

Adverse events and patient safety in Canadian health care

A recent study found that complications following surgery were the most common adverse events affecting patients in Canada.

ABSTRACT: The adverse event rate in Canadian hospitals is estimated to be 7.5 per 100 adult hospital admissions. Although only 36.9% of the events were considered preventable, 20.0% were associated with permanent disability or death. Similar rates are reported for other developed countries, with somewhat lower rates reported in two US studies. Surgery-related events were the most common, followed by drug-related or fluid-related events. Adverse events constitute a significant health care problem that requires better reporting of incidents coupled with improved consistency of care, enhanced communication, and heightened attention to the risks involved in care delivery.

The Canadian Adverse Events Study is the first national study of the incidence of adverse events in Canadian hospitals.¹ Published in May 2004, the study was based on methods developed by researchers at Harvard University to estimate adverse events in hospitals in New York State.^{2,3} Other researchers have since further developed and used these methods in Australia,⁴ England,⁵ New Zealand,⁶ and elsewhere. Adverse events (AEs) are defined as unintended injuries or complications that result in disability at the time of discharge, a prolonged hospital stay, or death. AEs are caused by health care management (the care provided to patients) rather than the patient's underlying disease process. Not all AEs are avoidable given current health care knowledge.

The Canadian Adverse Events Study relied on a review of 3745 medical records of adults in 20 hospitals in 5 provinces. Reviews were done in two stages. First, nurses or health data personnel reviewed the records for the presence of screening criteria that have been found to be associated with adverse events. Second, physicians reviewed those records that were positively screened to determine if there were adverse events and whether the events were preventable. Adverse

events were found in 255 patient records, with some patients having more than one adverse event. After adjusting for the sampling strategy, these findings yielded an adverse event rate of 7.5 per 100 hospital admissions (95% CI, 5.7–9.3). Physicians reviewing the medical records classified 36.9% of the events as preventable (95% CI, 32.0%–41.8%). For 65% of all adverse events there was either no disability at discharge or minimal to moderate impairment with recovery within 6 months. However, more than 20% of the adverse events were associated with permanent disability or death. Extrapolating these data to all adult patients hospitalized in acute care settings for medical or surgical (nonobstetrical) causes in Canada suggests that between 141 250 and 232 250 of the 2.5 million similar admissions in the year 2000 would have been associated with an adverse event. Applying the estimate based on reviews of the charts in our study suggests that between 52 100 and 85 700 of these

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adverse events might be prevented if usual care was provided.¹

These results from the Canadian Adverse Events Study are comparable to results from recent studies in New Zealand, Denmark, and England, but higher than the results from the two US studies, including a study done in Utah/Colorado,⁷ as well as the earlier Harvard Medical Practice Study done in New York state. The lower event rates in the US studies are partly the result of methodological differences and may also have been affected by the interest of the US researchers in negligence. This concern is in contrast with the interest in quality improvement and preventability in studies done outside of the US. Researchers later reanalyzed the results of the Utah/Colorado and Australian studies and found a number of differences that accounted for some of the variation in results between them. However, not all of the variation in results can be attributed to these differences, leaving a more than threefold variation in the results—10.6% versus 3.2% for the Australia and US studies when known differences are accounted for.⁸

While medical record review has become the standard method for assessing adverse event rates, such methods are inherently conservative since they depend entirely on the information in the patient chart. Other methods used to identify adverse events, including interviews with clinicians and direct observations of care, have identified higher rates of adverse events. In a recent French study, Michel and colleagues⁹ compared three methods for assessing care and identified more events when they used multiple interviews with clinicians during the hospital stay rather than relying on one interview or a review of the record after the patient was discharged. Each of the three methods used by the French investigators identified a sub-

stantial proportion of unique events that were not identified by the other two methods. An earlier US study comparing medical record review with physician self-reports also found that these different methods identify additional cases.¹⁰ These findings and the design of the Canadian study, which did not permit researchers to identify adverse events that occurred in one hospital but were detected on subsequent

between studies is partly due to variation in reviewer training and other methodological issues.

Other methods have identified a considerable system component in most adverse events. The results of root cause analyses of incidents, for example, suggest that multiple causes are usually implicated and that many “latent” or organizational issues contribute to these incidents.^{12,13}

More than 20% of the adverse events were associated with permanent disability or death.

admission to another hospital, suggest that the results of the Canadian adverse events study are an underestimate of the burden of injury occurring in the course of care in Canadian hospitals.

