Medication Error Reporting Systems: Problems and Solutions

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Reform of medication error reporting systems will help to prevent easily avoidable mistakes and their often serious consequences. If such reform is to be successful, we need to see a significant investment of resources and a 'culture shift', to make reporting medical errors accepted throughout healthcare. The 'medication use process' is central to these reforms — it is both here, and in the provision of education and information that hospital pharmacy has an important role to play.

'To Err is Human', the Institute of Medicine (IOM) report on medical errors, was released in November 1999 and immediately captured the attention of both public and healthcare policy makers [1]. In March 2001, the second IOM report, 'Crossing the Quality Chasm: A New Health System for the 21st Century,' was published [2]. The 'chasm' report extends the findings of the 'error' report to other important dimensions of healthcare quality. The recently released report from the Agency of Healthcare Research and Quality (AHRQ) recommends strategies for changes that institutions and practitioners alike can adopt to make an improved and safer healthcare system [3]. As a result of these and other reports, there is a heightened awareness among all healthcare professionals that we must now focus our efforts on ensuring safer systems within our healthcare organizations.

The safe use of medications is an important component of many patient safety initiatives, and is a core mandate of the pharmacy profession. It is reflected in the credo 'first do no harm' shared by all medical and allied health professionals. The introduction of many new drugs and technologies necessitates constant vigilance from pharmacists and healthcare professionals for the detection of new kinds of errors.

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Pharmacists must learn to detect medication errors, actual or potential, to understand their causes, and to propose system-wide changes to reduce the risks to patients. Medication error reporting is a necessary part of these aims. If the ultimate objective is to reduce or prevent injury to patients from medication errors, then sharing the lessons taught by errors should have the highest priority in error reduction efforts.

Barriers to effective error reporting

The structure of many existing hospital error reporting programs does not help us in learning about system changes that may be indicated and are necessary to address the cause of the errors. Existing reporting programs tend to play a traditional role of counting and sorting errors for statistical and trending purposes — their design frequently only allows the collection of minimal objective information for legal risk management, and often does not provide opportunities for system-wide quality improvements. A number of

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David has written many articles and columns on safe medication practices published in various professional journals, *Hospital News*, and *HealthcarePapers*, and has given many talks on medication errors and their prevention strategies. David was also one of the recipients of the Year 2000 ISMP Cheer's Award which is given to individuals with distinguished efforts and achievements in promoting safe medication practices. Presently, David is the President and CEO of ISMP Canada. Since January 2001, he has also been a member of the Board of Trustees of ISMP USA.

barriers have been identified that stand in the way of changes to this mode of reporting:

- **Culture of blame.** Although practitioners are becoming aware that many patient injuries stemming from medication errors can be attributed to missing safeguards in existing systems, we continue to blame individuals for adverse outcomes. This attitude, the 'sharp end' approach, will suppress error reporting — practitioners will continue to fear disciplinary actions. It is well recognized that many important factors contributing to injury originate at the 'blunt end', where organization policies, procedures and resource allocation decisions are made. Identification of root causes of injury can lead to improvements that prevent their recurrence. The culture of blame must be changed to a culture of patient safety, to encourage more reporting of medication errors whether they are followed by injury or not.
- **Lack of leadership.** Pharmacists recognize the need for medication error reporting and are willing to devote their energies to system improvements. This goal cannot be achieved without organizational leadership and support. Administration and senior medical staff must provide the leadership needed to ensure commitment and to provide the proper supportive infrastructure for creating and sustaining a culture of safety. On a broader level, government agencies, senior policy makers, professional organization leaders and regulatory bodies must assign the highest priority to patient safety.
- **Lack of statutory protection.** In Canada, many Provinces do not have statutory protection for internal hospital reports and peer-review. This has inhibited both practitioners and hospitals from reporting errors. In the US, some States have limited institutional peer-review protection. The first IOM report asked for a legislative push to extend such peer-review protection to the information included in voluntary reporting systems, so that reporters would be adequately protected [1] — subsequently, Oklahoma was the first US State to pass a bill providing full peer-review protection in June 2001 [4]. At a hospital level, a written policy of non-punitive medication error reporting needs to be developed, which should clearly articulate the value of error reports for the sole purpose of discovering system weaknesses and identifying improvement opportunities.
- **Benchmarking errors.** Medication error rates based on incident reporting do not provide a valid measure of patient safety. A high error rate could suggest either unsafe practices, or the existence of an organizational culture that promotes error reporting. Similarly, a low error rate could suggest either a successful and safe organizational practice, or an inherently punitive approach that inhibits error reporting [5].

