To err is human

The pharmacy industry moves toward a systems approach to error prevention

BY JAN WEAVER

Human beings inevitably make mistakes. This realization finally is prompting the healthcare industry to consider a systems-oriented approach to preventing medication errors. Providers are moving from the traditional malpractice paradigm of individual blame to a more constructive approach that examines protocols, human factors, and product design.

JULIE SWEANY/ARTIST

Lucian Leape, MD, a pioneer in healthcare errors research, made this analogy in a 1995 *Journal of the American Medical Association* article, "Systems Analysis of Adverse Drug Events": "Errors are like symptoms of disease—they can be caused by multiple conditions, and treatment of the error or symptom does not correct the underlying malfunction."

Leape presented 10 steps for reducing medication errors at last year's multidisciplinary healthcare errors prevention conference in Rancho Mirage, Calif.

The sheer number and costs of errors should be enough to suggest that current methods aren't working. Deaths resulting from medication errors occur at a rate of one to two per day. And according to one recent estimate, prolonged hospital stays caused by preventable adverse drug events cost an average of $2.8 million per year at a typical teaching hospital.

Heightened awareness. While these figures are persuasive, it might have been the widely publicized death of *Boston Globe* healthcare reporter Betsy Lehman at the Dana-Farber Cancer Institute in 1994 that provided the impetus for change. She died from a fourfold overdose of a chemotherapy drug while undergoing treatment there for advanced breast cancer. The error—misinterpretation of an ambiguous drug order—occurred not because one practitioner erred, but dozens. Lehman, a savvy healthcare consumer, had nonetheless fallen victim to a massive oversight that can be attributed only to faulty systems.

Recent national initiatives reflect a growing awareness of medication errors and a shift to a systems approach to correcting them. At the Rancho Mirage conference, Nancy Dickey, MD, chair of the board of trustees of the American Medical Assn., announced the AMA's establishment of a National Patient Safety Foundation. The Foundation will "target the interaction between human factors and complex management systems that can result in patient injury when it breaks down," she told conference attendees.

At this same conference, the Joint Commission on Accreditation of Healthcare Organizations announced an "accreditation watch" policy that will identify those healthcare organizations where preventable injury or death has occurred. Under the "watch," organizations are required to provide a "root cause analysis" of an error within 30 days.

Late last year, the National Coordinating Council for Medication Errors Reporting and Prevention released some simple recommendations aimed at reducing medication errors. Established in 1995, NCCMERP is an independent council composed of representatives of provider organizations, consumer lobbies, manufacturers and regulators. Their goal is to "promote reporting, understanding and prevention of medication errors," according to a Food and Drug Administration bulletin.

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The data dilemma. Meanwhile, United States Pharmacopoeia (USP) is asking healthcare organizations to contribute their models for medication error reporting systems. Their goal is to "stimulate the development of reporting systems within healthcare organizations and encourage reporting to national databases."

Because the U.S. system is voluntary, errors tend to be under-reported. This creates a barrier to addressing errors because it is impossible to ascertain their scope. To compound the problem, many different definitions of errors exist. One study might define an error as any deviation from recommended procedures. Another might define this deviation as an error only if it results in an adverse event.

Susan Proulx, PharmD, vice president of operations at the Institute for Safe Medication Practices (ISMP) says: "We get all the FDA's *MedWatch* reports and all USP's reports. Even so, we only get a very small piece of what's actually going on out there. We can't get real numbers."

Located in Warminster, Pa., ISMP provides error-prevention consulting services to healthcare providers and to pharmaceutical manufacturers.

Despite under-reporting, ISMP's public affairs advisor Rebecca Wilfinger says that a growing body of error data is providing momentum for change. "It's like we've reached 'critical mass,'" she says. "You can really see the difference when information about a product that has been associated with errors is shared with other healthcare providers," she adds. "But that critical mass couldn't have been formed before you had the data to make those decisions."

Human factors. Error reporting is stifled by several things, including fear of litigation and punishment. ISMP's Proulx describes the healthcare industry's traditionally punitive mindset. "When an error occurs, it's assumed that someone didn't look at the product carefully enough, or that someone wasn't doing their job correctly," she says. ISMP instead looks at the factors that allowed the error to occur. "We look at what went wrong, not who did it," Proulx says.

