Accelerating Change Today

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FOR AMERICA'S HEALTH

FEBRUARY 2000

Reducing Medical Errors and Improving Patient Safety

Success Stories from the Front Lines of Medicine

THE NATIONAL COALITION ON HEALTH CARE
THE INSTITUTE FOR HEALTHCARE IMPROVEMENT

Accelerating Change Today (A.C.T.)

FOR AMERICA'S HEALTH

A.C.T. is a collaborative initiative of the National Coalition on Health Care and the Institute for Healthcare Improvement. It aims to improve the quality of health care in the United States through the identification of "best practices" and administrative and clinical innovations that are: (1) yielding better patients outcomes; (2) making the delivery of care more efficient; (3) increasing access to timely medical care; (4) making the health system easier to use; (5) lowering costs, and (6) reducing medical errors and inappropriate care. The initiative seeks to accelerate the spread of best practices and innovations throughout the health system by publishing them and through presentations at medical meetings and health care and business symposia. A central purpose is to make a broad range of health care stakeholders, including consumers and those who pay the health care bill, more aware of cutting-edge efforts to improve the quality of health care. The initiative will actively encourage the replication of best practices in health care facilities.

About This Publication

This report presents the stories of institutions and organizations that made a commitment to change and innovation in the field of patient safety and medical error reduction. The profiles herein reflect some of the most pioneering and innovative efforts underway in this field. The health facilities and organizations discussed in this report were identified by a team of six experts (see credits and acknowledgements). Their choice is in no way meant to imply that other institutions and health care facilities are not undertaking meaningful and laudable efforts to reduce errors and enhance patient safety.

THE NATIONAL COALITION ON HEALTH CARE

NCHC is the nation's most broadly representative alliance working to improve America's health and health care. It is comprised of 90 member organizations. They include some of the nation's largest businesses, labor unions, health care providers, consumers groups and religious organizations. The Coalition was founded in 1990. It is non-profit and non-partisan. Its members are united in the belief that America needs better, more affordable health care and that all Americans should have health insurance. Former Presidents George Bush, Jimmy Carter and Gerald R. Ford serve as the Coalition's Honorary Co-Chairs. Former Iowa Governor Robert D. Ray and former Congressman Paul G. Rogers of Florida are the Coalition's Co-Chairmen. NCHC is in Washington, DC. Founder and President Henry E. Simmons, M.D., M.P.H., F.A.C.P., is a widely respected pioneer in the field of health quality assessment and improvement.

THE INSTITUTE FOR HEALTHCARE IMPROVEMENT

IHI is an independent, non-profit education and research organization based in Boston, MA. It was founded in 1991 with the goal of fostering collaboration among health care organizations to improve the quality of health care. IHI each year holds a wide array of educational forums, symposia and workshops, and demonstration projects for medical professionals and health care administrators. IHI's co-founder and President, Donald M. Berwick, M.D., M.P.P., a practicing pediatrician and clinical professor at Harvard Medical School, is one of the nation's leading authorities on health care quality.

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Profiles of institutions and organizations that made a commitment to change... and a difference

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THE INSTITUTE FOR HEALTHCARE IMPROVEMENT

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Can we make health care SAFE?

BY LUCIAN L. LEAPE, M.D.

MEDICAL ERRORS—the very term sounds ominous. And well it should. When you enter a hospital or a nursing home, or go to a doctor's office, you don't always expect to be cured, but you certainly don't expect to be hurt! Yet, when the prestigious Institute of Medicine (IOM) in November 1999 released the landmark report, *To Err Is Human: Building a Safer Health System*, many Americans were shocked. The report contained this sobering, if not new, statistic: each year more than *one million* people in the U.S. suffer from preventable medical injuries and 100,000 die from them. As the media widely reported at the time, that's more than died in 1998 from breast cancer, AIDS and motor vehicle accidents combined.

The IOM panel, on which I served, called on health care organizations, doctors' groups, regulators, government agencies and Congress to make patient safety a priority. Within weeks, Congress launched hearings, President Clinton held a Rose Garden ceremony to appoint a task force, and a host of other groups launched initiatives. Health insurer Aetna said it would spend an extra $1 million this year on patient safety research. The American Hospital Association said it would join forces with the Institute for Safe Medication Practices to provide hospitals with proven strategies to reduce errors. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced it will begin making random inspections at hospitals to probe errors. And a business group led by, among others, General Motors, said it would pressure hospitals and doctors it contracts with to reduce errors.

This new momentum is profoundly welcome. After all, numerous past warnings, based on research results, went relatively unheeded. A critical mass appears now to have been reached. Indeed, it may not be hyperbole to say that a deep cultural shift on this issue is underway. At its core, this shift means redefining how to accomplish one of the basic tenets of medical practice: "*First, do no harm*."

The vital first task is to recognize that, as in other complex fields of science, technology, engineering, and human endeavor, errors in medicine are caused by failures in the systems and organizations that human beings build.

The evidence is overwhelming. Medical errors most often result from a complex interplay of multiple factors. Only rarely are they due to the carelessness or misconduct of single individuals. Yet, in the past, rather than addressing those underlying system design faults, error prevention strategies have relied almost exclusively on enhancing the carefulness of caregivers, heavily reinforced by fear of punishment for failure. But punishment drives reporting of errors underground, preventing the very systems examination that is needed to discover and correct the underlying causes. As the stories that follow show, when punishment is removed, reporting of errors sharply increases—often by 10 or even 20-fold.

Discontented, even horrified, by the status quo, a small band of health care leaders and organizations began to coalesce in the mid-90s around the mission of dramatically reducing medical errors. Their persistence and willingness to try new solutions has borne fruit, created models that have reduced some types of medical errors by 80 to 90 percent in just a couple of years, and yielded many important lessons.

The first is that leadership is essential. In its absence, efforts will be fragmentary, uncoordinated, and have only minor effects. The leaders of the institutions profiled in this publication understand that. They made highly visible commitments to make their institutions safer.

Second, change is difficult. Even with the most enlightened leadership, creating a non-punitive atmosphere is a major challenge. The urge to punish is deeply entrenched. And it is reinforced by the sincere belief of many doctors and nurses that errors result from individual carelessness. If there is any lesson to be learned from safe industries, it is that fear, reprisal, and punishment produce not safety but defensiveness, secrecy and personal anguish.

Third, health care professionals and staff are anxious to deliver safe care. When shown effective methods for changing systems to make them safer, doctors, nurses, and pharmacists eagerly and energetically embrace them.

Fourth, the problem of medical errors is not due primarily to a lack of knowledge. Rather, the chief culprit is inadequate dissemination and implementation of ideas and practices we know work. Recently, for example, the National Patient Safety Partnership (NPSP) released a list of 16 proven and accepted best practices in medication safety. Many have been known for years. Yet, most are not in place in the vast majority of hospitals, and no hospital in the country uses them all.

Fifth, safety pays. A single, preventable adverse drug event in a teaching hospital has been estimated to cost over $4,000. A serious injury can cost hundreds of thousands of dollars. Reducing injury rates by even 10 to 15 percent can yield large-scale savings. Most systems-level changes for safety require few extra resources. And even those that do require a significant up-front investment produce a full payback rapidly. For example, the most expensive system to allow doctors to write their orders at computer terminals may require an initial investment of $2 million to $3 million. But the proven ability of such a system to reduce medication errors by 50 to 80 percent within a year or two means most hospitals recoup the investment in a few years.

Finally, there are significant external barriers to improving patient safety. Hospital efforts to restructure their approaches to error prevention may be overruled by state boards of nursing, pharmacy or medicine, departments of health, or the courts. Reason: these institutions are still locked into a blame and punish approach to errors and a focus on individual culpability. In the name of accountability, a nurse loses her license because of a medication error or a doctor

is sued for an error-induced injury. The fear of malpractice litigation thus becomes a major barrier to openly discussing or reporting errors.

WHAT WE NEED TO DO

Reducing the risk of error in health care will require a substantial and sustained effort at all levels of the health care system. It must become a priority goal wherever care is given—the doctor's office, the hospital, and the nursing home. That goal must be supported by the commitment of both human and financial resources. The chief executive officer—or other leader—must articulate the vision of safe care that he or she calls upon others to work toward.

Leadership is also needed to redefine accountability. Some have been concerned that not punishing people for making errors relieves them of responsibility. Actually, the converse is true. In a safety oriented organization, every employee feels and accepts a personal responsibility to identify unsafe conditions, report them, and work toward their elimination.

Health care organizations must hold workers accountable to perform their duties carefully, conscientiously, competently, and safely. But they will still make errors. Who is responsible? The organizations and systems. Who is responsible for the systems? Managers. Consider a nurse who makes a serious medication dose error. If one of the factors leading her to make the error is that she is working a second shift, or has a doubled patient load, or is inadequately trained for her responsibilities, whose responsibility is that?

Of course, if a doctor or nurse has injured a patient through an error caused by egregious misconduct, neglect, or criminal activity, he or she must be punished. But if such a person had a prior history of reckless behavior and disregard of safe practices, why has he or she been permitted to continue working?

Simply put, management must "manage" for patient safety just as they manage for efficiency and profit maximization. And safety must become part of what a hospital or health care organization prides itself on.

But accountability needs also to work in reverse. Regulators and accrediting bodies should be held accountable to the public and the professions to set and enforce safety standards. The plain fact is that many hospitals do not initiate error reduction programs because no one demands it. Inertia prevails. If, for example, the JCAHO or the Health Care Financing Administration (which runs Medicare) were to require full implementation of the NPSP safe medication practices for accreditation or payment, I'm quite sure nearly 100% compliance would occur within a short period of time. Likewise, if the Food and Drug Administration required pharmaceutical companies to label medications in a standardized, readable manner, in bar-coded packages, and if they only approved new drug names that would not be confused with other medicines, medication errors would decline substantially.

Safe industries don't shy away from standards that reduce the risk of injury. They embrace them, recognizing the only way to achieve safe practice is to clearly spell out what it is and require it. We have strict rules governing working hours, procedures, equipment, and maintenance for our airlines and railroads. But we have few such rules in health care. The need is obvious, and opportunities abound: standards for maximum working hours, work loads, staffing ratios, expertise (pharmacy, intensivists, ER specialists, etc.), safe medication practices, and many others.

The IOM panel called for the Agency for Healthcare Research and Quality to establish a Center for Patient Safety. One of the key functions of such a Center would be to convene groups to set such standards.

Finally, regulators and accrediting bodies need to become much more positive forces for safety in health care, both in terms of preventing errors and in the way they react to them. When mistakes occur, they need to shift their focus from individuals to organizations, requiring both a thorough investigation of the underlying systems failures and a plan that addresses those failures.

The publication you hold in your hands presents case studies of hospitals, health facilities and organizations that have made the commitment to systematically reduce the risk of patient harm in health care. Their stories show the dramatic results that can be achieved, often in a short period of time. The profiles also shed light on the obstacles that get in the way of reducing errors, the mechanisms by which change occurs most efficiently in organizations, and the very human process of shifting the prevailing paradigm on this issue. The stories will enlighten you. But more than that, I hope they will motivate you to act—to push your institutions to get involved in the struggle to make sure that health care, first and foremost, does no harm.

