

Medication Error Events in Ontario Acute Care Hospitals

Joan A Marshman, David K U, Robert WK Lam, and Sylvia Hyland

ABSTRACT

Background and Objective: In 2002, the Institute for Safe Medication Practices Canada (ISMP Canada) collaborated with several hospitals to determine the feasibility of using an electronic system to document and report medication error events and assess medication-use processes. This article provides an overview of the events reported and makes limited comparisons with similar data from US studies.

Methods: A standard electronic submission system for documenting medication error events was made available to 14 acute care hospitals in Ontario. The hospitals collected data on medication error events identified by usual criteria and procedures over a 12-month period and submitted the data to ISMP Canada electronically. Analysis of the data focused on the frequency of errors by severity of consequence to the patient, type of outcome, therapeutic class of drugs involved, stage of the medication-use process at which the error occurred, types of error, and hospital-identified cause(s). Parallel analyses were undertaken for the subsets of reported errors classified as adverse drug events (ADEs) and potential ADEs.

Results: The 4243 errors examined represent 0.86 errors per bed and 0.25 errors per 1000 doses of medication dispensed. Only 120 (2.8%) of the errors resulted in or possibly contributed to patient harm and were classified as ADEs. No error resulted in death. The 685 errors (16.1%) that reached patients and for which monitoring or intervention were required, but that were not implicated in patient harm, were classified as potential ADEs. The most commonly involved drug classes were central nervous system agents (including analgesics, sedatives, and antipsychotic drugs) (25.6%), blood formation and coagulation agents (12.7%), anti-infective drugs (12.3%), cardiovascular drugs (12.0%), and hormones and synthetic substitutes (9.9%). The most frequently involved individual drugs were insulin, warfarin, heparin, morphine, furosemide, potassium chloride, epoetin, electrolyte solutions, and cefazolin. Errors occurred most frequently in the medication administration process (56.6%) and the order entry and transcription stages (32.6%) of the drug-use process. Contributing factors most frequently identified included miscommunication of a drug order; environmental, staffing or workload problems; lack of staff education; and lack of quality control or independent check systems.

Conclusions: The participating hospitals were willing to submit medication error reports electronically, and compilation of the resulting data provided a snapshot of medication error events detected and documented using usual practices. A very small proportion of the events resulted in harm to patients, but a

RÉSUMÉ

Historique et objectif : En 2002, l'Institut pour l'utilisation sécuritaire des médicaments du Canada (ISMP Canada) a collaboré avec plusieurs hôpitaux pour déterminer la faisabilité d'un système électronique permettant de documenter et de signaler les événements indésirables liés aux médicaments, et d'évaluer les processus d'utilisation des médicaments. Cet article donne un aperçu des événements signalés et établit des comparaisons limitées avec des données semblables tirées d'études américaines.

Méthodes : Un système électronique standard de déclaration d'événements indésirables liés aux médicaments a été fourni à 14 hôpitaux de soins de courte durée en Ontario. Ces hôpitaux ont collecté les données sur les événements indésirables liés aux médicaments détectés selon des critères et des démarches habituels sur une période de 12 mois et ont soumis ces données par voie électronique à ISMP Canada. L'analyse des données a porté principalement sur la fréquence des erreurs selon la gravité de leurs conséquences pour le patient, le type de résultat, la classe thérapeutique des médicaments en cause, l'étape à laquelle l'erreur est survenue dans le processus de distribution des médicaments, les types d'erreur et la ou les causes attribuées par l'hôpital. Des analyses parallèles ont été entreprises pour les sous-classes d'erreurs signalées comme étant des événements indésirables liés aux médicaments (EIM) et des EIM potentiels.