Their approach is proactive, employing a technique used in the aerospace, automotive, and chemical industries to anticipate and prevent errors. Known as failure mode effects and analysis, "It looks at a given process, identifies possible or likely errors, and gauges what their effect will be—even before they take place," wrote ISMP president and co-founder Michael Cohen in a 1994 issue of *Hospital Pharmacy.*

While ISMP offers a proactive approach, the request for a consult is often in response to an error that has already occurred, Proulx says. But this is starting to change. "Some hospitals are being proactive. They admit their system isn't perfect and call in ISMP," she goes on.

During a consult, ISMP representatives spend one to two days at the hospital, extensively reviewing its drug prescribing, dispensing, and administration systems, and talking with various departments—nursing, pharmacy, physicians, and P&T committees. In addition, they might concentrate on particular problem areas, such as oncology, the emergency room, or the intensive-care unit. Finally, they talk to the front-line practitioners, "the ones doing the

work." ISMP develops a report based on their observations.

In addition to offering consulting services, ISMP publishes a subscriber-supported newsletter featuring analyses of selected incidents with recommendations to prevent them. They also publish articles in pharmacy and nursing journals, reaching 1.5 million healthcare professionals per month. Proulx says their audience will expand to 1.75 million as a result of plans to publish in physician publications. These include *Family Practice News, Internal Medicine News,* and *OB-Gyn News.* "Our role is to get the word out to as many people as possible," Proulx says.

The error trail. Medication errors may begin with product naming, labeling, and package design, and may occur at any stage before the drug reaches the patient—prescribing, dispensing, or administration. ISMP has identified 13 different systems along this route to which FMEA can be applied.

To counter these common errors, ISMP uses such FMEA principles as standardization of drugs and dosages, simplification of procedures, and use of redundancies or fail-safes that ensure an order is checked and double-checked. Unit dosing is one kind of fail-safe system, Proulx says, and is used by a high percentage of hospitals for oral solids, as well as for IV medications and liquids.

Clinical Drug Information Specialist Sara Beis, RPh, MS, describes fail-safes employed at Henry Ford Health System in Detroit. Prescription forms there are designed to include the patient's diagnostic code so the pharmacist can ensure the appropriate drug was ordered. For pediatric prescriptions, another space is provided to include the patient's age so the pharmacist can verify the dosage, Beis explains.

FMEA recognizes that not all errors can be prevented. So, systems built on FMEA principles are designed with "error traps" that prevent mistakes from becoming accidents. The measures Beis describes could be viewed as errors traps because they prevent the error from reaching the patient.

Why has the healthcare industry been slow to embrace these methods that have proved useful in other industries for decades? Healthcare professionals simply are "not systems oriented," Beis says. By nature and by training, they are driven by individual achievement, not teamwork, she says. But since errors occur along the entire spectrum of care, a multidisciplinary team approach is needed to address them properly.

Packaging matters. Because mistakes result from the interaction between people and products, ISMP also contacts drug manufacturers about errors related to packaging, labeling, or nomenclature. If their

research uncovers a problematic product characteristic, they can alert the pharmaceutical manufacturer to the potential for error. "Usually, they won't do anything until a real problem occurs because it's costly [to change packaging]," Proulx says. However, a company will sometimes contact ISMP when it is planning to repackage or rename a product.

Product-related errors can occur when two drugs similarly have spelled or pronounced names, or when their packaging looks similar. "If you're looking for a green vial with a pink stripe on the side, as soon as you see a vial that looks like that, you won't bother reading the name because you'll think you've found what you were looking for. But it sometimes turns out that drug A and drug B both have similar-looking vials, and you picked drug B by mistake," Proulx says.

Deadly errors have frequently occurred because the packaging for potassium chloride was at one time nearly identical to that of sterile water for injection. ISMP's Cohen said that ISMP and the FDA had 70 such cases on record before the product was renamed and relabeled in 1993. Since then, no reports of potassium chloride/sterile water mix-ups have been made. Cohen's comments were published in the *American Journal of Health-System Pharmacy's* 1995 proceedings of the multidisciplinary conference, "Understanding and Preventing Drug Misadventures."

Playing telephone. In most cases, the redundancies advocated by FMEA create "layers of safety" that prevent errors from becoming accidents. But in the case of handwritten or verbal drug orders, these intermediaries might actually increase the possibility of errors of transcription or translation. "These checks can increase the possibility for error," Proulx says. This is where computerized prescribing can help. Physicians' use of computerized order entry would reduce errors of both verbal and written communication.

Such a system would work in concert with a database containing information about all likely dosages for various drugs. A request that seems inappropriate or out of range would elicit a warning, asking the physician to confirm the order. The computer can also be programmed to provide warnings in the case of a drug name that could easily be confused with another.

