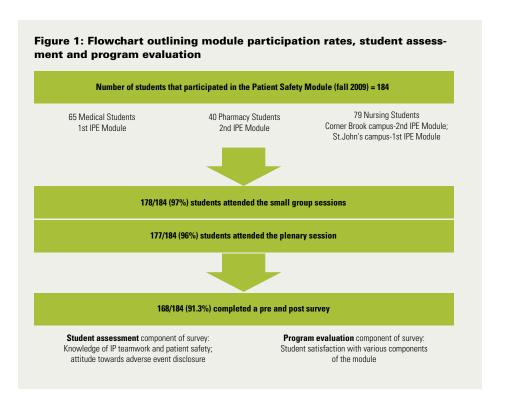
The instrument measuring student attitude toward adverse event disclosure was adapted from a survey tool assessing students' attitudes about quality, safety and teamwork developed by Cox et al. (2009). It was piloted with a small sample of students from participating academic units. This 13-item five-point Likert scale was administered to

the students before and after the module implementation. A 14-item five-point Likert scale measuring students' knowledge of inter-professional teamwork and patient safety, as well as their satisfaction with the module, was administered post-implementation.

Student assessment data demonstrated a significant attitude shift toward teamwork, adverse event reporting and documentation to improve patient safety. Similarly, students reported that they had increased knowledge about patient safety, the importance of the inter-professional team and the role of other health professionals in delivering safe patient care. Program evaluation data demonstrated high student satisfaction with the learning experience (see Table 1).

Students' responses to open-ended questions also demonstrated knowledge and an attitude change in relation to patient safety, including the importance of inter-professional collaboration, occurrence reporting and taking responsibility for an error as a team (as opposed to blaming individual team members). Students additionally commented on aspects of the module they particularly enjoyed, including the small-group inter-professional discussion, the Standardized Patient program role-plays and the panel discussion.

Data were collected from students six months after module implementation to determine if there was a sustained change in attitudes toward adverse event disclosure. On the instrument measuring student attitude toward adverse event disclosure,



there were no significant changes in eight items such as "making errors in healthcare delivery is inevitable" and "healthcare professionals should routinely share information about clinical errors and what caused them," indicating that students still held positive attitudes on these items. On the other hand, students demonstrated a negative attitude shift on five items including "to consistently achieve good healthcare outcomes, patient care must be well coordinated" (p = .012) and "errors that reach the patient should be reported, even if the patient is not harmed" (p = .007). Data collection will occur again at one year postimplementation in the fall of 2010.

Lessons Learned

As with all IPE activities, there are several challenges that have to be resolved. The first of these is the logistics involved in putting together this learning experience, including finding a common time for the curriculum team to meet and for students to participate. The first challenge was addressed by adding additional members to the team. This increased the likelihood there would be at least one faculty member from each participating academic unit present at all planning meetings to ensure that the material prepared was accurate and congruent with the professional competencies. Finding a common time for students to participate in IPE activities is an ever-present challenge as the academic units have different schedules. This requires advance planning, patience, a measure of goodwill and a strong commitment to

Table 1. Student satisfaction with the Patient Safety module*

Survey Statement	n	Mean
This learning experience has enhanced my understanding of patient safety.	166	4.25
I learned about the role of the inter-professional team in delivering safe patient care.	166	4.27
I learned about the role of my profession on an inter-professional team in delivering safe patient care.	166	4.17
I learned about the role of other health professionals in delivering safe patient care.	166	4.21
This learning experience enhanced my understanding of the process of adverse event disclosure.	165	4.27
I feel that I have an introductory knowledge base regarding patient safety.	165	4.23
I am now aware of the competencies required by healthcare professionals to deliver safe patient care.	165	4.09
I feel better prepared to participate in an inter-professional team.	166	4.10
The learning objectives for this module were clear.	165	4.06
The workload for this module was fair.	166	4.25
This module was well organized.	165	4.29
The following activities were useful in facilitating my learning:		
Online course information	165	4.00
Case study	166	4.34
Small-group, inter-professional learning experiences	166	4.40
Standardized patient disclosure role-play	164	4.35
Panel/group discussion	164	4.36
I would recommend this module to other learners.	165	4.25
Overall, this was a meaning learning experience.	164	4.30

^{*168} students rated the module on a five-point Likert scale

IPE on the part of all participating academic units as they may be asked to make adjustments in their program to allow their students to participate.

Creating the instructional materials for this IPE module was more complex and time consuming than anticipated. All instructional material had to be easily understood because participating students were at varying stages of their education and some of the small-group facilitators were not health professionals. This necessitated many iterations of the case study and the development of the auxiliary learning materials that were posted on D2L. The time involved in creating these materials proved to be worthwhile. Neither the students nor facilitators voiced any concerns regarding the learning materials.

When developing the materials, the curriculum team was cognizant of making students aware that both system factors and individual factors contribute to the occurrence of adverse events. There were a number of system issues in the case that contributed to the error, and some students remarked on this. As one student stated in the post-module survey, "When errors occur, the inter-professional team takes responsibility as a team (a system error), rather than individual human error, so the team can work together to prevent the error from happening again." It was also important that all members of the healthcare team involved in the case study contributed in some way to the error to avoid labelling one profession as the cause. In this case, the physician, pharmacist and nurse all contributed to the error and to its non-reporting.

Conclusion

In summary, the first implementation of the Patient Safety IPE module had a positive effect on student knowledge and attitudes toward inter-professional teamwork, patient safety and adverse event

disclosure. Over time, we anticipate this module will contribute to creating a culture of patient safety within healthcare settings. HQ

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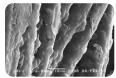
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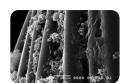
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Using SBAR to Communicate Falls Risk and Management in Inter-professional Rehabilitation **Teams**

Angie Andreoli, Carol Fancott, Karima Velji, G. Ross Baker, Sherra Solway, Elaine Aimone and Gaétan Tardif

Abstract

This study implemented and evaluated the adapted Situation-Background-Assessment-Recommendation (SBAR) tool for use on two inter-professional rehabilitation teams for the specific priority issue of falls prevention and management. SBAR has been widely studied in the literature, but rarely in the context of rehabilitation and beyond nurse-physician communication. In phase one, the adapted SBAR tool was implemented on two teams with a high falls incidence over a six-month period. In phase two, process and outcome evaluations were conducted in a pre-post design comparing the impact of the intervention with changes in the rest of the hospital, including the perceptions of safety culture (as measured by the Hospital Survey on Patient Safety Culture); effective team processes, using the Team Orientation Scale; and safety reporting, including falls incidence, severity and near misses. This study suggests that the adapted SBAR tool was widely and effectively used by inter-professional rehabilitation teams as part of a broader program of safety activities. Near-miss and severity of falls incidence trended downward but were inconclusive, likely due to a short time frame as well as the nature of rehabilitation, which pushes patients to the limit of their abilities. While SBAR was used in the context of falls prevention and management, it was also utilized it in a variety of other clinical and non-clinical situations such as transitions in care, as a debriefing tool and for conflict resolution. Staff found the tool useful in helping to communicate relevant and succinct information, and to "close the loop" by providing recommendations and accountabilities for action. Suggestions are provided to other organizations considering adopting the SBAR tool within their clinical settings, including the use of an implementation tool kit and video simulation for enhanced uptake.

Background

The physical, psychological, social and economic consequences of falls and falls-related injuries have been well documented in the literature. Each year in Canada, approximately one third of healthy, community-dwelling older adults experience a fall (Registered Nurses Association of Ontario [RNAO] 2007). Falls in hospitals are almost three times this rate and account for up to 84% of all in-patient incidents (Halfon et al. 2001). There is compelling evidence, however, that falls can be prevented through timely risk detection and appropriate management. Numerous guidelines have emerged over the past decade outlining best practice for falls risk prevention and management both within healthcare settings and in the community (American Geriatrics Society, British Geriatrics Society and American Academy of Orthopaedic Surgeons Panel on Falls Prevention 2001; RNAO 2007). Inherent within these guidelines is the need for strong inter-professional team collabora-

tion and communication. Communication breakdown has long been cited as the leading cause of inadvertent patient harm, including falls (Joint Commission on Accreditation of Health Care Organizations 2004). All too frequently, however, communication is context or personality dependent and influenced by a myriad of factors including gender, culture, profession and structured hierarchies within healthcare (Leonard et al. 2004).

The Toronto Rehabilitation Institute (Toronto Rehab), a large academic rehabilitation and complex continuing care hospital, has embarked upon a novel patient safety strategy to improve team communication. In a pilot study, we adapted and implemented a structured communication tool - the Situation-Background-Assessment-Recommendation (SBAR) process – for use in a rehabilitation setting, with promising results (Boaro et al. 2010; Velji et al. 2008; see Figure 1 for the adapted SBAR tool). The SBAR tool is a situational briefing model that provides appropriate assertion, critical language and education to a safety issue (Leonard et al. 2004). While many organizations have implemented the SBAR tool, there is little evidence regarding its effectiveness beyond the acute care environment and nurse-physician communication. The pilot study offered preliminary insights into how SBAR may be used and evaluated within an inter-professional rehabilitation team. This current study builds upon our previous work in three ways: it implements SBAR on two rehabilitation units with high falls rates; it focuses team communication around the high-priority issue of falls prevention and

management; and evaluates processes and outcomes specific to patient safety culture, team communication, and falls incidence and severity.

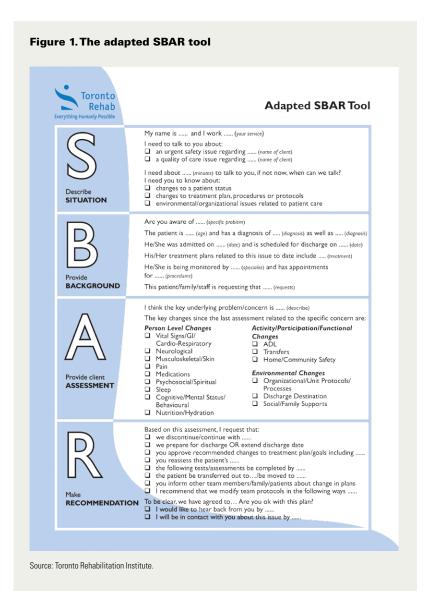
Methods

This project had two phases: in phase one we implemented the adapted SBAR tool and in phase two we evaluated its processes and outcomes.

Phase One: Implementation of the Adapted SBAR Tool

Study Teams

The geriatric and the musculoskeletal rehabilitation units were



chosen for this study. Both units are similar in size, admit similar patient populations (older adults with multiple co-morbidities) and have similar lengths of stay (ranging from 35 to 40 days). They are also comparable in terms of falls incidence. In the two years leading up to the study, falls on these units constituted 43% of all reported falls in our organization (excluding longterm care).

Participants

Clinical and non-clinical staff members and leaders of the geriatric rehabilitation (50/55) and musculoskeletal rehabilitation (35/50) units participated in this study. Participants included health professionals who deliver direct patient care (e.g., health disciplines, nurses and physicians), as well as support staff who have a critical role within the unit (e.g., porters, housekeeping and volunteers). In both study groups, all health disciplines, physicians and unit leaders participated.

Education Sessions

The implementation of the SBAR process occurred over a six-month period. A series of three education workshops (a total of four hours) introduced staff to key elements of patient safety including communication breakdown in healthcare. a systems approach to safety culture, openness to reporting incidents and near misses and the use SBAR to facilitate communication. Role-playing using reallife case examples related to falls risk assessment, prevention and management was used to demonstrate how SBAR may be

Table 1. Study teams pre- and post-intervention

Safety Dimension	Pre-intervention (%)	Post- intervention (%)	Change (%)*	Critical Ratio Test (z>1.96)*
Overall Perceptions of Safety	38	59	20	4.43
Frequency of Events Reported	45	52	8	1.29
Manager Expectations Promoting Safety	77	82	5	1.11
Organizational Learning	72	85	14	3.04
Teamwork within Units	73	82	9	2.23
Communication Openness	42	54	13	2.33
Feedback and Communication about Error	52	67	15	2.70
Non-punitive Response to Error	39	51	13	2.31
Staffing	40	56	16	3.49
Management Support for Patient Safety	71	78	8	1.57
Teamwork across Hospital Units	63	79	17	3.82
Handoffs and Transitions	30	57	28	5.76

^{*}Legend: Those results presented in shaded grey boxes are considered clinically improved (>5%); in blue boxes are considered statistically improved (z>1.96); and in yellow boxes represent no change.

implemented in clinical situations. These scenarios provided participants with powerful feedback in learning how to apply the tool.

Sustaining the Use of SBAR on the Units

Our previous work supported using local champions to reinforce the use of SBAR during the implementation phase and beyond. We also used a series of reminder tools including pocket cards, posters, telephone prompts and educational binders that were located strategically throughout the units. A member of the research team or SBAR champion also attended weekly team rounds as a way to further reinforce the use of SBAR, and to understand the situations in which SBAR was being used (or not), with whom and in what context.

Phase Two: Outcome and Process Evaluation of the Effectiveness of the Adapted SBAR Tool

The three main outcome measures of this study examined staff perceptions of patient safety culture, team effectiveness and falls incidence, including fall severity and near-miss reporting.

Outcomes were measured using a pre-post test design, and data from the study teams are presented in aggregate form. The process evaluation involved a multimodal approach that aimed to better understand the context and uptake of SBAR on the two inter-professional teams.