Résultats : Les 4243 erreurs évaluées représentaient 0,86 erreur par lit et 0,25 erreur par 1000 doses de médicament distribuées. Seulement 120 (2,8 %) des erreurs ont entraîné ou possiblement contribué à un effet délétère pour les patients et ont été classées comme des EIM. Aucune erreur n'a entraîné la mort. Les 685 erreurs (16,1 %) ayant touché les patients et ayant nécessité une surveillance ou une intervention, mais qui n'ont pas été préjudiciables à leur santé, ont été classées comme des EIM potentiels. Les classes de médicaments le plus souvent intéressées étaient les médicaments du système nerveux central (dont les analgésiques, les sédatifs et les antipsychotiques) (25,6 %), les agents hématopoïétiques et les anticoagulants (12,7 %), les anti-infectieux (12,3 %), les agents cardiovasculaires (12,0 %) ainsi que les hormones et leurs substituts synthétiques (9,9 %). Les médicaments le plus souvent mis en cause individuellement étaient l'insuline, la warfarine, l'héparine, la morphine, le furosémide, le chlorure de potassium, l'époétine, les solutions d'électrolytes et la céfazoline. Les erreurs sont survenues le plus fréquemment durant le processus d'administration des médicaments (56,6 %) ainsi que dans la saisie des ordonnances et leur transcription (32,6 %). Les facteurs contributifs le plus fréquemment recensés incluaient une mauvaise communication

larger proportion had the potential to cause harm, and patient monitoring or intervention was required to prevent injury. Strategies for reducing the incidence of medication errors must recognize the contribution of both human and system factors to error events.

Key words: medication errors, hospital errors, patient safety, voluntary reporting

Can J Hosp Pharm 2006;59:243-50

INTRODUCTION

Medication errors, which are monitored as a component of hospitals' quality-of-care programs, were the focus of increased attention in the 1990s.¹⁻⁴ With the release of the US Institute of Medicine report *Crossing the Chasm: A New Health System for the 21st Century*,⁵ prevention of medication errors became an integral part of broadened and intensified patient safety initiatives. In Canada, a workshop cohosted in 2000 by the Canadian Society of Hospital Pharmacists and Health Canada stimulated development of the Canadian Coalition on Medication Incident Reporting and Prevention, which in turn spearheaded development of a proposal for the Canadian Medication Incident Reporting and Prevention System. In 2002, the report of the National Steering Committee on Patient Safety, *Building a Safer System—A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*,⁶ recommended adoption of nonpunitive reporting policies and the tracking of patient safety data. The importance of understanding and reducing medication errors in hospitals has also been emphasized by many Canadian researchers.⁷⁻¹²

Various strategies have been used to detect and document medication errors in hospitals. Methods used in previous research have included direct observation¹³; review of medical records, medication orders, and/or medication administration records^{1,14}; solicitation of reports from staff ("stimulated self-reporting") linked with records review^{2,14,15}; and computer monitoring.¹⁶ However, voluntary reporting programs for errors are garnering more attention¹⁰ because they offer the prospect of sustainability. Voluntary reporting is consistent

de l'ordonnance; des problèmes d'environnement, de personnel ou de charge de travail; un manque de formation du personnel; et un manque de contrôle de la qualité ou l'absence de systèmes de vérification indépendante.

Conclusions : Les hôpitaux participants étaient disposés à soumettre des rapports d'erreurs de médication par voie électronique, et la compilation des données obtenues a permis de dresser un portrait des événements indésirables liés aux médicaments détectés et documentés au moyen des méthodes habituelles. Une très faible proportion des événements ont entraîné un effet délétère pour les patients, mais une plus grande proportion des événements avaient un potentiel délétère et ont nécessité une surveillance ou une intervention afin d'éviter toute lésion. Les stratégies visant à diminuer les erreurs de médication doivent tenir compte des facteurs liés aux humains et aux systèmes qui contribuent à leur survenue.

Mots clés : erreurs de médication, erreurs durant l'hospitalisation, déclaration volontaire

with the recent paradigm shift in patient safety, away from a punitive focus on individual health care providers and toward an institutional culture of safety, with a focus on systems factors that affect the manner in which providers function. Several national voluntary reporting systems for medication errors operate in the United States^{17,18} and the United Kingdom.¹⁹

