Medication Safety Alerts

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LIFE AFTER THE CANADIAN ADVERSE EVENTS STUDY

On May 25, 2004, the long-awaited Canadian Adverse Events Study[1] was published in the *Canadian Medical Association Journal*. This was the first national study undertaken in Canada to examine the rate of adverse events in the country's hospitals. Experience from other countries where this type of analysis has been done suggests that availability of accurate data on the scope of the problem is a critical requirement for propelling the patient safety movement forward.

The investigators in the Canadian study reviewed the charts for a random sample of 3745 adult admissions to 20 hospitals. The charts were initially screened on the basis of criteria predictive of the occurrence of an adverse event. An "adverse event" was defined by the researchers as "an unintended injury or complication that results in disability at the time of discharge, death or prolonged hospital stay and that is caused by health care management rather than by the patient's underlying disease process".[1] Charts with at least one of the criteria were further evaluated by physician reviewers to assess the level, cause, and preventability of the adverse event.

Among all charts reviewed, the rate of adverse events (weighted for the sample frame) was 7.5%. The most common adverse events were related to surgery and administration of drugs or fluids. As a result of their findings, the investigators made the following estimates of the national incidence of adverse events:

- 185 000 of 2.5 million patients admitted yearly to an acute care hospital (1 in 13 adults) experience an adverse event.
- about 70 000 adverse events (1 in 33) are preventable.
- 9250 to 23 750 preventable deaths occur annually in Canadian hospitals.

Earlier chart reviews from other countries, such as the United States,[2,3] the United Kingdom,[4] Australia,[5] New Zealand,[6] and Denmark,[7] have shown adverse event rates ranging from 2.9% to 16.6% of hospital admissions. The US Institute of Medicine report, *To Err is Human*,[8] released in 1999, indicated that as many as 98 000 preventable deaths were occurring annually in the United States because of medical error.

Of particular interest to pharmacists is the fact that drug- or fluid-related events comprised 24% of the total adverse events.[1] The following examples were rated by reviewers as having virtually certain evidence of preventability[9]:

- delirium caused by benzodiazepines given to a patient with hepatic encephalopathy
- echogenic mass on a mechanical heart valve caused by subtherapeutic anticoagulation
- drug-induced renal failure
- digoxin toxicity resulting from deteriorating renal function
- adrenal insufficiency resulting from lack of steroid therapy for a steroid-dependent patient

These examples are typical of patient scenarios seen daily by hospital pharmacists. Upon review of the clinical details, it is evident that inappropriate use or monitoring of drug therapy and, in some cases, lack of appropriate drug therapy were responsible for many of

the preventable adverse events identified. In contrast, adverse drug events that could have been caused by traditional medication errors related to drug distribution and administration were not readily apparent. These findings have raised some questions that merit further investigation.

The Canadian Adverse Events Study[1] was not designed to identify medication errors which may not be easily detected in a chart review and may not be well documented in the patient record. The study methods included an initial screen for possible adverse events according to 18 specific criteria such as adverse drug reaction, escalation of care, or unexpected death. Although there have been well-publicized errors related to concentrated potassium chloride and high-potency narcotics, their rate of occurrence may be small in comparison to the rate of inappropriate drug use and monitoring. Many safety initiatives have focused on aspects of drug distribution and administration, such as unit-dose drug delivery, automation, and barcoding. These are important measures, but efforts to improve patient safety must consider the entire spectrum of the medication use process, which includes prescribing and monitoring.

The study's conclusion that 37% of adverse events occurring in hospital patients are preventable provides a compelling reason for pharmacists to take a leading role in improving patient safety. Daily interactions between patients and pharmacists could have prevented many of the medication-related adverse events identified in the study. Other investigators have demonstrated reductions in preventable adverse drug events of 66% in intensive care patients[10] and 78% in general medicine patients[11] when pharmacists participate in physician rounds. Although progress has been made, pharmaceutical care processes have not been fully implemented in all Canadian hospitals, which leaves patients at a disadvantage. The development of treatment protocols and guidelines can also contribute to safety. For example, the implementation of routine prophylaxis for deep vein thrombosis through development of postoperative pathways could significantly reduce the number of patients who are needlessly put at risk for complications.[12]