Staff Perceptions of Safety Culture

Staff perceptions of patient safety culture were measured using the Hospital Survey on Patient Safety Culture (HSOPSC; Westat et al. 2004). The 43-item survey can be used to track changes in patient safety culture over time, as well as to evaluate the impact of patient safety interventions at both the organization and unit levels. The survey consists of 12 patient safety domains and has been found to be valid and reliable. All Toronto Rehab staff (n = 1,700) were sent the survey prior to the implementation of SBAR and approximately 12 months later. Response rates pre- and post-intervention were 31% (n = 520) and 33% (n = 569), respectively. The study teams had a response rate of 87% (n = 74) pre-intervention and 69% (n = 59) post-intervention. Surveys were analyzed using the "5% rule of thumb" as suggested by the survey authors; that is, results must be at least

Table 2. Study teams compared with the rest of the hospital pre- and post-intervention

	Pre-interv	Pre-intervention*			Post-inte	rvention*		
Safety Dimension	Study Units (%)	Rest of Hospital (%)	Difference (%)	Critical Ratio Test (z >1.96)	Study Units (%)	Rest of Hospital (%)	Difference (%)	Critical Ratio Test (z >1.96)
Overall Perceptions of Safety	38	59	-21	6.60	59	63	-4	1.05
Frequency of Events Reported	45	53	-8	1.95	52	56	-4	0.69
Manager Expectations Promoting Safety	77	76	1	0.46	82	76	6	1.93
Organizational Learning	72	72	0	0.18	85	77	8	2.37
Teamwork within Units	73	79	-5	2.09	82	81	1	0.34
Communication Openness	42	58	-16	4.35	54	56	-2	0.39
Feedback and Communication about Error	52	62	-10	2.58	67	64	3	0.72
Non-punitive Response to Error	39	45	-6	1.77	51	48	3	0.71
Staffing	40	52	-12	3.64	56	52	4	0.91
Management Support for Patient Safety	71	76	-5	1.60	78	80	-2	0.47
Teamwork across Hospital Units	63	65	-2	0.68	79	67	12	3.41
Handoffs and Transitions	30	47	-17	4.90	57	51	6	1.62

*Legend: Those results presented in shaded grey boxes are considered clinically improved (>5%); in blue boxes are considered statistically improved (z>1.96); in yellow boxes represent no change; in purple boxes are considered statistically worse; and in pink boxes are considered clinically worse (≤5%).

5% higher or lower to be considered clinically significant. We also tested for statistical significance within the study units, as well as compared with the rest of the hospital, which served as our control group.

Study Teams Pre- and Post-intervention

Over the study period, the geriatric and musculoskeletal rehabilitation teams showed clinically meaningful change (using the 5% rule of thumb) in all 12 safety dimensions of the HSOPSC. Many of these improvements were greater than 10% and ranged as high as 28% in the Handoffs and Transitions dimension, which is an area of emphasis for the organization. Nine of the 12 safety dimensions were also statistically significant (Table 1).

Study Teams Compared with the Rest of the Hospital Pre- and Post-intervention

At baseline, the aggregated results for the study teams scored clinically lower than results for the rest of the hospital in nine of the 12 safety dimensions, and statistically lower in six dimensions (Table 2). Many of these dimensions were related to teamwork and communication. Post-intervention, intervention units scored clinically higher in four safety dimen-

Table 3. Comparison in change scores within the study teams and the rest of the organization

	Pre-post R	esults for Study Team	Pre-post Results	for Rest of Hospital
Safety Dimension	Change (%)	Critical Ratio Test (z>1.96)	Change (%)	Critical Ratio Test (z>1.96)
Overall Perceptions of Safety	17	4.43	4	1.98
Frequency of Events Reported	4	1.29	3	1.50
Manager Expectations Promoting Safety	5	1.11	0	0.17
Organizational Learning	8	3.04	5	2.39
Teamwork within Units	6	2.23	3	1.43
Communication Openness	15	2.33	-2	0.61
Feedback and Communication about Error	13	2.70	2	0.88
Non-punitive Response to Error	9	2.31	3	1.19
Staffing	16	3.49	0	0.39
Management Support for Patient Safety	3	1.57	4	2.69
Teamwork across Hospital Units	14	3.82	2	1.28
Handoffs and Transitions	23	5.76	4	2.04

^{*}Legend: Those results presented in shaded grey boxes were considered clinically improved (>5%); in blue boxes were considered statistically improved (z>1.96); and in yellow boxes represent no

sions: Manager Expectations Promoting Safety, Organization Learning - Continuous Improvement, Teamwork across Units and Handoffs and Transitions. Two of these dimensions were also statistically significant.

Table 3 examines these change scores in greater detail. It compares the changes within the study units and the control group pre- and post-intervention. While the organization showed some improvements in clinical (one dimension) and statistical scores (four dimensions), the study teams demonstrated clinically significant change in 10 dimensions and statistically significant change in nine.

Team Orientation Scale

The Team Orientation Scale was administered to the study teams at baseline and following the implementation of SBAR. This scale measures team effectiveness and incorporates issues of team communication, team perspectives and valuing others, and is part of a larger questionnaire based on the cognitive-motivational survey by Millward and Purvis (1998). The survey and its domains have been found to be valid and reliable. Pre-and postimplementation, the study teams showed significant change in four of the 10 items, including items that emphasized effective and agreed-upon methods of communication, and a belief that participants' contributions were valued (Table 4).

Safety Reporting

Falls incidence and severity, as well as near-miss reporting, were examined through our online reporting system. Severity ratings were categorized in four levels (no harm, minor, moderate and major) and tracked over an 18-month period, including the six months leading up to and following the study period. Both near-miss reporting and the number of major falls demonstrated an overall decreasing trend across both the organization and the study units. Conversely, total falls showed an increasing trend on the study teams. These data do not account for repeat fallers; nor do they consider whether falls increased on these units or if staff were simply reporting more incidents. Figure 2 shows the total number of major falls, or falls causing serious injury, on the two study team units rehabilitation units compared to the entire organization.

Process Evaluation: How Was SBAR Used?

The aim of the process evaluation was to further explore the uptake (or not) of SBAR on the two inter-professional rehabili-

Table 4. Team Orientation Scale pre- and post-intervention

Item	Pre-intervention (% Agree)	Post- intervention (% Agree)	Change (%)	Critical Ratio Test (z >1.96)
Team members act upon the information I communicate to them.	74	83	9	1.00
2. I am able to communicate effectively with team members.	74	91	17	2.12
3. This team has agreed methods for communication.	40	79	39	4.16
4. Communication between team members is unclear.	37	69	32	3.33
5. I regularly communicate with other members of the team.	96	94	-2	-0.04
6. I act upon the information that other members of the team communicate to me.	96	96	0	-0.38
7. All team members' perspectives are important.	100	96	-4	0.95
8. This team believes it is important to consider the perspectives of all team members.	82	87	5	0.49
9. I believe other team members value my contribution to our work.	78	93	15	1.97
10. Each team member plays a valuable role within the team.	95	96	1	0.003

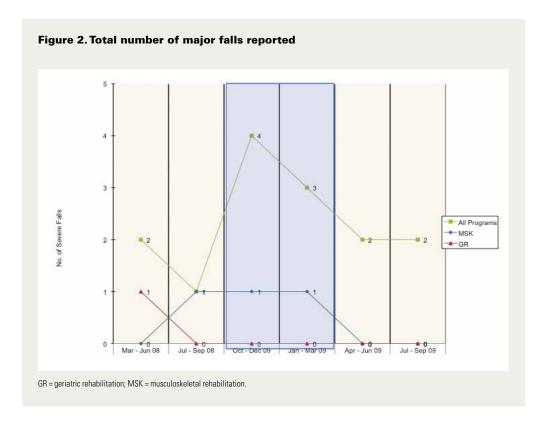
^{*}Legend: Those results presented in blue boxes were considered statistically improved (z>1.96); and in yellow boxes represent no change

tation teams and to provide additional contextual understanding of our results. To do this, we conducted brief one-on-one interviews with all participants mid-way through the study. We also held focus groups (n = 18) on each of the study units at the end of the implementation period. Each focus group was conducted by two experienced moderators and was audiotaped and transcribed verbatim. These groups provided us with an in depth understanding of the enablers of and barriers to using structured communication on inter-professional teams. For example, at the beginning of the study participants regularly said to us, "We are good communicators. Why do we need SBAR? We do this already!" At the end of the study, however, this notion had changed. Many participants expressed that while they were able to provide the situation and background of an issue; they only sometimes offered their assessment and rarely made a recommendation.

Three main themes emerged from this evaluation. First, staff used SBAR to communicate falls prevention and management; but they also used the tool in a variety of other clinical and non-clinical contexts, for example, as a debriefing tool and to discuss changes in team processes. Second, participants used SBAR in situations that they perceived to be sensitive or hierarchical in nature (e.g., when approaching their manager or during conflict resolution). And third, staff used the tool in urgent situations (e.g., changes in a patient's health status); but they also used it in a variety non-urgent situations, including changes in a patient's treatment plan and during transitions in care.

Recommendations for the Adoption of SBAR in Other Clinical Settings

Results from this study suggest that SBAR was widely and effectively used by inter-professional rehabilitation teams as part of a broader program of safety activities. In particular, we have seen compelling changes in staff perceptions of safety culture, as well as effective team processes and communication. Based on experiences with both our pilot and expanded studies, we offer the following recommendations to other organizations considering adopting structured communication tools:



- the implementation phase that reinforced an iterative "learning-in-action" approach. This allowed us to refine the tool and our processes.
- · Consider implementing SBAR in clinical environments with teams that may be underperforming. We implemented SBAR onto two teams with a high falls incidence. Implementing change initiatives, even pilot studies, on highperforming teams may be a lost opportunity. Staff found the tool useful in helping to communicate relevant and succinct information and to "close the loop" by providing recommendations and accountabilities for action.

- Sustain the momentum. SBAR champions emerged naturally from the study teams and were an effective means to reinforce, encourage and model the use of SBAR. We also included clinical and support staff in both phases of the study, which made the SBAR process relevant to the entire rehabilitation unit and additionally recognized the key role that support staff play in patient safety within the organization. Finally, we found that reminder tools, such as telephone prompts and pocket cards were useful and widely utilized.
- Recognize the diversity of the SBAR conversation. We asked teams to structure their SBAR conversations around communicating the issue of falls risk and management (e.g., SBAR to communicate falls risk assessment, as a handoff mechanism at shift change to discuss falls issues or as a post-falls debriefing tool); however, staff also used the tool in a multitude of other urgent and non-urgent situations. Whatever the context, SBAR was not used randomly - staff consistently used the tool for what they perceived to be sensitive or hierarchical issues.
- Consider the value of context-dependent and relevant case examples to reinforce the value of SBAR during **education sessions.** We developed role-playing scenarios from clinical situations that were meaningful to the study teams, as an effective means to practise the SBAR process. We also built in evaluative and tracking mechanisms throughout
- Use our implementation tool kit. From our previous work, we developed an implementation tool kit for enhanced uptake of SBAR in other healthcare settings. This tool kit is currently in its second edition (Trentham et al. 2010) and includes a video DVD showing SBAR in action. The DVD uses falls prevention and management as a platform to highlight inter-professional team communication in two different scenarios: during team rounds and between two clinicians on the nursing unit. Each of these scenarios demonstrate both ineffective and effective team communication. The accompanying facilitator's guide emphasizes key teaching moments for educators to consider when SBAR education sessions. The tool kit and DVD are available free of charge at www.torontorehab.com/SBAR.

Study Limitations

We used falls incidence and near-miss reporting as well as severity of falls as proxy measures for safety. While near-miss and total major falls showed a decreasing trend, total falls on the study units increased. It does not seem that SBAR had a significant impact on these measures for a few reasons. First, the data may be trended across a time frame that is too short to determine accurate results and may therefore be inconclusive. Second, the nature of rehabilitation is to push patients to the limits of their abilities in order to maximize function. In this way, the risk of falls and other events are an inherent part of the rehabilitation process.

We cannot attribute changes in safety reporting and perceptions of patient safety solely to this study; instead, these changes should be considered within the context of a range of patient safety initiatives at Toronto Rehab. For example, new initiatives regarding leader engagement, upgrades to our online reporting system and a corporate-wide falls best practice initiative have all increased awareness of safety and incident reporting across the organization.

We used the 5% rule of thumb to suggest clinically significant change in the HSOPSC; however, this guideline was meant to be used with large sample sizes. We chose to aggregate the study results for a number of reasons, including statistical power. It would also be interesting to look at the study units individually with the specific purpose of sharing key learnings across our organization.

The adapted SBAR process is an effective way to communicate urgent and non-urgent safety issues and has the potential to be widely used among interprofessional teams.

Conclusions

The purpose of this study was to implement and evaluate the adapted SBAR tool for use on two inter-professional rehabilitation teams for the specific priority issue of falls prevention and management. Issues of patient safety and communication have been studied in the literature, but usually from the perspective of acute care and involving nurse-physician communication. This study contributes to the literature in patient safety by examining the influence that strong inter-professional team collaboration and communication can have on falls prevention and management in rehabilitation. These results suggest that the adapted SBAR process is an effective way to communicate urgent and non-urgent safety issues and has the potential to be widely used among inter-professional teams. Our next steps are to consider SBAR as one of our organizational best practices and as part of "how we do business". While SBAR has been adapted for use within our setting, it is one of a number of structured team communication tools. Our hope is that these learnings are transferable to other healthcare settings, settings that also recognize the importance (and challenges) of communicating in inter-professional teams. HQ

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Optimizing Physician Handover Through the Creation of a Comprehensive Minimum Data Set

Niraj K. Mistry, Alene Toulany, John F. Edmonds and Anne Matlow

Abstract

Handover is defined as the communication of information between individuals and teams of healthcare providers to support the transfer of patient care and maintain professional responsibility and accountability. Poor handovers are increasingly recognized as potentially dangerous for patient safety and are associated with adverse events. One suggested method to improve the timely and efficient exchange of clinical information at handover and to reduce discontinuities in care is through the use of a minimum data set (MDS).

The objective of this study was to describe the process of developing a single comprehensive hospital-wide MDS, created through an analysis of current handover processes and customary information tools used to support physician handover (MDHO) at a large quaternary care pediatric academic health sciences centre. A 20-item questionnaire was administered in person to a senior resident or fellow on each of 49 services identified to objectively assess MDHO processes, including frequency, consistency, format, participants and duration, for each service. The presence, type, location, responsibility for updating and security characteristics of MDHO tools used to support MDHO were also analyzed. The MDHO tools currently in use were collected and analyzed to create a comprehensive cross-institutional MDS.

The analysis indicates that MDHO is highly consistent in terms of frequency, processes, participants, duration and the

use of written tools to guide information exchange across departments. However, many best practice recommendations for MDHO are not being followed. Further, many of the existing MDHO tools in use have a similar content structure and already contain a majority of the components of a comprehensive MDS.

Current local consistency in practice will allow for improved acceptance and adoption of an MDHO tool that continues to meet the clinical and administrative needs of physicians but also addresses needs for data accuracy and security. These additional specifications can be met through the use of information communication technologies.

