

The Scope of the Medication Error Problem

a report by

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Background

The subject of medical errors is currently possibly the most important and widely scrutinized in healthcare. The national media – including both the healthcare news sources and the general news outlets – is paying close attention. The February 2003 episode at Duke University Hospital in Durham, North Carolina, in which inattention to blood type led to tragic consequences for a heart transplant patient brought an intense focus onto the serious nature of medical errors. Dozens of studies conducted worldwide since the 1960s provide irrefutable evidence that medical and medication errors occur every day in every healthcare institution.

Medication errors, the most prevalent kind of medical errors, have been occurring for decades. In 1982, the *American Journal of Hospital Pharmacy* published a report measuring medication errors in nursing homes and small hospitals.¹ At that time, evidence gathered from the 1960s in hospitals in the US, the UK, and Canada depicted a medication error rate in hospitals at roughly one error per patient per day, excluding ‘wrong time’ errors. In the fall of 2002, the American Medical Association (AMA) published research depicting a medication error rate of 19%, in a study conducted at 36 hospitals and skilled-nursing facilities.²

Dr David W Bates and his colleagues at Harvard University published research in April 1995 that studied the relationship between medication errors and Adverse Drug Events (ADEs,³ defined as drug errors that have the potential to harm a patient). The study pinpointed ‘missing dose’ errors, in which a patient’s dose was accidentally skipped – by far the most common mistake. Besides injuring patients, the study’s authors reported that medication errors cost money and waste time.

The scope and magnitude of medication errors have been thoroughly recorded, analyzed, and published by leading research teams. An important study published in 1999 by the Institute of Medicine (IOM), entitled *To Err is Human: Building a Safe Health System*,⁴ intensified the spotlight on the occurrence, clinical consequences, and cost of ADEs in hospitals. This report has been hailed as a seminal call to improve patient safety, particularly through more accurate medication administration. The article had prompted over 700 media citations as of May 2002.

Efforts to Monitor and Record Errors

The emergence of a truly organized medication error reporting system first appeared in 1975 under the appropriate name of the Medication Errors Reporting (MER) program. It was and is a voluntary medication error reporting system that was developed by the Institute for Safe Medication Practices (ISMP), a non-profit-making organization that works closely with the healthcare industry, regulatory agencies, professional organizations, and the pharmaceutical industry. The ISMP provides information and education about ADEs and their prevention. In 1991, the MER program was transferred to US Pharmacopoeia (USP), which continues to administer the program today.

In 1984, the FDA implemented the Medical Device Reporting program, which required manufacturers to report device-related adverse events to the FDA. In 1990, the Safe Medical Device Act amendments expanded the FDA’s authority by requiring that user facilities (for example hospitals and nursing homes) report device-related serious injuries and deaths to the manufacturer and directly to the FDA.

In 1995, The National Coordinating Council for Medication Error Reporting and Prevention (NCC

1. K N Barker, R L Mikeal, R E Pearson, N A Illig, and M L Morse, “Medication Errors in Nursing Homes and Small Hospitals”, *American Journal of Hospital Pharmacy*, 39 (June 1982), pp. 987–991.
2. K N Barker, E A Flynn, G A Pepper, D W Bates, and R L Mikeal, “Medication Errors Observed in 36 Health Care Facilities”, *American Archives of Internal Medicine*, 162 (September 9, 2002), *American Medical Association*, pp. 1,897–1,903.
3. D W Bates, D Boyle, M B Vander Vliet, J Schneider, and L Leape, “Relationship Between Medication Errors and Adverse Drug Events”, *Journal of General Internal Medicine*, April 1995, pp. 199–205.
4. *Institute of Medicine (1999), To Err is Human: Building a Safer Health System, Washington, DC: National Academy Press.*

MERP) was established. Formed by 15 consumer, healthcare-provider, practitioner-and-institution, manufacturer, and regulatory organizations, the NCC MERP hoped to promote the reporting, understanding, and prevention of medication errors. In its first year, the NCC MERP had hoped to stimulate the development of reporting systems within healthcare organizations and to encourage reporting to national databases.

The NCC MERP was the first to set standards for the identification, reporting, and tracking of medication errors and to establish an inventory of reporting models.⁵ It was also significant because it pointed to systems utilizing computer-based tracking to reduce the potential for medication error throughout the entire healthcare system.

By 1996, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), an independent, not-for-profit organization that evaluates and accredits nearly 20,000 healthcare organizations, initiated a sentinel event-reporting system for hospitals. The function of the sentinel event-reporting system relies on the reporting of events that have resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition. JCAHO requires that an organization experiencing a sentinel event conduct a root-cause analysis – a process for identifying the basic or causal factor of the event.