The Canadian Adverse Events Study and other smaller studies have focused on adverse events in hospitals; however, medication-related adverse events also occur outside the hospital setting.[13] The transfer of care within hospitals, and from hospitals to the community and vice versa, is a high-risk situation presenting opportunities for error. Pharmacists in both hospital and community settings play an important role in the enhancement of medication safety and represent an important resource for the health care team, as well as for the patient. The Canadian Society of Hospital Pharmacists (CSHP) and the Canadian Pharmacists Association have formed a joint task force to address issues related to "seamless care", and this topic was a featured agenda item at the CSHP annual general meeting in Edmonton in August 2004. Seamless care promotes communication between health care providers in the hospital and those in the community for patients moving between these 2 levels of care. The patient and his or her family or caregiver form an integral part of the communication process and the health care continuum. Clear and complete documentation is needed to ensure uninterrupted patient care and to avoid the loss of critical information.

Adverse events are expensive. The Canadian Adverse Events Study[1] found that an adverse event resulted in an average additional length of stay of 6 days per event. Bates and others[14] published similar data in 1997, reporting an increase in length of stay of 4.6 days for preventable adverse drug events and estimated postevent costs of US$4685 per event. The financial impact of these events is significant and provides additional support for investing in preventive strategies.

The Canadian health care system is admired by many and continues to be a good system serving the broad Canadian public. Nonetheless, pharmacists in all settings continue to represent an underutilized resource within the health care system. The Canadian Adverse Events Study emphasizes that there is room for improvement in the area of patient safety; for pharmacists, there is a unique opportunity for a leadership role in the area of medication safety.

References

1. Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;170:1678-86.
2. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study. *N Engl J Med* 1991;324:370-7.
3. Thomas EJ, Sutddert DM, Burstin HR, Oraw EJ, Zeena T, Williams EJ, et al. The nature of adverse events in hospitalized patients. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 2000;38(3):261-71.
4. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review [published erratum in *BMJ* 2001;322:1395]. *BMJ* 2001;322:517-9.
5. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The Quality in Australian Health Care Study. *Med J Aust* 1995;163:458-76.

6. Davis P, Lay-Yee R, Briant R, Schug S, Scott A, Johnson S, et al. Adverse events in New Zealand public hospitals: principal findings from a national survey. Wellington: New Zealand Ministry of Health; 2001. Occas Pap 3. Available at: www.moh.govt.nz/publications/adverseevents. Accessed 2004 Jul 12.
7. Schioler T, Lipczak H, Pedersen BL, Mogensen TS, Bech KB, Stockmarr A, et al. Danish Adverse Event Study. [Incidence of adverse events in hospitals. A retrospective study of medical records.] *Ugeskr Laeger* 2001:163:5370-8. Danish.
8. Kohn, LT, Corrigan JM, Donaldson MS. *To err is human: building a safer health system.* Washington (DC): National Academy Press; 1999.
9. Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. e-Appendix 3: Brief description of clinical details of adverse events occurring in 255 patients, by corresponding maximum degree of preventability [online appendix]. *CMAJ* 2004;170. Available at: http://www.cmaj.ca/cgi/content/full/170/11/1678/DC3. Accessed 2004 Jun 10.
10. Leape LL, Cullen DJ, Dempsey Clapp M, Burdick E, Demonaco HJ, Ives Erickson J, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA* 1999;282:267-70.
11. Kucukarslan SN, Peters M, Mlynarek M, Nafziger DA. Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units. *Arch Intern Med* 2003;163:2014-8.
12. Leape LL, Berwick DM, Bates DW. What practices will most improve safety? *JAMA* 2002;288:501-7.
13. Forster AJ, Asmis TR, Clark HD, Saied GA, Code CC, Caughey SC, et al. Ottawa Hospital Patient Safety Study: incidence and timing of adverse events in patients admitted to a Canadian teaching hospital. *CMAJ* 2004;170:1235-40.
14. Bates DW, Spell N, Cullen DJ, Burdick E, Laird N, Petersen LA, et al. The costs of adverse drug events in hospitalized patients. *JAMA* 1997;277:307-11.

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