In 2002, the Institute for Safe Medication Practices Canada (ISMP Canada), an independent not-for-profit organization, made its newly developed Analyze-ERR version 1 software package²⁰ available to a sample of acute care hospitals in Ontario as part of a research project. This software package allows systematic documentation of medication errors* in health care settings, and facilitates compilation and analysis of such reports. The goal of the project was to assess the feasibility for hospitals of using the software to document medication error events detected by the hospitals' usual criteria and procedures, voluntarily reporting those errors electronically to an independent body for shared learning, and assessing medication-use processes with a focus on patient safety. At a multicentre level, the compiled reports provided a first opportunity to examine the similarities and differences in profiles of voluntarily reported medication incidents between Canadian hospitals and those in the United States, where differences in prescribing practices, hospitals' incident reporting systems, staffing practices, and medication

*Increasingly the term "medication incident" is replacing the traditional term "medication error" in reference to a preventable potential or actual adverse drug event; however, the latter term has been retained in this report because it is the term used in the Analyze-ERR software.



delivery technologies might affect the relevance of error reports for Canadian health care.

This report provides a descriptive overview of the medication error events identified and documented by participating hospitals and reported voluntarily in a standard format to ISMP Canada. Secondly, the report also examines subsets of events characterized as adverse drug events² (ADEs) and potential ADEs and makes comparisons with the results of selected US reports.

METHODS

The Analyze-ERR software presents the user with an easy-to-follow record format that can be completed largely through the use of drop-down menus. The data fields include outcome or endpoint category of the error, based on selected features of the taxonomy of medication errors of the US National Coordinating Council for Medication Error Reporting and Prevention²¹; the type(s) of drug involved; the stage of the medication-use process at which the error occurred; the type of error; and the causal factors perceived by the reporting individual to have contributed to the error event. Definitions of the report fields, menu options, and instructions for use are provided in the software manual.²⁰ Some fields are mandatory, and electronic transmission to ISMP Canada was prevented if a report lacked information for any mandatory field.

Participating hospitals were recruited by broadcast e-mail to the chief executive officers of all member hospitals of the Ontario Hospital Association and a notice posted on the ISMP Canada Web site.²² Any hospital that volunteered, possessed an interdisciplinary team of health care professionals available to participate in the study's self-assessment survey,²³ and agreed to offer staff members training on use of the software program was included. Of the 34 hospitals that volunteered, 17 were randomly selected to use the error analysis software within their organizations, according to stratification based on medication safety self-assessment scores and blocks based on regional location.† Of the 17 study hospitals, 14 agreed to submit reports electronically to ISMP Canada. The hospitals were instructed to use their usual processes for identifying, documenting, and internally reporting medication errors during the study period. The hospital-selected staff members usually responsible for collecting event reports, typically pharmacists

but also risk managers in some cases, were trained to enter the reports into the electronic database according to the existing taxonomy of medication errors.²¹ Each hospital was asked to designate one person to transmit these reports in batch mode to ISMP Canada. All reports transmitted to ISMP Canada were encrypted automatically, and information elements that might identify the reporting hospital or the patient were removed. Reports were subsequently downloaded from the ISMP Canada Web server to a secured central database, which served as the data source for this report. The database was checked to identify and eliminate duplicate reports (on the basis of event date and characteristics).

Analysis of the resulting database, using the Analyze-ERR software program and Microsoft Access 97, was based on the information domains and menu options provided to users, was guided by the goal of providing information that was thought to be informative to Canadian hospital personnel, and permits limited comparisons with US data. Errors that resulted in or possibly contributed to patient harm (categories E through I in Table 1) were classified as ADEs. Errors that reached the patient and for which monitoring or intervention was required, but that were not implicated in patient harm (category D in Table 1), were classified as potential ADEs. The results of the analysis are expressed as frequencies and proportions of all reported events or specific types of events.

Approval for this project was obtained from the University of Toronto Health Sciences Research Ethics Board and from the ethics review boards of participating hospitals as required.

RESULTS

A total of 4243 medication error reports were transmitted to ISMP Canada during the period May 2002 to June 2003. Although each individual hospital reported errors for a 12-month period, the start-up times were staggered, and the time elapsed from first to last report was therefore 14 months. The participating hospitals, in communities ranging in size from towns to metropolitan centres, had a total of 4938 beds and included 5 teaching hospitals, 6 community hospitals with fewer than 200 beds, and 3 community hospitals with 200 beds or more. There were approximately 241 000 admissions to the study hospitals during the staggered 12-month reporting periods, and roughly 16.8 million medication doses were dispensed. The majority of errors were detected by nursing personnel (76.1%), with smaller proportions detected by pharmacy personnel (20.6%), physicians (1.3%), and patients (0.5%).