Guiding principles and characteristics of an effective medication error reporting system

There are certain principles critical to designing a successful medication error reporting system, whether for internal hospital use or for use in an external national system. The Institute for Safe Medication Practices Canada (ISMP Canada) has outlined the following set of guiding principles:

- reporting will be voluntary
- it will invite active participation from health professionals and consumers
- it will provide a choice of reporter anonymity
- it will provide confidentiality of reported information
- it will clearly define a non-punitive approach to reporting
- it will encourage reporting of both potential and actual errors, and of patient injuries stemming from errors
- it will provide feedback of error analysis and timely recommendations.

Administrative personnel and all staff involved in building the reporting system must agree with these principles. Additional features that will facilitate the use of a reporting system and will assist in capturing the required information include:

- ease of use
- availability of both electronic and paper formats
- standard taxonomy
- severity of outcomes
- searchable and retrievable data
- report generation
- root cause analysis.

The Analyze-ERR program

ISMP Canada, working with its sister organization in the US (ISMP USA), has designed and developed the Analyze-ERR software: a medication error reporting and root cause analysis program [6]. The software has been beta-tested by five hospitals and will also be included in a research study to assess the impact of error prevention interventions on medication safety in 30 hospitals in Ontario, Canada.

A unique feature of this program is the division of the database into two separate and distinct components: event reporting and root cause analysis. The data within the two components are dissociated once the report is completed. Identified system deficiencies and weaknesses are not traceable to the particular event. Analyze-ERR adheres to the medication error taxonomy developed by the National Coordinating Council for Medication Error Reporting and Prevention based in Washington, DC, USA. The reporters or hospital's safe medication practice committee are prompted to input the event's root causes, and the aggregate root cause data can be trended to suggest areas of system weakness of the organization.

The Analyze-ERR program can also serve to export selected database records to a national reporting program. The records exported will contain no patient, reporter, or institution identifiers.

A critical role for pharmacists

Medication use is a complex process. In an institutional setting, it starts with physician prescribing, followed by nurse transcribing, pharmacist dispensing, medication administration, and patient monitoring. Many safeguards have been recommended for each of these phases, including the application of a computerized physician order entry system (CPOE), point-of-care unit dose-dispensing cabinet, and bar-coding technology. Pharmacists can be involved in almost all these processes. For example, as the medication orders come from CPOE to the pharmacy system, pharmacists must screen the drug orders with safety checks before dispensing the medication. Similarly, drugs being dispensed from the automated dispensing cabinets should be controlled by the pharmacy system via the patient's medication profile. Pharmacists applying the pharmaceutical care practice model should monitor the drug efficacy and its side effects. They can also play a leadership role in educating other healthcare professionals and advocating safe medication use.

Many medication errors occur in settings outside hospitals. Indeed, the great majority of drug use is in the community and long-term care

Medication Incident Reporting Program in Hong Kong

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The main responsibility of the Hospital Authority of Hong Kong (HA) is the delivery of secondary and tertiary specialist care with medical rehabilitation through its network of healthcare facilities. The authority also provides some primary medical services, and currently manages 44 public hospitals/institutions, 49 specialist outpatient clinics, and 10 general outpatient clinics. As of 31 December 2000, the HA managed a total of about 29 000 hospital beds with about 50 200 full-time staff.

In 1994, the HA Medication Incident Reporting Program was first implemented to provide a structured and systematic mechanism to identify and record medication-related incidents occurring in the HA hospitals. The program enables the causes of incidents to be studied in order to minimize their recurrence and to improve patient safety. In 1995, 7800 medication incidents were reported — this figure has progressively increased to about 23 000–26 000 incidents per year. Between 1995 and 2000, the voluntary incident reporting rates ranged between 0.05% and 0.13%, similar to rates of 0.2% reported from US health organizations [1,2].

The program has adopted a two-tier reporting mechanism, where medication incidents in the HA hospitals are reported voluntarily within each hospital using standardized forms with a grading system according to the severity of incidents. Completed reports are reviewed periodically by a multidisciplinary panel with representatives from medical, nursing, and pharmacy staff in order to identify the underlying causes of each incident so that appropriate preventive or remedial measures are recommended to the Hospital Chief Executive. Statistical data and those incidents that have involved patients are reported quarterly to the Hospital Authority Head Office (HAHO) using the standardized forms. The HAHO analyses and monitors the overall trend of medication incidents and considers appropriate organization-wide measures to reduce risks.

