

# Reducing Medication Errors

## A Regional Approach for Hospitals

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### Abstract

Since the Institute of Medicine's report, *To Err Is Human*, and the subsequent publication, *Crossing the Quality Chasm*, the subject of reducing medical errors has gained considerable attention from patients, healthcare providers, employers and government organisations in the US. Most nonoperative errors are related to medications. Medication errors lead not only to negative repercussions subjectively experienced by both the patient and the healthcare staff, but also to additional expenditures due to complications.

Education, adapting new safety systems and technology, and having clinical pharmacists play a larger role in the medication process can all help in solving the problem of medication errors. Designing and executing a rational system to reduce medication errors is particularly germane in the current era of increased demands for quality healthcare in the setting of cost-containment pressures.

In the Delaware Valley (Philadelphia and surrounding area) of Pennsylvania, USA, a consortium of healthcare providers in cooperation with the Health Care Improvement Foundation (HCIF), and two non-profit organisations – the ECRI

(formerly the Emergency Care Research Institute) and the Institute for Safe Medication Practices (ISMP) – have combined to establish and promote safe medication practices under a programme known as the Regional Medication Safety Program for Hospitals. At the core of the programme are 16 medication safety goals, which centre on establishing an institutional culture of safety, modifying infrastructure and clinical practice to reflect this culture, and using technology to facilitate these changes. It is believed that this rational campaign to improve patient safety may serve as a paradigm for other regions around the world.

“It was the best of times; it was the worst of times...” – Charles Dickens, *A Tale of Two Cities*.

Never before in the history of medicine have so many diagnostic and therapeutic modalities been available to patients. Neonates who would have died in the recent past are resuscitated and supported in neonatal intensive care units (ICUs). Disorders that were untreatable are now responding to new medications and therapies. Transplants and other equally complex procedures have become almost commonplace. Despite these advances, medical journals and the lay press continue to allege that healthcare facilities pose a danger to the public. The purpose of this article is to provide an overview of the environment in which the Regional Medication Safety Program for Hospitals has been created and implemented, including a review of the literature regarding medical error and the subset of medical error most relevant to the programme, medication error.

## 1. Medical Error

Medical error is an international problem of enormous scope and, as such, has been recognised in reports from around the world. In 1995 the Quality in Australian Health Care Study was published, reporting that 16.6% of hospital admissions studied were associated with adverse events. Half of these events were judged to be preventable, and disability resulting from the events ranged from temporary in 46.6% of events to death in 4.9% of events.<sup>[1]</sup> In 2001, a group of British researchers published the results of a retrospective review of medical records from two London hospitals. Their review found that 10.8% of patients experienced an adverse event, half

of which were judged to be preventable, and one-third led to moderate or greater disability or death.<sup>[2]</sup> Also in 2001, the Canadian Institutes of Health Research and several other organisations in Canada issued a call for proposals to study health-system error in Canada in order to end the ‘culture of silence’, further emphasising the international nature of this trend.<sup>[3]</sup>

Since the publication of a report from the Institute of Medicine (IOM – part of the National Academy of the Sciences, Washington, DC, USA) entitled *To Err Is Human* in 2000,<sup>[4]</sup> the public, the press and the medical profession in the US have developed an intensified interest in medical mishaps and errors. This report made several statements that raised public consciousness, not the least of which was: “at least 44 000 and perhaps as many as 98 000 Americans die in hospitals each year as a result of medical errors”. The authors continued by stating that “deaths due to medical errors exceed the number attributable to the 8th-leading cause of death”, and further, “more people die in a given year as a result of medical errors than from motor vehicle accidents (43 458), breast cancer (42 297) or AIDS (16 516)”. The report is a self-described ‘call to action’ to make healthcare safer, with a goal of achieving a threshold improvement in quality over the next 10 years. A follow-up to the first report, *Crossing the Quality Chasm*, was published the subsequent year.<sup>[5]</sup> This report proposed six aims for improvement, stating that healthcare should be safe, effective, patient-centred, timely, efficient and equitable. This report also noted that changes are required in structures and processes of the environment especially in four areas: applying evidence to healthcare delivery, us-

ing information technology, aligning payment policies with quality improvement and preparing the workforce.

To generate these statements, the authors of the IOM report relied on incidence statistics from published studies extrapolated to a broad admissions base. Among the most important works cited in the report were the Harvard Medical Practice studies I and II.<sup>[6,7]</sup> These studies were originally undertaken to evaluate adverse events with regard to malpractice claims, out of an interest in tort reform in addition to quality of care. The researchers reviewed 30 195 medical records, randomly sampled from a population of 2 671 863 nonpsychiatric patients discharged from non-federal acute care hospitals in New York, USA, in 1984. An adverse event was defined as “an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both”. Negligence was defined as “care that fell below the standard expected of physicians in their community”.