The author is an adjunct professor of health policy at the Harvard School of Public Health.

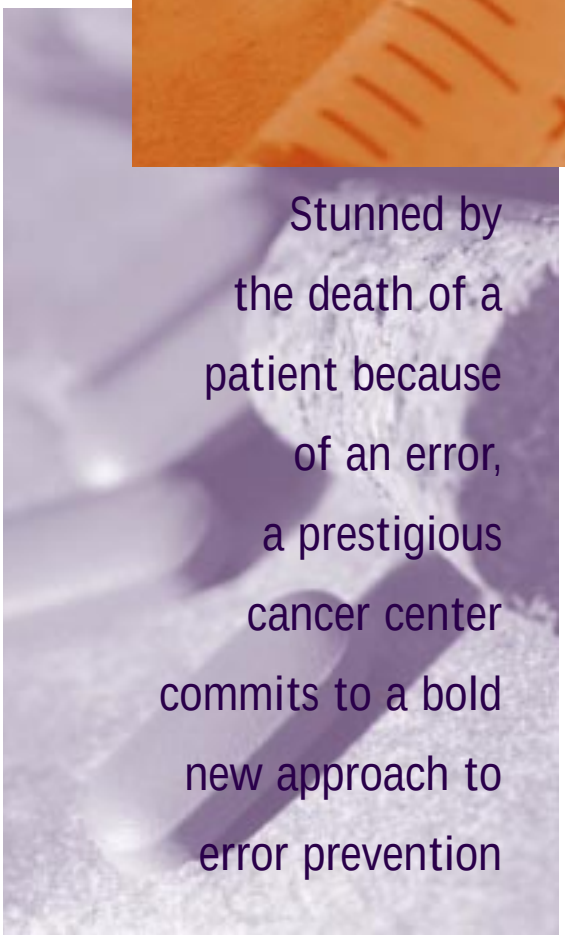
THE INSTITUTE OF MEDICINE'S KEY RECOMMENDATIONS

- Congress should create a federal Center for Patient Safety that sets national goals for medical error reduction and tracks progress in meeting those goals.
- Congress should authorize the creation of a nationwide mandatory medical error reporting system to collect data on errors that result in death or serious harm to patients.
- Federal and state laws should encourage the development of voluntary medical error reporting systems in all health care facilities, to include reporting of all events that could have harmed patients.
- Data and information on medical errors should be legally protected when used by professional peer review organizations to improve health care quality.
- Medical professional societies and health care licensing bodies should focus greater attention on patient safety.
- The Food and Drug Administration should increase attention to the safe use of drugs.
- Health care facilities and organizations should make continually improved patient safety a declared and serious aim and implement proven medication safety practices.

BACK FROM THE BRINK

Making Chemotherapy Safer

BY CHRISTINE PAUL



Stunned by the death of a patient because of an error, a prestigious cancer center commits to a bold new approach to error prevention

Dana-Farber Cancer Institute
Boston, Massachusetts

Every medical facility's worst nightmare became a reality for Boston's prestigious Dana-Farber Cancer Institute in the early winter months of 1995. Two patients being treated in an experimental drug study for advanced breast cancer, the Institute belatedly discovered, had received massive overdoses of chemotherapy in November 1994. On December 3, one patient had died as a direct result of the error. The other suffered permanent heart damage. Complicating a tragic situation for all, the patient who died—Betsy Lehman, 39—had been a medical reporter for the *Boston Globe*. The paper trumpeted the death when it learned that a medical error was the cause. And it dug into every crevice to ferret out what had happened and affix blame. The case quickly attracted national media attention and was followed closely for months. Indeed, the Dana-Farber incident became the highest profile medical mistake in the U.S. in decades, perhaps ever.

Stephen Sallan, M.D., a senior oncologist at Dana-Farber when the overdoses occurred and now chief of staff, recalls that difficult time: "It shocked and saddened us in very profound ways, both professional and personal. For months, a pall hung over the Institute. Everyone was deeply affected, because after all, we are caring and conscientious people in the business of saving lives."

As in the wake of all tragedies, life goes on for the survivors—but it is also changed forever. Reeling from the bad publicity and glare of the spotlight, Dana-Farber undertook a painstaking internal examination of what went wrong. State authorities also probed the case. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) placed the Institute on temporary probation. Five years later the investigations and lawsuits are only beginning to wind down.

But Dana-Farber didn't stop at just uncovering what went wrong. Seeking to wrest from the tragedy something of lasting value not only for Dana-Farber but for health care facilities and patients everywhere, the Institute's leadership boldly committed themselves to making Dana-Farber a model of patient safety and error prevention.

Today, many experts in the field think they have succeeded. Dana-Farber has pioneered new systems to prevent mistakes in the delivery of chemotherapy agents—systems that are being emulated by others. And in making error prevention a top priority throughout, Dana-Farber has raised the profile—in a positive way—of the very issue that brought the facility to its knees just a few short years ago. "We wanted to find and fix the root causes of our mistakes. But we also wanted to make our systems the best in the world at preventing errors while providing the latest in cancer care," says James Conway, M.B.A., Dana-Farber's chief operations officer.

A pharmacist rechecks the drug order with a technician as part of Dana-Farber's drug order entry system. *(Photo by Steven Gilbert, StudioFlex Productions)*

High-tech safeguards

Like many hospitals that have traced the "root cause" of a fatal medical error, Dana-Farber's doctors, nurses and administrators discovered that behind the human error that caused the death were a host of "systems errors." The saga began when Betsy Lehman and Maureen Bateman, 52, were admitted on November 14 and 16, respectively, for treatment of recurrent breast cancer. The physician in charge of their care was fully aware of the protocol of the clinical study under which they were to be treated. It was designed to test whether cimetidine, a common anti-ulcer drug, could boost the tumor-killing effects of cyclophosphamide, a powerful anticancer drug. The drug therapy was to be administered over four days, followed by a bone marrow transplant to restore the patients' blood-forming and immune cells, which unavoidably are destroyed by high doses of chemotherapy.

Unfortunately, the doctor wrote the drug's total four-day dose to be given daily for four days. The backup system in place at the time was not designed to catch such an error. Nurses involved with the patients' care were able to check the order against the protocol to ensure that the right drug, dosage, frequency, route and time were being followed per the doctor's written order. In this case, however, a protocol written and approved by research scientists, rather than the clinicians administering it, seemed to confirm that the high dosage level was appropriate. "The fact that physicians and scientists think of dose in terms of course of therapy, and nurses and administrators think in terms of daily dose, played a significant role in the overdose," says Conway. At the time, there was no computer system in place to monitor the amount of the drug ordered—and signal a possible error. As a result, both women received four times the daily dose. It was a toxic blow to their hearts. Lehman died three weeks later. Bateman survived, but with a damaged heart, and died of cancer several years later.

Dana-Farber's first corrective action was to put in place a computerized system for drug and chemotherapy orders. It also launched a series of backup systems and set in motion a many-pronged effort to strengthen its "team approach" to treatment and care delivery. Finally, it sought to create an institutional culture that encouraged the reporting of errors, no matter how small.

When you walk into Dana-Farber's clinical areas today, you're very likely to see something you would not have seen just a few short years ago: a physician at a computer terminal. In many hospitals and clinics, computers are, of course, indispensable for administrative purposes. But doctors and nurses still order treatments and make care decisions based on "hard copy"—written patient charts and other paper-based forms. Dana-Farber is changing all that.

"We basically asked which pieces of our system could be taken out of human hands and given to a computer with built-in safeguards," says Lawrence Shulman, M.D. Shulman oversees Dana-Farber's clinical service for adult patients, for which drug ordering is now completely computerized. (The hospital's pediatric service is reviewing a transition to a similar system.) "As for the components that remain in human hands, we designed a comprehensive system of double and triple cross-checks," he added.

Gone are slips of paper, handwritten scribbles and lined paper that can easily hide a critical decimal point. Instead, for adult cancer patients the doctors must fill out an electronic form. After typing in the patient's name, weight, and height (critical to proper dosing), the physician indicates the intended drug, dose, and number of days it is to be dispensed. The computer compares this data with a preprogrammed set of drug-specific guidelines with established high-dose limits and route of administration. Dana-Farber's staff developed these guidelines by searching the scientific literature and drawing on their own expertise. The primary focus is on the "five rights": give the right drug to the right patient at the right dose through the right route at the right time. If the doctor makes a mistake—for example, typing in 300 milligrams instead of 30 milligrams—the computer signals a possible error. The only way to override a dosage that exceeds the preestablished limit is for a senior physician to provide a reason for the deviation. Such changes are then double-checked by nursing and pharmacy staff. The system handles more than anticancer drugs. It

A WAKE-UP CALL

Dana-Farber's staff and patients as well as academic experts in medical-error prevention are often asked to share their insights at local, regional and national conferences. Below are key messages directed to health care stakeholders.

PATIENTS

"The best thing you can do is let your health care providers know when something isn't going well and how they might help. Once it's on their radar screen, they can start dealing with it."

Judie Beard, cancer survivor, member of Patient-Family Advisory Council

PHYSICIANS

"We need to acknowledge that we're all human beings and that error is always a possibility. We need to work together to create an environment and culture that minimizes the likelihood of error."

Lawrence Shulman, M.D., Vice Chair of Clinical Services, Adult Oncology

NURSES

"Listen to the users of the system—the nurses, doctors, pharmacists and patients—and encourage them to identify ways to simplify and standardize the system."

Susan Grant, R.N., Chief of Nursing and Patient Care Services

PHARMACISTS

"Don't just focus on the individual person or individual departments. Instead, work together to look at the whole patient-care system."

Sylvia Bartel, R.Ph., Director of Pharmacy

RISK MANAGERS

"Promote a non-punitive environment for reporting error. It encourages the reporters to identify system problems and assists in preventing errors."

Maureen Connor, R.N., Director of Risk Management

EXECUTIVE OFFICERS

"The effort to prevent medical errors can only be successful if executive leaders make patient safety one of their priorities."

James Conway, M.B.A., Chief Operations Officer

TRUSTEES

"The function of Dana-Farber's board of trustees has changed in fundamental ways. They now see error prevention and quality control as central to their role."

Richard Bohmer, M.B.Ch.B., M.P.H., Senior Lecturer, Harvard Business School

also automatically signals for auxiliary treatments, such as anti-nausea drugs, to be included in the patient's treatment.

Dana-Farber's customized computer system cost $1.7 million. It's an integration of two computer checking systems—a pharmacy checking system developed at Dana-Farber and an order-entry system adopted from Brigham and Women's Hospital, a sister institution (See story page 12). Since 1996, through a joint venture titled Dana-Farber/Partners CancerCare, three premier Boston institutions—Dana-Farber, Brigham and Women's, and Massachusetts General Hospital—provide collaborative services in adult oncology. Today, the majority of care provided at Dana-Farber consists of chemotherapy done in an outpatient setting. Surgery, radiation therapy, and other procedures requiring hospitalization are done at its sister hospitals. To further integrate the drug order-entry system, an even more sophisticated computer system is now being phased in gradually at all three institutions.