Current efforts are focused on a root cause analysis, which showed unidentified underlying causes in about 50% of 'near-misses' and in about 10% of cases where errors happened and reached the patient. Consistent with US data reported to the Institute of Safe Medication Practice [3], insulin, potassium chloride, and morphine top the list of the 10 medications for which errors are most frequently reported in the HA, and strategies have been devised by working groups to safeguard use of these medications. In addition, compiled statistical information and case studies, with information about their circumstances, causes and advice, are disseminated regularly to all HA staff for education, as well as to the lay press for public accountability. In order to facilitate data collection, analysis, review, and the generation of medication incident reports, a longer-term solution is being developed in the form of an integrated electronic HA-wide incident reporting system. This system will incorporate other current reporting mechanisms in the HA, including the adverse drug reaction reporting and medical device error reporting. The system will be accessible through local area networks safeguarded with hierarchical security. Once in position, it could also improve the follow-up process.

Information technology solutions are being used increasingly in our medication management system. Electronic prescribing using the Medication Order Entry system was first introduced in HA hospitals in 1996, in both inpatient and outpatient settings. Together with other improvement strategies, this resulted in a 25% reduction in the reported medication incidents caused by transcription, illegibility, and unclear prescription. Modifications and improvements are still in progress to 'design error out of the system'. Continuous improvement of the medication management system could lead to the integration of patient and drug information at the point of prescribing and dispensing, which would enable checking of allergy, dosage range, drug–drug interactions, and therapeutic duplication. The introduction of such a system HA-wide could potentially prevent many errors. Nevertheless, there is clearly no universal foolproof remedy for all medication incidents. Technology is a tool that is complementary to human intervention. System improvement, staff training and participation, as well as patient education are pivotal to a safe medication use process.

References

1. Shannon RC, DeMuth JE. Comparison of error detection methods in the long term care facility. *Consulting Pharmacist* 1987;2:148–51.
2. Van Leeuwen DH. Are medication error rates useful as comparative measures of organizational performance? *Jt Comm J Qual Improv* 1994;20:192–9.
3. DPPR—a Final Glance. *USP Quality Review* 2000;75:1–6.

facilities [7]. However, only limited data are available about this large segment of medication users and the potential risk of injury following medication error. There is an important role for pharmacists, both in leading research efforts and in implementing best and safe practice in the non-hospital setting.

Pharmacists applying the pharmaceutical care practice model should monitor the drug efficacy and its side effects

National reporting and prevention programs

There are many tragic stories of fatal adverse drug events that should have been easily preventable. Citing from the Canadian experience alone, Courtney Braund of Nova Scotia died from the inadvertent intrathecal administration of vincristine [8], and Jeffrey Brown of Ontario died when concentrated potassium chloride solution instead of furosemide was injected [8]. It is frustrating to learn about these tragic events when identical events have already been reported elsewhere in Canada and internationally. Serious adverse drug events like these could be easily avoided by sharing information between practitioners and institutions — at the moment none of this information is shared.

This observation has been echoed by Aneez Esmail (University of Manchester, Manchester, UK) [9], "The most tragic part about the story of Courtney Braund is that mistakes like this are still occurring. The injection of vincristine intrathecally is an international problem, and we don't need detailed studies in each country to find solutions." Esmail went on to emphasize, "... the lesson for research in medical errors is that we need more cooperation and thinking about solutions rather than more studies that continue to highlight the problem."

There are national error reporting systems established in many countries, including in the US:

- the Medication Error Reporting Program operated by United States Pharmacopoeia in cooperation with the ISMP
- the Joint Commission on Accreditation of Healthcare Organization's sentinel event reporting system
- the FDA MedWatch program that handles adverse drug reaction reports
- the FDA's Office of Post Marketing Drug Risk Assessment that also receives medication error reports from both practitioners and industry.

These organizations and their reporting systems collaborate to varying degrees.

In Canada, there was no national reporting system until early 2000, when ISMP Canada was founded. ISMP Canada, like its sister organization in the US, is an independent, non-profit organization established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety. It uses a voluntary practitioner reporting system and receives quality reports of importance from all over Canada. ISMP Canada has issued a number of critical alert bulletins with recommendations to Canadian healthcare providers on a number of hazardous situations.