†The 34 volunteer hospitals were divided into intervention (i.e., software use) and non-intervention groups for a broader study of hospital medication-use processes with a focus on patient safety. The results of that broader study have not yet been reported.



Table 1. Frequency of Error Events by Type of Outcome (Endpoint)

Endpoint	No. (%)	
A. Circumstances or events with the capacity to cause error	410*	
B. An error or omission occurred but did not reach the patient.	1203	(28.4)
C. An error occurred that did reach the patient but did not cause the patient harm.	2205	(52.0)
D. An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm and/or required intervention to preclude harm.	685	(16.1)
E. An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.	97	(2.3)
F. An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.	20	(0.5)
G. An error occurred that may have contributed to or resulted in permanent harm to the patient.	1	(<0.1)
H. An error occurred that required intervention necessary to sustain life.	2	(<0.1)
I. An error occurred that may have contributed to or resulted in the patient's death.	0	(0)
Outcome was not specified.	30	(0.7)
Total	4243	100

*This endpoint represents hazardous situations, rather than errors, and these events were not included in the total number of error events.

Only 120 (2.8%) of the reported error events (categories E through I in Table 1) were classified as ADEs, and none of these events resulted in death. Of the remainder, 685 (16.1% of the total) (category D in Table 1) reached the patient and were classified as potential ADEs.

Most Frequently Reported Drug Classes

The therapeutic classes of drugs most frequently involved in reported events, as well as in the ADE and potential ADE subsets, were central nervous system agents (including analgesics, sedatives, and antipsychotic agents), blood formation and coagulation agents, anti-infective agents, cardiovascular drugs, and hormones and synthetic substitutes (Table 2). Collectively, these drug classes were involved in more than two-thirds of all reported events. Of the 16 events involving diagnostic agents (American Hospital Formulary Service code 36), 11 were ADEs. Individual drugs most frequently involved were insulin ($n = 188$), warfarin ($n = 173$), heparin ($n = 138$), morphine ($n = 132$), furosemide ($n = 98$), potassium chloride ($n = 95$), epoetin ($n = 70$), electrolyte solutions ($n = 69$), and cefazolin ($n = 68$).

Stages of the Medication-Use Process

More than half of the reported errors occurred at the medication administration stage (Table 3), with lower frequencies for errors in the categories of order entry and transcription (i.e., order entry by the pharmacy and transcription to the medication administration record) and dispensing and delivery. Errors involving physician ordering and monitoring were reported much less frequently.

The predominant types of medication administration error that were reported (Table 4) were dose omission and ordering or administration of an improper dose. The only other type of error accounting for more than 10% of errors was ordering or administration of the wrong drug.

Underlying Causes of Errors

The reporting rate for underlying causes was considerably lower than that for other data fields (Table 5). Overall, the most frequently reported cause of errors was miscommunication of the drug order. Other causes identified in 10% or more of cause-specified error reports included working environment, staffing, or workflow problems; lack of staff education; and lack of quality control or independent check systems. Problems with drug name, labelling, or packaging accounted for slightly less than 10% of errors. However, events involving an infusion device presented a markedly different causal profile: a problem with the technology for drug delivery was cited in 23 (64%) of 36 reports.

