Problems with Medical Devices May Be Severely Under-Reported

Kim J. Vicente, PhD
Professor, Department of Mechanical & Industrial Engineering
University of Toronto, ON

Stephanie Kern
Administrative & Research Assistant
Department of Mechanical & Industrial Engineering
University of Toronto, ON

Abstract
The purposes of this study were to determine whether registered nurses are familiar with the Health Canada Medical Device Problem Report Form, and if so, how often they use it to report problems and concerns compared to how often they experience problems and concerns with medical devices. A survey was mailed to a random sample of 1,000 Ontario nurses to collect demographic information and to determine their familiarity with the aforementioned form, as well as the frequency with which they encounter problems/concerns with medical devices. Seventy-two and a half percent of the nurses reportedly have problems/concerns with medical devices at least yearly, yet 94.2% of them did not know that the Health Canada Medical Device Problem Report Form existed. Therefore, problems/concerns with medical devices encountered by registered nurses may be severely under-reported to Health Canada, contributing to an underestimate of the actual threat that devices pose to patient safety.

According to the landmark Canadian Adverse Events Study, between 9,250 and 23,750 people die annually from preventable adverse events in Canadian hospitals, making patient safety an important issue in public health (Baker et al. 2004). Nursing leaders have an important role to play in addressing this issue by actively participating in risk identification, problem solving and implementation of necessary changes (Nicklin 2003). Many factors contribute to patient safety, but one key

problem that is of concern to the nursing profession is the use of medical devices (i.e., instruments that are used in the delivery of healthcare). Canadian nurses have identified increasingly sophisticated technology and lack of properly functioning equipment as important risk factors (Nicklin and McVetty 2002), suggesting that medical devices represent a non-trivial threat to patient safety. Indeed, there are over 455,000 devices currently licensed for sale in Canada (Auditor General of Canada 2004), illustrating the pervasiveness of device usage. Moreover, adverse medical device events have been found to occur 83.7 times per 1,000 hospital admissions (Samore et al. 2004), showing that nurses' concerns about device risk are justified.

To make progress on this issue, healthcare agencies must implement post-market surveillance programs – a systematic means of obtaining feedback about the safety of medical devices in clinical settings (Auditor General of Canada 2004; White and Weick-Brady 1997). Health Canada has created a Medical Device Problem Report Form for this purpose. While many hospitals have internal reporting systems, the information obtained from them is rarely shared with other institutions, so their impact on improving device safety is limited. Because this form is administered by Health Canada, it is a potentially very powerful feedback mechanism, providing a national (rather than a merely local or regional) basis for sharing lessons learned from experience. Reporting of problems using this form is mandatory for device manufacturers and voluntary for anyone else.

This research focuses on voluntary reporting only. Nurses have a potentially critical role to play in providing valuable information via this reporting system because they are users of many medical devices. In the United States, registered nurses are among the most frequent discoverers of device-related incidents and the most frequent reporters of device problems in a federal regulatory reporting system for monitoring devices (White and Weick-Brady 1997). In Canada, regulators can benefit fully from the insights and lessons that nurses have to offer only if nurses are made aware that the Health Canada Medical Device Problem Report Form exists. Little research appears to have been conducted in Canada to investigate whether this is the case.

Accordingly, the purposes of this study were to determine whether registered nurses are familiar with the Health Canada Medical Device Problem Report Form, and if so, how often they use it to report problems/concerns compared to how often they experience problems/concerns with medical devices. Our primary aim was not to judge the knowledge of individual nurses, but rather to take a blame-free, systems approach that seeks to evaluate the effectiveness of the communication link between federal regulators and registered nurses.

Methods

Participants

A random sample of 1,000 registered nurses was selected from the College of Nurses of Ontario (CNO) mailing list. Participation was voluntary and unpaid. Institutional ethics approval was obtained for the study.

Materials

A survey was designed to collect demographic information (gender, age, years of nursing work experience and area of patient care), and to ask six additional questions, listed in Table 1. The following definitions were provided to participants:

a) Concerns: Anything that relates to the inadequate safety, effectiveness or quality of a medical device.
b) Problems: Poor design of the device, manufacturing defects and vague labels or errors in directions for use.

A pilot test was conducted to ensure that the instructions and questions were easy to understand.

Procedure

A covering letter, an informed-consent form, the survey itself and a stamped, self-addressed envelope were mailed to each participant. Responses were requested

Table 1. Survey questions asked of participants

1. Before filling out this survey, I was already aware that the Health Canada Medical Device Problem Reporting Form existed, and that I can use it to report any concerns or problems associated with the use of medical devices.

   TRUE FALSE (If you answered FALSE, then go to question #5.)

2. I have used the Medical Device Problem Reporting Form at least once.

   TRUE FALSE (If you answered FALSE, then go to question #5.)

3. I was informed by Health Canada that some kind of action type was taken based on the information I provided on the form.