Background

The communication of information to support the transfer of patient care and professional responsibility and accountability, referred to as handover or handoff, is essential to patient safety and occurs commonly in healthcare (Australian Commission on Safety and Quality in Health Care [ACSQHC] 2010). The World Health Organization (WHO 2007) has listed "communication during patient care handover" as one of its "High 5" patient safety initiatives. Aligned with these strategies, Accreditation Canada has identified (handover) communication as one of six patient safety goals in the essential practices to enhance patient safety and minimize risk, known as the required organizational practices (Accreditation Canada 2008).

Improving effective communication from the time of admission to discharge is also a leading patient safety goal espoused by the Joint Commission (2006) in the United States.

Each individual handover is a potential safety risk to the patient, and, indeed, breakdown in communication is recognized as the leading root cause of sentinel events (WHO 2007). New resident work-hour restrictions are making handovers increasingly frequent among care teams (Kemp et al. 2008; Professional Association of Interns and Residents of Ontario 2008). Ineffective handover can lead to inappropriate treatment, delays in diagnosis, increased healthcare costs and patient morbidity and mortality (Bulau 1992; Petersen et al. 1994; Priest and Holmberg 2000; Pronovost et al. 2002). Growing awareness of the frequency and impact of communication errors in handovers has led to calls for improving their safety and efficacy.

Growing awareness of the frequency and impact of communication errors in handovers has led to calls for improving their safety and efficacy.

Clinical handover has been a key initiative for the Australian Commission on Safety and Quality, which has completed an extensive, structured and evidenced-based literature review regarding the effectiveness of improvement interventions in clinical handover (Wong et al. 2008). Standardization of clinical handover through the creation of a minimum data set (MDS) was a frequent strategy used in both the quantitative and qualitative studies examined. An MDS refers to the minimum content that must be contained and transferred for an individual patient handover (ACSQHC 2010). There are many possible MDSs for handover; but regardless of the MDS used, this standardization strategy is strongly supported by a recent systematic review of residents' and attending physicians' handovers in the United States (Riesenberg et al. 2009). While a number of MDSs have been developed and implemented, there is little evidence that any of these have been developed through an analysis of information tools already being used for handover (Agency for Healthcare Research and Quality [AHRQ] n.d.; Mikos 2007; Wong et al. 2008).

The objective of this study was to describe the process for the handover of patient information and the content of handover documents used at a quaternary care academic health sciences centre and to identify an MDS that is generalizable across all divisions throughout the organization. This study represents the first phase in our development of a single comprehensive hospital-wide electronic handover tool that is to be embedded within the existing electronic medical record (EMR).

Methods

This study was conducted at The Hospital for Sick Children (SickKids), a 300-bed quaternary care academic health sciences centre in Toronto, Ontario, with pediatric and level III neonatal intensive care units, hematology-oncology and bone marrow and solid/multi-organ transplantation programs.

The hospital Morbidity and Mortality Committee's monthly reviews of safety reports identified physician handover (MDHO) as a potential hazard in the institution, and the medical director of patient safety was charged with assembling a working group to review current processes and make recommendations to improve MDHO by the end of the calendar year (10 months later). At that time, there were no formal policies, guidelines or procedures about the content and processes of MDHO, although relevant policies such as confidentiality of patient information were in existence. Recognizing that MDHO happens at many levels throughout the patient care experience, a multidisciplinary working group was purposively constituted with (1) representation from key areas where MDHO takes place, (2) staff as well as house staff, (3) representation from informatics and (4) those who had previously expressed an interest in the vulnerabilities in the handover procedure. The membership included the medical director of patient safety, who acted as chair (A.M.); a hospitalist, an intensivist, the physician leader of the critical care response team, an anesthesiologist, an emergency room physician, a general surgeon, senior pediatric residents (N.M. and A.T.) and the medical director of informatics (J.E.). The initiative focused solely on multi-patient handovers between physicians, including all levels of trainees and attending staff, that occur for daytime, overnight or weekend coverage.

A quantitative and qualitative approach was undertaken in which questionnaires were used to objectively determine the MDHO process, existing tools were collected and a content analysis was performed to create an MDS. This study was approved at SickKids as a quality improvement project.

Participants

Of the 86 medical surgical and diagnostic services identified, 37 operated on daytime schedules only (e.g., pathology, laboratory medicine etc.) and did not participate in MDHO, leaving 49 services appropriate for questioning. A senior resident or fellow who had direct involvement in the MDHO process on that service during a one-week period in September 2009 was identified and approached to be surveyed.

Questionnaire

A 15-item MDHO processes questionnaire was constructed that included a combination of multiple-choice and open-ended questions to objectively assess MDHO frequency, consistency, process, participants and duration. An additional five multiple-choice questions were used to determine the presence, type, location, responsibility for updating and security characteristics of the tools used to support MDHO (Appendix 1, http:// www.longwoods.com/content/ 21925). The questionnaires were pilot-tested for content validity, structure and clarity among the co-authors and with two colleagues. The survey was administered to each designated physician face to face by one of the authors and participation was voluntary and anonymous as identifying information was not collected.

Representatives from each of the 49 services eligible for participation completed the survey, representing a response rate of 100%.

MDS Generation

Following the questionnaire administration, a hard copy of the current, most up-to-date version of the MDHO tool used by each service was collected for analysis. Of the 49 services identified, 30 services maintained a regular patient list, which was analyzed for formatting (horizontal versus vertical orientation, number of columns, number of pages, number of patients, presence of a header or footer and description of section titles).

Results

MDHO Processes Questionnaire

Of the 49 services identified, seven services were surgical and 42 were medical. Thirtyfive services consistently conducted MDHO twice daily, four services handed over once daily and 10 services handed over on an as-required basis depending on the patient census and number of physicians on service (Table 1). Overall, MDHO was quite consistent within each service. Most morning MDHOs took place between 6:15 and 8:30 on weekdays and between 6:30 and 9:00 on weekends. Evening MDHOs took place between 16:30 and

Table 1. MDHO processes questionnaire results for 35 services that handover twice daily

	Answering '	Number of Services Answering "All/Most of the Time" (%)		
Question	a.m.	p.m.		
In general, how often does MDHO take place?	32 (91)	34 (97)		
How consistently does MDHO take place at these times?	35 (100)	35 (100)		
Where and how does MDHO usually take place?				
Face-to-face (verbal):	30 (86)	31 (89)		
On a ward	13 (43)	15 (48)		
In a conference room	8 (27)	4 (13)		
During walk-around rounds	3 (10)	2 (7)		
In the trainee lounge or office	6 (20)	10 (32)		
Over the phone (verbal)	4 (11)	3 (9)		
Electronically via e-mail or intranet list (non-verbal)	1 (3)	1 (3)		
How consistently does MDHO take place in this way?	30 (86)	34 (97)		
Who attends MDHO most often?				
Residents only	7 (20)	4 (11)		
Residents and fellows	7 (20)	8 (23)		
Fellows only	12 (34)	15 (43)		
Residents, fellows and nurse practitioners	3 (9)	4 (11)		
Residents, fellows and staff	5 (14)	2 (6)		
Residents, fellows, nurse practitioners and staff	1 (3)	2 (6)		
How long does MDHO usually take?				
<5 minutes	4 (11)	4 (11)		
5–15 minutes	16 (46)	9 (26)		
16–30 minutes	11 (31)	13 (37)		
31–45 minutes	0 (0)	6 (17)		
>45 minutes	4 (11)	3 (9)		

17:30 on weekdays and between 14:00 and 17:30 on weekends. MDHO was also very consistent in terms of where it took place and how it was conducted (Table 1): a majority took place among residents or fellows and very few were attended by staff physicians.

Table 2. MDHO tools questionnaire results for 30 electronically generated service lists*

Characteristic	Number of Lists (%)
Location of list	
Public drive (list accessible from any computer on intranet)	13 (43)
Private drive (list accessible from enabled computers on intranet)	7 (23)
Computer (accessible on certain computers only)	5 (17)
Data warehouse	5 (17)
Type of list	
Word processing program (Microsoft Word)	24 (80)
Computerized spreadsheet program (Microsoft Excel)	1 (3)
Database program (data warehouse)	5 (17)
Responsible for updating list	
Residents only	3 (10)
Residents and fellows	5 (17)
Residents, fellows and nurse practitioners	9 (30)
Residents and medical students	5 (17)
Fellows only	6 (20)
Fellows and nurse practitioners	2 (7)
Security of list (password protected)	
Yes	20 (67)
No	10 (33)

EMR = electronic medical record; MDHO = physician handover.

Most morning MDHOs lasted 15 minutes or less, whereas most evening MDHOs took longer. MDHOs took place in various locations, including the ward nursing stations and the trainee office or lounge. MDHOs were done by telephone, e-mail or using computerized records.

MDHO Tools Questionnaire

Of the 49 services surveyed, eight did not maintain a regular patient list; one list contained information for two services within the same division. Another service used an entirely handwritten list maintained by the person on call each day,

which was not available for review. Thus, 39 electronically maintained and paper-printed lists to support MDHO were available for analysis. All lists were updated for each handover by residents or fellows and rarely by attending physicians (Table 2).

Of the 39 lists, nine used common vendor-supplied filters built into the existing EMRs to generate patient lists that contained minimal demographic and administrative information (location, name, date of birth and medical record number), a single admitting diagnosis and the name of the primary responsible physician. These nine lists were secure as they were generated from within the password-protected environment of the EMRs and did not require user input, aside from the maintenance of a current list of in-patients on each service.

The remaining 30 lists were electronically generated and not EMR linked (Table 2). They were individually maintained by the medical students, residents, nurse practitioners and fellows on each service, and accessible from all computers on the hospital intranet or designated computers with access to a specific shared virtual hard drive (see Table 2). Twenty MDHO lists were password protected. Microsoft SharePoint - a content management system that allows the setup of a centralized, password-protected space for sharing Microsoft Office documents - was used by two services, and their lists were accessible only from designated computers within their department's trainee workrooms or on the ward. Finally, one division had recently designed and implemented an

MDHO list generated from its patient database system that imported demographic information, current problem lists and treatment protocols, with an additional area for free-text entry.

Interestingly, a majority of services within SickKids are using various electronic MDHO tools to support verbal information exchange with visual data at MDHO. While these tools may meet the clinical and administrative needs of physicians, they were not without issues. The majority of MDHO systems in use were not secure. As many as one third of the MDHO lists were not password protected; and among those lists that were, the passwords were not unique to each user and, in some cases,

^{*}A total of 39 (of 49 [80%]) lists were electronically generated. Nine of these were linked to EMRs. The remaining 30 (61%) outlined in this table were not EMR linked.

a single password was used across multiple service lists. Additionally, a majority of the lists could be accessed on any computer on the hospital intranet. The information completeness and accuracy of the handover lists was not assessed; however, given that all data had to be manually entered into the various electronic MDHO lists, there were likely transcriptional errors.

MDS Generation

All the lists except one were organized in a horizontal tabular format, with a majority having five to six columns (Table 3); one list was written in paragraph format. On average, each list was close to three pages long and contained information for about 13 patients. Over half of the lists were organized by patient location, including floor and room number, while the remaining lists were organized in alphabetical order according to patient name. Nearly all the MDHO lists had a header or footer that contained administrative details and information about the care providers, including the service name, members of current service team and contact information together with other service-specific useful phone numbers. Finally, over three quarters of the lists contained four of the major sections (Table 3).

Using this information and a modified Delphi method, the content of what the working group considers a generalizable, hospital-wide standardized handover MDS was created (Table 4). Aside from those broad categories and subcategories contained in Table 3, additional subcategories include review frequency, resuscitation concerns and the date and time of last update. Members of the working group agree that it is important to identify those patients who are a priority for review and who have the potential to deteriorate. Furthermore, if there are patients who have any risk factors for a difficult resuscitation, it is important for the oncoming physicians to be aware of those issues. Finally, the need to know the precise time that the MDHO list was updated is also

Table 3. Minimum dataset generation from MDHO content analysis for 30 electronically generated service lists*

Characteristic	Number of Lists (%)
Horizontal orientation	25 (83)
Average number of columns (mean ± SD)	5.7 ± 2.0
Average number of patients (mean ± SD)	12.7 ± 8.9
Average number of pages (mean ± SD)	2.9 ± 3.0
Presence of header or footer	28 (93)
Section titles	
Demographic and administrative information	30 (100)
HPI/PMHx/diagnosis/presentation/issues/problems	27 (90)
Laboratory and other investigations/significant results/pending tests	9 (30)
Medications/treatments/procedures/diet/fluids/tubes/lines/drains	23 (77)
Plan/follow-up/to-do tasks	26 (87)

HPI = history of presenting illness; MDHO = physician handover; PMHx = past medical history; SD = standard deviation. *Not linked to electronic medical records.

Table 4. Standardized physician handover list minimum dataset for **SickKids**

Column 1: Patient demographic and administrative information
Name
Medical record number
Location (ward, room number)
Date of birth
Date of arrival/length of stay
Anthropometrics: weight, height
Review frequency
Resuscitation concerns (e.g., Rapid Response Team following, difficult airway etc.)
Date and time of last update
Column 2: HPI/PMHx/diagnosis/presentation/issues/problems
Column 3: Laboratory and other investigations/significant results/pending tests
Column 4: Medications/treatments/procedures/diet/fluids/tubes/lines/drains
Column 5: Plan/follow-up/to-do tasks

HPI = history of presenting illness; PMHx = past medical history.

Table 5. Summary of MDHO Best Practice Strategies and Recommendations

Standardization

Standardized process for MDHO using specific, agreed-upon techniques including mnemonics if suitable

Preparation – a formally recognized plan instituted at the end of a shift or change in service with adequate time during the shift dedicated for verbal exchange of information

Verbal exchange of patient information that includes:

Face-to-face communication:

III patients are given priority

Insight on what to anticipate or what to do

Read-back - ensure an interactive process, two-way communication

Flexibility to discuss anticipated events, recommendations and ask questions

Content exchange summary that includes the following aspects: Standardized content/template or a technological solution

should be used for accessing and recording patient information

Inclusion of all patients to be handed over

Available in a centralized location

All data kept up to date in both completeness and accuracy

Anticipated events clearly labelled Action items highlighted

Communication skills

Improve general communication skills to overcome language and ethnic barriers

Limit hierarchy and social barriers

Provide training and education on handover expectations, especially to new users

Evaluate the handover process

Physical environment

Location - private space to avoid breeching patient confidentiality

Limit interruptions, distractions and noise

Address physical environment – lighting issues, space to write

Recognize transfer of responsibility and accountability

MDH0 = physician handover.

felt to be important to patient safety and communication.