Using these definitions, the authors of the Harvard Medication Practice study I estimated the incidence rate of adverse events in New York, USA, in 1984 to be 3.7%, of which 1.0% were due to negligence.<sup>[6]</sup> Furthermore, they found that 56.8% of adverse events resulted in minor impairment with complete recovery in 1 month, 13.7% resulted in disabilities lasting 1–6 months, 2.6% gave rise to permanent disability, and 13.6% caused death.<sup>[6]</sup> Rates of adverse events increased strongly with increasing age ( $p < 0.0001$ ); the  $p$ -value for differences in the rates of adverse events between groups of clinical specialties was  $p < 0.0001$ ; there was no difference with regard to rates of negligence.

The results of the Harvard Medical Practice study II focused on the nature of the adverse events identified in the chart review. Of the adverse events identified, 47.7% involved operative events, and 52.3% nonoperative. Of the operative events, most were due to wound infections (13.6%) or technical complications (12.9%). Of the nonoperative events, most were drug related (19.4%).<sup>[7]</sup> In evaluating the

site of the adverse events 41% were found to have occurred in the operating room, 27% in the hospital room, and 3% combined in the emergency room, ICU, and labour and delivery suites. All other locations in the hospital contributed to 5% of the total.

In 2000, Thomas et al.<sup>[8]</sup> published results from a study using similar methods to review 15 000 randomly sampled nonpsychiatric discharges from hospitals in Utah and Colorado, USA, during 1992. They reported adverse events occurring in 2.9% of hospitalisations in each state, of which 32.6% were due to negligence in Utah and 27.4% in Colorado. They found that death occurred in 6.6% of the adverse events, and 8.8% of the negligent adverse events. This study concurred with the Harvard Medical Practice study II results in that 44.9% of all adverse events were operative in nature.

Johnson et al.<sup>[9]</sup> demonstrated the economic impact of medical errors using a random sample of 794 patients from the Harvard Medical Practice studies. They estimated the entire cohort's costs due to medical injuries to be US\$161 million for medical care, US\$276 million for lost wages, and US\$441 million in lost household production, for a total of US\$878 million for the group (1989 values). In a later study, Thomas et al.<sup>[10]</sup> also followed through on the chart reviews in the Utah and Colorado cohorts to quantify the costs of medical injuries. Of the 459 adverse events detected, 265 were determined to be preventable. The total costs were US\$662 million for adverse events and US\$308 million for preventable adverse events (1996 values). When extrapolated over the 33 million admissions in the US each year, this resulted in an estimate of US\$37.6 billion for the annual national costs of adverse events, and US\$17 billion for preventable adverse events. The IOM report cited these numbers as well, stating that “total national costs (lost income, lost household productions, disability and healthcare costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between US\$17 billion and US\$29 billion, of which healthcare costs represent over one-half”.<sup>[4]</sup>

McDonald et al.<sup>[11]</sup> commented on the two different messages of the IOM report, “One is cool and

measured, and calls for understanding the cause of errors in the healthcare system". They continued "The other message in the IOM report is hot and shrill. It shouts about death and disability in US hospitals". They pointed out that the Harvard Medical Practice study and the Colorado and Utah study was observational in nature, and not designed to describe causal relationships. These authors also stated that, "the Harvard study includes no information about the baseline risk of death in these patients or information about deaths in any comparison group". If in fact the deaths and disabilities were overstated, the cost data would only multiply the error.

Brennan,<sup>[12]</sup> one of the principal authors of the Harvard Medical Practice studies, has also voiced caution against drawing conclusions from the numbers of deaths. "If one extrapolates from our studies in New York and in Colorado and Utah in order to calculate the number of deaths nationwide due to substandard care, the total decreases from 92 000 deaths in 1984 (on the basis of the data in New York) to 25 000 in 1992 (on the basis of the data in Colorado and Utah)."

While there may be disagreement regarding the rates of error detected in these studies, the underlying truth is that medical errors exist. Leape,<sup>[13]</sup> another author of the Harvard Medical Practice studies, agreed that the study's most serious limitation was that it was a retrospective medical record review. Yet he continued that "many important events in patient care are not recorded in the medical record", and that, "some errors are not even known to clinicians caring for the patient". Overall, he suspected that the record review led to an underestimate of the prevalence of injury for three reasons: first, it is unlikely that reviewers found errors that did not exist; second, neither of these studies had even begun to address errors in the outpatient setting; and third, prospective studies invariably measure higher error and injury rate than record reviews. Even the best studies to date are limited in their ability to define with confidence the scope of medical error, but, ultimately, any rate of error is unacceptable to the public. Therefore, there is universal interest from

all constituencies to reduce the number of errors that occur within the healthcare system.

## 2. Medication Errors

As stated in the Harvard Medical Practice study II, most nonoperative medical errors were related to medications.<sup>[7]</sup> Several systems are available to collect reports of adverse drug events (ADEs). In response to heightened attention, more events are being reported and more data are becoming available. For example, Phillips *et al.*<sup>[14]</sup> published a retrospective analysis of mortalities associated with medication errors reported to the Adverse Drug Reporting System of the US FDA from 1993 to 1998. Through the database the FDA receives both US and foreign reports of adverse events from manufacturers that have a drug application filed with the FDA. A total of 5366 medication errors were reported over this time frame. Among those, 469 were associated with patient deaths. The setting of the error was a hospital in 46.7% of cases, patient's home in 14.9%, ambulatory pharmacy in 4.7%, physician's office in 4.7%, other site in 4.5%, and unstated in 24.5%. The most common classes of medication involved in fatal incidents were central nervous system agents including opioids (26.9%), antineoplastics (15.4%), and cardiovascular drugs (12.6%).