Double and triple checks

When it's time to dispense medicines, the checking continues. Before ordering a drug from the pharmacy, a nurse reenters the patient's weight and height into the computer. If they differ by more than 5 percent, the computer returns the order to the senior physician for reverification and signature. The discrepancy may be caused by a measuring or reporting error, or it may be due to a change in the patient's weight, which is not uncommon in cancer therapy.

At the pharmacy, there's another computerized review—for drug-drug, drug-food, or drug-allergy reactions. The drug order is checked against the patient's medical history, including allergies, current lab results, verification of registration in a clinical study, and the protocol itself—anything that might signal possible error.

Once okayed and prepared by the pharmacy, the drug is then delivered to the nursing station. Two nurses check the drug's label, as well as the patient's wristband, to ensure it's going to the right patient. For experimental therapies, there's a triple-check. The patient is then closely monitored to detect and respond to any adverse reactions such as weakness and nausea—which often become even more pronounced with higher doses of chemotherapy. Betsy Lehman, for example, had voiced complaints. But such side effects were not unexpected. And in the absence of the comprehensive checking system that is now in place, the physician's error in writing the order went undetected. In fact, her overdose wasn't discovered until three months later when an assistant data manager was recording research statistics.

Cultural shift

That lapse got Dana-Farber's doctors and administrators to ask some bold questions. Were nurses, pharmacists, and technicians reluctant to question a physician's orders or treatment plan? Did the professional culture encourage their input? Was

everyone working together to ensure that care was both optimal and safe? The discouraging answer was that communication between these various health professionals around the issue of medical errors and patient safety was less than optimal. That led Dana-Farber to commit to nurturing a "team approach" to the prevention of errors similar to that emphasized in, say, doing an operation.

To that end, Dana-Farber set up a Pharmacy Performance Improvement Team. The team meets twice a month and is now part of the 15-member Pharmacy and Therapeutics Committee. Says Sylvia Bartel, Dana-Farber's pharmacy director, "Each of us can freely question any aspect of a proposed treatment plan." Beyond that, management has emphasized that all personnel should feel free to raise questions if they see anything that doesn't look right. Physicians are also exhorted to work with nurses and pharmacists to continuously review treatment decisions. And as new cancer treatment protocols are developed, they are evaluated by a multidisciplinary team which puts safety high on its criteria list.

This questioning spirit is especially important in shaping the guidelines for experimental therapies, which often carry higher risks. Certain patients, whose disease progression affords them no other options, are willing to receive new drugs, drugs at new strengths, or in novel combinations with other medications or procedures. Betsy Lehman, for example, had volunteered to be part of a breast cancer study involving high doses of one drug whose powers were enhanced by another.

The team's focus is on anticipating problems and preventing errors in the first place, not just trying to fix things after they occur. Pooling their expertise often leads to unanticipated solutions. "I could never go back to our old clinical practice model," says Bartel. "Sometimes I wonder why we didn't think of this before; it makes so much sense. Then I realize it's because we didn't have to think about it; the culture wasn't there to support it."

Patients are also considered "team members." "The more informed the patient is, the safer we all are—the patient and the system. We encourage them to speak out," says Susan Grant, R.N., Dana-Farber's chief of nursing and patient care services. Indeed, Dana-Farber has made ongoing patient education a top priority. A new Patient-Family Advisory Council advises staff on ways to enhance care. Some Council members accompany the medical staff on hospital rounds to get patient feedback. "We are truly welcomed on these rounds," says cancer survivor Judie Beard. "When mistakes are uncovered, the staff genuinely wants our input."

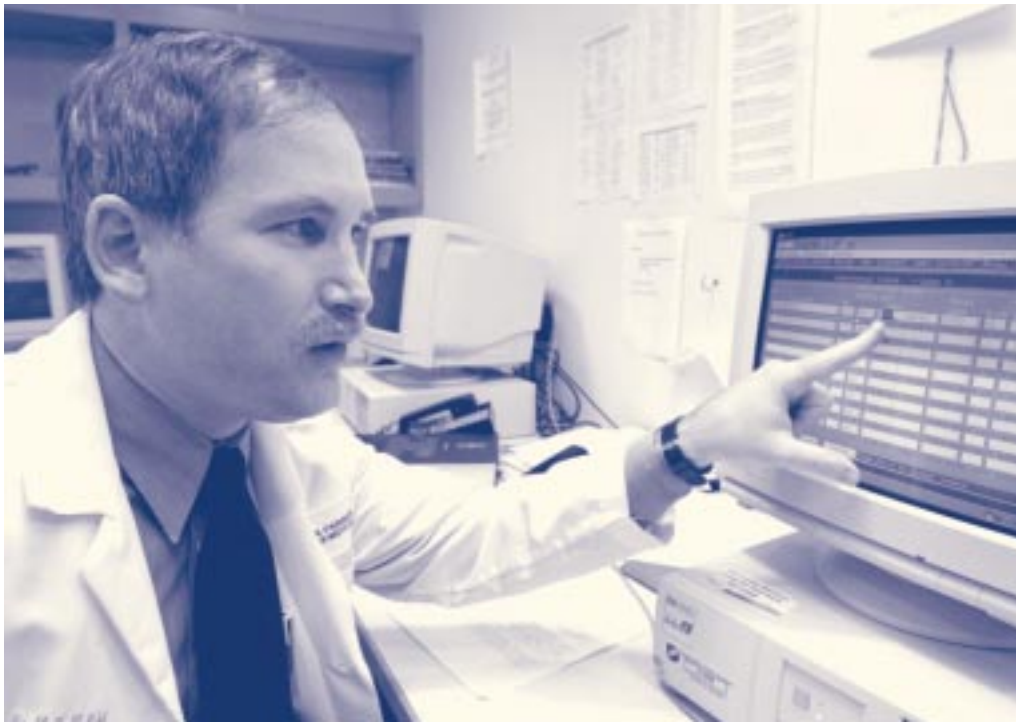
Reporting errors

But by far the toughest job Dana-Farber undertook was to ensure errors would in fact be uncovered—and reported. It set about to implement a "non-punitive" system of error reporting. But it was launching such an effort amid a tense environment of suspicion in the wake of the overdose events.

Although Institute leaders realized systemic errors were the major factors in the cases of Betsy Lehman and Maureen Bateman, they had in fact dismissed the resident physician who had made the original error. The senior attending physician in charge at the time was also fired. In addition, 15 nurses recently have reluctantly accepted reprimands by the Massachusetts Board of Registration in Nursing for their roles in the incident. Three other nurses do not agree with the Board's position and will soon face hearings.

The Institute's current leadership is understandably reluctant to comment on these personnel matters. They focus instead on the future and the importance of establishing a system that will make firing people unnecessary (except in cases of intentional or truly negligent behavior that leads to patient harm or puts a patient at risk of harm).

"Removing the threat of judgment of the individual frees people up to discuss system failures. But you have to be careful to not decrease the incentives for personal vigilance, accountability and responsibility," says Richard Bohmer, M.B.Ch.B., M.P.H., who teaches health care management at Harvard Business School. At the same time, Bohmer and other management experts say health facilities have held a wrong-headed notion of what would keep errors in check. "The general assumption [before] at Dana-Farber was, if you hire the best people, give them the best training and provide the best equipment, that excellence in care is a happy coalition of these organizational elements," says



Rather than a handwritten order that can be misread, physicians enter drug orders via a computerized ordering system. (*Photo by Steven Gilbert, StudioFlex Productions*)

CHANGING THE PARADIGM

"EVERYTHING'S FINE"

FROM	TO
All is Fine!	Endless Opportunities
Errors Rare	Errors Everywhere
Tell as Little as You Can	Tell Whatever You Can
Keep Board Out	Actively Involve Board
MD's Don't Participate	Doc's Actively Involved
Middle Management Must Fit	Exec's Will Lead Staff
Error Rate is Average	No Threshold for Errors

"WHO DID IT! JUST FIX IT! I WANT NO MORE!"

FROM	TO
Just Give Me a Name	Look for the Root Cause
Penalize the Reporter	Thank the Reporter
Add More Checks	Simplify the System
It Will Pass	You Will Carry the Burden
Fix as They Happen	Set Reduction Priorities

Bohmer. "For years, they got away with this line of thinking—lots of hospitals have gotten away with it."

Dana-Farber's shift to non-punitive error reporting is still evolving and far from perfect. But "compared to the past," says Robert Soiffer, M.D., co-chair of the Pharmacy and Therapeutics Committee, "there's been a dramatic increase in staff reporting of errors—about 60 to 80 each quarter." Most have been minor and not affected patients directly, he says. Several "near misses" have occurred since the overdose incident, although nothing of that magnitude. All were caught by the pharmacy staff who questioned ordered prescriptions.

The Institute's response to a March 1999 incident is telling. A physician-in-training (a fellow) injected a patient with a local anesthetic in preparation for a bone-marrow aspiration. The patient suffered a seizure but later fully recovered. A committee was immediately convened to review the incident and interview the physician. They probed the incident to see if any processes should be changed. It turned out the fellow had used a dose slightly higher than standard. New guidelines for the use of the anesthetic were established within weeks as were a new set of guidelines for performing bone marrow aspirations and biopsies. In addition, a new procedure was put in place to more extensively train and monitor physicians-in-training who are learning the procedure. At the conclusion of the investigation, in a memo to his colleagues, the doctor expressed his gratitude for the "professional respect and treatment he received in a potentially embarrassing situation."

Maureen Connor, R.N., who oversees Dana-Farber's risk-management program, says the new reporting climate produces results. "Health care providers and patients are more willing to report every error, down to the smallest mistake. With this information, we can move forward and deal with it," she added.