   TRUE FALSE

4. Which of the following best summarizes how often you have used the Medical Device Problem Reporting Form?

   a) daily b) weekly c) monthly d) yearly e) never

5. Which of the following best summarizes how often you have experienced a concern or problem associated with the use of a medical device?

   a) daily b) weekly c) monthly d) yearly e) never

6. Do you have any suggestions as to how to improve medical device problem reporting? (Please feel free to make any additional comments in this space, as well.)

within one month. Participants were told that the primary purpose of the survey was to determine how well known and widely used the Health Canada Medical Devices Problem Reporting Form is among registered nurses.

Dependent variables

Answers to the categorical questions were used to calculate frequency counts. Answers to the quantitative questions were used to calculate means and standard deviations.

Data analysis

Percentages were calculated for answers to the categorical questions. Ninety-five percent confidence intervals were calculated for answers to the quantitative questions.

Results

A total of 260 responses were received. The demographic characteristics of the sample are shown in Table 2, as are the population statistics obtained from the CNO. The sample is representative of the population.

Table 2. Demographic characteristics of the sample compared to that of the CNO population (95% confidence intervals are shown in parentheses)

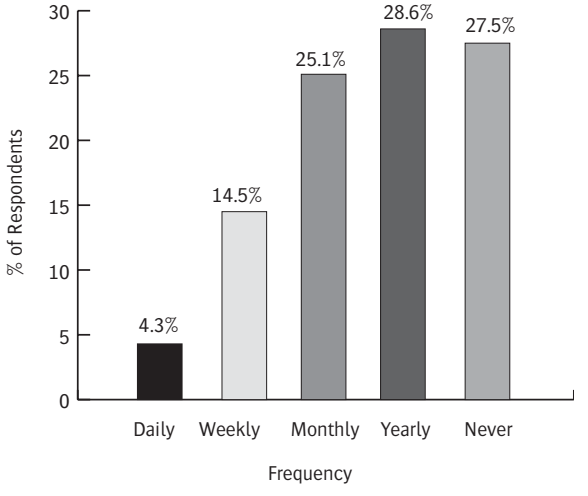
	Survey Sample	CNO Population
Gender (% female)	96.7	96.3
Average Age (yrs)	44.3 (43.1, 45.5)	44.7
Average Experience (yrs)	20.5 (19.3, 21.7)	not available

A total of 245 respondents (94.2%) reported that they were not familiar with the form. There was no significant difference in demographic statistics between these respondents and the others. Of the 15 respondents who were familiar with the form, three (20%) reported that they had filled it out at least once, and of these three, none reported receiving a notification from Health Canada that action was taken after they filed a report.

Figure 1 shows the reported frequency of problems/concerns with medical devices across all respondents. Seventy-two and a half percent of the respondents stated that they encounter problems/concerns at least yearly.

Table 3 breaks down the problem frequency data as a function of area of patient care. Areas where medical devices are more prevalent (e.g., hospitals, nursing homes/geriatrics) tended to report a more frequent incidence of problems/concerns than other areas (e.g., physician's office, research).

Figure 1. Percentage of reported frequency of problems/concerns with medical devices (N=260)



A total of 129 respondents (49.6%) took the trouble to answer the final question asking for suggestions or additional comments, suggesting a high level of interest in the survey topic. This subjective impression is confirmed by the content of these respondents' comments. Several nurses explicitly thanked us for

Table 3. Percentage of respondents per category of patient care and frequency of problems/concerns

Frequency	Hospital	Nursing Home/ Geriatric	Community	Administrative	Physician's Office	Research
Daily	6%		10.2%			
Weekly	19.2%		2.0%	28.6%		
Monthly	31.3%	14.3%			11.1%	
Yearly	23.6%	85.7%	34.7%	28.6%	44.4%	50%
Never	19.8%		53.1%	42.9%	44.4%	50%
*N	182	7	49	7	9	2

*Note: 5 respondents did not answer this question.

conducting this research, and for consulting them rather than other healthcare workers. For example, one wrote: "Nurses use most of the equipment in hospital/clinical settings yet we are always the last to know about things like this! Healthcare never ceases to amaze me. …Thanks for involving us in this!" Some respondents provided specific case studies or examples to illustrate the importance of medical devices to patient safety, even though the survey did not request such information. Several respondents stated that, now that they learned about the form, they would use it and tell their co-workers about it, too.

By far the most common recommendation for improving reporting was to educate staff or raise awareness about the existence of the form via in-service training, device instructions, journals, conferences, unions, professional associations, manufacturers, university curricula and Health Canada. Interestingly, quite a few respondents explicitly stated that dissemination efforts should be targeted directly at front-

line nurses, not nursing managers, suggesting that communication between the two may be weak (e.g., due to high levels of workload).