A February 2000 study of the 50 states by the National Academy for State Health Policy revealed that there are a good number of mandatory state medical error reporting systems that track ADEs.⁶ Their survey sought to explore the current state activities and the issue of error reporting. To their surprise, all 50 states responded, but their findings provided some interesting disclosures:

- that there is a confirmed lack of universal use or interpretation of the terms 'medical error' and 'adverse event';
- that no states have a fixed and codified definition of a medical error;
- that only two states use the term 'adverse event';
- that states cite under-reporting and inadequate resources as their two greatest concerns with their reporting systems; and

- that many states noted that the area of medical error reporting is one of their greatest technical assistance needs.

While this survey provided a quick look into what states are doing to track and reduce medical errors and adverse events, the National Academy for State Health Policy is committed to continuing its exploration of the issues involved in reducing errors and improving patient safety.

The Classification of Medication Errors

For the purpose of understanding drug errors, it is important to distinguish one type of error from another. Basically, a medication error is a discrepancy between the dose ordered and the dose received. A medication error occurs under one of the following conditions.⁷

- omission error – the failure to give an ordered dose;
- wrong dose error – an amount of medication is given that differs from that ordered by more than 17% (10% for injectables);
- unordered drug error – a medication is administered that was never ordered for that patient;
- wrong form error – a dose is given in a different form than what was ordered;
- wrong time error – administration of a dose more than 30 minutes before or after it is due;
- wrong route error – a medication is administered using a different route than was ordered;
- deteriorated drug error – the drugs are expired, or the physical or chemical integrity of a medication's dosage form has been compromised;
- wrong rate of administration error – infusions or intravenous fluids are administered at a rate other than that which was prescribed;
- wrong administration technique error – for example failing to wipe an injection site with alcohol prior to administering an injection; and
- wrong dose preparation error – for example administering an oral suspension without shaking the container.

5. *Institute of Safe Medication Practices (2003), ISMP's Focus on Knowledge..., single-page handout, ISMP's informational packet.*

6. *National Academy for State Health Policy web site: http://www.nashp.org/_pressrelease_page.cfm*

7. *E L Allen and K N Barker, "Fundamentals of Medication Error Research", American Journal of Hospital Pharmacy, 47 (March 1990), pp. 555–571.*

Why and Where do Medication Errors Occur?

According to the ISMP, medication errors are never the result of a single, isolated human error.⁸ Instead, they result from multiple small breakdowns in the systems for handling drugs. Such systems cross all professional boundaries and include patients themselves. For example, medication errors occur when patients neglect to tell their care-giver about all of the medications they take, including herbal remedies, over-the-counter drugs, and nutritional supplements. Failure to provide comprehensive information can result in a serious drug or herbal interaction or a false blood test result.

According to a study led by Dr Lucian Leape and published in 1995,⁹ 44% of ADEs occurred after the prescription order was written, i.e. during the medication delivery and administration processes. Conversely, 56% of the ADEs detected in the study were due to prescription errors that occurred either in the pharmacy or the physician's office. This tends to confirm the findings of the IOM's 1999 report, which called for systematic approaches to the prevention of medication errors.

Medication errors also stem from misleading or confusing medication names and from labeling and packaging problems. In 1997, the ISMP established Medical Error Recognition and Revision Strategies, Inc. to assist pharmaceutical companies in analyzing the safety of their proposed trademarks before they reach the marketplace, to determine the likelihood that it might be vulnerable to user error.

A further study published by the *American Journal of Health System Pharmacists* in 1997 drew attention to errors occurring in hospital pharmacies with intravenous (IV) admixture compounds.¹⁰ The study

was conducted in five hospital pharmacies located in regions throughout the US. The researchers observed and recorded 145 errors for 1,679 observed doses. The results of the study suggest that, across the US, nine of every 100 IV doses that require compounding in the hospital pharmacy contain one or more errors when they are delivered to the nurse.

The Medical Impact of Medication Errors

According to an article published in February 2003, entitled "The Business Case for Medication Safety", medication errors are the most common type of medical errors made in hospitals, causing an estimated 7,000 patient deaths every year.¹¹ Medication errors happen with a regularity that some find hard to believe. A study conducted in 36 hospitals and published in 2002 found that in-patients are probably subjected to about two medication errors every day.¹²

Fatal medication errors are not new. A previous study, published in 1983, reported that a labeling error resulted in vincristine and methotrexate being exchanged and given by the wrong route; the intrathecal vincristine was ultimately fatal.¹³ Other articles published in the 1970s and 1980s describe multiple deaths caused by one or more medication errors.^{14–16} Earlier, in 1966, the University of Arkansas published research¹⁷ that classified 66.1% of 654 detected medication errors (excluding 'wrong time' errors) as 'serious.' Serious errors involved drugs that were deemed harmful when misused, as judged by a two-pharmacist panel.