Discussion

A structured and standardized approach, including an MDS, for physician-to-physician handover is recognized as critical to improving patient safety during care transitions (Arora et al. 2009; Patterson et al. 2004; Riesenberg et al. 2009; Wong et al. 2008). While a number of MDS and standardized protocols exist, they are meant to provide structure to the MDHO process, and their use and implementation by hospitals may

require more specific details than those provided (AHRQ n.d.; Mikos 2007; Wong et al. 2008). Thus, we completed this study to better understand the local environment and current practices for MDHO.

Some key principles were invoked in developing a local standardized handover MDS. First, key stakeholder involvement was enlisted by ensuring that representatives from key disciplines, such as trainees as well as attending physicians, participated on the working group. Second, our goal was to build on existing structures and processes; thus, an internal scan of existing practices allowed us to harness similarities and to assess the degree of change that was going to be incurred in MDHO across the organization.

The benefits of an EMR-integrated MDHO tool are numerous.

As a result of this process, we recognize that MDHOs at SickKids are very consistent in terms of frequency, consistency, process, participants, duration and use of written tools to guide information exchange. However, many best practices recommendations are not being followed (Table 5) (ACSQHC 2010; Arora et al. 2009; Riesenberg et al. 2009; Wong et al. 2008). MDHO takes place in physical settings where distractions occur and patient privacy and confidentiality might be violated. Direct face-to-face communication, which is almost always preferred (Solet et al. 2005), is lacking in some MDHOs, denying the participants the appreciation of facial expressions and body language, which provide additional information about the level of concern regarding a patient's needs.

Perhaps our most significant finding was that many of the existing MDHO tools already contain components of a comprehensive MDS (Tables 3 and 4). This local consistency in practice will allow for improved acceptance and adoption of an MDHO tool that continues to meet the clinical and administrative needs of physicians, but also affords increased data accuracy through decreased transcriptional errors and increased security and confidentiality. These additional specifications can be met through the use of technology.

The use of information communication technologies, such as electronic handover tools, has been suggested to help reduce communication errors and adverse events and to improve the timely and convenient exchange of clinical information during handover (Petersen et al. 1998). As such, our next steps are to use information technology system design methodologies to create an MDHO tool embedded within our existing commercial EMR system. The benefits of an EMR-integrated MDHO tool include improving information completeness and legibility,

compliance with privacy legislation and data security, improved accuracy by mitigating the need for repeated manual data transcription, remote accessibility and the fact that these tools are preferred by residents when compared with written handovers (Anderson et al. 2010; Bernstein et al. 2010; Peterson et al. 1998; Ram and Block 1992; Volpp and Grande 2003). There is also the potential added benefit of accessibility by all members of the healthcare team, improving inter-professional communication between physicians, nurses and other allied healthcare professionals (Sidlow and Katz-Sidlow 2006). Additional functionalities will include the ability to print an MDHO list so it is readily accessible; to sort the list by ward, bed number or physician; and to highlight high-priority patients to be reviewed and tasks needing urgent completion (Cheah et al. 2005).

While a number of MDS and standardized protocols exist, their use and implementation by hospitals may require more specific details than those provided.

Limitations

This study has several limitations. The scope was restricted to intra-departmental MDHOs and did not include handovers across different departments, disciplines or institutions, perhaps limiting the generalizability of the results to other clinical care transition interfaces. Furthermore, the survey methodology used facilitated the inclusion of many care interfaces, while denying access to the rich qualitative data that may have further informed development of the tool. Also, participants may have altered their answers because the interviewer was present during the questionnaire completion.

Conclusion

Today's healthcare environment is very complex and interconnected and, as a result, not conducive to prescriptive interventions. As such, the need for flexible standardization through adaptive systems that take into account the local processes and culture is an integral component of ensuring effective, efficient and safe healthcare. In the future, perhaps strategies involving both providers and patients/families in the handover process may prove to be the ultimate way to improve communication during MDHO. Patients and their families are the only constant within this system and may therefore be in position to play critical roles in ensuring the safest and best-quality healthcare (WHO 2006).

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Assessment of Safety Culture Maturity in a Hospital Setting

Madelyn P. Law, Rosanne Zimmerman, G. Ross Baker and Teresa Smith

Abstract

The Manchester Patient Safety Culture Assessment Tool (MaPSCAT) was used to examine the levels of safety culture maturity in four programs across one large healthcare organization. The MaPSCAT is based on a theoretical framework that was developed in the United Kingdom through extensive literature reviews and expert input. It provides a view of safety culture on 10 dimensions (continuous improvement, priority given to safety, system errors and individual responsibility, recording incidents, evaluating incidents, learning and effecting change, communication, personnel management, staff education and teamwork) at five progressive levels of safety maturity. These levels are pathological ("Why waste our time on safety?"), reactive ("We do something when we have an incident"), bureaucratic ("We have systems in place to manage safety"), proactive ("We are always on alert for risks") and generative ("Risk management is an integral part of everything we do"). This article highlights the use of a new tool, the results of a study completed with this tool and how the results can be used to advance safety culture.

The measurement of patient safety culture has been a top priority for many healthcare organizations across Canada. This interest stems partly from the fact that it is a requirement of Accreditation Canada, but it also because leaders have understood the importance of examining the underlying values that drive staff behaviour in relation to patient safety. These behaviours include such things as reporting adverse events, working as a team and making decisions that consider and optimize patient safety at all points of care. The quest for measurement of patient safety culture has led to the development of numerous tools that differ in their theoretical underpinning, origins and applications. The current study seeks to contribute to this knowledge base by providing an overview of a new measurement tool titled the Manchester Patient Safety Culture Assessment Tool (MaPSCAT) and detailing how this tool has been used in an acute care setting to gain valuable insights into the patient safety culture.

The Manchester Patient Safety Culture **Assessment Tool**

In order to improve safety culture, it is essential to base changes on a framework of safety culture that takes into account the multi-dimensional nature of the concept (Hale 2000). In line with this idea, Parker et al. (2006a) looked to the theoretical typology of organization culture based on James Reason's (1997) adaption of the Westrum (1996) model. This typology distinguishes between cultures based on how information is handled, and identifies three different levels of organizational culture - pathological, bureaucratic and generative. In addition to detailing the style of information processing in a unit, the typology references the role of leaders who shape the unit's culture through their symbolic actions and provide rewards and punishments that communicate what they feel is important; these then influence the views of the workforce (Westrum 2004). Westrum (2004) suggests that good information flow and processing has important effects on patient safety (such as good teamwork), and that an open and generative culture means a better uptake of innovations and response to danger signals.

Parker et al. (2006a) first adapted this framework for an empirical study in the petroleum industry, extending the number of levels of safety culture to five and applying them to a range of dimensions. This resulted in a normative framework identifying "good" or "bad" safety cultures and illustrating how safety culture could be improved. The framework also facilitated the comparison of organizational cultures and subcultures (Lawrie et al. 2006). This work was then expanded to the healthcare field with the development of the Manchester Patient Safety Framework. This framework was developed through extensive reviews of the literature in healthcare and consultations with experts in the field. It was tested with healthcare professionals and formulated into a research tool, MaPSCAT. The MaPSCAT is the result of collaboration between researchers in the United Kingdom and Canada who were interested in developing a patient safety culture tool that is rooted in acute care and based on the Manchester Patient Safety Framework. The 10 different dimensions of safety culture used in this tool are outlined in Table 1. Within these 10 dimensions, statements were developed to reflect five increasingly mature levels of safety culture. The levels of safety maturity range from pathological through reactive, bureaucratic and proactive and, finally, to generative. At the lowest level of safety culture, pathological refers to "why do we need to waste our time on patient safety," next reactive refers to taking patient safety seriously once an event has occurred. The bureaucratic level of culture refers to having systems in place to deal with patient safety issues, and then proactive is when the organization is alert and thinking about patient safety issues that might occur. At the generative level of safety culture maturity patient safety is seen as an integral part of everything that the organization engages in (NPSA, 2006) .

Table 1. Ten dimensions of patient safety culture

Dimension	Description	
Commitment to overall continuous improvement	This dimension has statements reflective of the investment in the quality agenda and the purpose of policies and procedures.	
Priority given to safety	This dimension reflects statements about how seriously safety is taken in the organization in relation to patient and public involvement and patient safety practices.	
System errors and individual responsibility	This dimension reflects how reports are received and viewed – as either an opportunity to blame or improve.	
Recording incidents and best practice	This dimension relates to the use of reporting systems (i.e., user friendly) and the types of incidents that are reported (i.e., full incidents and near misses).	
Evaluating incidents and best practice	This dimension relates to how the incidents are being investigated and analyzed and the output of the investigations.	
Learning and effecting change	This dimension outlines statements reflective of what happens after an event, what mechanisms are in place to learn from the incident and how changes are introduced.	
Communication about safety issues	This dimension is reflective of the systems in place to communicate, the quality of information sharing and communications with patient about safety.	
Personnel management and safety issues	This dimension discusses the way in which safety issues and staff problems are managed as well as the link between safety and recruitment and retention practices.	
Staff education and training	This dimension reflects training aims, resources and the purpose of training in regards to patient safety information.	
Teamwork	This dimension is related to the structure of teams, the function of the teams and how information is shared across team members.	

Source: NPSA (2006)

Table 2. Example of MaPSCAT statement choices

10.3 Information flow and sharing

There are official mechanisms for the sharing of ideas and information within and across teams, but these are not used effectively.

Teams operate defensively, cascading information to team members as necessary

Teams operate secretively, and information is not shared even between

Teams are open to sharing information and may share with people external to the organization.

Teams are totally open, sharing information with others from diverse organizations, locally, nationally and even internationally.

MaPSCAT= Manchester Patient Safety Culture Assessment Tool

This tool was tested and validated in acute care settings in Canada and the United Kingdom before the implementation in the current study (Law et al. 2008, June). This validation process resulted in the modification, retesting and finalizing of 24 questions for the survey. Some were dropped due to a lack of agreement in the ranking. Therefore, there are one, two or three questions per dimension that are calculated together to create a result for that safety dimension.

The MaPSCAT advances the research in safety culture measurement as it (1) measures 10 dimensions of safety culture, (2) examines these dimensions on a safety maturity scale, (3) aggregates scores to create a safety culture profile and (4) provides guiding statements on how to improve the safety culture.

Patient Safety Culture Dimensions

In a number of reviews of culture assessment tools, it has been found that there is variation in the types and number of safety culture dimensions that are encompassed in the tools (Colla et al. 2005; Fleming and Hartnell 2007; Flin et al. 2006; Pronovost and Sexton 2005). What can be gleaned from these reviews are some common categories of communication and reporting and recording of events. Three of the reviews identified dimensions of leadership, safety systems, teamwork and values and beliefs about safety and teamwork. Learning and individual factors such as personnel resources and job satisfaction were also highlighted in two reviews. Added to these, the MaPSCAT includes the dimensions of incident evaluation and continuous improvement. Previous tools and their dimensions stemmed mostly from the United States and were rooted in high-reliability theory. Yet, the structures and operations of healthcare systems vary across countries. Thus, a tool designed in one system may not have the same relevance in other national systems (Waterson et al. 2010), so a tool developed and validated in a number of countries helps to increase confidence in using the tool. As well, it has been proposed that a patient safety culture measurement tool designed for use in acute care should be rooted in the customs and practices of acute care in order to be applied to this setting (Parker et al. 2006b).

Multi-dimensional Approach

This idea of a multi-dimensional approach to assessing safety culture is not new (Fleming and Wentzell 2008), but its implementation as an organizational survey is. Fleming and Wentzell (2008) provide details of the Patient Safety Culture Improvement Tool, which was envisioned to be used by hospital teams to identify and discuss specific cultural issues. However, reliability and validity are pending the further testing of this tool. The MaPSCAT was developed through an extensive study that involved healthcare professionals ranking the safety statements, re-working problematic statements and dropping certain statements, followed by retesting (Law et al. 2008). This study has aided in establishing the validity of the instrument, although the MaPSCAT will still require further psychometric testing such a factor analysis following the collection of additional data.

This multi-dimensional approach in the MaPSCAT has respondents read a series of statements about a dimension that reflect the various levels of safety maturity. Then respondents must choose the statement that best reflects their culture. Table 2 provides one series of statements posed to participants.

The tool requires the participants to read all of the statements before determining which one they will select. The statements are not set up in a logical progression of the safety culture maturity levels. Most safety culture assessment tools provide specific statements to participants and ask them to rate these on a scale of agree or disagree (Singer et al. 2003). Anecdotal evidence through the course of this work has pointed to some participants' preference for the MaPSCAT format in which "they had to really think about their answers" instead of simply putting a check mark beside a list of answers.

Patient Safety Culture Profile

Another unique and useful feature of this tool is that individual responses for each of the 24 questions can be aggregated indicating the unit level of safety culture for 10 dimensions. The perceived levels of safety culture for each of the components form a profile of safety culture that portrays how the organization is doing on that specific dimension of safety.

Utility for Creating Change

Finally, given that this tool is directly based on a theoretical model of safety culture maturity, organizations receiving their safety culture profiles can refer back to the model and understand what higher levels of culture in specific dimensions might look like. For example, if an organization received a rating at the bureaucratic level of learning and change, the members could refer to the framework and see that in order to move to the

proactive and or generative level, they should focus their efforts on engaging staff and patients in the investigation and learning about safety events. Thus, this tool not only provides scores on the culture but also offers a basis from which to initiate efforts for cultural changes.

Overall, the MaPSCAT is a new and unique way in which to measure patient safety culture. In order to demonstrate the utility and implementation of this tool, the following study provides details of a pilot project conducted at Hamilton Health Sciences (HHS) using this measurement tool.

Research Methodology

The pilot study employed survey methods using the MaPSCAT quantitative tool. Program directors across HHS were contacted by the assistant vice-president of quality, patient safety and clinical resource management and asked if they would consider being involved in this research project; five directors initially agreed to participate. Due to program realignments, one director had to later withdraw the program.