Another system has shown an increase in the number of hospitals reporting data, and the number of events reported. The US Pharmacopeia (USP) Med MARx system, a web-based system that allows anonymous reporting and tracking of medication errors, received reports from 3% of the nation's hospitals in 2000. In that reporting year, 184 hospitals reported 41 296 medication-error records to USP, an increase from 6224 errors reported by 56 facilities in 1999. Of these errors, 3% reportedly harmed or led to the death of patients. Young<sup>[15]</sup> further noted that "for the second consecutive year, insulin, heparin, and morphine were the products most commonly associated with potential and actual errors", and also "distractions, workload increases, and inexperienced staff members remained the most common factors contributing to medication errors".

Outside the US, the WHO established a database, >30 years ago, to capture data to identify rare ADEs that could not be found through clinical trial programmes. The scope of this database has expanded over time to include drug safety monitoring, and as of 1998 was receiving data from >49 countries, with an annual influx of approximately 150 000 reports per year. Data are analysed and reported through newsletters, quarterly reports to clients, websites, and discussion groups.<sup>[16]</sup>

The Institute for Safe Medication Practices (ISMP – Huntingdon Valley, PA, USA) operates a database accessible by e-mail, website, or telephone that can be used to access the USP-ISMP Medication Errors Reporting Program (MERP). Reports lead to notification of USP, FDA MedWatch Program, the ECRI (formerly known as the Emergency Care Research Institute – Plymouth Meeting PA, USA) [for device-related problems], and pharmaceutical manufacturers (for product-related problems). The ISMP Med Safety Alert publishes trends and specific examples based on the analysis of reported cases.

A study by Bates et al.<sup>[17]</sup> demonstrated the scope and nature of medication errors within the hospital environment. In a random sample of 4031 adults admitted to medical or surgical units at two tertiary care facilities, 247 ADEs and 194 potential ADEs were discovered over a 6-month period. This represented event rates of 6.5 ADEs and 5.5 potential ADEs per 100 admissions, or 1600–1900 events per hospital per year. One percent of these errors were classified as fatal (none preventable), 12% life threatening and 30% serious. Of the ADEs identified, 56% occurred at the stage of ordering, 34% at administration, 6% at transcription and 4% at dispensing. In a related work, Cullen et al.<sup>[18]</sup> reported rates of preventable ADEs in ICUs to be nearly twice the rate of non-ICUs (medical ICU 19.4 ADEs per 1000 patient-days, surgical ICU 10.5 ADEs per 1000 patient-days, compared with medical general care units at 10.6 per 1000 patient-days and surgical general care units at 8.9 per 1000 patient-days). Importantly, after adjusting for the number of drugs administered, the rates no longer differed.

Paediatric populations may be at even greater risk of receiving a dose of medication in error. Kozer et al.<sup>[19]</sup> reviewed medication errors reported to the pharmacy department at a large tertiary care paediatric hospital between April and November 2000. Despite the availability of a unit-dose system for dispensing drugs and a computerised system for prescribing medications, 20 errors were spontaneously reported where the dose was mistaken by a factor of ten (representing a rate of 1 per 22 500 doses). Of these, five doses reached the children and 15 were intercepted. Kaushal et al.<sup>[20]</sup> published a review of medication errors and ADEs among paediatric units at two urban teaching hospitals. Over a 36-day period, there were 616 medication errors (5.7%) or 55 medication errors per 100 admissions. Of note, 64 patients had three or more errors, and the authors identified 115 potential ADEs representing a rate of 10 per 100 admissions. Most errors involved dosage, followed by route of administration.

The elderly are also very susceptible to ADEs. Denham and Barnett<sup>[21]</sup> reported that older people in the UK “comprise 18% of the population but receive 45% of all prescription items”. They found that one in every ten admissions to acute geriatric units in 1980 was wholly or partly due to adverse drug reactions. The number of reports of serious reactions also increases with age. The Harvard Medical Practice study II found that patients aged >64 years had adverse events and negligence-related adverse events at rates more than twice that for patients <45 years of age. Moreover, although only 27% of the population hospitalised in New York in 1984 were aged >64 years, those patients accounted for 43% of the adverse events.<sup>[7]</sup>

### 3. Sources of Error

Why do errors persist in the healthcare industry, whereas other industries (e.g. airlines, manufacturing) have successfully reduced their rates of error? There are problems intrinsic to the healthcare industry, as well as outside pressures, some of which are regionally specific, that encourage errors.

Most production-based companies have relative control over the raw materials, timing and environ-

ment of the process. In healthcare, however, there is a high degree of uncertainty. A manufacturing firm can plan and prepare for its next product with certainty, whereas healthcare providers may not know which product will be required until the helicopter lands or ambulance arrives, when seconds and minutes will count. In addition, healthcare customers may arrive unconscious without history, identification or the ability to define their wishes, needs or expectations. Often, even with conscious patients, decisions are required when only incomplete data sets are available. Patients may not be able or willing to provide all of the information necessary for caregivers.