DISCUSSION

The reporting of medication errors is essential for assessing quality of care and identifying opportunities to enhance medication-related patient safety. In this study, the overall rates of hospital-reported medication errors during staggered 12-month reporting periods were 0.86 per bed, 1.76 per 100 admissions, and 0.25 per 1000 doses of medication dispensed. Only 2.8% of the reported events were perceived as possibly contributing to patient harm (either temporary or permanent) and



Table 2. Therapeutic Classes of Drugs Most Frequently Identified in Error Event Reports

Therapeutic Class of Drug (AHFS Code)	Type of Event; No. (%) of Events*		
	Reported Error Events (n = 4243)	Potential ADEs (n = 685)	ADEs (n = 120)
Central nervous system drugs (28)	1085 (25.6)	151 (22.0)	24 (20.0)
Blood formation/coagulation agents (20)	537 (12.7)	123 (18.0)	12 (10.0)
Anti-infectives (08)	522 (12.3)	82 (12.0)	17 (14.2)
Cardiovascular drugs (24)	510 (12.0)	79 (11.5)	21 (17.5)
Hormones and synthetic substitutes (68)	422 (9.9)	111 (16.2)	14 (11.7)
Vitamins (88)	274 (6.5)	52 (7.6)	11 (9.2)
Gastrointestinal drugs (56)	274 (6.5)	31 (4.5)	4 (3.3)
Electrolytes, caloric, and water balance agents (40)	235 (5.5)	41 (6.0)	10 (8.3)
Autonomic drugs (12)	136 (3.2)	22 (3.2)	2 (1.7)
Other	511 (12.0)	61 (8.9)	21 (17.5)

AHFS = American Hospital Formulary Service, ADE = adverse drug event.

*A single event may involve multiple drugs; therefore, the numbers of events for various drugs do not sum to the *n* value in the corresponding column heading.

Table 3. Frequency of Errors by Stage of Medication-Use Process

Stage of Medication-Use Process	Type of Event; No. (%) of Events*		
	Reported Error Events (n = 4243)	Potential ADEs (n = 685)	ADEs (n = 120)
Administration of medication	2396 (56.6)	559 (81.6)	87 (72.5)
Order entry and transcription	1383 (32.6)	95 (13.9)	30 (25.0)
Dispensing and delivery	771 (18.2)	75 (10.9)	8 (6.7)
Physician ordering	297 (7.0)	35 (5.1)	14 (11.7)
Monitoring	167 (3.9)	51 (7.4)	10 (8.3)

ADE = adverse drug event.

*A single event may involve errors at more than one stage.

Table 4. Types of Process Error

Type of Error	Type of Event; No. (%) of Events*		
	Reported Error Events (n = 4243)	Potential ADEs (n = 685)	ADEs (n = 120)
Dose omission	1216 (28.7)	197 (28.8)	41 (34.2)
Improper dose	1092 (25.7)	216 (31.5)	37 (30.8)
Wrong drug	438 (10.3)	86 (12.6)	8 (6.7)
Wrong time	240 (5.7)	31 (4.5)	2 (1.7)
Wrong strength or concentration	132 (3.1)	25 (3.6)	1 (0.8)
Wrong patient	129 (3.0)	29 (4.2)	2 (1.7)
Wrong rate	106 (2.5)	22 (3.2)	6 (5.0)
Monitoring error	67 (1.6)	20 (2.9)	4 (3.3)
Wrong dosage form	58 (1.4)	4 (0.6)	1 (0.8)
Wrong route of administration	55 (1.3)	11 (1.6)	1 (0.8)
Wrong duration	33 (0.8)	3 (0.4)	0 (0)
Deteriorated drug error	16 (0.4)	3 (0.4)	0 (0)
Wrong technique	12 (0.3)	4 (0.6)	2 (1.7)
Other	649 (15.3)	34 (5.0)	15 (12.5)

ADE = adverse drug event.

* Percentages may not sum to 100 because of rounding.



Table 5. Underlying Causes* of Errors

Underlying Cause†	Type of Event; No. (%) of Events‡					
	All Reported Events (n = 1796)		Potential ADEs (n = 198)		ADEs (n = 61)	
Miscommunication of drug order	693	(38.6)	63	(31.8)	23	(37.7)
Environmental, staffing, or workflow problem	394	(21.9)	56	(28.3)	17	(27.9)
Lack of staff education	343	(19.1)	54	(27.3)	15	(24.6)
Lack of quality control or independent check systems	211	(11.7)	33	(16.7)	5	(8.2)
Drug name, label, or packaging problem	174	(9.7)	18	(9.1)	4	(6.6)
Drug storage or delivery problem	146	(8.1)	12	(6.1)	5	(8.2)
Critical patient information missing	90	(5.0)	10	(5.1)	2	(3.3)
Drug delivery device problem	64	(3.6)	9	(4.5)	5	(8.2)
Patient education problem	31	(1.7)	13	(6.6)	2	(3.3)
Critical drug information missing	30	(1.7)	4	(2.0)	1	(1.6)

ADE = adverse drug event.