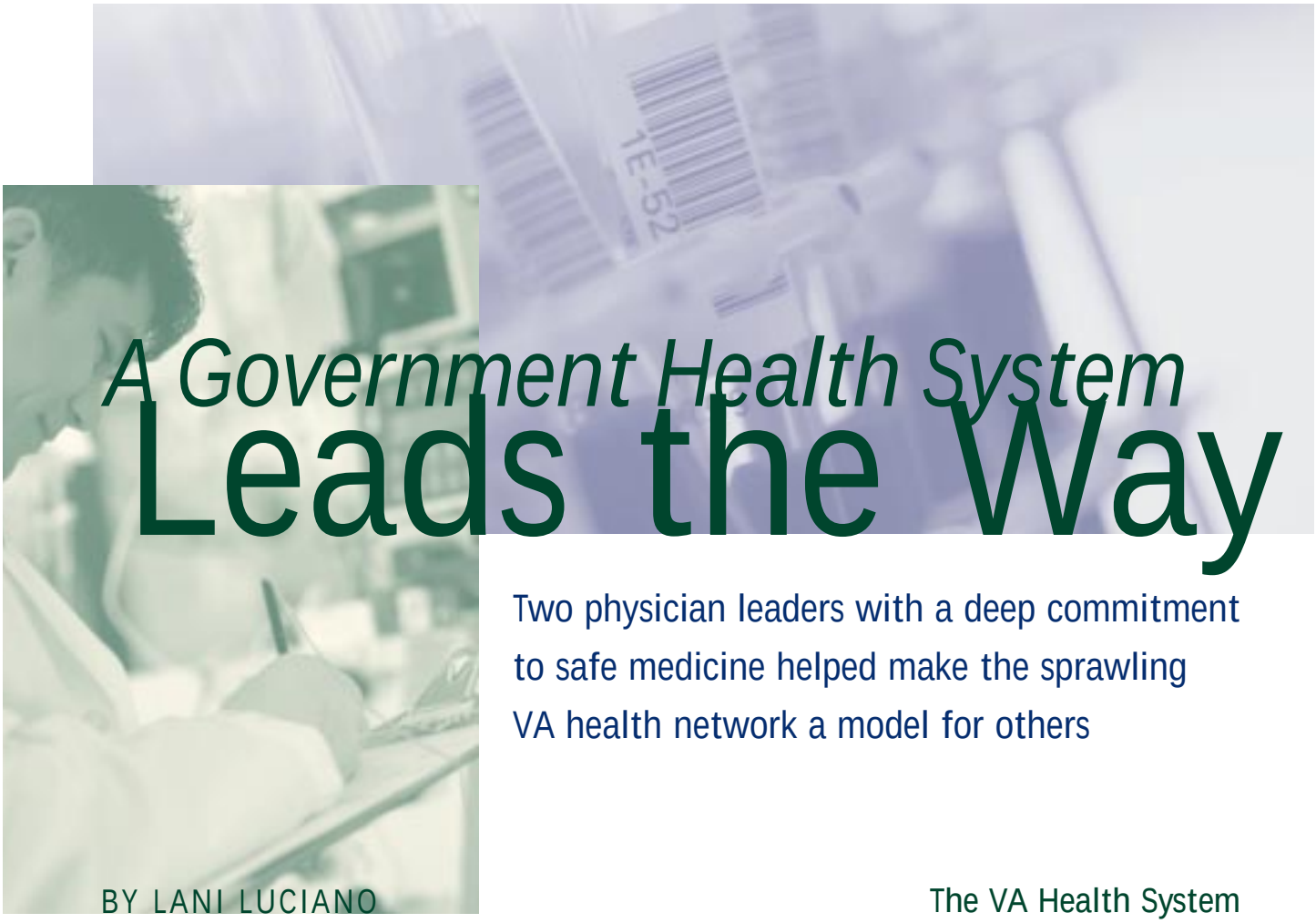
The Next Steps

Dana-Farber officials say they will sustain the commitment to error reduction in other ways as well. For example, with funding from the Risk Management Foundation in Cambridge, MA, Institute personnel will participate in a Harvard study of error prevention in the ambulatory setting. The study's goal is to define—and ultimately prevent—errors that can occur in outpatient clinics, doctors' offices, nursing homes and centers that do outpatient surgery.

Dana-Farber physicians, nurses, pharmacists and administrators are also often on the road, sharing their message with thousands of people at meetings and conferences nationwide. "We realized that we had the burden of our action and the responsibility to correct it," says David Nathan, M.D., Institute president since 1995. "But we also realized we had the power to help others learn from our experience."

And others are learning. Several cancer centers have switched to a safer way of handling medication orders since the overdose tragedy at Dana-Farber. Some, including Memorial Sloan-Kettering in New York, are implementing computerized order-entry systems.

But no system, whatever its advantages, will eliminate the need to be constantly on guard, watching for every possible crack in the safety shield. Says Dr. Nathan, "Even with the best effort, error prevention requires eternal vigilance."



A Government Health System Leads the Way

Two physician leaders with a deep commitment to safe medicine helped make the sprawling VA health network a model for others

BY LANI LUCIANO

When Kenneth Kizer became Under Secretary for Health in the U.S. Department of Veterans Affairs (VA) in 1994, he knew he was taking on a major challenge. Long-maligned for shoddy care, the VA system is also famous for being an entrenched and highly politicized bureaucracy resistant to change.

"I saw *Born on the Fourth of July* like everyone else," the 48-year-old physician administrator says, "but I also knew that the VA's problems were no worse than average. They were just more visible." Kizer set about making a series of changes at the VA that shook the institution. Among them were decentralizing the VA's power and emphasizing outpatient-based primary care. In the process, more than half of all acute care hospital beds have been eliminated. But it was a commitment he made in 1997 that has recently catapulted the VA into the limelight, and could be judged Kizer's most enduring legacy. (He stepped down as the VA's administrator in July 1999 and now heads the National Quality Forum, a private non-profit group.)

After the *St. Petersburg Times* documented a series of fatal medical errors at VA hospitals—a report that led to Congressional hearings—Kizer decided to make a virtue of visibility. He testified in 1997 that such errors not only occurred but were far more common than most people understood—both at VA hospitals and other health care facilities. And he pledged to Congress that he would wage an all-out campaign against medical errors in the VA system. "I thought, let's put all the problems out there and use heightened awareness to correct them, not just in the VA but throughout health care."

It was a bold move that by most accounts has paid off. Media attention in late 1999 surrounding a report from the Institute of Medicine (IOM) on medical errors included numerous favorable mentions of the VA's effort to address the problem. And the VA's own report—tallying medical errors in its system for the first time—was positively perceived as an exercise in government openness. The VA report documented nearly 3,000 errors that resulted in some 700 patient deaths between June 1997 and December 1998.

About half (277) of the deaths were suicides. Of these, an undetermined number—but perhaps most—can be considered "medical errors" by virtue of being preventable if proper care had been rendered. The other half were associated with an assortment of medical mishaps, including improper insertion of catheters and feeding tubes, botched surgery, falls, and patients receiving the wrong drug or too much of the right drug.

The VA Health System

The VA report was an almost instant beacon for other, private health facilities and systems to begin tracking errors more systematically and preventing them. Indeed, the watchword now in the hospital industry is "if the VA can do it, we certainly can."

The $18.3 billion VA is the nation's largest integrated hospital and health care system. It includes 172 hospitals, 600 outpatient clinics, 132 nursing homes, 206 counseling centers, 73 home health care agencies, and assorted other programs. The VA employs 200,000 people, and more than three million veterans a year seek medical services at VA hospitals. Indeed, to Kizer, the VA's national presence, size, and status as a government entity—plus its vital role in medical research and training—made it ideal for setting the national example he had in

mind. "We capture a huge amount of data, we're too big to ignore and, since government employees can't be individually sued, our system is freer than most to admit mistakes."

The first steps came in January 1998. Kizer gathered the VA's effort into a single administrative entity, the Patient Safety Improvement Initiative. Later that year, Kizer recruited former astronaut James Bagian to head the VA's newly formed National Center for Patient Safety, headquartered in Ann Arbor, MI. Bagian, a physician, mechanical engineer, and veteran of two space flights, was one of the lead investigators on the 1986 Challenger accident. His new mandate was both simple and staggering: identify errors and potential errors in the VA system and figure out how to prevent them. "I heard the theme from *Mission Impossible* playing in my head," jokes Bagian, whose playful demeanor belies his rock-hard resolve.

The initiative aims to reduce medical errors through changes in everything from administrative procedures to contracting, technology support, nurse training, and medical practice itself. A few parts of the multi-faceted effort are well underway—such as the new program to track and report errors. But Bagian is quick to point out that most are still evolving.

The first big test of a systemwide change, he says, will be a requirement that all hospitals put in place a bar-coding system similar to, but more sophisticated than, the kind grocery store check-out clerks use to read the price of foods. All VA hospitals must have the system by June 2000. Bagian says the decision was accelerated because an initial test at two VA hospitals in Kansas proved the technology dramatically successful. It reduced the medication error rate 70 percent over a 5-year period.

The Colmery-O'Neil VA Medical Center in Topeka, KS, began testing an early version of the bar-coding system in 1994. Now they have 35, $2,700 hand-held battery-operated computer terminals, two per 30-bed ward.

The system works this way: patients and staff wear bar-coded identification strips, and all medications also have their own ID strips. Before medicating a patient, a nurse or staff member laser-scans all three strips—from the patient, nurse, and medication—into the computer. In a few seconds, the software verifies that the right person is receiving the right drug in the right dose at the right time. The program screens for half a dozen other potential problems, such as drug interactions. If everything checks out, the software simply records the event—preserving an electronic record. If not, it flashes an immediate warning.

The 350-bed hospital—like almost all other U.S. hospitals—previously had no formal system of verifying medication prescriptions at the "point of care." Doctors and nurses were simply exhorted to double check, says Edgar Tucker, director of the VA's Eastern Kansas division. And that was not proving to be good enough, Tucker says.

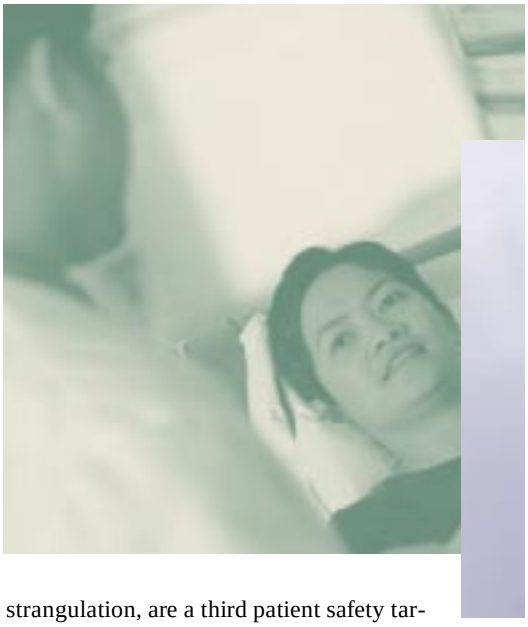
Many of the hospital's nurses worried at first that the new system was mainly a way to track efficiency and boost work loads. But the very quick decline in errors dispelled skepticism, Tucker says. Medication error rates at the hospital plunged from an average 34 per month in 1993 to six per month by mid-1999. Similar results were obtained at the VA hospital in Leavenworth, KS.

A similar bar-coding system eventually will be required for blood products used in transfusions. Says Kizer: "This is a relatively low-cost, high-benefit safety improvement that all hospitals can and should invest in."

Other Initiatives

A second innovation the VA undertook was to revise its medication storage procedures. Following the advice of the National Patient Safety Partnership (NPSP)—a group the VA founded in 1997 with 11 other organizations—all VA facilities must remove a host of particularly hazardous medications from areas where patients are cared for. Heading the list is the drug most frequently involved in medication errors—concentrated potassium chloride. It can cause cardiac arrest when injected in undiluted amounts. Also banished are concentrated epinephrine, digoxin, insulin, lidocaine, pancuronium and verapamil. Such drugs can cause significant harm or even death if delivered to the wrong patient or given in inappropriate doses.

Physical restraints, which cause an estimated 100 deaths a year, most due to



strangulation, are a third patient safety target. The VA is conducting intensive workshops to teach staff alternative ways to safeguard patients without using restraints. The training is paying off. According to Judith Salerno, the physician who is the agency's chief consultant for geriatrics and extended care, two-thirds of all VA nursing homes are currently restraint-free.