Site contacts at each of the programs were provided with surveys in individual envelopes. The study participants were asked to read the consent, fill out the questionnaire and return it in the sealed envelope. All of the questionnaires were returned to the principal investigator via the site contacts. In order to enhance the response rate, two sets of communications were conducted in each of the programs. First, as the surveys went out, individuals were sent an e-mail outlining the study and asking them to fill out the questionnaire. At one week before the deadline for returning the surveys, staff were sent another communication to ask them to fill out the survey and return it to the site contact. The inclusion criteria for individuals filling

out the surveys was as follows: (1) participants must have responsibilities within the unit that are associated with patient care (i.e., managers, physician, nurses, technicians, allied health professionals and other support staff); (2) participants must be able to read English (the questionnaires has not been translated into other languages); and (3) participants must have completed their probationary period in their current position since it was felt that such experience was needed to have an adequate understanding of safety culture issues in the unit.

Results

Study Participants: Response Rate

A total of 360 surveys were given out across the programs. The response rates ranged from 33 to 85% within the four programs,

with an overall response rate of 45.3% (previous research reported response rates between 26 and 91% [Flin et al. 2006]). Therefore, the data are reflective of 163 HHS staff from four programs.

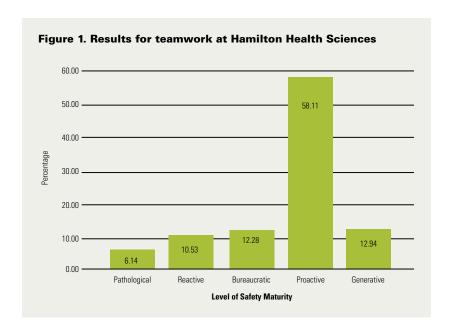
Nursing respondents had the greatest representation in the survey (63%); there was low representation from physicians, with only 2.5% of the questionnaires filled out by this group. The remaining respondents included allied health, technicians, educators, managers and support staff.

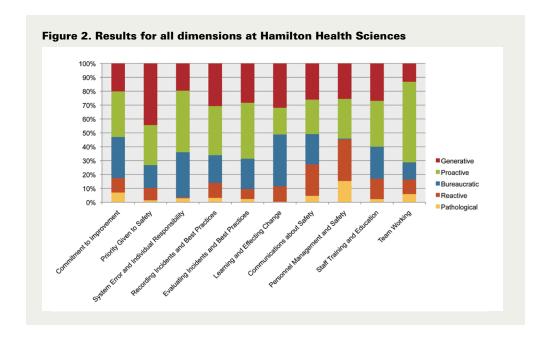
Survey Results

For each of the 10 components on the survey, 10 graphs were made to depict the ratings based on the percentage of responses at that level of safety maturity. The graph in Figure 1 demonstrates results for the dimension of teamwork.

Although the graphs such as the one presented in Figure 1 provide an excellent overview of the results for each dimension separately, one graph representing results in all dimensions aids in the comprehensive view of the results (Figure 2).

One of the main questions for researchers and decisionmakers alike is deciding which level to discuss and highlight in the results and, for the applied aspect, where to focus strategies to enhance the patient safety culture. Fleming and Meakin (2004) propose one solution to this dilemma: they suggest that one should select the highest level, where 66% of participants select that level or a level above. For example, in Figure 2, the result for teamwork would be considered proactive as more than 66% of respondents indicated proactive or higher. It was outlined that this approach may provide confidence that this is the minimum level achieved. Therefore, the following summary reflects this framing of how to understand these results.





Summary by Level

Proactive and Generative Culture

A generative culture is seen as the highest level of safety, where the management of "safety is an integral part of everything we do," and a proactive culture is seen as one in which "we are always on alert and thinking about patient safety issues." Respondents rated priority given to safety (73.01%), evaluating incidents (68.42%) and teamwork (71.05%) at the proactive level or higher (see Figure 2). This suggests that staff believe that safety is taken very seriously by the organization and in their own daily work. As well, respondents believe that the organization has a strong teamwork environment that is also focused on evaluating incidents. It should be noted that the dimension of system error and individual responsibility was within 2.24% of reaching this level, and the recording incidents dimension was within 0.16% of this rating level.

Bureaucratic Culture or Higher

A bureaucratic culture is defined as one in which "we have systems in place to manage safety." The bureaucratic level or higher reflects the majority of the responses (see Figure 2), with six of the 10 dimensions being evaluated in this way: commitment to continuous improvement (82.4%), system error and individual responsibility (96.26%), recording incidents and best practices (85.84%), learning and effecting change (88.29%), communications about safety (72.56%) and staff training and education (82.34%). In relation to all of these dimensions, a broad statement can be made that emphasizes the fact that this organization has gone to great lengths to ensure a framework

for safety is in place and that there are policies and procedures available for patient safety. However, there are further opportunities to enhance the implementation of these patient safety practices to improve the overall patient safety culture.

Reactive Culture or Higher

A reactive culture is defined as one in which "we do something when there is an event," and this was the rating in the dimension of personnel management for safety (84.41%; see Figure 2). This may reflect the fact

that some individuals feel that staff support for patient safety is minimal, and this is reflected is staff behaviour.

Discussion

The results provided by this tool allow decision-makers to understand where they are doing well, and to celebrate these successes, as well as where there remain opportunities to enhance the safety culture. This information is conveyed through dimension summaries and graphic profiles that link to an overarching framework for safety maturity. The questionnaire provides a summary of safety culture dimensions, versus a copious amount of information from a large number of individual survey questions. With the MaPSCAT, decision-makers can examine their scores at these levels and refer back to the framework to see what types of statements and actions are aligned to higher levels of culture. It is important to provide results in a way that will ensure their uptake (Goering et al. 2003); this format may enhance decision-makers' ability to do so. This unique way of studying and presenting the results may make MaPSCAT more appealing to decisionmakers than previous tools as MaPSCAT helps to provide ideas and direction for moving the culture forward.

Conclusions

It is evident that staff at HHS perceive there to be a high priority given to safety, an appropriate focus on evaluating incidents and a great teamwork environment in their organization. The results indicate that, in six other dimensions, the organization has taken steps to move the culture forward and is committed to the overall safety agenda through the development of a framework with policies and programs to enhance safety. However,

more work is needed to further embed the values and behaviours that they would like to achieve to move toward higher levels of safety culture.

Implications

This is the first Canadian study using the MaPSCAT, and it was met with great interest and positive response at the leadership level. Leaders outlined that the summaries on the specific dimensions were helpful in allowing them to identify target areas of improvement. For example, they felt they would be able to reflect and then conceptualize future directions in the area of learning and change at a broad level as compared with simply focusing in on specific survey questions. Further research is needed to determine the extent to which this format will aid in the initiation of safety culture change efforts.

It is also important to recognize that safety culture responses vary if subcultures exist (Schien 1996), and to factor that in the design of culture research (Fleming and Wentzell 2008). Although the results were combined, there could be considerable variation by program or by health professional. Further analysis may reveal additional information from which to gauge program specific improvements. This level of segmentation in the initiation stages of the data analysis would help to address results within the local context and to assist in targeting change. The MaPSCAT appears to be a promising alternative for measuring patient safety culture in acute care, although further research and application are needed. HQ

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Healthcare Culture and the Challenge of Preventing Healthcare-Associated Infections

Michael Gardam, Paige Reason and Liz Rykert

onsider the following story: A patient in a teaching hospital is about to be examined by a resident physician. When asked by the patient to wash his hands, the resident refuses, saying he has done so recently. The staff physician then enters the room and the patient speaks of his disappointment regarding the actions of the resident. The staff physician is displeased and states that the patient should not be mistrusting his physicians. Later, when booking his followup appointment, the patient asks not to be seen by the resident. The staff physician overhears and, in front of other patients, angrily tells the patient not to return to his clinic because of his disruptive behaviour.

This story illustrates what we believe to be the fundamental challenge to decreasing healthcare-associated infections (HAIs). It is hard to imagine the lay public siding with the physician in this story; yet we fear that many healthcare workers would feel the patient was being unreasonable. Simple interventions such as hand hygiene, environmental cleaning and the appropriate use of barriers such as gowns and gloves have been shown to be quite effective in limiting the spread of bacteria and viruses in healthcare settings. Similarly, other uncomplicated interventions such as "practice bundles" have been shown to decrease infections resulting from mechanical ventilation, surgery and central intravenous catheters. Yet, getting healthcare workers to become interested and consistently comply with these interventions has been shown to be remarkably difficult. We

have previously written about some of the root causes for this discordance (Gardam et al. 2009), and all point to the same fact: our prevalent healthcare culture neither values these interventions nor acknowledges the connection between poor practice and poor patient outcomes, despite overwhelming evidence to the contrary, including plain common sense.

Traditional strategies for controlling these infections typically involve healthcare worker education around best practices, environmental cleaning, surveillance for colonized or infected patients and varying forms of isolation when certain infections are detected. While necessary, none of these strategies focus or likely impacts on healthcare culture. It is often said that "culture eats strategy for breakfast," and we believe that our current state of affairs is a testament to the fact that in the absence of culture change, the enforcement of these measures only takes us so far.

Recognizing this, we have embarked upon an unconventional strategy that indirectly addresses and changes the prevalent culture. The strategy, called positive deviance (PD), is relatively new to healthcare but has been employed in international development work to address problems with deep cultural roots as diverse as child malnutrition, female genital cutting and smoking cession among prisoners.

The term positive deviance comes from the observation that in every community there are certain individuals or groups whose uncommon behaviours and strategies enable them to find better solutions to problems than their peers, despite having access to the same resources and facing similar or worse challenges (Positive Deviance Initiative 2010). In other words, these individuals deviate from the mean behaviour or functioning of the population.

What makes PD different from traditional change strategies is the focus placed on uncovering existing solutions that come from the people who are affected by, or contribute to, the problem. While individuals with solutions are invariably present in the population, their practices may not be recognized as solutions by others around them. When solutions are uncovered through a community-owned discovery process, the participants themselves determine the best way to create conditions for the spread of these behaviours. Unlike an approach of sharing and enforcing best practices, the PD approach recognizes the need to be extremely sensitive to initial conditions and local variability and incorporates those differences as a central part of any change effort.

PD is best learned by doing and is most effectively practised in settings where the problem is concrete and requires some degree of behavioural or social change to solve it. When the focus of the work is on shifting culture and emphasizing the importance of behaviours and interactions among people, a set of guiding principles or minimum specifications is a helpful way minimize control and maximize creative adaptation and ownership (Zimmerman et al. 2001). These guiding principles include the following:

- Community ownership is needed of the entire process, including getting started, defining the problem, discovering uncommon practices and finding ways to spread these practices to others. This typically requires strong direction from front-line staff and support from leadership to remove barriers when needed.
- People get involved voluntarily, driven by their own interest and passion for solving a problem. A PD effort is not something that can be assigned to people - over time, they begin to follow.
- People need to own the decisions that impact them. The phrase "nothing about me without me" is often cited as way of reminding people that when they start to talk about the role(s) of others in a problem, they need to find ways to invite those "others" in.
- PD involves transferring behaviour instead of knowledge. PD starts with the notion that you can act your way into a new way of thinking. This contrasts education-focused strategies that assume that knowledge will change behaviour.
- Members of the community rely on the social proof that "someone just like me" can take action and get results. For PD facilitators, this means learning from the people closest to the problem.
- Participants create their own set of performance indicators and monitor their progress over time to determine

how they are doing. The PD process relies on data to track change, but those data must be meaningful to those receiving them (Positive Deviance Initiative 2009).

The application of these principles has led to the creation of a set of tools and approaches to engaging both the frontline staff and leadership in the healthcare setting. These tools include ways to get the process started, methods to discover PD behaviours and processes to include everyone in the tracking and dissemination of the work.

Getting Started

A PD approach to a problem such as HAIs typically begins with an initial launch. There is no correct way to introduce PD as it depends on the local culture. In some cases the launch is a hospital-wide event, while in others it can range from is a small series of information sessions for interested staff to simply getting started. In most cases, people create a way to meet and share their findings as the work gets under way. Several tools have been used in the healthcare setting, including discovery and action dialogues (DADs), improvisational acting (improv) and theory of inventive problem solving (TRIZ).

DADs are short 15- to 30-minute conversations that take place among a small group of diverse participants. They can be led by a wide variety of people, although typically the leader is from the front line. The leader takes the group through a list of questions (Table 1). The results are recorded and shared with the larger group. In many cases, ideas that emerge or barriers that exist can be addressed immediately. DADs are repeated at different times of the day or on different shifts to capture various perspectives. A fundamental aspect of the DAD process is that the front-line staff identify and act on their ideas, thus fostering ownership of both the problem and the solutions.

Improv is used to re-enact situations and behaviours among participants in ways that allow an audience to experience the situation and learn from it. The process works with real scenarios and recruits participants to act together. Afterwards, staff lead the discussion with audience members to talk about what they have witnessed.

Table 1. Leading questions for discovery and action dialogues

- 1. How do you know when someone has an infection (or some other problem)?
- 2. What do you do to protect yourself and others from this problem?
- 3. What keeps you from doing this every time?
- 4. Who do you know who seems to do a better job?
- 5. Does anyone have any ideas about what we should do next?
- 6. Are there any volunteers to work on these ideas?

Source: Adapted from the Billings Clinic.

TRIZ is a method of revealing creative and surprising solutions to barriers identified in the workplace (Terminko et al. 1998). In PD, this process has been used as a way for people to imagine through reverse engineering how they might achieve an outcome that is the opposite of the desired effect. For example, a group might be asked how to ensure that every patient will acquire an infection by designing a system to reliably deliver that outcome every time. When the adverse system is compared with the current one, the group typically realizes that their current system has inadvertently been designed to spread infection. This different perspective provides participants with new ways to think about what needs to change.

Focus groups and appreciative inquiry have been used to support the PD process in community settings, as well as tools such as a social network or community mapping to help build a fuller understanding of the context and resources the community has. There is no one tool to use in any specific situation. Rather, groups engaged in the PD process are meant to experiment with various tools to learn what works for them and in what circumstance. Should a team feel that they are not making progress, it may be time to try a different tool.

Does PD Work?