Further adding complexity to the healthcare system, multiple teams with different perspectives and expertise must interface in delivering care to one patient. This interface must occur in real time and often during emergency conditions, rather than being scheduled during a time convenient for the participants. To get one medication to a patient requires a correct order from a physician; transcription, unless a computerised order entry system exists and the physician is physically able to interface with the system at the time the medication is required; dispensing, where a pharmacist must read and prepare the medication in question; transport, to deliver to the floor; and administration of the medication to the patient. Within this multiple participant system there are many nodes where error may occur.

External factors, when superimposed on this complexity, encourage error. The evolution of managed care in the US has led to several changes in the healthcare delivery system. Many services that traditionally were provided within a hospital are now delivered outside the hospital. These may be provided in physicians' offices, in outpatient procedure-based facilities (such as surgical centres or chemotherapy centres), in skilled nursing facilities, or at homes through home health agencies. It sometimes seems that the expectations of payers and the practices of physicians are changing faster than the supporting infrastructure can be built. For example, a migration from an inpatient setting to an outpatient setting has occurred in the treatment of deep vein

thrombosis. Payers refuse to reimburse for the service in the inpatient setting, but have not developed an infrastructure to provide nursing, laboratory support, medication availability and provider reimbursement in the outpatient setting. This instability, given the multiple nodes required to deliver a treatment to a patient, creates an environment that makes the new practice, which is really a change in the delivery model of an old practice, prone to error.

Moreover, when these more stable patients are moved from acute care hospitals to other care settings, the patients who remain in hospital are those with more severe illness. In addition to this shifting in the delivery of services, managed care has led to a decrease in the length of stay for patients. Therefore, more services are being delivered within shorter periods, while the complexity of services delivered continuously increases.

Managed care has led to lower reimbursements for care, and many hospitals have been forced to reduce staffing and cut budgets to accommodate these payment patterns. The days of nurses and pharmacists doing rounds with physicians, residents and students are gone. As staffing levels decrease, areas of overlap are reduced, exposing gaps that are prone to error. The US is facing a shortage of nurses; therefore, many hospitals are understaffed or may be using contract staff who may be less familiar with protocols and types of systems used in the facility. Fewer nurses may mean more errors and complications. Needleman et al.<sup>[22]</sup> reported that, among medical patients, a higher proportion of hours of care per day provided by registered nurses and a greater absolute number of hours per day provided by registered nurses were associated with a shorter length of stay and lower rates of urinary tract infections and upper gastrointestinal bleeding. A higher proportion of hours of care provided by registered nurses was also associated with lower rates of pneumonia, shock or cardiac arrest, and failure to rescue (defined in the study as "death of a patient with one of five life-threatening complications – pneumonia, shock or cardiac arrest, upper gastrointestinal bleeding, sepsis, or deep venous thrombosis – for which early identification by nurses and medical and nurs-

ing interventions can influence the risk of death”). However, the authors were unable to measure an association between staffing levels and the rate of in-hospital death.

As if sicker patients, lower pay and fewer staff were not enough, many areas in the US are facing a liability crisis with malpractice insurance costs soaring. Hospitals are closing trauma centres and shutting down labour and delivery services, because necessary personnel are unavailable. Physicians and groups are seeking early retirement, moving across state lines, or closing practices entirely. Providers resist discussing errors and potential errors out of fear of liability.

Decreasing lengths of stay, sicker inpatients, rapidly changing practices, lagging infrastructure and instability in the clinician pool all add to the intrinsic uncertainty that promotes error in the healthcare industry. Although these problems may be more difficult to overcome than those of a production industry, there are ways to limit their effects and reduce overall error rates.

## 4. Solutions to the Problem of Medication Errors

### 4.1 Education

Often considered the initial step, education is necessary, but not alone sufficient, to eliminate medication error. Education will generate the next wave of researchers, end-users and leaders armed with a greater awareness of the possible causes of error. Rosebraugh et al.<sup>[23]</sup> have published results from a survey evaluating the current quality of medication error education in the US. In the spring of 2000 the survey was sent to internal medicine clerkship and residency directors. From the clerkship results, the authors reported that 53% of schools did not have rotations that included clinical pharmacology or adverse drug reaction education in the third or fourth years of training. Of the residency programme respondents, 64% reported that they had existing education programmes; yet 80% stated that they would add further content if available. The finite time periods available for delivery of graduate

and postgraduate curricula allow new topics to move in only by replacing other topics. The fact that this change is already starting bodes well for success as future physicians enter the practice years better prepared to deal with these issues, and with a better understanding of the required solutions.

Education may have impact through several interventions that are inexpensive and able to be rapidly deployed. Among paediatric patients, documenting the dose calculation with the patient's weight and the final ordered dose may allow rapid identification of error. Removal of dangerous drugs from floor stock and permitting independent dose calculation checks by pharmacists prior to the first administration will prevent further medication error.<sup>[24]</sup> Since roughly one of every four errors reported to MERP involves a pair of drugs whose names look or sound alike,<sup>[25]</sup> educating prescribers about this risk may alert them to be especially careful when using these drugs.