*As defined by Leape and others,³ page 37.

†A single event may have multiple causes.

‡Underlying cause was not reported for all error events. Therefore, the sample sizes for reports of underlying causes (total, potential ADEs, and ADEs) are smaller than the total numbers of reported error events.

requiring monitoring and/or intervention (i.e., ADEs), and none of these events resulted in patient death. However, monitoring or intervention was instituted for a further 16.1% of errors (potential ADEs). More than one-quarter of all reported error events (28.4%) were identified before they reached the patient. Most reported events involved commonly used medications.

Errors occurred most frequently in the administration and order entry or transcription stages of medication use. The most common types of error were omission of a dose and ordering or administration of an improper dose or the wrong drug. The higher frequency of administration errors was expected because multiple administrations often flow from a single medication order or dispensing event. Also, as noted by Hicks and others,²⁴ “[as] medications . . . get closer to the patient, there is less opportunity to intercept and avert an error.” Five types of underlying factors dominated the reports: miscommunication of drug orders; environmental, staffing, or workflow problems; lack of staff education; lack of quality control or independent check systems; and problems with drug name, labelling, or packaging. In contrast, in events involving an infusion device, problems with drug delivery technology predominated. Although the relative frequencies of these causes must be interpreted with caution (because of the low reporting rate and biases inherent in the methods), it is clear that multiple factors, both human and system, are perceived as contributors.

The results of the current study showed both similarities and differences in comparison with key multihospital studies of medication errors from the United States, although the validity of these comparisons

is limited by differences in the methods used to detect and classify events and in the criteria for exclusion of error data. The current study assessed errors that were reported voluntarily, and all error events identified and documented by the hospitals’ usual criteria and procedures were included in the analysis. In these respects the study process was similar to the Medication Error Reporting Program (sponsored by the Institute for Safe Medication Practices [US] and the United States Pharmacopoeia) and the MEDMARX Program (sponsored by the United States Pharmacopoeia). In contrast, in the study by the Adverse Drug Event Prevention Study Group,^{2,3} error reports were solicited from staff, patient records were reviewed systematically to detect reportable events, and event reports were evaluated independently by physician reviewers, who excluded errors for which the potential for injury was judged to be minimal. Not surprisingly, that study’s “active” seeking of errors resulted in a higher overall rate of error reports than in the present study (7.3 per 100 admissions and 1.76 per 100 admissions, respectively) despite the exclusion of events deemed to have minimal potential for injury. Among the apparent similarities between the current study and the MEDMARX analysis of 2002 error events²⁴ are the proportion of error events perceived as (possibly) contributing to patient harm (either temporary or permanent) (2.8% and 1.98%, respectively). However, a higher proportion of the errors reported in the current study required monitoring and/or intervention (16.1% and 7.5%, respectively).

In both the present study and that of the Adverse Drug Event Prevention Study Group^{2,3} reported errors



frequently involved central nervous system drugs (analgesics, sedatives, and antipsychotic drugs), anti-infective agents, and cardiovascular drugs. Furthermore, in both the current study and the MEDMARX program,²⁴ the 10 most frequently reported drugs included insulin, morphine, heparin, warfarin, cefazolin, furosemide, and potassium chloride, the first 4 of which have been flagged by MEDMARX as “high-alert” medications. A further similarity to the findings of MEDMARX²⁴ and others¹³ is the relatively high frequency of errors in the categories of dose omission and wrong dose. A notable difference between the current study and some key US studies is the much lower proportion of reported errors in physician prescribing: 5.9% of all errors and 9.4% of errors (possibly) causing patient harm in the current study, compared with 56% of preventable ADEs reported by Bates and others² and 21% of all errors in the MEDMARX study.²⁴ These differences may reflect different interpretations of classification criteria, differences in orientation of reporting personnel (process or outcomes), and/or inadequate capture of errors at the physician ordering stage in the current study.