The most commonly identified AEs in the Canadian study were surgery-related events. The second most common AEs were drug- or fluid-related events. These results are similar to other national studies, which have found operative events (including adverse events that occurred up to 30 days postsurgery) to be the most frequently occurring AEs. In these studies, reviewers have been allowed to indicate more than one type of procedure or event related to the adverse event, including system events such as lack of equipment and poor communication. Relatively few system events were recorded in the Canadian study, but studies in other countries have identified a significant contribution from system causes. In New Zealand, for example, the reviewers identified system issues in nearly one-quarter of all adverse events.¹¹ The difference

In 1999, the results of the US studies were translated into newspaper headlines when the Institute of Medicine (IOM) used them to estimate that between 44 000 and 98 000 Americans die each year in hospital as a result of adverse events.¹⁴ These estimates drew criticism from some researchers, who noted that while the adverse events were regrettable, many of these deaths might have occurred despite the adverse event.^{15,16} Nevertheless, the other key message of the IOM report, *To Err is Human*, was that most adverse events resulted from poorly designed systems and flaws in the increasingly complex care provided within hospitals. This message has been widely applauded and has led to efforts to improve the consistency of communications, care protocols, and equipment design.

Despite considerable activity, some knowledgeable observers in the US do not believe that hospital care is safer now than it was 5 years ago when the IOM report was released.^{17,18} While there have been large investments in the US in computerized physician

order entry systems, improved medication safety protocols, and heightened regulation and accreditation requirements, there is limited evidence of improved outcomes. The slow pace of these patient safety efforts in the US has been interpreted by some as a sign that the necessary changes are difficult to implement; others interpret this result as a sign that we need clearer articulation of goals and national standards, and greater investment in technology, training, and research.

The Canadian study was launched in 2002 after it became clear that the results of the US study and the IOM report recommendations were not being interpreted as applicable to Canadian health care. Yet now with the Canadian results widely disseminated, we know that raising awareness is not all that is needed to improve safety. Canadian data have helped establish an estimate of the scale of the patient safety issue within Canadian hospitals, but improvements in safety will still require considerable efforts in many areas.

The release of the Canadian study was preceded by a 2-year period in which the study investigators and representatives of professional associations and governments worked together to prepare for the release of the results. Representatives from more than 35 organizations attended meetings to discuss the ongoing Canadian study and to develop patient safety strategies. These efforts helped to advance patient safety initiatives and may have sped the launch of the Canadian Patient Safety Institute (CPSI) in 2004. CPSI has launched a number of important initiatives, including Safer Healthcare Now!, the Canadian adaptation of the successful 100,000 Lives campaign in the US.

The Canadian Adverse Events Study focused only on adult acute care. The methods and tools are now being

adapted for hospital-based pediatric care and home care. Simplified versions of the review tools are also being created for audit purposes. While publishing national evidence on adverse events has served an important purpose in highlighting patient safety, local data are still needed to guide improvement within each region, hospital, and department. Essential next steps include ensuring better reporting of incidents and adverse events using internal reporting systems or audits, and implementing focused interventions to improve care processes, communications, and awareness of the risks that accompany care.

Competing interests

None declared.

References

- Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;170:1678-1686.
- Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370-376.
- Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991;324:377-384.
- Wilson RM, Runciman WB, Gibberd RW, et al. The Quality in Australia Health Care Study. *Med J Aust* 1995;163:458-476.
- Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: Preliminary retrospective record review. *BMJ* 2001;322:517-519.
- Davis P, Lay-Yee R, Briant R, et al. Adverse events in New Zealand public hospitals I: Occurrence and impact. *NZ Med J* 2002;115:U271.
- Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 2000;38:261-271.
- Thomas EJ, Studdert DM, Runciman WB, et al. A comparison of iatrogenic injury studies in Australia and the USA. I: Context, methods, casemix, population, patient and hospital characteristics. *Int J Qual Health Care* 2000;12:371-378.
- Michel P, Quenon JL, de Sarasqueta AM, et al. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *BMJ* 2004;328:199-200.
- O'Neil AC, Petersen LA, Cook EF, et al. Physician reporting compared with medical-record review to identify adverse medical events. *Ann Intern Med* 1993;119:370-376.
- Davis P, Lay-Yee R, Briant R, et al. Adverse events in New Zealand public hospitals II: Preventability and clinical context. *NZ Med J* 2003;116:U624.
- Rex JH, Turnbull JE, Allen SJ, et al. Systematic root cause analysis of adverse drug events in a tertiary referral hospital. *Jt Comm J Qual Improv* 2000;26:563-575.
- Bagian JP, Gosbee J, Lee CZ, et al. The Veterans Affairs root cause analysis system in action. *Jt Comm J Qual Improv* 2002;28:531-545.
- Institute of Medicine. *To Err is Human*. Washington, DC: National Academy Press; 2000.
- McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA* 2000;284:93-94.
- Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors: Preventability is in the eye of the reviewer. *JAMA* 2001;286:415-420.
- Leape LL, Berwick DM. Five years after *To Err is Human*: What have we learned? *JAMA* 2005;293:2384-2390.
- Wachter RM. The end of the beginning: Patient safety five years after "to err is human." *Health Aff (Millwood)* 2004; Suppl Web Exclusives:W4-534-545. **BBM**