### 4.2 Systems Approaches

The next step is to move from a philosophy of human error to one of systems error. Humans are prone to error, so safety engineers must develop systems to identify and preferably to prevent multiple possible errors. An analogy can be drawn from automobiles with built-in passive safety systems. The engine will not start unless the transmission is in park. The transmission will not shift from park to drive or park to reverse unless the brake is applied. So when a driver is rushing, the systems prevent him/her from driving through the garage door. That garage door may even have a sensor to stop it from closing if it senses resistance. These systems make drivers safer without their active involvement or acceptance.

Safety systems are particularly applicable in the hospital setting, because when an error occurs in the hospital it is rarely if ever due to a single person's mistake. Usually a series of unchecked errors would need to occur for a patient to receive an incorrect medication. For example, for a patient to receive a medication to which he/she is allergic, at least five points in the system of care must fail:

1. The physician ordering the drug should be aware of the patient's drug allergy history.
2. The patient's allergy information should also be available to the pharmacy and should be cross-referenced to intercept the physician's oversight before dispensing the drug to the nursing unit.
3. The nurse administering the drug should, likewise, be aware of all reported allergies.
4. Passive identifiers such as allergy bracelets should be worn by the patient.
5. Finally, the patient (if awake and alert) should be asked about their allergies prior to drug administration.

In a systems analysis evaluating 334 errors, Leape et al.<sup>[26]</sup> identified 16 major systems as the underlying causes of the errors. Failure in dissemination of drug knowledge accounted for 29% of the errors. Seven systems failures accounted for 78% of the errors. The good news from this study was that hospital personnel willingly participated in the detection and investigation of drug use errors and were able to identify underlying systems failures. No single solution will resolve all healthcare system errors. Solving these problems requires a re-engineering of healthcare delivery with a focus on the system, rather than the individual participant.

#### 4.3 Technology

Examples of technology-based attempts to reduce medication error include computerised prescriber order entry (CPOE) systems, bar-code medication identification and computerised infusion devices. CPOE has received considerable emphasis as an available resource to deal with medication error. One study of CPOE implementation at a large tertiary care hospital has been published in which error rates were compared at baseline and after implementation of CPOE or CPOE plus a team-based intervention<sup>[27]</sup> From this analysis, non-intercepted serious medication errors decreased from 10.7 events per 1000 patient-days to 4.86 events per 1000 patient-days. Preventable ADEs declined from 4.69 to 3.88 per 1000 patient-days, while non-intercepted potential ADEs declined from 5.99 to 0.98 per 1000

patient-days. From this analysis, the team intervention conferred no additional benefit over CPOE.

Despite the effectiveness documented above, there remain several factors that limit the ability to implement CPOE. The first is cost. Of all the technologies being evaluated in the realm of patient safety, CPOE remains one of the most expensive, with an investment in the range of millions of dollars. If hospitals had unlimited capital to invest, the cost of these systems would not be an issue. However, most administrators have limited capital, with several competing initiatives. While CPOE may eliminate handwriting and decimal point issues, it may create light-pen or keystroke errors. There may be other unintended sources of error, such as verbal orders inaccurately entered by staff when physicians are unable to access the system. In addition, dosage errors, allergy errors and drug-drug interactions are not eliminated by the order entry process, but by the accompanying decision support software. These packages are rapidly evolving and vary among vendors; therefore not all CPOE systems are created equal. Timing is also an issue, since these implementations may be disruptive and may require interfaces with legacy systems to be effective.

A possible alternative tool for reducing medication errors is bar-code medication administration. The US Veterans Health Administration implemented a system of hand-held scanners and notebook computers, to verify that the medication about to be administered was the correct medication, in the correct dose, at the right time and delivered to the correct patient. Errors are documented for trending and corrective action planning. The pharmacist leading the project reported a substantial reduction in the occurrence of errors.<sup>[28]</sup> Such a system is less costly than CPOE and more easily implemented. Staff acceptance may be an issue, as well as staff training. Despite several calls for mandatory bar coding, not all medications are currently identified by bar code to the degree necessary to allow such a system to be effective. Drug manufacturers cite the costs of such a change to be more than \$1 billion. Even if all medications were bar coded, vendors of such technology would need to adopt uniform standards to



allow all systems to read the factory-placed codes.<sup>[29]</sup> Currently the Veterans Health Administration repackages 65–70% of its drug products.<sup>[28]</sup> However, the results seem to support their decision making: the Veterans Affairs medical centre in Topeka, USA, has reported a 75% reduction in wrong medications dispensed, a 93% reduction in patient mix-ups, an 87% reduction in wrong administration times, a 70% reduction in missed doses and a 62% reduction in dose errors.<sup>[28,30]</sup>