This study reflects existing error detection and internal reporting practices of a convenience sample of Ontario hospitals with an interest in using a new software package to systematically document medication error events. Undoubtedly, recruitment of volunteer hospitals biased the participant group in favour of institutions with an active interest in improving their medication error detection, reporting, and analysis capabilities, and openness to anonymously sharing event reports with a neutral third party. However, rendering error event reports anonymous precludes determination of between-hospital variability in reporting rates based on number of admissions, patient days of care, or doses of medication dispensed. Spontaneous, informal feedback from participating hospitals indicated that the software was particularly beneficial to those institutions that had previously used paper-based systems; however, feedback was not systematically collected from all participating hospitals. Because the error event data were reported voluntarily, their completeness and validity were limited by the completeness of hospitals’ internal event reports, their transformation to Analyze-ERR-based submissions, and any hospital policies that might have constrained the reporting of errors to a third party. The study design included 2 features to maximize validity and completeness: first, hospitals were provided with the software and employees were trained in its use; second, the reporting

system protected the anonymity of hospitals by stripping reports of any information identifying hospital or patient. Because these results are based on a small sample of volunteer hospitals, and because they represent events detected by hospitals’ usual criteria and procedures, they cannot be used to estimate the total number of patients harmed by medication errors in Ontario hospitals. Furthermore, the 685 errors classified as potential ADEs undoubtedly represent a conservative estimate, since additional errors that reached the patient but did not cause harm might have had the potential to do so.

Overall, the results of this study of medication-related errors support the recent call¹² for systematic reporting and monitoring of adverse events, “judicious application of new technologies”, and improvement of coordination among health care providers. In his critical review of reporting systems for adverse events, Leape¹⁷ identified 4 means by which reporting of errors external to the originating facility can lead to improved safety: providing alerts to new hazards, disseminating information about individual facilities’ experience in using new methods to prevent errors, identifying trends and hazards through central analysis, and developing “best practices” guidelines. The continuing electronic reporting of medication errors to ISMP Canada by several of the hospitals in the study, well after study completion, as well as more recent uptake of the software by other hospitals in Ontario and other Canadian provinces, indicates their support for compiling and sharing information about medication errors to improve patient safety. This increasing adoption has enabled ISMP Canada to disseminate to Canadian hospitals more broadly based information on trends and hazards, has stimulated improvements in the software for Canada-wide use, and has provided valuable information for the development of the Canadian Medication Incident Reporting and Prevention System, a national system for learning from medication errors. Leape¹⁷ also identified 7 characteristics of successful reporting systems: nonpunitive, confidential, independent of any authority with power to punish, expert analysis, timely, systems-oriented, and responsive. These criteria are met by both of the major national voluntary reporting systems focusing on medication error in the United States (the Medication Error Reporting Program and the MEDMARX Program) and by the ISMP Canada initiative described in this report. Nevertheless, other factors that may contribute to underreporting include lack of time and perceived lack of benefit, as well as fear of breach of confidentiality. Hospitals should establish strategic priorities based on their own error profiles, as well as information from



shared aggregate error data. Finally, these strategies should recognize that many error events are rooted in the interaction of human factors (e.g., limitations of memory) and systems factors such as methods for communicating drug orders; workflow, environment, and staffing; education; quality control and independent check systems; and names, labelling, and packaging of drugs.