Most of the work with PD has been done outside of traditional healthcare settings. In Vietnam, a large randomized prospective PD study focusing on childhood nutrition was conducted in 12 communities in the northern part of the country. Monthly measures were taken on 240 malnourished children (120 children in communities undertaking the intervention and 120 children in non-intervention communities) over a six-month period, and then again at 12 months. The investigators found that the children from the intervention communities had better growth, ate and breastfed more frequently, ate larger portions of food, experienced fewer respiratory infections and had mothers who were more likely to share new information about child care and feeding with neighbours than did children in non-intervention communities (Marsh et al. 2004; Sternin et al. 1997, 1999).

A three- and four-year follow-up study assessed the sustainability of this project. Weight and nourishment measures of older and younger siblings in intervention communities were compared with to those in non-intervention communities. Both older and younger siblings in intervention communities tended to be better nourished than their non-intervention comparators (Mackintosh et al. 2002). The authors concluded that growthpromoting behaviours that were identified, shared and practised through the PD intervention persisted years after the program had ended (Mackintosh et al. 2002).

In 2006, a smoking cessation program used PD to improve rates of cessation among prisoners in New South Wales. By highlighting positive deviant behaviours (i.e., non-smokers and quitters) and encouraging the adoption of these successful strategies, smoking prevalence in the study population dropped by 20% over the 15-month study period (Awofeso et al. 2008). Further, the authors found that three months after the program started, 70% of quitters were still not smoking, compared with an average of 52% for comparable non-PD programs (Awofeso et al. 2008).

PD is new to the healthcare setting; hence, the data supporting its use for this purpose are currently limited, albeit growing. The American PD MRSA Prevention Partnership implemented PD in six acute care hospitals with the goal of reducing rates of healthcare-associated methicillin-resistant Staphylococcus aureus (MRSA). Hospitals of different sizes were included, as were both teaching and community hospitals. From 2006 to 2008, PD was used on at least one pilot unit per site to improve facility compliance with evidence-based infection control precautions such as active MRSA surveillance, hand hygiene, contact isolation precautions and environmental cleaning (Lindberg et al. 2008). All sites reduced their MRSA infection rates by a minimum of 33%, with one site in Billings, Montana, decreasing its rate by 89% (Lindberg et al. 2008).

It is important to note that none of the infection control interventions used in this study are new and all have been proven effective in the literature countless times. Rather, it is the important contribution of PD to improving these organizations' abilities to apply and sustain the application of these interventions that is significant.

Similarly, a Brazilian team used PD to bring about improvements in healthcare worker compliance specifically related to hand hygiene (Marra et al. 2010). The investigators collected baseline hand hygiene data on two nursing units, implemented PD on one unit and then implemented it on the second unit three months later. They showed a time-dependent statistically significant stepwise increase in hand hygiene compliance on the two units that was associated with statistically significant increases in the use of alcohol-based hand rubs and decreases in HAIs.

The initial significant success in the US pilot hospitals has prompted other American and, more recently, Canadian hospitals to implement PD to help reduce rates of HAIs. The PD process at University Health Network was started by front line staff in 2008 without a formal launch on two floors at the Toronto Western Hospital that have subsequently shown sustained reductions in HAIs (Figure 1). Subsequently, PD was formally launched at University Health Network in the spring of 2009, and several different programs have being actively using the aforementioned tools to engage interested front-line staff. For example, improv has proved popular to help tackle some thorny issues such as how to manage meal trays that have been in isolation rooms and how to address inappropriate physician behaviour. DADs have been used in all areas that have started PD, and we have found TRIZ to be an effective icebreaker to get participants to start thinking about the problem.

A new Canadian study, funded by several partners including

the Canadian Patient Safety Institute and Becton Dickinson, is examining the use of PD to decrease superbug infections in five hospitals (Canadian Positive Deviance Project 2010); however, given that it is at an early stage, data are not yet available.

Like any quality improvement project, it is important to track appropriate indicators. The very nature of PD makes it impossible to identify which staff-led initiative or combinations of initiatives result in improvements as, typically, many are implemented. Measurement thus focuses on traditional infection control process and outcome measures such as gown and glove use, hand hygiene compliance and rates of various HAIs. Serial attitude and behavioural surveys as well as social network mapping have also been used to track culture change.

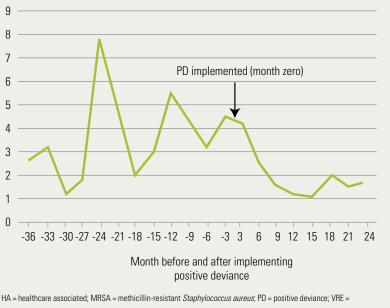
Conclusion

The circumstances that lead to the development of HAIs are complex. It is unusual to be able to determine one specific cause of a hospital's history of infections; rather, myriad potential causes can be identified

and these causes are different in different situations and settings. Furthermore, some causes may go unrecognized. Because of this, one should not expect that a "best practice" approach that requires healthcare workers to act in a certain way will bring about the desired changes in most settings. Rather, a method that allows for local approaches and tools to improve practice will likely be more effective in bringing about change and sustaining it over time.

PD is best applied to complex problems that are deeply rooted in culture. The small but emerging PD literature suggests that it is a powerful technique that can help change healthcare worker actions and, later, the prevalent culture. Likely the key factor contributing to this success is that the ideas and actions that result from the PD process come from the people who are "touching the problem." Unlike brainstorming, where ideas that come from the front line are subsequently filtered, the PD process empowers the group to learn from the positive deviants from within the group and then act. This in turn leads to sustained behavioural change. As one would expect, rarely can one identify an exact action that has brought about a sustained change; rather, improvement is typically a result of multiple small actions that have interacted in unpredictable ways. This reality can be quite uncomfortable for practitioners who are used to the tenets of evidence-based medicine and who consider the

Figure 1. Combined rate of HA-MRSA, VRE and Clostridium difficile infections per 1,000 patient-days on two medicine floors before and after the implementation of positive deviance



Source: University Health Network (2010)

randomized controlled trial as the best evidence. PD is messy, relationship focused and, on the surface, appears uncontrolled; but this is what one would expect of an effective strategy for a complex problem (Zimmerman et al. 2001).

Although the Canadian PD study is in its infancy, we have learned a great deal from its implementation. This experience has led to a successful proposal to incorporate PD into a revamped Safer Healthcare Now! intervention - A New Approach to Controlling Superbugs was launched Canada-wide in May 2010. One of the key challenges facing this project is the simple, daunting fact of Canadian geography, making it unfeasible to have groups meet with each other and coaches on a regular basis. Rather, the coaching and support will be provided virtually through teleconferences, webinars, an online community of practice and social media. The rollout of this whole-scale approach to PD has just begun, and it is far too early to comment on its success. We believe, however, that this important, necessary and undoubtedly challenging step is necessary to bring a new approach to the problem. As we have discussed, decades of approaching infection control practice in more traditional ways involving education and audits have not taken us to where we need to be. Approaches such as PD that acknowledge the complexity of the challenge are needed if we hope to make healthcare a safer experience for our patients. HQ

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Dimensions of Patient Safety Culture in Family Practice

Luz Palacios-Derflingher, Maeve O'Beirne, Pam D. Sterling, Karen Zwicker, Brianne K. Harding and Ann Casebeer

Abstract

Safety culture has been shown to affect patient safety in healthcare. While the United States and United Kingdom have studied the dimensions that reflect patient safety culture in family practice settings, to date, this has not been done in Canada. Differences in the healthcare systems between these countries and Canada may affect the dimensions found to be relevant here. Thus, it is important to identify and compare the dimensions from the United States and the United Kingdom in a Canadian context.

The objectives of this study were to explore the dimensions of patient safety culture that relate to family practice in Canada and to determine if differences and similarities exist between dimensions found in Canada and those found in previous studies undertaken in the United States and the United Kingdom. A qualitative study was undertaken applying thematic analysis using focus groups with family practice offices and supplementary key stakeholders.

Analysis of the data indicated that most of the dimensions from the United States and United Kingdom are appropriate in our Canadian context. Exceptions included owner/managing partner/leadership support for patient safety, job satisfaction and overall perceptions of patient safety and quality. Two unique dimensions were identified in the Canadian context: disclosure and accepting responsibility for errors.

Based on this early work, it is important to consider differences in care settings when understanding dimensions of patient safety culture. We suggest that additional research in family practice settings is critical to further understand the influence of context on patient safety culture.

Background

Since the release of the Institute of Medicine report *To Err Is Human: Building a Safer Healthcare System* (Kohn et al. 1999), more attention has been paid internationally to the issues surrounding patient safety. The safety of healthcare has been shown to be influenced by its organizational culture (Nieva and Sorra 2003; Schutz et al. 2007; Wachter 2004), which is the pattern of assumptions, values and norms within an organization (Schein 1990) and is the primary driver of safety (Ruchlin et al. 2004). If the organizational culture does not support patient safety, unsafe care will continue to occur (Baker and Norton 2001; Gaba et al. 2007; Pace 2007; Pronovost and Sexton 2005; Singer et al. 2007; Wachter 2004; Westrum 2004).

Organizational culture is a broad construct composed of many subsets of culture, one of which is safety (Clarke 1999; Hofstede 1980; Reiman and Oedewald 2004). The focus on safety culture began in the nuclear power and aviation industries (Health and Safety Commission 1993) and is now recognized as an important component in the delivery of healthcare (Blegen et al. 2009; Clarke 1999; Fleming and Wentzell 2008; Gaba et al.

1994; Ginsburg and Tregunno 2007; Hofstede 1980; National Patient Safety Agency [NPSA] 2006; Reiman and Oedewald 2004; Stock and Mahoney 2008). NPSA defines safety culture as one in which "both the individuals and the organisation are able to acknowledge mistakes, learn from them, and take action to put things right...[It] is open and fair, and one that encourages people to speak up about mistakes" (2006: 17, 21). It also has been suggested that "safety culture is a critical element necessary to achieve reductions in medical errors and adverse events" (Stock et al. 2007: 375). To improve patient safety, a shift in culture from "blame and shame" to "just and trusting" is required (Reason 1997).

In order to improve patient safety culture, it is necessary to be able to interpret and measure it. To date, the majority of research on patient safety culture interpretation and measurement has focused on acute care settings. Singla et al. (2006) performed a systematic review of existing instruments or tools developed in the United States to measure patient safety culture in acute care. They found 13 instruments identifying 23 dimensions of patient safety culture. These dimensions were grouped into six broad categories: management/supervision, risk, work pressure, competence, rules and miscellaneous. One of these instruments, the Stanford Instrument (Singer et al. 2003), was modified to fit the Canadian acute care context (York University n.d.).

Family practice settings differ from acute care in organizational structure, administrative and clinical processes and the reason for and type of visits.

Family practice settings differ from acute care in organizational structure, administrative and clinical processes and the reason for and type of visits. In family practice, a formalized organizational structure with set policies and procedures is rare; services such as specialist care, laboratories and diagnostic imaging are off site; there is less control over the patients' environments (Hammons et al. 2002; O'Beirne and Sterling 2009; Schutz et al. 2007); the turnaround of results is much slower; and patients are more likely to be seen for chronic issues rather than conditions of high acuity (Dovey et al. 2002a, 2002b).

Family practice also differs in relation to the types of incidents reported and in the strategies and interventions used to improve patient safety. In family practice, most incidents are related to failure or delay in diagnosis, failure or delay in referral, medication contraindication, medication prescription errors (Dovey et al. 2003; National Patient Safety Agency 2006) and test results management (Elder et al. 2009). In acute care, interventions and strategies focus on standardizing operating procedures in order to mitigate incidents. In family practice, interventions and strategies focus on "diagnosis, medication prescribing, dispensing and administration, and communication within practices, between different professions and between primary and secondary care" (National Patient Safety Agency 2006: 20).

Given the substantial differences in care settings, it is important to understand if and how differences influence or alter dimensions of patient safety culture. Unfortunately, very little work has been published on measuring patient safety culture in family practice. In the United States, three groups have developed sets of dimensions for family practice (Agency for Healthcare Research and Quality n.d.; Modak et al. 2007; Schutz et al. 2007), tied to respective questionnaires. Also, a framework of dimensions has been developed in the United Kingdom (Kirk et al. 2007). The dimensions from the three US sources and the UK source were similar but not identical. In the Canadian context, patient safety culture dimensions for family practice have not been developed. However, major distinctions among Canada, the United States and the United Kingdom exist within their incentives and management structures for family practice. In the United States, most of the family practice delivery is privately funded and delivered through managed care. In the United Kingdom, the delivery is primarily publicly funded and organized into "primary care trusts" (National Health Service 2009). In Canada, family practice care delivery is publicly funded and privately delivered. This variance in governance of family practice among the US, UK and Canadian contexts suggests that further exploration is required to better understand what dimensions are and are not appropriate for measuring patient safety culture in Canadian family practice.

As outlined, there are considerable gaps in knowledge concerning the dimensions of patient safety culture that need to be addressed specific to the family practice setting in the Canadian context. The remainder of this article discusses how investigation into these gaps has begun.

Purpose and Objectives

This study is part of a much larger program of research that focuses on patient safety in family practice - Medical Safety in Community Practice (MSCP; O'Beirne and Sterling 2009). The purpose of the MSCP research is to collect incident information from family practices located within Alberta Health Services, Calgary Zone, and to collaborate with these practices to develop, implement and evaluate risk management strategies to increase patient safety. The overarching purpose of the study presented in this article was to explore patient safety culture within family practice settings in order to enhance the understanding of this relatively under-studied setting. Primary objectives were (1) to begin to determine the dimensions of patient safety culture for family practice in Canada and (2) to subsequently determine if differences and similarities exist between dimensions found in

Canada and those found in previous studies undertaken in the United States and the United Kingdom.

Methods

This qualitative case study involved identifying the dimensions of patient safety culture of relevance to family practice in Canada. A convenience sample of five clinics was chosen from the MSCP program. These clinics were invited via telephone to participate in the focus groups for this study. Two clinics accepted the invitation. One of these clinics was well entrenched in the patient safety study; the other was new to the study. A third focus group was held that involved informed stakeholders, including patient safety experts and family physicians, staff and patient advocates (members of a panel in the MSCP program). These focus groups were what Stewart and Shamdasani (1990) described as "compatible and heterogeneous" because they had

a diversity of practitioners and professionals with a common interest in patient safety. A semi-structured script was used to guide discussion on the dimensions that participants felt were important to patient safety culture.