The Economic Impact of Medication Errors

In 1985, The St. Paul Fire and Marine Company reported an average award of US\$18,273 per

8. Institute for Safe Medication Practices (2003), ISMP's Focus on Cooperation..., single-page handout, ISMP's informational packet.

9. L L Leape, D W Bates, D J Cullen, et al., "Systems Analysis of Adverse Drug Events", *Journal of the American Medical Association*, 274 (1995), pp. 35–43.

10. E A Flynn, R E Pearson, and K N Barker, "Observational Study of Accuracy in Compounding IV Admixtures at Five Hospitals", *American Journal of Health-system Pharmacists*, 54 (April 15, 1997), pp. 904–912.

11. T Kinninger and L Reeder, "The Business Case for Medication Safety", *Healthcare Financial Management*, February 2003.

12. K N Barker, E A Flynn, G A Pepper, D W Bates, and R L Mikeal, "Medication Errors Observed in 36 Health Care Facilities", *Archives of Internal Medicine*, 162 (2002), pp. 1,897–1,903.

13. M E Williams, A N Walker, J P Bracikowski, et al., "Ascending Myeloencephalopathy Due to Intrathecal Vincristine Sulfate: A Fatal Chemotherapeutic Error", *Cancer*, 51 (1983), pp. 2,041–2,047.

14. N S Irey, "Adverse Drug Reactions and Death: A Review of 827 Cases", *JAMA*, 236 (1976), pp. 575–578.

15. J W Buehler, L F Smith, E M Wallace, et al., "Unexplained Deaths in a Children's Hospital: An Epidemiologic Assessment", *New England Journal of Medicine*, 313 (1985), pp. 211–216.

16. J B Cooper, C D Long, R S Neubower, et al., "Critical Incidents Associated with Intraoperative Exchanges of Anesthesia Personnel", *Anesthesiology*, 56 (1982), pp. 456–461.

17. K N Barker, W W Kimbrough, and W M Heller (1966), A Study of Medication Errors in a Hospital, *Fayetteville: University of Arkansas*.

medication error-related insurance claim between 1982 and 1985.¹⁸ At that time, hospital attorneys said that most claims relating to medication errors were settled out of court for much larger amounts, because they are hard for the care-provider to defend.¹⁹ The cost of litigation and the size of the possible monetary award can be significant by any standard. By 2000, the median compensation award for medication errors rose to US\$668,000 per award.²⁰

Healthcare providers face additional economic consequences when medication errors occur. Although no standard exists for prescription dispensing errors in the ambulatory setting, a national standard has been established for medication administration errors in nursing homes: an error rate exceeding 5% can result in the withholding of reimbursement by the federal Centers for Medicare & Medicaid Services.²¹

Currently, the cost of medication errors in the US is estimated to be US\$2 billion annually in terms of lost income, lost household production, disability, and healthcare costs.²² Although new patient-safety information technology has the potential to reduce common medical errors made in hospitals, such technology requires the investment of millions of dollars at each installation site.

On the other hand, having verifiable evidence proving that providers have reduced their medication errors saves them money. In its 21 April 2003 issue, *Drug Topics* magazine reported that pharmacies would soon be given lower insurance premiums if and when they can prove that they have lowered their error rate.²³ The article stressed that insurance companies are interested in results rather than programs, technological innovations, or testimonials. An error reduction program must work and there must be proof that it works.

Recognized Medical and Medication Error Reporting Systems

The most current list of recognized medical and medication error reporting systems, utilized in the US and internationally, is as follows:

- State Adverse Event Tracking;
- FDA;
- MedWatch;
- Adverse Event Reporting System;
- Center for Biologics Evaluation and Research;
- Center for Error and Accident Reporting System;
- Vaccine Adverse Event Reporting System;
- Manufacturer and User Device Experience Database;
- JCAHO Sentinel Event Reporting;
- USP-ISMP Medication Error Reporting Program;
- USP MedMarx; and
- Emergency Care Research Institute Medical Device Safety Reports.

With the release of the 1999 IOM report,²⁴ the awareness of errors was raised to a new level. The IOM reports noted that medication-related errors were a problem and occur quite frequently in hospitals. The report provided eye-opening statistics indicating that two of every 100 admissions experience a preventable ADE.