Beefing up the science base of error reduction is also a priority. Four VA centers—in Palo Alto, CA, Cincinnati, OH, Tampa, FL, and White River Junction, VT—have been designated Patient Safety Centers of Inquiry. Each will get $1.5 million over the next three years to conduct research and identify safety techniques and technologies other industries are using which may have health care applications.

But both Kizer and Bagian say the biggest challenge in reducing medical errors and making hospitals safer places is changing the culture of medicine. As Kizer encapsulates it: "Can you imagine a nurse yelling 'Doctor, stop!' or even mentioning 'Are you sure you want to do that?' No, you can't, and that needs to change."

Bagian says the initiative aims to replace medicine's fault-finding hierarchy with the institutional trust and sense of personal responsibility typical of "high-reliability" organizations—such as his former employer, NASA.

Though brimming with ideas he'd love to execute right away, Bagian knows the effort will take time and that he must move deliberately and cautiously. To that end, he is field-testing several projects before trying to implement them at all VA facilities. One is revamping of VA's error data repository, known as the Safety Events Registry (SER). All VA personnel can report to the SER so-called "sentinel"

"Close calls show us weaknesses in the system just as harmful events do, but at a much lower cost in human misery and wasted resources."

events—incidents or situations that caused significant harm to a patient. But Bagian wants to make the system a repository for close calls, too—events or situations which could have resulted in an accident, illness, or injury, but didn't.

"Close-calls show us weaknesses in the system just as harmful events do, but at a much lower cost in human misery and wasted resources," Bagian says. To identify problems that require the most urgent attention, the SER uses a safety assessment code. It rates individual incidents on both their severity of harm to the patient and their frequency of occurrence. Incidents that cause great harm or occur often are targeted for immediate intervention.

Paradoxically, Bagian says, making SER a more useful tool for improving patient safety will depend a great deal on making VA doctors, nurses, and technicians feel safer using it. "It's the front-line folks, the clinical and risk management staff, that will make this initiative work. We need their trust and their input," says Bagian.

To foster that trust, he has rewritten the VA's Patient Safety Improvement handbook. The new version stresses institutional and interpersonal cooperation, not personal consequences. And it emphasizes that reported errors are subject to analysis leading to corrective action and preventive measures rather than punitive action against staff members. The sole exception is a criminal or deliberately unsafe act.

The VA's efforts to uncover mistakes are aided by its exemption from the legal liability cloud that hangs over private hospitals. Neither the VA nor its doctors, as government employees, can be sued by patients or their family members if a mistake that resulted in patient harm is uncovered. This has made it easier for the VA to encourage error reporting. But Bagian doubts that this protection has played that big a role. Rather, he says, fear of job loss or punishment is the obstacle.

"We don't favor the beatings-will-continue-until-morale-improves approach," smiles Bagian. "We want people to understand that all problems merit analysis because they're opportunities to intervene. Everyone on the team has to buy into that crucial belief." The new handbook and the system it promotes are currently being tested in Florida, Puerto Rico, California and Nevada. This effort also will test on-site "root-cause" analysis training at all VA facilities by September 2000. The goal of the three-day sessions, he says, is to foster new attitudes, not impose new hard and fast rules or formulas. "The old model was, you stressed who was at fault. The new model is that we understand you do not come to work to make errors, and we want to minimize the risk that you will do so," says Bagian.

Getting information on errors and potential errors is but half the calculus in improving safety, however. The other half is responding. Under a new set of directives from Bagian, error analysis must culminate in an action plan that moves to solve the problem. Simplistic remedies, such as "nurses must pay more attention" are no longer acceptable, and even thoughtful, plausible solutions are subject to ongoing scrutiny for effectiveness. Says Bagian: "We'll get monthly progress reports and we'll be able to tell by the content whether the staff really got the message or not. If not, we'll head back there and figure out where we missed the boat and how to do it better."

The VA also has not been afraid to use some tried and true methods of inducing change to reduce errors. Recognition through awards is important. But putting some money on the line appears to pay off, too. Individuals who suggest broadly applicable safety improvements qualify for bonuses of up to $5,000. Institutions can garner up to $25,000. Topeka's medication scanning system won the maximum prize in 1999.

Continuing education for staff members is also a critical component of the initiative. In 1999, the VA became the country's first health system to require that all permanent employees complete thirty hours of continuing education each year, ten of which focus on quality improvement and patient safety. Bagian also wants to launch a magazine devoted to safety, such as those published by the Navy and Air Force. "They're filled with inspiring you-are-there type stories that make you consider how you'd handle a sudden problem. They're absorbing to read and they stimulate you to think."

Yet another idea is to increase the use of simulators for medical procedures. Such devices allow doctors and nurses to practice procedures and emergency drills, and make mistakes, using equipment—including computerized human dummies—before they ever perform them on real patients. (See story page 24.) VA facilities are also under orders to double the number of autopsies they perform. Currently, 15 percent of patients who die in a VA hospital get an autopsy. Medical experts have agreed for years that autopsies are very useful tools for learning about medical mistakes.

Bagian is far from blasé about the challenge ahead. To build a system where safety permeates the culture will take years, he acknowledges. "We will need everybody up and down the chain of command, from Congress to doctors and patients to believe in this new approach," he says. "We have to encourage and praise and reward all the steps forward, including baby steps, so that people are comfortable taking bigger steps. But once we reach critical mass, I think the momentum will be unstoppable."

Making Doctors Computer Literate

BY JANE ROESSNER

Coaxing physicians to give up pen and paper cut errors sharply and saved $5 million to $10 million at one inner city hospital.

Brigham and Women's Hospital
Boston, Massachusetts

Even as the e-health boom gains momentum, many health facilities are still far behind in adapting to the brave new world of information technology. And though they have seen computerized machines—like CAT scans and MRIs—revolutionize medicine, many hospitals have not yet put computers to use to increase productivity, streamline administrative functions, enhance research, and improve quality. Some health care institutions, though, are blazing trails in this form of computerization that the rest of the industry is certain to follow. Brigham and Women's Hospital, a 726-bed academic medical center in Boston, MA, is one such facility. Among the most powerful changes: Brigham's physicians today write all their orders for treatment and medications on a computer screen, rendering paper orders a thing of the past.

The payoffs have been many. Doctors and nurses say it saves time and makes them feel more professional, efficient, and confident. And hospital administrators say the system has saved them between $5 and $10 million a year. But it's the direct benefit to patients—in reduced errors—that's likely to compel other hospitals to follow suit quickly. Serious medication errors at the hospital have decreased by 55 percent over the past few years.

Brigham and Women's began to embrace the computer age as early as 1989. It built the Brigham Integrated Computing System (BICS), a clinical information system running on a network of over 6,000 computers. Physicians, nurses, and administrators used the system to access lab results, discharge summaries, and other clinical data. By 1991, the hospital's administrators were casting about for more specific ways to use computers to improve both the delivery and quality of care.

A key target emerged soon enough: "iatrogenic injuries"—injuries to patients that occur during hospitalization—and, more specifically, injuries due to medication errors. Studies at the time estimated that "adverse drug events" were far and away the most common medical error and cost U.S. hospitals over $20 billion per year. In addition, the problem seemed to be on the rise as the health system became more complex and medicines became more plentiful and powerful. With 36,000 inpatients and 610,000 outpatients per year seen at four different sites, the Brigham's administrators knew

they had a significant opportunity to improve quality and save money.

David Bates, a fellow in general medicine at the Brigham at the time, couldn't have agreed more. A pioneer in quality research, Bates had found that both the existing processes by which physicians ordered medications as well as the way they were administered were fraught with problems and invited errors. His research found that 56 percent of adverse drug events at the Brigham occurred because of errors at the time of ordering. Bates discerned early on that the primary source of the problem was the age-old tradition of handwritten orders. Doctors were scribbling their drug and test orders on forms with triplicate copies, one of which would be torn off and taken to the pharmacy (or shot through pneumatic tubes). Also, about half of the medications issued by the pharmacy were recorded as having been written by "doctor unknown," and in an astounding 80 percent of lab orders, the doctor's name could not even be determined.

And despite exhortations to write more clearly, physicians' handwriting stayed notoriously illegible.

Bill Churchill, director of the Brigham's pharmacy since 1990 and a pharmacist there since 1974, says deciphering the ordering physician's name was the least of the problems. "We simply couldn't read the doctors' orders," he says. "Different people would use different symbols and abbreviations for medicines, and the pharmacy didn't know what they meant. You couldn't tell if the order was for 0.5 milligrams or 5 milligrams."

The problem was compounded by dramatic advances in the pharmaceutical industry. "New drugs were coming online every day," Churchill says, "These were potent drugs with profound ability to help, but also to harm. And these drugs interact differently on each patient. Asking physicians to keep all of this information in their heads is a lot. Even for pharmacists who specialize in this, it can be overwhelming."

At the same time that the data were being gathered, a potential solution was being developed. Bates and others reasoned that a comprehensive computerized "order entry" system combined—and here was the trick—with a requirement that physicians write their medication orders on the computer would go a long way to solving the problem. In addition, Bates became convinced that the computer and new information technology could become a powerful "decision support" tool for physicians—giving them pertinent information at the time they were writing orders.

DESIGNING THE SYSTEM

Brigham and Women's set out building the order entry system in 1991. Jonathan Teich, then director of the hospital's Information Systems group, believed that the most potent application—the one that would have the biggest impact on care—was "the ability to challenge and critique and guide the physician's order at the time it was placed." At the same time, he and other designers recognized that a computerized order entry system would impose formalism onto what had been—rather bizarrely in retrospect—a largely informal process. In essence, the new system would be asking physicians to make a major change in the way they practiced medicine. Physicians are required to document all of their orders—not just for medications, but for lab and radiology tests, food, and activity—essentially everything they do in the process of caring for a patient. At the Brigham, some 16,000 orders are written each day, 40 percent of them for medications.

The team's first decision was to get physicians to buy into the system by designing it for them. Teich decided that if one aim was to promote decision support, doctors had to use the system themselves. They couldn't rely on nurses or administrative staff to enter their orders into the computer. To get doctors to use the system, Teich knew he had to make it easy to use and not time consuming. Physicians told the design team in no uncertain terms that if it took a lot more time, it simply would not fly. The team made the computer format resemble the written forms doctors were used to, but they also imposed standards on how the screen should be filled out. The final conceptual challenge was to find the right balance of decision support information. Too much would overwhelm doctors. Too little would undermine physician buy-in and the hoped-for reduction in errors.

In the end, the team settled on a menu of medications. For each medication, software offered a "pick list" of appropriate doses. Before any medication order would be accepted, physicians were required to enter dosage, method of delivery (for example, by mouth or intravenously), and frequency.

But the key new element was this: as soon as the physician completed an order, it would be checked for errors. For example, if the patient was found to be allergic to the drug the doctor was ordering or was already getting another drug that didn't mix with the new one, the computer would alert the physician. If the doctor chose to override such an alert, he or she would have to enter the rationale for the override. Orders were then sent directly to the pharmacy. There, they underwent a second check for errors.