Another tool to reduce error is a computer-facilitated infusion device or 'smart pump'. Automated infusion devices for the intravenous administration of therapeutic agents have existed since 1960s. Their use has been prone to ADEs primarily caused by administration errors due to keypad data entry mistakes and free-flow phenomena. Although most pumps in current use address the issue of free flow, the data entry difficulties persist. To address these issues, ALARIS Medical Systems of San Diego, California, USA has developed an innovative intravenous administration unit. This unit, consisting of a pump and a computer processor, combines drug delivery, monitoring and data management functions. The core of this system is its multifunctional safety software, which is designed for safer administration and monitoring of intravenous therapy, thereby increasing patient safety and reducing the potential for ADEs. The hospital inputs its formulary (or unit-specific formulary) and standard dosage regimens into the unit. Hard limits (which define a range that cannot be overridden) and soft limits (which can be overridden by a clinician) of dosages are defined. Subsequently, if a clinician keys in a dose that does not fall within the established protocol, an alert ensues and the infusion halts until the discrepancy is resolved. ADEs are therefore intercepted prior to drug administration. Importantly, the software logs all programming events and tracks errors that have been averted during its use, thereby providing information to facilitate quality improvement initiatives. Compared with the cost of CPOE, implementing this smart pump technology is considerably less expensive, and it can be completed quickly within a unit or facility. In addition to focusing on errors at

the level of administration (pump data entry), this system may pick up errors in dosage or drug based on the formulary programming. Considering the cost of ADEs in subsequent care, extended lengths of stay, and liability, the return on investment associated with this relatively less expensive technology should be very favourable.

#### 4.4 Clinical Pharmacist Interventions

A less technological approach to reducing errors involves clinical pharmacists playing a larger role in the medication process. This intervention may be at the level of order review in the pharmacy or participation in decision-making processes at the site of care delivery. The latter intervention may be most effective in environments more prone to error, or in environments where error is more likely to result in serious injury. Since error rates are higher in ICU environments, and paediatric and elderly populations are more prone to injury; ICUs, neonatal ICUs, oncology units, transplant units, geriatric units and similar settings may be best suited for this type of intervention. Pharmacist participation on medical rounds in the ICU has been shown to decrease the rate of preventable ordering ADEs by 66%, from a rate of 10.4 to 3.5 per 1000 patient-days. Over the course of the intervention, physicians accepted 99% of the pharmacist's recommendations related to drug ordering.<sup>[31]</sup> Clinical pharmacist involvement in the paediatric ICU has also been evaluated; it appears to be effective in reducing errors and also is cost-effective.<sup>[32]</sup> Although at this time recruiting pharmacists with clinical experience can be difficult, this intervention is one that can occur quickly and is comparatively cost-effective.

### 5. The Regional Medication Safety Program for Hospitals

In response to the public attention to the prevalence of medical error in the current environment, the Health Care Improvement Foundation (HCIF), a 501 (c) (3) affiliate of the Delaware Valley Healthcare Council (DVHC) in Philadelphia, PA, USA formed a unique partnership with ECRI and the ISMP to advance patient safety by focusing on re-

ducing medication errors. Through the successful implementation of the Regional Medication Safety Program for Hospitals, which utilises education, technology and pharmacist involvement in a systems approach, hospitals throughout the Delaware Valley will adopt a uniform set of 16 safety practices that have been proven to reduce the potential for medication error and thereby improve the safety of all patients throughout the region.

This regional effort coincides with national efforts previously mentioned to implement the IOM's recommendations for building a culture of safety. By combining the expertise of ECRI and ISMP with the ability of HCIF to organise its member hospitals, health systems' adoption of the recommended practices should greatly reduce adverse medication events in the Delaware Valley region. Upon successfully demonstrating that such a collaborative effort can improve patient safety, the Regional Medication Safety Program will have the potential to serve as a model for national efforts.

At the core of the programme are 16 medication safety goals (table I). Pre-programme self-assessment surveys of existing practices determine the safety status of each hospital prior to incorporating the safety goals. Participating hospitals are asked to perform an anonymous self-assessment evaluation on each of the programme's 16 action goals to assist in establishing region-wide aggregate baseline data. Beginning with an overall catalogue of 96 questions gauged to measure their performance relative to the 16 action goals, each facility received 18 different questionnaires for 18 different job functions at their facility. Each questionnaire is designed to obtain key information from each respondent. The respondents (and their related departments or areas) are shown in table II. The aggregate results of this survey will then be compared with a similar exercise conducted at the conclusion of the programme to measure the entire region's aggregate success in addressing medication safety.

The programme guides the hospitals by providing them with reviews of current practices and potential technology solutions, assistance in the development of individualised action plans, and support

through educational programmes. Hospitals, however, retain the autonomy to fund and implement the plans in a manner that is consistent with local resources and environment. Overall, the programme has concrete benchmarks of success in terms of process (the number of collaborating hospitals); outputs (progress toward achieving the 16 safety goals); outcomes (efficacy of programme interventions to produce systemic reforms); and dissemination (the potential to serve as a model for national replication). The collaboration has been funded by contributions from the participating hospitals, philanthropic foundations and private industry.