"You have to be careful [with these warnings] so that you don't bombard the health professional with them. If that happens, the warnings may be ignored," Proulx adds. She recommends being selective about the information that is included. Alerts may be appropriate for newer drugs or those that can have more serious consequences if improperly prescribed.

While technological solutions are promising, existing information systems in hospitals are hindered by a lack of integration. Pharmacy and laboratory computers frequently are not linked, and patient records are often unavailable to pharmacists.

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crease of 154 patient life years. The average cost per life-year saved decreased by $8,400.

Measures are critical. If we consider the types of outcomes used in cost-benefit and cost-effectiveness analysis, there is another reason why CEA has more practical application than CBA. In order to compare outcomes across different types of programs, CBA requires us to convert outcomes into a common denominator. This is generally dollars, but other measures, such as years of life saved, can also be used. These measures must be fairly definite and comparable across treatments.

However, we are still in the early stages of outcomes measurement, and often we do not know for certain what the impact of a particular intervention will be. This is certainly true of the more subtle outcomes. According to Mary Cifaldi, RPh, MHSA, manager of health outcomes research at Hoechst Marion Roussel, "One of the biggest challenges facing outcomes research today is the development of tools that are sensitive to outcomes such as quality of life."

CEA, on the other hand, uses cost indicators to compare different approaches to treatment. Cost measures are much easier to obtain. The cost of an intervention that reduces or eliminates hospital utilization, for example, can readily be compared to the cost of an intervention carried out in an inpatient setting.

The widespread transition from inpatient to outpatient treatment settings, which characterized health care in the 1980s, was supported by CEA studies. Once the efficacy of new treatment modalities, such as outpatient chemotherapy or same-day surgery, was demonstrated, it only remained to compare the costs of the new and old approaches.

Both CBA and CEA offer us a way to account for efficiency in our decisions about clinical programs. If we are trying to determine the best use of our resources, or if two clinical interventions have equal merit in terms of their efficacy, these tools enable us to make meaningful comparisons between the alternatives. What is sometimes forgotten is that CBA and CEA force us to think about clinical outcomes. In order to conduct a meaningful analysis, we must first determine the clinical benefits of each program or treatment under consideration.

This is the real challenge facing health care providers today. All managed care delivery systems will have to learn to use resources wisely, but the successful ones will be those that offer improved-health status outcomes. **MHC**

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"The pharmacist may not have access to essential information on a patient to determine whether a dose is appropriate. They need to know whether the patient has an allergy or kidney damage that may affect the dosing or scheduling of a drug," Proulx says.

The last line of defense. One of the most effective error traps is an informed patient. Proulx stresses the need to make patients or their caregivers active participants in their care. Patients who have been educated about their medication are able to catch errors before a drug is administered.

In January, Health and Human Services Secretary Donna Shalala recognized the patients' role in error prevention by unveiling the MedGuide plan, which requires pharmacists to provide understandable written drug information for patients. The program is a joint public-private endeavor conceived by a 34-member steering committee representing pharmacists, physicians, and consumer and patient advocacy groups.

The MedGuide plan is "aimed at improving patient understanding of prescription drugs and reducing the misuses of medications that currently lead to thousands of hospitalizations each year," according to an HHS press release. Under it, compliance is voluntary unless the plan's objectives are not met. The new rules require useful drug information to reach 75% of patients by 2000 and 95% of patients by 2006. MedGuide will allow each pharmacy to develop its own way of communicating drug information.

"We're hoping that the MedGuide initiative on top of OBRA will help in getting information out to the patients," Proulx says. The 1990 Omnibus Budget Reconciliation Act requires pharmacists to counsel all patients receiving first-time prescriptions.

A study of prescribing errors published recently in *JAMA* strengthens the argument for pharmaceutical care. Timothy Lesar, PharmD, and colleagues found the most common errors at Albany Medical Center, N.Y., were caused by the physician's failure to consider patient characteristics when selecting drugs and dosages.

Such fine tuning must be based on extensive drug knowledge, which is the domain of the pharmacist, not the physician.

Lesar recommended improved prescriber education to combat errors as well as an "expanded use of the expertise of pharmacists through better integration with the healthcare team."

In addition to a pharmacist's expertise, though, the drive to reduce medication errors will depend on communications. Long ago, the epigramist Alexander Pope had it: "To err is human. To forgive divine." A modern complaint twists this: "To err is human. To really screw up takes a computer." This , when we confront medication errors, can be further amended: "To err is human. To avoid screwing up takes a computer." **MHC**

Jan Weaver's last story was on the management of congestive heart failure.