The focus groups were facilitated by one of the research team members and ran for one hour or less. Each group had between four and six participants. In total, five physicians, one nurse, six office staff members, one healthcare administrator and one layperson participated. All focus groups were tape-recorded. After the first focus group, participants suggested adding a definition of patient safety culture, and this was provided for the remaining groups. By the third focus group, no new information was emerging.

Tape recordings were transcribed, data coded and field notes used to supplement and clarify the data (Morse and Field 1995). Three researchers individually performed thematic analyses (Morse and Field 1995) on the focus group transcripts. The existing dimensions from the United States and United Kingdom were used as one lens for analysis; however, analysis remained open to identify new and emergent perspectives from the study participants. When comparing results, themes and dimensions of patient safety culture were convergent among

the reviewers. The discussion and revision of themes focused primarily on how these similar concepts were named. A final review of emergent themes and dimensions of patient safety culture was undertaken by five researchers, serving to further triangulate results and allow for additional reflective interpretation of the study participant data. If the wording was different but the concept the same, the language used in the US study (Agency for Healthcare Research and Quality n.d.) was adopted.

The analyses of our review of existing literature and our own data highlight several important results. Thirteen dimensions of patient safety culture relevant to family practice in our Canadian cases were identified. Table 1 illustrates the dimensions and compares them with those in the US and UK studies. Each of these dimensions is further described in Table 2, which provides

Table 1. Patient safety culture dimensions in family practice: comparison of US and UK cases with Canadian cases

Dimension*	US and UK Cases	Canadian Cases
Organizational learning	Х	Х
Communication about error	Х	Х
Staff training	Х	Х
Teamwork	Х	Х
Patient care tracking/follow-up	Х	Х
Communication openness	Х	Х
Patient safety and quality issues	Х	Х
Office processes and standardization	Х	Х
Information exchange with other settings	Х	Х
Work pressure and pace	Х	Х
Overall ratings on quality and patient safety	Х	Х
Owner/managing partner/leadership support for patient safety	Х	
Job satisfaction	Х	
Overall perceptions of patient safety and quality	Х	
Disclosure		Х
Accepting responsibility for error		Х

^{*}Dimensions from the three US sources (Agency for Healthcare Research and Quality [AHRQ] n.d.; Modak et al. 2007; Schutz et al. 2007) and one UK source (Kirk et al. 2007) were similar but not identical, and we chose the wording of AHRO.

Table 2. Dimensions, descriptions and examples for the Canadian cases

Dimension	Description of Dimension	Narrative Example	
Organizational learning	Illustrates the level of learning that occurs from incidents within the practice, and work to improve those problems	"Well, in my opinion, it's hard to anticipate every aspect of the type of mistakes that can be made, but when a mistake is brought forward, something is done to address it so it hopefully does not happen again. And it's not disregarded."	
Communication about error	Shows the openness of the practice members to admitting errors and discussing them with others	"Creating an atmosphere where people feel comfortable bringing forward mistakes."	
Staff training	Reflects how well the office ensures staff members are trained in what they are required to do	"In-service training in various aspects of what the staff are doing would definitely help."	
Teamwork	Identifies respect, working relationships and helping others in the work load as part of teamwork	"The idea of teamwork is hugely important. The people that contribute are present at the decision; co-operate in that collegial world of encounter."	
Patient care tracking/ follow-up	Measures the extent offices perform proper follow-up and tracking of patients	"Well, having test results going astray is big, especially when something has been missed. If there was something important in the results"	
Communication openness	Reflects how open all members of the office are in voicing their opinion and accepting others	"I think it's important that everyone feels free to contribute their ideas because everyone has a different role and, maybe, just a different way they to about things."	
Patient safety and quality issues	Reflects things that can happen in medical offices that affect patient safety and quality of care (e.g., access to care, medication and medical records)	"In a perfect healthcare setting would be timely access to a physician, appropriate evaluation, proper medication and compliance by the patient and also appropriate laboratory investigation and follow-up on that."	
Office processes and standardization	Identifies procedures, processes, workflow and standardization	"It is creating processes within our medical environments that allow patients or clients to move through these processes in a positive manner."	
Information exchange with other settings	Captures how often the office has had problems exchanging accurate, complete and timely information with external settings (laboratory, diagnostic imaging, specialists)	"Because the clinic does not notify us when they've received our referral we are now attaching a cover that says please respond that you have received this referral. They haven't returned our faxes, but we just started that last week."	
Work pressure and pace	Explores distractions and volume of work	"If the environment you are working in is too distracting, it's unsafe."	
Overall ratings on quality and patient safety	Measures overall ratings on patient-centred, effective, timely, efficient and equitable healthcare	"Part of patient safety is getting the most up-to-date evidence- based care."	
Disclosure	Reflects disclosure of error to the patient	"Patients are confident in knowing that if something gets missed, it will be brought to their attention it's not hidden from them; it's disclosed."	
Accepting responsibility for error	Illustrates that individuals can accept that they made an error	"I think it's important if you have made a mistake to say, 'I'm sorry, I made a mistake,' because mistakes happen and it's not that you purposely try to make mistakes during your day at work."	

some examples of the Canadian perspectives found in the data.

As Table 1 shows, three patient safety culture dimensions in family practice found in the US and UK cases were not found in the Canadian context: owner/managing partner/leadership support for patient safety, job satisfaction and overall perceptions of patient safety and quality. Two new dimensions were identified: disclosure and accepting responsibility for errors.

The data reported here explore the dimensions of patient safety culture in Canadian family practice settings in comparison with data found in the US and UK studies. Several interesting findings warrant discussion and further examination.

Discussion

The dimensions found in family practice in Canada identified in Table 1 suggest that there is considerable consistency of patient safety culture dimensions in our Canadian cases when compared with the US and UK cases; but, there also appear to be some differences. Eleven of the existing dimensions were relevant in the Canadian context, three were not identified and two new dimensions were discovered.

There are many possible reasons for these differences. The absence of the dimension owner/managing partner/leadership support for patient safety could be due to the difference in governance found in these countries. In Canada, clinics are run more as a partnership, without an overlying organizational structure. It is difficult to explain the absence of the dimension job satisfaction in the Canadian study, but it is interesting to note that this dimension was also not found in studies of acute care in Canada (York University n.d.). It is possible that, in this study, job satisfaction was captured as an attribute (subcategory) under other dimensions such as office processes and standardization. Overall perceptions of patient safety and quality may simply have been too broad a dimension to emerge separately in our cases. This is an area that needs further exploration.

Two new dimensions were found to be relevant in Canadian family practice settings: While *disclosure* is closely aligned with the existing dimension *communication about error*, it concerns communicating outside the clinical team to patients and families. *Accepting responsibility for error* appears to be unique and distinct, going beyond communicating about an error to admitting fallibility. These new dimensions may have arisen as a consequence of recent media coverage and emphasis in Canada on disclosure and accepting responsibility (Health Quality Council of Alberta 2006; Windwick et al. 2007). Perhaps these dimensions were missing in the US and UK cases due to the earlier timing of the studies.

It is important to stress both the strengths and limitations of the study findings. Potential limitations to the study include the following: (1) participants may not have felt comfortable enough to openly express themselves in front of their colleagues, although this risk was minimized through careful facilitation of

the focus groups; and (2) the small sample size from one city did not include all types of family practices (ranging from a single family physician practice with few employees and little organizational structure to multi-physician, multi-employee practices with some organizational structure). The major strength of the study is that it adds early and additional knowledge to understanding dimensions of patient safety culture in family practice, and it is the first of its kind in a Canadian setting.

Given that this is one early study with only a few Canadian cases, clearly more research is required to confirm and extend this initial exploratory case analysis. However, considering the significant consistency of dimensions found in common with those in the earlier US and UK studies, there is some promise for transferable lessons more generally for family practice in Canadian settings.

It is important to consider context when adapting existing tools created in other jurisdictions.

This study identified 13 dimensions relevant to patient safety culture in Canada. Based on this early work, it is important to consider context (country and setting) when adapting existing tools created in other jurisdictions. The dimensions found in this study will be used to develop a tool to measure patient safety culture in family practice in Canada. With this tool, we will be able to estimate patient safety culture and measure changes in culture after the implementation of safety or quality interventions.

While our work makes important contributions to understanding the dimensions of patient safety in family practice settings, additional exploration and evaluative research are needed. We encourage others to add to our empirical and theoretical knowledge of the role that culture plays in the capacity to develop and sustain patient safety in Canadian family practice settings. We also suggest that additional comparative research would provide valuable insight into how best to understand and measure the influence of patient safety culture in different countries with varying organizational arrangements for care and, especially, among distinct care settings.

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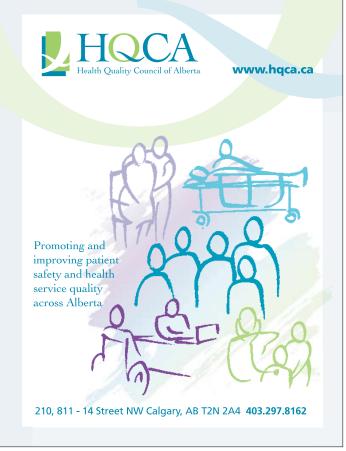
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- Other conditions or diseases involving an increased risk of hemorrhage
- Injuries to and operations on the central nervous system, eyes and ears
- Spinal/epidural anesthesia is contraindicated where repeated high doses of FRAGMIN (100-120 IU/kg given twice daily or 200 IU/kg once daily) are required, due to an increased risk of bleeding

SPECIAL POPULATIONS

Pregnant Women:

The multi-dose vial of FRAGMIN (25,000 IU/mL) contains benzyl alcohol (14 mg/mL) as a preservative. Benzyl alcohol has been associated with a potentially fatal "Gasping Syndrome" in neonates. Cases of Gasping Syndrome have been reported in neonates when benzyl alcohol has been administered in amounts of 99-404 mg/kg/day. Manifestations of the disease include: metabolic acidosis, respiratory distress, gasping respirations, central nervous system dysfunction, convulsions, intracranial hemorrhages, hypoactivity, hypotonia, cardiovascular collapse and death. Because benzyl alcohol may cross the placenta, FRAGMIN preserved with benzyl alcohol should not be used in pregnant women.

There are also postmarketing reports of prosthetic valve thrombosis in pregnant women with prosthetic heart valves while receiving low molecular weight heparins for thromboprophylaxis. These events led to maternal death or surgical interventions.

Pregnant women with prosthetic heart valves appear to be at exceedingly high risk of thromboembolism. An incidence of thromboembolism approaching 30% has been reported in these patients, in some cases even with apparent adequate anticoagulation at treatment doses of low molecular weight heparins or unfractionated heparin. Any attempt to anticoagulate such patients should normally only be undertaken by medical practitioners with documented expertise and experience in this clinical area.

Teratogenic Effects: As with other low molecular weight heparins (LMWH), FRAGMIN should not be used in pregnant women unless the therapeutic benefits to the patients outweigh the possible risks. There have been reports of congenital anomalies in infants born to women who received LMWHs during pregnancy, including cerebral anomalies, limb anomalies, hypospadias, peripheral vascular malformation, fibrotic dysplasia and cardiac defects. A causal relationship has not been established nor has the incidence been shown to be higher than in the general population.

Non-teratogenic Effects: There have been postmarketing reports of fetal death when pregnant women received low molecular weight heparins. Causality for these cases has not been established. Pregnant women receiving anticoagulants, including FRAGMIN, are at increased risk for bleeding. Hemorrhage can occur at any site and may lead to death of mother and/or fetus. Pregnant women receiving FRAGMIN should be carefully monitored. Pregnant women and women of child-bearing potential should be informed of the potential hazard to the fetus and the mother if FRAGMIN is administered during pregnancy.

Nursing Women:

It is not known whether FRAGMIN is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when FRAGMIN is administered to nursing women.

Pediatrics:

The safety and effectiveness of FRAGMIN in children have not been established.

Geriatrics:

Elderly patients receiving low molecular weight heparins are at increased risk of bleeding. Careful attention to dosing intervals and concomitant medications, especially anti-platelet preparations, is advised. Close monitoring of elderly patients with low body weight (e.g., <45 kg) and those predisposed to decreased renal function is recommended.

Patients with Extreme Body Weight:

Safety and efficacy of low molecular weight heparins in high weight (e.g., >120 kg) and low weight (e.g., <46 kg) patients have not been fully determined. Individualized clinical and laboratory monitoring are recommended in these patients.



Safety Information

WARNINGS AND PRECAUTIONS

Special Warnings and Precautions

The multi-dose vial of FRAGMIN (25.000 IU/mL) contains benzyl alcohol (14 mg/mL) as a preservative. Benzyl alcohol has been associated with a potentially fatal "Gasping Syndrome" in neonates. Because benzyl alcohol may cross the placenta, FRAGMIN preserved with benzyl alcohol should not be used in pregnant women (see Special Populations, Pregnant Women).

General

FRAGMIN should NOT be administered intra-muscularly.

FRAGMIN CANNOT BE USED INTERCHANGEABLY (UNIT FOR UNIT) WITH UNFRACTIONATED HEPARIN (UFH) OR OTHER LOW MOLECULAR WEIGHT HEPARINS (LMWHs) AS THEY DIFFER IN THEIR MANUFACTURING PROCESS. MOLECULAR

WEIGHT DISTRIBUTION, ANTI-Xa AND ANTI-IIa ACTIVITIES, UNITS AND DOSAGES. SPECIAL ATTENTION AND COMPLIANCE WITH INSTRUCTIONS FOR USE OF EACH SPECIFIC PRODUCT ARE REQUIRED DURING ANY CHANGE IN TREATMENT.

<u>Cardiovascular</u>

Use in Patients with Prosthetic Heart Valves: Cases of prosthetic valve thrombosis have been reported in these patients who have received low molecular weight heparins for thromboprophylaxis. Some of these patients were pregnant women in whom thrombosis led to maternal and/or fetal deaths. Pregnant women are at higher risk of thromboembolism (see WARNINGS AND PRECAUTIONS, Patient Selection Critera, SPECIAL POPULATION, Pregnant Women).

Use in Unstable Coronary Artery Disease: When thrombolytic treatment is considered appropriate in patients with unstable angina and non-Q-wave myocardial infarction, concomitant use of an anticoagulant such as FRAGMIN may increase the risk of bleeding.

Gastrointestinal

FRAGMIN should be used with caution in patients with a history of gastrointestinal ulceration.