THE ROLLOUT

The commitment of the hospital's leadership proved to be a vital ingredient to successfully implementing the new system. CEO Dick Nesson was a persuasive champion. He personally mustered the support of the hospital's department chiefs. Indeed, when one chief threatened to instruct his residents to refuse to use the system, Nesson made it clear that every department was required to at least give it a try.

After a one-month pilot trial on the bone marrow transplant unit in January 1993, initial rollout began in May 1993 and continued for the next 18 months. The rollout took place, says John Glaser, the Brigham's chief information officer, in "punctuated bursts"—first in Medicine, including general medicine, cardiology, and oncology; and then, after a two-month pause, in Surgery, and then in Obstetrics and Gynecology.

Like the design itself, the rollout put the doctor front and center. The operative principle in the short run was to minimize problems for the physician, even if it meant putting other departments (for example, the lab or radiology) and the nursing staff in an awkward position—between the paper

world and the electronic world—for a period of time. Indeed, when the new system went into effect, a variety of questions about workflow bubbled up. For example, if a physician writes orders for postoperative care before surgery, how and when are those orders activated? What happens if those orders say "continue all medication," but the medications change in the interim? How is it indicated that orders have been taken care of?

"Lots of things had to be handled explicitly that were handled implicitly in the paper world," explains Gil Kuperman, a physician and one of the system's designers. "Humans can be ambiguous. Computers aren't."

"Lots of things can be handled explicitly that were handled implicitly in the paper world. Humans can be ambiguous. Computers aren't."

Physicians were invited to use a "feedback" button on the screen to air grievances and suggest improvements in the system. Teich recalls that in the first week of rollout, his department received 122 pieces of "hate mail" via the feedback button. "We felt better," he says, "when we realized that 99 of them came from the same person." The feedback mechanism also invited physicians to interact with the system; they became active participants in making the system better, not passive victims of its intrusion into their lives.

In time most physicians responded positively, Teich says. They liked the basic information about proper doses and frequency for medications. And they liked the computer's ability to calculate the right dose of potassium for a particular patient. But the single greatest perceived benefit by physicians, and the one that really saved time, was the ability to write orders from remote locations—for example, writing an order for a patient on the 12th floor when they were on the 9th floor; or even writing orders from home.

But, as anticipated, there were complaints. The major one involved the added time commitment. Before computerized order entry, doctors spent approximately two percent of their time writing orders; the new system was using 10 to 12 percent of their time, according to a time/motion study. That translated into an average 40 minutes a day longer writing orders. Fortunately, as they adapted to the system, doctors recovered an average of 20 minutes of that time. But it wasn't enough. So the designers set about trying to make the process more efficient.

Their first discovery was that a significant amount of time could be saved if doctors wrote orders in groups rather than singly. While writing single orders could take as much as five times as long on the computer as by hand, writing orders in groups was much faster. For example, writing orders one by one for patients who needed a blood thinner was time-consuming—at five minutes per patient, for forty patients, taking over three hours. To facilitate "group orders," the system's designers built one screen with a spreadsheet listing all patients in certain categories. Doctors could then write orders for blood thinner for many patients at once—a process that turned out to require only seven seconds per patient. It proved to be a critical change, improving efficiency all around.

CONTINUOUS IMPROVEMENT

Getting the initial bugs out and weaving computerized order entry into the day-to-day fabric of the hospital took about a year. The next step was to add the "decision support" component.

Decision support was designed with two goals in mind: reducing errors (e.g., "patient X is allergic to medication Y") and reducing costs (e.g., "would you like to switch to this equivalent, cheaper drug?"). The basic notion behind "real time" decision support is that the computer can modify the physician's decisions by displaying information at the time the physician is ordering medications.

The Brigham's system offers five modes of decision support:

• It alerts physicians to potential drug interactions, patient contraindications or allergies;

• It calculates proper doses—determining the right amount of a particular medication for a particular patient at a particular time. The system's designers researched the hospital's database to determine the most commonly ordered doses of particular drugs. Using this information, they constructed "pick lists" of doses, highlighting the dose most commonly ordered.

• It presents drug substitution information. The designers recognized the power of the system as a tool to change physicians' behavior. When physicians ordered the common ulcer treatment and prevention drugs Zantac® or Tagamet®, the system suggested they consider substituting Axid®, a less expensive but equivalent medication. The intervention allowed physicians to make the switch by simply pressing an "OK" button. In the very first week the intervention was introduced, physicians elected to substitute the less expensive medication an astounding 94 percent of the time.

• It can alert physicians to potentially dangerous situations. For example, if a lab test for a patient indicated a low potassium level, the computer would query if the patient was also taking digoxin—a potentially dangerous combination. If so, the computer would identify and page the patient's physician, at any hour of the day, informing the physician of the reason for the page and asking for action. Physicians were overwhelming in their support of this feature, giving it a 96 percent approval rating.

• It can track patients' test results for kidney function and alert doctors and staff if medication doses exceed recommended levels for people with abnormal kidney function. Dubbed the Nephros Project, this feature was made a part of the decision support because so many adverse drug events involved patients with kidney problems. Doses of quite a few common drugs that would be appropriate for a patient with normal kidney function could be dangerous or even fatal

in a patient with low kidney function. As a result of Nephros, the percentage of orders with dosing that is appropriate for kidney function has increased from 30 percent to 70 percent.

RESULTS—AND THE FUTURE

Computerized physician order entry at the Brigham is now six years and some 35 million orders old. It has become an integral part of providing care at the hospital. Paper orders are a rapidly fading memory. Thirteen thousand orders are entered daily at the Brigham, 88 percent of them by a physician. On an average day, 386 of these orders are changed by a physician because the computer suggested doing something different. An average of four times a week, a physician cancels a chemotherapy order because the dose is too high.

Any way it's cut, computerized order entry has earned its keep. Research by David Bates concludes that the system has yielded a 55 percent reduction in serious medication errors—those that either had the potential for harm or actually resulted in injury. In all, the system saves $5–10 million per year, with most savings coming from use of less expensive drugs and tests.

As well as it has performed, the system at the Brigham has been due for an upgrade for several years. That is now underway. The biggest issue has been the network, which has been at capacity for some time, with about 3,200 linked PC's. This is being replaced with a faster network. Also, all applications are being moved to a faster, more flexible software program.

In addition, plans are underway to extend the drug order entry system to the outpatient setting—the 610,000 patients treated annually at the Brigham's outpatient sites. Even though the primary care sites already use an electronic medical record, computerizing ordering will be challenging. Primary care physicians see many more patients, each for a much shorter time. Although the range of orders is narrower in the primary care setting, there are many more orders per day. Moreover, it will be more difficult to "require" independent primary care physicians to use such a system than the hospital's own physicians.

The hope is that physicians will buy into the system because it can help them navigate the complex rules of managed care—the varying rules plans have that specify which drugs and which tests are covered, under which conditions. These can change from month to month and it's almost impossible for physicians to keep up. According to John Glaser, an order entry system with decision support information on every plan's formulary—updated regularly—could be highly attractive. Brigham and Women's researchers project that such a system could reduce outpatient medical errors by as much as 80 percent and cut the cost of medications under capitated contracts by as much as 25 percent for a savings of an estimated $20 million per year.

As for the more distant future, Brigham management is looking closely at adapting computer assistance and decision support to emergency room operations and to involving patients more directly in their own care. For example, on-site computers, with internet links, could help people understand health issues and treatment choices for their condition. They could also help people communicate directly with doctors and other health providers. It's the brave new world that many experts envision. And the Brigham is already heading in that direction.

BUILD YOUR OWN OR BUY OFF THE SHELF?

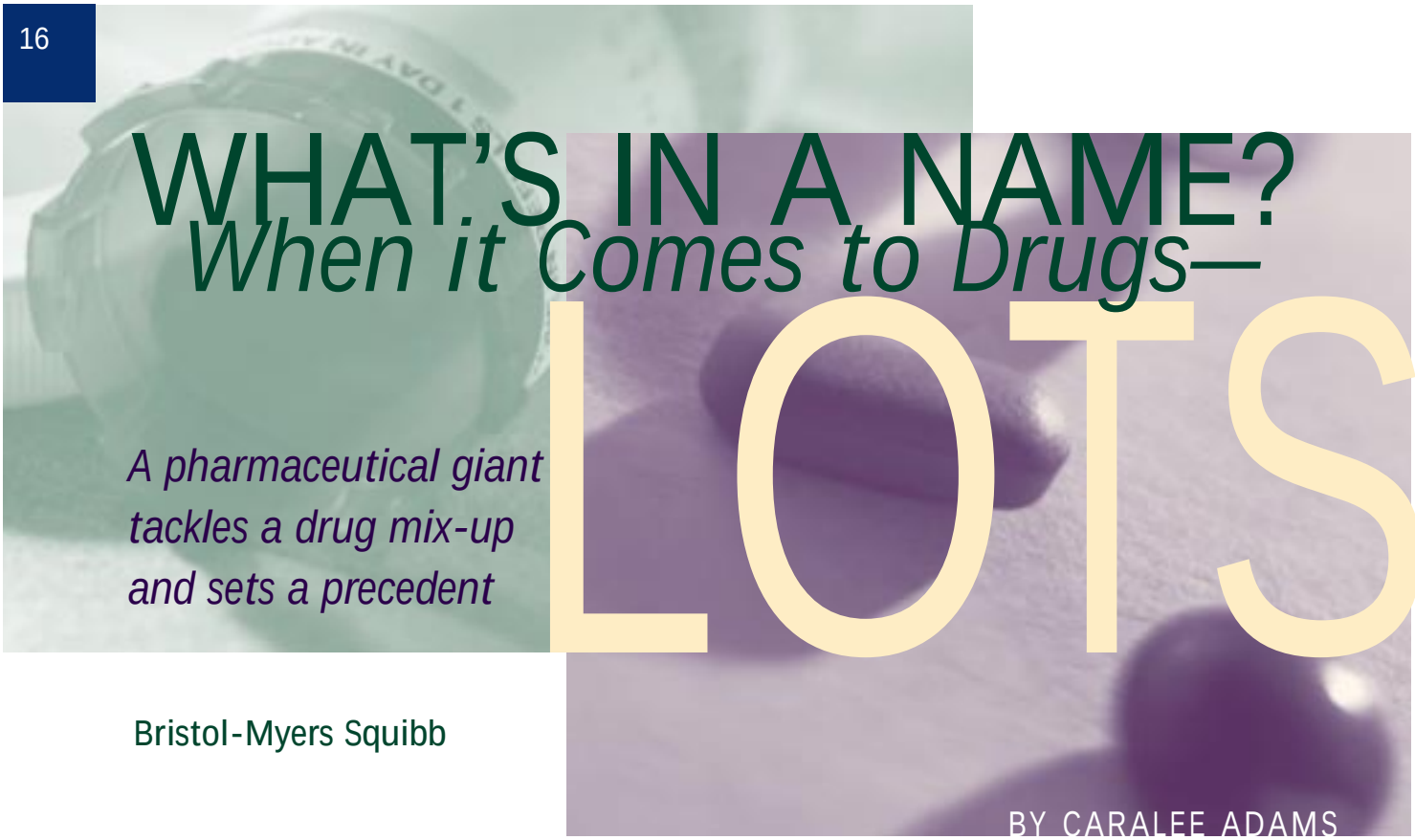
Building a computerized order entry system cost Brigham and Women's Hospital about $1.4 million in 1993; thereafter, annual maintenance has cost about $500,000 a year. How many hospitals have the resources—financial, medical, and technical—to build such a system? How does a home-grown system compare with a ready-made one?