The IOM report advised a four-tiered approach to the issue of recognizing and reporting medication errors:

- establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety;
- identify and learn from errors through mandatory and voluntary reporting efforts with the aim of making sure the system continues to be made safer for patients;

18. *St. Paul Fire and Marine Company, "Hospital Medication Claims"*, *Malpractice Digest*, 12 (Autumn 1985), p. 3.
 19. *K N Barker, J A Harris, D B Webster, et al., "Consultant Evaluation of a Hospital Medication System: Analysis of the Existing System"*, *American Journal of Hospital Pharmacies*, 41 (1984), pp. 2,009–2,016.
 20. *Jury Verdict Research (2002), Medical Malpractice Verdicts, Settlement and Statistical Analysis*, Horsham, PA: LRP Publications, p. 6.
 21. *Healthcare Financing Administration, "Appendix N - Surveyor Procedures for Pharmaceutical Service Requirements in Long-term Care Facilities"*, in *State Operations Manual*, 281 (2002), Baltimore, MD: Centers for Medicare & Medicaid, available at: <http://cms.hhs.gov/manuals/pub07pdf/AP-J-N.pdf> (accessed September 3, 2002).
 22. *T Kimminger and L Reeder, "The Business Case for Medication Safety"*, *Healthcare Financial Management*, February 2003.
 23. *K Baker, "Can We Lower Insurance Rates if We Cut Med Errors?"*, *Drug Topics*, April 21, 2003, p. 75.
 24. *Institute of Medicine (1999), To Err is Human: Building a Safer Health System*, Washington, DC; National Academy Press.

- raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and
- create safety systems inside healthcare organizations through the implementation of safe practises at the delivery level.

Prior to the release of this report, Dr Ken Barker and his colleagues were busy developing their own 'observation-based' medication error detection and tracking system, Auburn University Medication Error Detection System (AU MEDS). AU MEDS was installed in a 500-bed hospital system in 1997 and was the only system that incorporated all four parts of the IOM's recommended solution outlined above.

When AU MEDS was first installed, Auburn University helped the hospital to identify an appropriate employee (a nurse) who was then trained as the hospital's AU MEDS Certified Medication Observer (CMO). After a five-day training program, Auburn University administered a final CMO certification test. The newly trained CMO then started to observe and record approximately 100 medication administrations during regular rounds, between the hours of 8am and noon. Next, the CMO reviews the chart and patient records to discern discrepancies between the medications that were administered and the original order, then records the observations, including errors, in Auburn's proprietary AU MEDS software database. The database then tabulates and formats the data into reports and integrates seamlessly with Microsoft Access and PowerPoint, graphically providing several layers of analysis, which help identify the clues to cause of discrepancies between what was prescribed and what

was actually administered to the patients. The CMO then shares the AU MEDS reports with the nursing staff, the pharmacy and therapeutics committee, risk managers, and the executives so that appropriate and timely adjustments in operations can be planned and implemented as soon as possible.

Research conducted at 36 hospitals and skilled-nursing facilities in Georgia and Colorado and published in the *Archives of Internal Medicine*²⁵ on 9 September 2002 and in the *American Journal of Health-Systems Pharmacy*²⁶ on 1 March 2002 discovered that a medication error occurred in one in every five medication dosages given in hospitals and skilled-nursing homes. A panel of three physicians, experienced with such judgments, rated 7% of the observed errors as potential ADEs. In other words, in a healthcare institution treating 300 patients, assuming 10 doses are administered per patient in one day, this would mean that almost 40 potential ADEs occurred in that facility each day.

The study also found that 7% of the errors detected were potentially harmful to a patient and concluded that the direct observation method was a more efficient and accurate method of detecting and tracking medication administration errors than reviewing charts and incident reporting, by a factor of 373:24:1, respectively.

At the time the first AU MEDS system was installed, the hospital had a baseline medication accuracy rate of approximately 80%. Two years later, in 1999, the hospital's accuracy rate had improved to 90%; in 2002, the accuracy rate had reached 95% and was still climbing. This is a far cry from the AMA report that noted a medication error rate of 19%. ■

25. K N Barker, E A Flynn, G A Pepper, D W Bates, and R L Mikeal, "Medication Errors Observed in 36 Healthcare Facilities", *American Archives of Internal Medicine*, 162 (September 9, 2002), *American Medical Association*, pp. 1,897–1,903.

26. E A Flynn, K N Barker, G A Pepper, D W Bates, and R L Mikeal, "Comparison of Methods for Detecting Medication Errors in 36 Hospitals and Skilled-nursing Facilities", *American Journal of Health-System Pharmacy*, vol 59, no. 5 (March 1, 2002), pp. 2,314–2,316.