Several respondents noted that they already spend much time filling out paperwork, so adding significantly to that load would be undesirable. Suggestions were made to reduce the level of effort required to file a report by putting the form online, creating a 1-800 telephone number, appointing a contact person responsible for reporting, harmonizing existing institutional reporting systems with the Health Canada form and making the form easy to find and fill out.

Other suggestions focused on providing incentives for reporting, such as adopting a blame-free culture, taking remedial action quickly, providing prompt feedback about the actions taken and providing (unspecified) rewards for reporting.

Discussion

There appears to be severe under-reporting to Health Canada of medical device problems/concerns from registered nurses in Ontario. Research in systems safety reveals that this weak level of feedback is common in many organizations, and causes managers or regulators to underestimate severely the magnitude of safety threats in a system (Rasmussen 1997; Vaughan 1996). Furthermore, learning from experience becomes very difficult because the vital information for doing so is largely unavailable to those responsible for regulating safety (i.e., Health Canada, in this case).

These results need to be put into context. Procedures for reporting problems/concerns with medical devices likely differ across organizations. In some agencies, the responsibility for filling out the Health Canada form may not lie with nurses. In these cases, nursing expertise may not be fully captured because it is (at least) once removed from the filling out of the report. In other institutions, problems/concerns with medical devices may be reported using internally created forms instead of the Health Canada form. In these cases, the information obtained will likely be shared only within the one institution rather than across the entire country.

The findings of this study have important implications for improving patient safety. Post-market surveillance of medical devices plays a crucial role in regulating their safety, so there is a strong need to publicize the existence of the form – at least among Ontario registered nurses – and to provide incentives and facilitate reporting so that rates are increased to a level that reflects the true frequency of problems/concerns in clinical settings. By identifying safety threats, developing remedies and implementing them on a nationwide basis, it may be possible to make the most of nursing expertise and greatly improve the safety of medical devices in Canada.

This study has several limitations. The response rate was 26%, but questionnaires are known to lead to low response rates (Rouse 1991). The demographic characteristics of the nurses who were not familiar with the form do not differ significantly from those that were familiar with it or from those of the CNO population, suggesting a lack of bias. However, there may be an unaccounted-for variable that could have caused the sample to be biased, so the results should be interpreted with caution. Moreover, as only one province and one profession were investigated, the generalizability of the results to other provinces and to physicians and biomedical engineers/technicians is unknown. However, as mentioned above, even if other healthcare practitioners file reports, their perspective does not take the place of nursing expertise. Therefore, the statistics related to under-reporting uncovered in this study are significant and deserve remedial action. As active participants in risk management, nursing leaders can tell all their colleagues about the existence of the form and encourage them to share their experiences with regulators.

Acknowledgments

This research was funded by an E.W.R. Steacie Memorial Fellowship from the Natural Sciences and Engineering Research Council of Canada awarded to the corresponding author. The authors would like to thank Judy Costello, Mary Ferguson-Pare, Lianne Jeffs, Kathleen Macmillan, Mary Kay McCarthy, Peter Norton, Denis Roy, Kathy Sabo, Janet Salaff, Colin Smith and Anna Tupis for their generous help with this work.

References

Auditor General of Canada. 2004. Report of the Auditor General of Canada to the House of Commons. Chapter 2 – Health Canada – Regulation of Medical Devices. Ottawa: Author.

Baker, G.R. et al. 2004. "The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada." *Canadian Medical Association Journal* 170: 1678–86.

Nicklin, W. 2003. "Patient Safety: Springboard to Nursing Accountability." *Canadian Journal of Nursing Leadership* 16: 66–68.

Nicklin, W.L. and J. McVetty. 2002. "Canadian Nurses' Perceptions of Patient Safety in Canadian Hospitals." *Canadian Journal of Nursing Leadership* 15: 11–21.

Rasmussen, J. 1997. "Risk Management in a Dynamic Society: A Modelling Problem." *Safety Science* 27: 183–213.

Rouse, W.B. 1991. *Design for Success: A Human-Centered Approach to Designing Successful Products and Systems*. New York: Wiley.

Samore, M.H., R.S. Evans, A. Lassen, P. Gould, J. Lloyd, R.M. Gardner, R. Abouzelof, C. Taylor, D.A. Woodbury, M. Willy and R.A. Bright. 2004. "Surveillance of Medical Device-Related Hazards and Adverse Events in Hospitalized Patients." *Journal of the American Medical Association* 291: 325–34.

Vaughan, D. 1996. *The Challenger Launch Decision: Risky Technology, Culture and Deviance at NASA*. Chicago: University of Chicago Press.

White, G.G. and M.D. Weick-Brady. 1997. "Improving Patient Care by Reporting Problems with Medical Devices." Rockville, MD: US Food and Drug Administration. Retrieved February 7, 2005. <http://www.fda.gov/medwatch/articles/mdr/mdr.pdf>.