References

- 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 I. *N Engl J Med* 1991;324:370-6.
- Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA* 1995;274:29-34.
- Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA* 1995;274:35-43.
- Leape LL, Cullen DJ, Clapp MD, Burdick E, Demonaco HJ, Erickson JI, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA* 1999;281:267-70.
- Institute of Medicine (US), Committee on Quality Health Care in America. *Crossing the chasm: a new health system for the 21st century*. Washington (DC): National Academy Press; 2001.
- National Steering Committee on Patient Safety. *Building a safer system—a national integrated strategy for improving patient safety in Canadian health care* [Internet]. Ottawa (ON): Royal College of Physicians and Surgeons of Canada; 2002 [cited 2005 Jul 17]. Available from: <http://rcpsc.medical.org/publications/index.php> [select by document title].
- Baker GR, Norton P. Making patients safer! Reducing error in Canadian healthcare. *Healthc Pap* 2001;2(1):10-31.
- Baker GR, Norton P. Adverse events and patient safety in Canadian health care. *CMAJ* 2004;170:353-4.
- U D. Medication error and patient safety. *Healthc Pap* 2001;2(1):71-6.
- U D. Medication error reporting systems: problems and solutions. *New Med* 2001;1(2):61-5.
- Wong J, Beglaryan H. Strategies for hospitals to improve patient safety: a review of the research. Toronto (ON): The Change Foundation; 2004.
- 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.
- Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. Medication errors observed in 36 health care facilities. *Arch Intern Med* 2002;162:1897-903.
- Kaushal R, Bates DW, Landrigan C, McKenna KJ, Clapp MD, Federico F, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA* 2001;285:2114-20.
- Dean B, Schachter M, Vincent C, Barber N. Causes of prescribing errors in hospital inpatients: a prospective study. *Lancet* 2002;359:1373-8.
- Jha AK, Kuperman GJ, Teich JM, Leape L, Shea B, Rittenberg E, et al. Identifying adverse drug events: development of a computer-based monitor and comparison with chart review and simulated voluntary report. *J Am Med Inform Assoc* 1998;5(3):305-14.
- Leape LL. Reporting of adverse events. *N Engl J Med* 2002;347:1633-8.
- Woolf A, Litovitz T. Reporting of adverse events [letter]. *N Engl J Med* 2003;348:1410-1.
- Katikireddi V. National reporting system for medical errors is launched. *BMJ* 2004;328:481.
- Analyze-ERR[®], version 1. *Medication error reporting and analysis software manual*. Toronto (ON): ISMP Canada; 2001-2002.
- NCC MERP taxonomy of medication errors [Internet]. Rockville (MD): National Coordinating Council for Medication Error Reporting and Prevention; 1998 [cited 2004 May 19]. Available from: <http://www.nccmerp.org/pdf/taxo2001-07-31.pdf>
- Institute for Safe Medication Practices Canada [homepage on Internet]. Toronto (ON): ISMP Canada; c2000-2004 [cited 2004 May 24]. Available from: <http://www.ismp-canada.org>
- Hospital medication safety self-assessment[™]*. Toronto (ON): ISMP Canada; 2001.
- Hicks RW, Cousins DD, Williams RL. Selected medication-error data from USP's MEDMARX program for 2002. *Am J Health Syst Pharm* 2004;61:993-1000.

Joan A Marshman, PhD, is Professor Emerita with the Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, Ontario.

David K U, MScPhm, is President and Chief Executive Officer of the Institute for Safe Medication Practices Canada, Toronto, Ontario.

Robert WK Lam, BSc(Pharm) is Technology Coordinator with the Institute for Safe Medication Practices Canada, Toronto, Ontario.

Sylvia Hyland, RPh, BScPhm, MHSc (Bioethics), is Vice President of the Institute for Safe Medication Practices Canada, Toronto, Ontario.

Address correspondence to:

David U
ISMP Canada
4711 Yonge Street, Suite 1600
Toronto ON
M2N 6K8

e-mail: davidu@ismp-canada.org

Acknowledgements

This project was supported by funding from the Ontario Ministry of Health and Long-Term Care. The diligence and effort of the staff of all hospitals participating in the data collection is greatly appreciated; their cooperation was pivotal to the implementation of this project. The authors also thank the Institute for Safe Medication Practices in the United States for sharing its experience in reporting error events and for helping to facilitate the development of a Canadian reporting system and the Analyze-ERR software. Appreciation is also due to Dr David Bates of Brigham and Women's Hospital, Boston, Massachusetts, for critiquing the manuscript, and to Marg Colquhoun, who was with Markham Stouffville Hospital, Markham, Ontario, at the time of the project and is now a Project Leader with ISMP Canada, for assisting with implementation of the project.