Hematologic

Hemorrhage: Bleeding may occur in conjunction with unfractionated heparin or low molecular weight heparin use. As with other anticoagulants, FRAGMIN should be used with extreme caution in patients at increased risk of hemorrhage. Bleeding can occur at any site during therapy with FRAGMIN. An unexpected drop in hematocrit or blood pressure should lead to a search for a bleeding site.

Platelets/Thrombocytopenia: Platelet counts should be determined prior to the start of treatment with FRAGMIN and, subsequently, twice weekly for the duration of treatment. Thrombocytopenia of any degree should be monitored closely. Heparininduced thrombocytopenia can occur with the administration of FRAGMIN. Its incidence is unknown at present.

Caution is recommended when administering FRAGMIN to patients with congenital or drug-induced thrombocytopenia or platelet defects.

During FRAGMIN administration, special caution is necessary in rapidly- developing thrombocytopenia and severe thrombocytopenia (<100 000/µL). A positive or unknown result obtained from in vitro tests for antiplatelet antibody in the presence of FRAGMIN or other low molecular weight heparins and/or heparins would contraindicate FRAGMIN.

Hepatic

FRAGMIN should be used with caution in patients with hepatic insufficiency, as these patients may have potentially higher risk of hemorrhage.

Peri-Operative Considerations

Spinal/Epidural Hematomas:

When neuraxial anesthesia (epidural/spinal anesthesia) or spinal puncture is employed, patients anticoagulated or scheduled to be anticoagulated with low molecular weight heparins or heparinoids for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis.

The risk of these events is increased by the use of indwelling epidural catheters for administration of analgesia or by the concomitant use of drugs affecting hemostasis such as non steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors or other anticoagulants. The risk also appears to be increased by traumatic or repeated epidural or spinal puncture.

Patients should be frequently monitored for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

The physician should consider the potential benefit versus risk before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis (see CONTRAINDICATIONS and ADVERSE REACTIONS).

When a higher dose (5000 IU s.c.) of FRAGMIN is administered for thromboprophylaxis in conjunction with surgery, no spinal/epidural invasion should be performed for at

least 12 hours following the last dose of FRAGMIN and the next dose should be held until at least 12 hours after the anaesthetic procedure. Alternatively, when a lower dose (2500 IU s.c.) of FRAGMIN is administered, the dose can be initiated 1 - 2 hours prior to surgery. FRAGMIN injection should be given after spinal/epidural anaesthesia and only if the anaesthesiologist considers the spinal/epidural puncture as uncomplicated. Indwelling catheters should not be removed or manipulated for at least 10 - 12 hours following the last dose of FRAGMIN.

Use in Knee Surgery: The risk of bleeding in knee surgery patients receiving low molecular weight heparins may be greater than in other orthopedic surgical procedures. It should be noted that hemarthrosis is a serious complication of knee surgery. The frequency of bleeding events observed with FRAGMIN in orthopedic surgery patients is derived from clinical trials in hip replacement surgery patients. The physician should weigh the potential risks with the potential benefits to the patient in determining whether to administer a low molecular weight heparin in this patient population.

Selection of General Surgery Patients: Risk factors associated with postoperative venous thromboembolism following general surgery include history of venous thromboembolism, varicose veins, obesity, heart failure, malignancy, previous long bone fracture of a lower limb, bed rest for more than 5 days prior to surgery, predicted duration of surgery of more than 30 minutes, and age 60 years or above.

Renal

FRAGMIN should be used with caution in patients with renal insufficiency.

Patients with impaired renal function should be carefully monitored because the half-life for anti-Xa activity after administration of low molecular weight heparin may be prolonged in this patient population. Dose reduction should be considered in patients with severe renal impairment.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Clinically significant adverse reactions observed with use of FRAGMIN and other low molecular weight heparins include bleeding events and local reactions, with a low incidence of thrombocytopenia and allergic reactions.

Post-Marketing Adverse Reactions

In post-marketing experience, the following undesirable effects have been reported:

Bleeding: Intracranial hemorrhage, gastrointestinal hemorrhage, retroperitoneal hemorrhage have been reported occasionally leading to fatality

Blood and Lymphatic System: thrombocytopenia, thrombocythemia

Skin and Subcutaneous Tissue Disorders: skin necrosis, alopecia, rash

Immune System Disorders: immunologically-mediated heparin-induced thrombocytopenia (type II, with or without associated thrombotic complications), anaphylactic reactions

Injury, Poisoning and Procedural Complications: spinal or epidural hematoma

DRUG INTERACTIONS

Drug-Drug Interactions

FRAGMIN should be used with caution in patients receiving oral anticoagulants, platelet inhibitors, non-steroidal anti-inflammatories and thrombolytic agents because of increased risk of bleeding. Acetylsalicylic acid (ASA), unless contraindicated, is recommended in patients treated for unstable angina or non-Q-wave myocardial infarctions.

Drug-Food Interactions

Interactions with food have not been established.

Drug-herb Interactions

Interactions with herbs have not been established.

Drug-lab tests Interactions

Interactions with lab tests have not been established.

Drug-lifestyle Interactions

Interactions with lifestyle have not been established.

To report an adverse event, please contact: your physician, pharmacist or Pfizer Medical Information: 1-800-463-6001.



Administration

DOSAGE AND ADMINISTRATION

FRAGMIN may be given by subcutaneous (s.c.) injection or by intermittent or continuous intravenous (i.v.) infusion, depending upon the circumstances. FRAGMIN must NOT be administered intramuscularly. Clinical trials conducted in support of clinical uses outlined below generally used subcutaneous dosing.

Dosing

Thromboprophylaxis in Conjunction with Surgery

The dose of FRAGMIN required for adequate prophylaxis without substantially increasing bleeding risk varies depending on patient risk factors.

General surgery with associated risk of thromboembolic complications: 2500 IU s.c. administered 1 - 2 hours before the operation, and thereafter 2500 IU s.c. each morning until the patient is mobilized, in general 5-7 days or longer.

General surgery associated with other risk factors: 5000 IU s.c. is given the evening before the operation and then 5000 IU s.c. the following evenings. Treatment is continued until the patient is mobilized, in general for 5-7 days or longer.

As an alternative, 2500 IU s.c. is given 1-2 hours before the operation, with 2500 IU s.c. given again no sooner than 4 hours after surgery, but at least 8 hours after the previous dose, provided primary hemostasis is obtained. Starting on the day after surgery, 5000 IU s.c. is given each morning, in general for 5-7 days or longer.

Elective hip surgery: 5000 IU s.c. is given the evening before the operation and then 5000 IU s.c. the following evenings. Treatment is continued until the patient is mobilized, in general for 5-7 days or longer.

As an alternative 2500 IU s.c. is given 1-2 hours before the operation and 2500 IU s.c. 4-8 hours after surgery, provided primary hemostasis is obtained. Starting on the day after surgery, 5000 IU s.c. is given each morning, in general for 5-7 days or longer.

The pre-operative dose may be omitted and an initial dose of 2500 IU s.c. administered 4-8 hours after the operation, provided primary hemostasis is obtained. Starting on the day after surgery, 5000 IU s.c. is given each morning, in general for 5-7 days or longer. Omission of the pre-operative dose may reduce risk of perioperative bleeding, however increased risk of venous thromboembolic events is possible. This option is based on the results of the North American Fragmin Trial (NAFT), which excluded patients at high risk of bleeding, i.e., documented cerebral or gastrointestinal bleeding within 3 months prior to surgery, defective hemostasis, e.g., thrombocytopenia (<100 x 10⁹/L), ongoing anticoagulant treatment.

Treatment of Acute Deep Vein Thrombosis

The following dosage is recommended: 200 IU/kg body weight given s.c. once daily. The expected plasma anti-Xa levels during subcutaneous treatment would be <0.3 IU anti-Xa/mL before injection and <1.7 IU anti-Xa/mL 3 - 4 hours after injection. In order to individualize the dose, a functional anti-Xa assay should be performed 3 - 4 hours post-injection. The single daily dose should not exceed 18 000 IU. The following weight intervals are recommended to be adapted to the single-dose prefilled syringes as in the table below.

Weight (kg)	Dosage (IU)
46-56	10 000
57-68	12 500
69-82	15 000
83 and above	18 000

For patients with increased risk of bleeding, a dose of 100 IU/kg body weight given s.c. twice daily or 100 IU/kg body weight administered over a period of 12 hours as continuous i.v. infusion, can be used . The expected plasma anti-Xa levels during subcutaneous treatment would be >0.1 IU anti-Xa/mL before injection and <1.0 IU anti-Xa/mL 3 - 4 hours after injection.

Normally concomitant treatment with vitamin-K antagonists is started immediately. Treatment with FRAGMIN should be continued until the levels of the prothrombin complex factors (FII, FVII, FIX, FX) have decreased to a therapeutic level, in general for approximately 5 days.

Extended Treatment of Symptomatic Venous Thromboembolism (VTE) to Prevent Recurrence of VTE in Patients with Cancer

Month 1: 200 IU/kg body weight given s.c. once daily for the first 30 days of treatment. The total daily dose should not exceed 18,000 IU daily.

Months 2-6: Approximately 150 IU/kg given s.c. once daily using the table shown below.

Weight (kg)	Dosage (IU)	
≤56	7 500	
57-68	10 000	
69-82	12 500	
83-98	15 000	
≥99	18 000	

Dose reductions for chemotherapy-induced thrombocytopenia: In the case of chemotherapy-induced thrombocytopenia with platelet counts <50,000/mm³, FRAGMIN should be interrupted until the platelet count recovers above 50,000/mm3. For platelet counts between 50,000 and 100,000/mm³, FRAGMIN should be reduced by 17% to 33% of the initial dose (allowing for dosage adjustment using the prefilled syringes), depending on the patient's weight (table below). Once the platelet count recovers to ≥100,000/mm³, FRAGMIN should be re-instituted at full dose.

Weight (kg)	Scheduled Dose (IU)	Reduced Dose (IU)	Mean Dose Reduction (%)
≤56	7 500	5 000	33
57-68	10 000	7 500	25
69-82	12 500	10 000	20
83-98	15 000	12 500	17
≥99	18 000	15 000	17

Unstable Coronary Artery Disease (Unstable Angina and Non-Q-Wave Myocardial Infarction)

120 IU/kg body weight given s.c. twice daily with a maximum dose of 10 000 IU/12 hours. The expected plasma anti-Xa levels during subcutaneous treatment would be >0.1 IU anti-Xa/mL before injection and <1.6 IU anti-Xa/mL 3 - 4 hours after injection. These levels were obtained from another patient population. Treatment should be continued for up to 6 days. Concomitant therapy with ASA is recommended.

Deep Vein Thrombosis in Hospitalized Patients with Severely-Restricted Mobility In hospitalized patients with severely-restricted mobility during acute illness, the recommended dose of FRAGMIN is 5000 IU administered by s.c. injection once daily. In clinical trials, the usual duration of administration was 12 to 14 days.

Use in Patients with Renal Impairment

All patients with renal impairment treated with low molecular weight heparins should be monitored carefully.

Administration of low molecular weight heparins to patients with renal impairment has been shown to result in prolongation of anti-Xa activity, especially in those with severe renal impairment (creatinine clearance <30 mL/min), which may lead to an increased risk of bleeding. This effect has not yet been determined for FRAGMIN. Consideration of dosage adjustment in patients with severe renal impairment should be undertaken.

Anticoagulation for Hemodialysis and Hemofiltration

Chronic renal failure, patients with no other known bleeding risk: Hemodialysis and hemofiltration for a maximum of 4 hours: dose as below, or only i.v. bolus injection of 5000 IU. Hemodialysis and hemofiltration for more than 4 hours: i.v. bolus injection of 30 - 40 IU/kg body weight followed by i.v infusion of 10 - 15 IU/kg body weight per hour. This dose normally produces plasma levels lying within the range of 0.5 - 1.0 IU anti-Xa/mL.

Acute renal failure, patients with high bleeding risk: i.v. bolus injection of 5 - 10 IU/kg

body weight, followed by i.v. infusion of 4 - 5 IU/kg body weight per hour. Plasma level should lie within the range of 0.2 - 0.4 IU anti-Xa/mL.

Dilution

FRAGMIN solution for injection may be mixed with isotonic sodium chloride or isotonic glucose infusion solutions in glass infusion bottles and plastic containers. *Post-dilution concentration:* 20 IU/mL.

As with all parenteral drug products, intravenous admixtures should be inspected visually for clarity, particulate matter, precipitation, discolouration and leakage prior to administration, whenever solution and container permit.

1 mL 10 000 IU

Isotonic NaCl Infusion (9 mg/mL) 500 mL

or

Isotonic Glucose Infusion (50 mg/mL) 500 mL

The infusion rate is 10 mL/hour. The solution should be used within 24 hours.



Study References

- **1.** Canadian Centre for Occupational Health and Safety (CCOHS). Diseases, disorders and injuries: needlestick injuries. http://www.ccohs.ca/oshanswers/diseases/needlestick_injuries.html. Accessed February 26, 2010.
- 2. FRAGMIN Product Monograph, Pfizer Canada Inc., July 2009.

SUPPLEMENTAL PRODUCT INFORMATION

Overdosage

Accidental overdosage following administration of FRAGMIN may lead to hemorrhagic complications. FRAGMIN should be immediately discontinued, at least temporarily, in cases of significant excess dosage. In more serious cases, protamine should be administered.

The anticoagulant effect of FRAGMIN is inhibited by protamine. This effect may be largely neutralized by slow intravenous injection of protamine sulphate. The dose of protamine to be given should be 1 mg protamine per 100 anti-Xa IU of FRAGMIN administered. A second infusion of 0.5 mg protamine per 100 anti-Xa IU of FRAGMIN may be administered if the APTT measured 2 to 4 hours after the first infusion remains prolonged. However, even with higher doses of protamine, the APTT may remain prolonged to a greater extent than usually seen with unfractionated heparin. Anti-Xa activity is never completely neutralized (maximum about 60%).

Particular care should be taken to avoid overdosage with protamine sulphate. Administration of protamine sulphate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis, have been reported with protamine sulphate, it should be given only when resuscitation equipment and treatment of anaphylactic shock are readily available. Refer to the protamine sulphate Product Monograph for further directions for use.

Product Monograph available on request.

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