Both ISMP USA and ISMP Canada post all alerts and warnings on their respective web sites, www.ismp.org and www.ismp-canada.org, which are open to any visitor — while efforts are being explored for a more workable international cooperative strategy, the use of web sites is one way to effectively share information about medical errors and their consequences between different countries.

In addition, the Canadian Coalition on Medication Incident Reporting and Prevention was established early in 2001. Its membership includes many healthcare professional organizations and healthcare agencies. The goal is to create a collaborative model to handle medication error reporting from all practice settings. The coalition is supported by Health Canada. It is expected that this national model will involve collaboration and data sharing between various reporting systems. More importantly, it should coordinate and disseminate useful information to the healthcare community to prevent adverse drug events. ISMP Canada will play an important role in making this national reporting system a success.

Voluntary versus mandatory reporting systems

There have been many discussions and debates on the question of voluntary reporting versus mandatory reporting systems. The IOM report recommends that, as well as the existing voluntary reporting systems, a mandatory reporting system should be established at the State level for medical errors causing serious injury or death [1]. The American Society of Health-System Pharmacists supports a mandatory reporting system only if certain criteria are met, including "an overall focus on improving the processes used in healthcare... [that] it be non-punitive in the sense that the submission of a report, per se, does not incur a penalty on the reporting institution or practitioner or others involved in the incident.....[that] adequate resources [are] devoted to report analysis, timely dissemination of advisories [10]."

Many patient safety experts feel that voluntary reporting is a more effective way to achieve the ultimate goals

However, many patient safety experts feel that voluntary reporting is a more effective way to achieve the ultimate goals. A comparison between voluntary and mandatory reporting is eloquently cited by Michael Cohen (ISMP, Huntingdon Valley, PA, USA), "To stimulate participation in reporting programs, voluntary, non-punitive reporting has proven to be an effective method for obtaining needed information about errors [11]. Existing mandatory reporting systems, which are inherently punitive in nature, have suppressed reporting and discouraged the open discussion of errors, which is necessary to develop and disseminate appropriate safety strategies. Conversely, voluntary reporting has been far more

successful at garnering a sufficient representative sampling of error reports, providing expert analysis, and disseminating high-leverage safety strategy effectively."

It should be noted that even if mandatory reporting programs offer an amnesty or immunity to reporters, they often punish those who fail to report. Practitioners do not need to be forced to report medication errors and patient injuries. Rather, they need freedom from institutional penalties, which is possible only with a voluntary reporting program. ISMP Canada is a strong advocate of non-punitive, voluntary error reporting programs, with patient safety as the principal goal.

Conclusion

Pharmacists can, and will, play a strong role in reducing medication errors and making the healthcare system safer. However, to maintain an effective medication error reporting system we need to develop and encourage a culture of patient safety, and to be provided with continuous support from senior healthcare leaders. Voluntary reporting systems, as they are oriented towards quality improvement, promote reporting and are more effective in obtaining information on errors needed for system improvement. National reporting systems are also required to coordinate and maintain an aggregated medication error database. Finally, information about medication errors and consequent injuries, and subsequently appropriate error prevention strategies, must be shared in the international healthcare community, as well as domestically.

References

1. Kohn LT, Corrigan JM, Donaldson MS, editors. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 1999.
2. Committee on Quality Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press, 2001.
3 Shojania KG, Duncan BW, McDonald KM et al., editors. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43* (Prepared by the University of California at San Francisco–Stanford Evidence-based Practice Center under Contract No. 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality, 2001.
4. ISMP Medication Safety Alert! 2001;**6**(10).
5. U D. Medication Errors and Risk Management in Hospitals. *Risk Management in Canadian Health Care* 2000;**2**:49–52.
6. Analyze-ERR program, ISMP Canada web site: www.ismp-canada.org/analyze-err.htm.
7. U D. Medication Error and Patient Safety. *HealthcarePapers*, 2001;**2**:71–8.
8. Baker RG, Norton P. Making Patients Safer! Reducing Error in Canadian Healthcare. *HealthcarePapers* 2001;**2**:10–31.
9. Esmail A. Better Cooperation and Less Measurement. *HealthcarePapers* 2001;**2**:33–7.
10. ASHP Statement on Reporting Medical Errors. *Am J Health Syst Pharm* 2000;**57**:1531–2.
11. Cohen MR. Testimony before the Committee on Health, Education, Labor and Pension, United States Senate. Hearing on Medical Errors: Understanding Adverse Drug Events, February 1, 2000.