According to the Brigham's Information Systems team, building a system from scratch makes sense for a hospital if three conditions are met:

- The hospital believes it can move faster than the market.
- The hospital is uncertain as to the best configuration of such a system, and wants to learn from rapid cycles of testing and fixing features.
- Many functions within the hospital are intertwined.

Hospitals that meet these conditions can usually develop a system that meets their needs better. The system is also likely to be cheaper in the long run than if purchased from a vendor. Doing it yourself also gives an organization deeper knowledge on using technology to improve care.

However, most community hospitals and smaller hospitals will not have the human resources to develop a system on their own, and will likely be better off purchasing one from a vendor. Although off-the-shelf systems won't have all the features or the flexibility of Brigham's system, most vendors in this sector—such as Cerner, Eclipsys, SMS, and HBOC—are making important improvements. The cost of off-the-shelf systems varies, depending in part on the computer networks already in place.



WHAT'S IN A NAME? *When it Comes to Drugs—* LOTS

A pharmaceutical giant tackles a drug mix-up and sets a precedent

Bristol-Myers Squibb

BY CARALEE ADAMS

Pharmaceutical giant Bristol-Myers Squibb Co. (BMS) had a problem. Reports were filtering into the company's Princeton, NJ, headquarters that one of its premier drugs—Platinol® (cisplatin), used to treat testicular, ovarian and advanced bladder cancer—was being confused by pharmacists and doctors with another anticancer drug it makes called Paraplatin® (carboplatin), used mostly to treat advanced ovarian cancer.

The issue was serious because the appropriate dose of cisplatin is about five to six times less than that for carboplatin. Mix-ups can be fatal. Indeed, the potential danger of a mix-up between the two drugs had been noted as early as 1991. The Institute for Safe Medication Practices (ISMP), based in Pennsylvania, had received a report of a woman about to get a bone marrow transplant who was to receive cisplatin. Because of a pharmacy dispensing error, she received cisplatin at the carboplatin dosage. She later died.

In another case that year, a nurse transcribed a telephone order wrong, writing cisplatin instead of carboplatin. The pharmacy dispensed the drug as written, and the patient received the higher dose. The next morning the physician saw the transcribed order, and the error was discovered. The patient died a week later.

Confusion was apparently occurring with the generic names (cisplatin and carboplatin) as well as the brand names (Platinol® and Paraplatin®) because they all shared the same "stem:" "platin."

But BMS at that point still was unsure whether they had a systemic problem on their hands—or whether the reports were isolated events due to fluke mix-ups. Even so, it took a precautionary first step in 1992—putting letters to the editor in various oncology medical, nursing and pharmacy journals warning of possible cisplatin mix-ups.

Reports of the error kept mounting, though. By the end of 1995, some 32 medication errors related to cisplatin had been reported to the Food and Drug Administration (FDA), and eight people had died, according to the FDA. That prompted BMS to add information to the label for Platinol® highlighting the potential mix-up. It also distributed letters to oncology health care professionals to alert them to the problem and to the discontinuance of one form of Platinol®, a powder for injection that had the highest potential to be confused with Paraplatin®.

Despite these steps, Frank Pasqualone, then director of policy and planning for BMS Oncology-Immunology, was still concerned. He worried that the inserts and warnings would go unread—as such inserts often are. And he was concerned that more patients might be harmed if BMS did not move aggressively. The ISMP also was urging the company to take stronger measures.

The Platinol®-Paraplatin® mix-up was then and still is symptomatic of a serious and growing problem: health professionals make drug dispensing and administrative errors every day—some of them life-threatening, even fatal—because the names of many drugs are so similar. In the most recent example, the FDA received 53 reports of dispensing errors involving the three sound-alike drugs Celebrex® (an arthritis drug), Cerebyx® (to treat seizures) and Celexa® (an anti-depressant).

The precise magnitude of the problem is difficult to gauge. There is no comprehensive record-keeping or data base that tracks it. According to the FDA, roughly half of the 6,000 medication errors reported to the agency between 1992 to 1997 were due to labeling or packaging issues. Of that half, some 27 percent were caused by generic or trade name confusion. But Jerry Phillips, the agency's associate director of medication error prevention, says studies indicate the number of medication errors reported to FDA—including mix-ups—represent only a small fraction of those that occur.

"It's a significant and persistent problem," concurs Bruce Lambert, an associate professor in the Department of Pharmacy Administration at the University of Illinois at Chicago. He says pharmacists and other health professionals have been concerned about it for years and have pressed the pharmaceutical industry to change their practices.

Magnifying the problem today, Lambert notes, is the growth in the number of medications. There are about 13,000 prescription drugs on the market now, according to IMS Health, a health care information company. And in the past decade, the number of new registered trademark drug names has quadrupled, from 744 new trademarks registered in 1988 to 3,038 in 1998. This creates a major challenge for an industry always striving to come up with catchy drug names—such as Prozac® and Viagra®.

Not surprisingly, with so much invested in brand names and the marketing that surrounds them, drug makers are usually very reluctant to change the name or package design of their products if a problem arises.

That ultimately was the problem facing BMS. But first the company sought to gather the facts on Platinol® mix-ups and reach out to experts. Pasqualone pressed his superiors to convene an advisory board of outside experts including five pharmacists, two nurses and one physician. The panel's central mission was to review the data and advise on a response to the Platinol®-Paraplatin® issue. But it was also charged with recommending ways to make the company's products safer in the future.

Pasqualone's mounting concern, assertive approach, and BMS's commitment to change their practices eventually set a precedent for the industry that reverberates today.

The independent advisory group gathered in Naples, FL, in January 1996. For eight long hours, and with company representatives on hand, it engaged in a process dubbed "failure mode and effects analysis." The group examined, in detail, the distribution of the two drugs from the time they were loaded onto trucks after manufacture to the moment they were injected into a patient in a hospital.

The vast majority of the mix-ups with Plantinol® and Paraplatin® were linked to the wrong container being chosen as it was dispensed by a pharmacist.

"It was clear that it was a problem being contributed to by their packaging," says Dominic Solimando, a pharmacist and oncology consultant in Arlington, VA, and a panel member. Indeed, the packaging designs of the original Platinol® and Paraplatin® boxes were extremely similar—which turned out not to be an accident. The packaging of all the oncology products were intentionally similar for purposes of product line consistency and brand recognition, a BMS spokesperson says.

Working with company staff, the panel came up with a number of recommendations:

- Redesign the cartons of both drugs to de-emphasize the generic name and eliminate the confusing similarities—put the letters "cis" in bold uppercase and red letters with the "platin" in smaller type.
- Add a graphic of a stop sign to the package to warn pharmacists and other users to verify the drug name and dose.
- Redesign the outer carton so the critical information is on more than one side of the box, making the warnings visible no matter how the box is placed on the pharmacy shelf.
- Put warnings of the maximum dosage of cisplatin on the vial.
- Put a set of three stickers on the carton to help certify the drug had been prepared at the proper dosage.
- Put the same stickers on I.V. bags; one is used by the pharmacist and another by the nurse.

Pasqualone set out to convince the company to make all the changes. It took time. But Pasqualone was determined.

Indeed, as 1996 progressed, the number of cisplatin-related problems mounted. Twenty-nine cisplatin medication errors were reported in that year, with another eight deaths—bringing the total since 1991 to 61 incidents and 16 deaths.

By spring, Bristol-Myers' management was firmly on board with the panel's and Pasqualone's suggestions. They gave the go-ahead for rapid action. Some of the outside experts were consulted as packaging changes were made. By October 1996 nearly everything the advisory panel had recommended had been put into place.

The company won't reveal the cost of the changes, but Pasqualone says it was a "significant investment." The costliest item was the advertising campaign to educate health care professionals about the product changes.

Notably, one change the panel did not recommend was changing the name of the drugs. Doing so would have added $5–10 million to the cost of the response, estimates Michael Cohen, president of the ISMP. Although Cohen favored a name change, the panel fully considered that option and the consensus was that changing the name would not have added to the prevention of the mix-ups. Instead, it would have confused pharmacists and perhaps even led to other drug mix-ups.

In the end, most agree that the company did the right thing. "All in all, we want people to act like Bristol-Myers Squibb did and fix the problem," says pharmacy management expert Lambert. "Whether they did so quickly enough is another question.... When errors come to light, we'd like to see (companies) be much more aggressive."

"Bristol-Myers Squibb set a good example of acting responsibly and using innovation to correct a problem that led to serious patient injury," says William Ellis, executive director of the American Pharmaceutical Association Foundation, a research group affiliated with a national professional society of pharmacists.

Cohen says BMS's actions should serve as a model to others. It was one of the first companies willing to reach out to outside experts and analyze what could be done to correct a problem with its product, rather than blaming outside forces, he says. But, he adds, the more global response to drug name mix-ups is careful testing of drug names, labels, and packaging *before* they are launched.

After the packaging changes were made in 1996 and the advertising campaign in 1996 and 1997, cisplatin-related medication errors and deaths declined dramatically. In 1997, six cisplatin errors were reported, with one patient death. In 1998, only one incident was reported. And by October 1999, two incidents had been reported. No deaths related to cisplatin overdoses were reported in 1998 or 1999.

Tackling Medication Errors HEAD ON

Putting one determined doctor in charge of reducing errors made all the difference at one Midwest hospital

Luther-Midelfort Hospital
Eau Claire, Wisconsin

BY KRIS REBILLOT

Like hundreds of hospitals in hundreds of similar towns, 310-bed Luther Hospital and Midelfort Clinic sit placidly amid the tree-lined streets of Eau Claire, WI, a city of 60,000 at the confluence of the Eau Claire and Chippewa Rivers. And like most doctors, Roger Resar thought Luther-Midelfort—hospital and clinic—were pretty safe places for the 2,000 patients a day that pass through their doors. As far as Dr. Resar could tell, a terrific team of physicians and nurses, backed up by a crackerjack administrative staff, were delivering top quality care in a well-greased system. Resar knew, of course, that errors sometimes occurred, as they do at every hospital. In his 22 years as a pulmonologist, he'd witnessed his share. But he felt Luther-Midelfort had a solid program to prevent serious errors before they occurred, catch them in a timely manner when they did, and address what went wrong.

Resar has a very different view today. And so do his bosses. After authorizing Resar in 1997 to assess errors and efforts to reduce them at Luther-Midelfort, the hospital's leaders came to a sobering reassessment of the success of their existing programs.

"I was astounded," says Resar. "We were finding 200 to 230 actual or potential medication errors for every 100 charts we reviewed. That means if you went to our hospital, you'd be at risk of two to three errors during your stay with us."