### 5.1 Action Goals

The essence of the programme is the identification and implementation of 16 action goals that will

**Table I.** The 16 goals of the Regional Medical Safety Program for Hospitals, Philadelphia, PA, USA

<b>Institutional culture</b>	
Establish an organisational commitment to the culture of safety	
Initiate medication safety education for all new and existing professionals	
Recognise safety innovation on a continuing basis	
Create an environment that encourages disclosure of medical errors to patients	
<b>Infrastructure</b>	
Designate a medication safety coordinator or officer, identify physician champions, and create an interdisciplinary safety team	
Promote greater use of clinical pharmacists in high-risk areas	
Establish area-specific guidelines for unit-stocked medications	
Create mechanisms to ensure availability of critical medication information to all members of the patient's care team	
<b>Clinical practice</b>	
Create a list of abbreviations and dose designations that should never be used	
Implement safety checklists for high-alert medications	
Implement safety checklists for infusion pumps and other medication-related devices	
Develop limitations and safeguards around verbal orders	
Perform failure-mode analysis during procurement process	
Implement triggers and markers to indicate potential adverse medication events	
<b>Technology</b>	
Eliminate the use of infusion pumps that do not have set-based free-flow protection to prevent accidental overfusion	
Prepare for implementation of computerised prescriber order entry systems	

**Table II.** The 18 job functions of individuals participating in surveys for the Regional Medical Safety Program for Hospitals, Philadelphia, PA, USA

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**Administration**

Chief Executive Officer  
 Chief Financial Officer  
 Chief Information Officer  
 Chief Medical Officer  
 Chief Operating Officer  
 Vice President, Patient Care Services

**Pharmacy**

Director, Pharmacy  
 Pharmacy Technician  
 Staff Pharmacist

**Nursing**

Nurse Manager (6 respondents)  
 Staff Nurse (6 respondents)

**Physicians**

Physician (6 respondents)  
 Resident (3 respondents)

**Other departments and areas**

Director, Biomedical Engineering  
 Director, Materials Management  
 Director, Risk Management  
 Quality Improvement Coordinator  
 Staff Education Coordinator

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significantly increase patient safety and decrease the risk of medication errors. While some institutions may have already implemented many of these goals, the programme will ensure that *all* hospitals in the region achieve these threshold objectives over a reasonable period of time. To assist each institution in implementing these 16 objectives, the partnership provides a wide array of technical, consulting and educational tools and services. The 16 action goals are categorised under four primary headings: institutional culture, infrastructure, clinical practices and technology (table I). A brief description of each area is outlined below.

### 5.1.1 Institutional Culture

The commitment to safety must permeate throughout the organisation from board leaders to the support staff. This is possible only when the culture of the institution encourages each employee to report errors or potential errors without fear of reprisal, recognises and rewards safety innovations,

and includes all stakeholders as part of the process, including the board, administration, physicians, employees, patients and patient families.

The programme assists each institution in creating this organisational culture by providing tools to review current policies, orient all new employees on medication safety, review medication safety annually during in-service education programmes, assist in development of continuing medical education (CME) programmes for medical staff, and encourage annual competency reviews for all professionals involved in the medication process. Programmatic tools include training videos, posters, sample policies, a patient pledge and in-service educational course outlines. In addition, the programme includes initiatives to directly involve and educate patients as well as the wider community about their role in medication safety. Finally, each hospital receives assistance to create a reward and recognition programme for safety innovation.

### 5.1.2 Infrastructure

While hospitals invest enormous resources in quality assurance efforts and are subject to extensive oversight by government as well as private accrediting bodies, the HCIF/ECRI/ISMP and the participating hospitals partnership believes there are additional steps that each organisation should take to support and enhance medication safety. Each institution should assign to an appropriate employee the role of medication safety officer, who will serve as liaison between the partnership and the hospital at the operational level. The safety officer is responsible for coordinating the institution's safety programme, establishing a hospital-wide medication safety committee, and representing the hospital on regional safety initiatives sponsored by the partnership. Hospitals are encouraged to have a full-time dedicated patient safety officer. While this may not be feasible in all cases, the programme is tailored to assist any patient safety officer by providing hands-on training, medication safety tools and scheduled on-site assistance. The cost of the patient safety officer is borne by the institution. Each institution should also identify a physician champion to work with the safety officer. Patient safety officers are encouraged

to seek out physicians interested in helping promote the medication safety agenda. The programme recognises that without physician support, many of the action goals may not be achievable. The programme encourages those physician champions to take an active role in promoting medication safety initiatives to their peers through one-on-one encounters, continuing medical education presentations and participation in hospital medication- and patient safety-related committees. Programmatic tools include train-the-trainer workshops, structural recommendations for safety committees and regional educational sessions on medication safety. Each hospital's patient safety officer receives two full days of medication safety training as part of this programme. Training includes strategies for implementing medication safety initiatives, overcoming barriers to implementation, optimum utilisation of the programme's tools and educational aids, and opportunities to network and collaborate.

To further strengthen the safety infrastructure at hospitals, the programme offers assistance in ensuring safe medication access and storage, recommending area-specific stock needs, reviewing the utilisation of unit-dose and premixed packaging, evaluating automated drug distribution systems and encouraging the standardisation of emergency equipment and medication. While the programme promotes the use of additional clinical pharmacists in high-acuity areas, this objective may be accomplished over an extended period.

Finally, tools designed to enhance existing communication mechanisms, such as sample job descriptions, educational opportunities, on-site safety reviews and sample intake forms, will help to ensure that all members of the delivery team are aware of critical medication information related to each patient.

### **5.1.3 Clinical Practices**

The alteration of certain clinical practices can lead to immediate improvements in medication safety. Since these practices involve all participants in the medication process, it is imperative that comprehensive in-service education programmes are an

integral part of any effort to modify existing practices.

The programme provides a list of abbreviations and dose designators that are problematic and should be eliminated; safety checklists for medications and devices with high probabilities of causing errors; protocols on reducing errors associated with verbal orders; and safety checklists for infusion devices within the institution. Finally, the programme provides each hospital with an educational tool to evaluate new drugs and devices for their error potential prior to introducing them into the institution, as well as a list of markers that may be indicative of potential errors requiring investigation.

### **5.1.4 Technology**

While technology continues to improve daily, no technology-based methods are currently available to eliminate completely the possibility of a medication error. Representatives of ECRI and ISMP are constantly monitoring the latest clinical information and medication delivery systems for their error reduction potential. Under this programme, all hospitals receive the latest information on relevant new technology as well as assistance in more effectively targeting scarce resources on this technology.

For example, ECRI will work with members of each hospital's staff to eliminate infusion pumps that do not have set-based free-flow protection. Education programmes will inform staff about the dangers of free-flow pumps. Hospitals will have the opportunity to review available alternatives to their existing free-flow inventory.

In addition, under the programme, ECRI and ISMP will provide the latest information on CPOE. A tool kit including infrastructure requirements, equipment specifications, the latest evaluation on current systems, and a request-for-proposal template will be provided to guide hospitals in the CPOE selection process.

## **5.2 Programme Progress**

Since its introduction in February 2001, the programme has sponsored several major educational seminars as well as numerous smaller sessions for healthcare providers representing medicine, risk

management, pharmacy and managed care. Information sessions have been provided for hospital trustees and administration and medical staff, who have provided the leadership and guidance necessary for assuring the programme's success. Two full-day comprehensive training sessions have been provided for hospital-appointed patient safety officers to assist them in operationalising the programme's objectives and implementation methods and strategies for the 16 action goals. Other educational programmes reviewed the culture of safety and CPOE systems.

Through the programme, hospitals have already received several tools and aids to assist them in implementing the 16 action goals. Each hospital received programme posters and a medication safety binder containing practical strategies for communication and implementation of the stated action goals. In addition, a series of medication and device safety checklists and CPOE procurement kits were provided. A safety training video relating to high-alert medications will be released in early 2003, and three other training videos are in production. As previously stated, the purpose of the Regional Medication Safety Program for Hospitals is to ensure that all Delaware Valley hospitals adopt and implement a uniform set of 16 proven medication safety practices that reduce the potential for medication error and benefit all patients throughout the region. Therefore, the only outcomes to be measured are the number of hospitals agreeing to participate and the success in implementing each of the 16 goals. The sole purpose of the programme is to move the entire region in a consistent and uniform fashion by providing leadership, direction, assistance and guidance.

For additional information about this programme, please access the Delaware Valley Healthcare Council's website at [www.dvhc.org](http://www.dvhc.org).

The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) recently designated the Regional Medication Safety Program for Hospitals one of the top five patient safety collaborative efforts in the US. Five of the eleven 2003 patient safety guidelines recently released by the JCAHO, mirror the programme's action goals.

## 6. Conclusion

Critics say that healthcare providers are slow to adapt systems that could make healthcare safer. Healthcare may have a higher rate of error than other industries, but healthcare also struggles with a higher level of intrinsic uncertainty, increasing complexity and a rapidly changing infrastructure. Although this situation does not, by any means, excuse medical error, it does make it more difficult to combat. Education, appropriate use of technology and expertise, and a systems approach provide the best opportunity for improvement.

The Regional Medication Safety Program for Hospitals offers a very real opportunity to improve care provided to all patients in hospitals throughout the Delaware Valley via the systematic introduction of attainable safety goals through a cohesive programme. While individual hospitals are constantly working to enhance the quality of their services, a region-wide coordinated campaign ensures that all patients rapidly benefit from advances in patient safety. The potential success of the programme is greatly enhanced by the unique partnership between HCIF, ECRI and ISMP, which results in an exceptional combination of access, knowledge, technical assistance and production capacity. The successful implementation of this programme will catapult this region's hospitals and health systems into a leadership position with regard to safe medication practices, by offering a proven programme that could benefit other hospitals in other regions of the world.

With few exceptions, neither consumers nor third-party payers have shown a willingness to pay more for a safer or higher quality product, or to share in the costs of the resources necessary to achieve these goals. Therefore, it remains a hard decision for a healthcare administrator, with shrinking reimbursements, increasing labour costs, sky-rocketing liability expenditures and competing demands for capital, to invest millions of dollars into a technology or process, unless there is a clear measurable benefit to the entity.

For lasting improvement to occur, research must identify the tools that are the most effective in reducing error, most cost-effective and most easily

implemented. Payment policies need to be addressed to compensate facilities for implementing these tools. Tort reform must be achieved to allow the open reporting, analysis, and discussion of error, which will lead to the systems reengineering that will prevent error.

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