Fortunately, the vast majority of the errors uncovered at Luther-Midelfort were minor. But the findings—from a painstaking year-long study of charts and procedures—frightened Resar, his colleagues, and the hospital's administrators. All realized that a process which allows too many small mistakes is the same process that leads inevitably to a big mistake. "Maybe we gave a sleeping pill to someone who shouldn't have gotten one. That's not a big deal. But what if someone got penicillin and they were allergic to it," Resar says.

Resar was put in charge of dramatically reducing errors at Luther-Midelfort. His first task was to take on medication errors—where most of the errors were occurring. Resar was also asked to build a new system of error reporting, which proved to be one of his toughest challenges.

The results so far have been highly rewarding, Resar says. Since mid-1998, medication errors at Luther-Midelfort have declined by 82 percent at the key points of patient care—admission, transfer from one department to another within the hospital, and discharge. Insulin errors have been cut by 50 percent after a standard dosing regimen was implemented. And 90 percent of patients on the blood-thinning drug Coumadin® are now getting the proper dose, up from 75 percent before improvements were made.

As part of the Mayo Regional Health System, and thus partner to the famed Mayo Clinic in Rochester, MN, Luther-Midelfort's initiative is being watched closely and eventually could have even broader application. Mayo runs 13 hospitals in 54 communities in and around Rochester.

The Mayo System and Change

Two factors have fueled the innovations at Luther-Midelfort—the sheer force of Resar's personality and an organization that came to embrace the cause and open itself to change. "You have to recognize that improvement is hard work," says Dr. Terrance Borman, the hospital's medical director. "It has to be someone's job. We've recognized that in order to help our doctors improve, we need doctors who are change agents." Ron Hitzke, Director of Inpatient Pharmacy Services, says Resar has been "the spark plug that keeps us going."

Dr. Patrick Macken, a nephrologist involved in many of Resar's projects, concurs. "He's recognized as an excellent doctor and a team player. He's very passionate about his work." Macken says the Mayo organization's commitment to let Resar do the nuts and bolts work of quality improvement has made all the difference. "Resar creates the new forms, he looks at the data, he's the one who works closely with the nurses."

Resar says getting physician buy-in is a key to the success of the initiative so far. "If you've been around a hospital long enough, you know the guys who carry the

big stick are the physicians. They have to be in on it from the beginning," he says. He also acknowledges the approach used at Luther-Midelfort to implement change: built a project in small steps—steering clear of making wholesale changes too quickly—and test changes first on a smaller scale. "We spend five minutes coming up with a form," says Resar. "We don't do a lot of planning because we know it probably won't be right the first time. Some organizations take months to design a form, but spending too much time thinking about it makes things too complicated." This system also allows physician "champions" to take part in short, 20-minute meetings aimed at improvements, instead of involving them in knock-down, drag out review sessions that are common in many organizations.

Tackling Medication Errors

The efforts at Luther-Midelfort started in 1997 when the hospital sent a number of staff members, including Resar, to a symposium on reducing medication errors. Resar and hospital leaders became converts to the emerging—but still minority—view that errors were a more serious problem at hospitals than generally appreciated.

Resar's first step was simply to start talking to staff about the issue. He queried nurses, doctors, pharmacists and purchasing agents, asking them blunt questions in informal and off-the-record conversations. His most pointed question was always, "Are there accidents waiting to happen?"

As these conversations progressed, it became clear to Resar that, one, errors were probably more common than believed at the hospital and, two, employees had been withholding information about them. Retribution had never been a big part of the corporate culture at Luther-Midelfort. But even in this positive work environment, the threat of punishment held sway. Nurses, faced with the choice of "telling" on colleagues (who could face disciplinary action) were not reporting medication mistakes—even the most minor ones.

Resar's informal survey yielded a list of key drug delivery issues—and specific medications—of biggest concern. That list came eventually to form the basis for a three-year, 11-part project. Resar's chart review further shaped the initiative as patterns emerged. Data showed, for instance, that 56 percent of the hospital's medication errors occurred at the "interfaces of care"—in other words, during admission, in-hospital transfers, and at discharge. Armed with this information, Resar and his team began their first formal improvement project in 1998 on a 40-bed medical unit. They committed to the creation of a "drug reconciliation process" to address medication errors occurring during the interfaces of care. They set a target: they would reduce actual and potential adverse drug events by 60 percent in three months.

They met the goal. The team began first by tackling medication mistakes occurring during the admission process. "We started with just five patients and two nurses on one shift," said Resar. "We took an idea and tried it. We didn't refine it to death. If it wasn't right, we let it go. If it worked we kept moving it to a larger cycle." The first step, he says, involved the simple act of moving the "admission medication notes"—typically buried in a pile of paper—to the front of the chart. "It took a lot of work just to get that done," said Resar. "We had to figure out what form to use, and we had to get people to move it."

Equally painstaking was the development of new protocols for admitting nurses who became accountable for unraveling the snarl of drug information. Elderly patients, for example, often are taking 12 to 20 different medications a day. "It was a nightmare," says Jane Justesen, a nurse manager.

During their initial chart study, for example, Resar discovered one case involving a disoriented elderly woman who took the anti-coagulant drug Coumadin® on a daily basis. The patient was admitted over a weekend by her primary physician's partner, who was unaware that the patient took the blood-thinner. The patient's regular doctor didn't catch the omission on Monday and as a result, the patient had a stroke during her stay.

Justesen's admitting nurses began to sit down with patients and their families to detail and verify every drug they were taking, its dosage, frequency, and when it was last taken. If needed, clinic records were pulled, and pharmacists were consulted. Everything was compared to a doctor's orders. If something didn't make sense and was time-sensitive, the doctor was called. The nurses had 24 hours to get the medication record in order.

Once the new admission process was established, Resar tackled medication errors associated with transfers from the hospital's intensive care unit. That effort involved the formidable task of getting two computer systems to work with each other—the Intensive Care Unit had a system separate from the rest of the hospital. Now, a process is in place allowing those systems to work in coordination. In addition, new forms make it easy for doctors to detail medications for patients leaving the ICU.

The discharge process was next. Typically, hospital pharmacists were spending 30 minutes to two hours per patient to discern precisely what the doctor's "discharge on home medication" orders meant.

Measures to prevent medication errors at Luther-Midelfort have involved the entire health care team and the patient, as well. *(Photo by Rick Gregerson)*

Working closely with the pharmacy staff, Resar built a new process within a couple of months. Now at discharge, the pharmacy's computer generates a record of every medication the patient has taken while in the hospital. All the doctor has to do is checkmark the medications he or she wants continued. Every drugstore in Eau Claire accepts the watermarked document as a prescription form.

"Not only does this save the doctors' time," says Hitzke, "It also prevents the potential for mistakes in transcription." Pharmacists also have more time to help patients. "We've always wanted to be more clinically involved, and this is a way to do that," says Hitzke.

Resar and the patient safety team also targeted specific drugs they found associated with errors and delivery problems. Chief among these were insulin for diabetics and Coumadin®, a blood thinner commonly prescribed for clotting disorders and heart rhythm irregularities. Resar's research found that about 20 episodes of low blood sugar were being identified among diabetics each week in the hospital. The problem: practically every doctor on staff used his or her own "sliding scale" to adjust insulin dosages to keep patients' blood sugar levels stable. "We were all trained differently; everybody had his or her own way of doing things," says Macken. "We identified 14 patients who were being cared for by nine doctors, who used 12 different scales for insulin. How were the nurses supposed to know what to do?"

Testing different options with a handful of patients under Macken's care, Resar worked with pharmacists to come up with a standard scale for insulin dosage. That scale is now being used for all diabetics admitted to the hospital. "The nurses are happy with it," said Macken. "The pharmacists are thrilled." The patients also won: insulin medication errors declined by 50 percent.

Problems involving blood-thinning drugs appeared even more life threatening. Clinic patients taking Coumadin® were being admitted to the hospital for either excessive bleeding, resulting from too much of the drug, or strokes, a potential result from getting too little of the drug. Adverse drug reactions also were being noted in patients taking Coumadin® in combination with certain antibiotics.

Once again, the problem stemmed from too many options. There are a number of ways to calculate Coumadin® dosage, and there are a wide variety of tablets available. In addition, Resar and Macken found that patients were coming in for lab tests when their primary physician was not available to read results. Partner physicians, unfamiliar with the patients, would make adjustments and order additional tests as a precautionary measure. Resar worked with Macken to come up with a standard nurse-run protocol for outpatients on Coumadin®. The result: a reduction in unacceptable blood clotting measurements from 25 percent to 10 percent in patients taking the drug. Today, nurses trained in drug interactions write all Coumadin® orders in the majority of clinic departments, and the patients come in for lab tests at a set time. Nurses have guidelines allowing them to adjust prescriptions with a requirement that they consult with physicians when lab results go too far out of range.

Affecting the Bottom Line

The payoff for these improvements is not only better quality care but cost savings. While Luther-Midelfort administrators have yet to measure the actual magnitude of the savings, there is little doubt they are significant. "We know at least 12 people were admitted for bleeding complications from Coumadin® last year," says Dr. William Rupp, the hospital's president and CEO. "By making the changes in our outpatient clinics, we've had no admissions for that this year. Coagulation measurements among patients are more stable because of our nurse-run protocols. We've been able to cut back the need for additional blood tests by 30–40 percent."

Rupp says other hospital CEOs ask him how he can afford to have a pulmonologist do administrative work. "I say we can't afford not to have him do it. Based on all of his improvement projects, I estimate Roger saves us four to six times what we pay him each year."

Rupp and Borman also champion the "pilot project" approach to change at Luther-Midelfort. The strategy is to test things on a smaller scale and let improvement projects grow naturally as the successes pile up and hospital staff adapts. That way, says Borman, "we get very little staff resistance." The change happens almost by osmosis, he adds. "Peer pressure kicks in because the ideas really work."

Innovations in patient safety are moving faster and faster through the Luther-Midelfort system, and momentum is building for larger systemwide quality improvements. The Coumadin® project took 18 months while the sliding scale insulin project took only two months to roll out. The "medication reconciliation" process aimed at the interfaces of care is now in place in 80 percent of the hospital. The process has evolved through 14 iterations. Most recently, Resar has given himself three months to implement a list of innovations recently devised by the Massachusetts Coalition for the Prevention of Medical Errors. These involve setting up educational review policies for oral medications given intravenously and the color coding of different drug delivery systems, among others.

And after a year-long effort that started out in just one department, a "nonpunitive" error reporting system is in place hospital-wide. As predicted, reports of errors from nurses and technicians have risen dramatically—up seven-fold in the first month after the policy was implemented in the spring of 1998. Says Rupp, "We have worked hard at changing the cultural fear of punishment. Now we tell people they'll get in trouble if they don't report an error—and they have a 48-hour period to let us know if something has gone wrong."

Resar says he has the proverbial "job that is never finished." But his enthusiasm for the work—and the mission—is undiminished. In years past, "we were benchmarking ourselves against mediocrity," Resar says. "Now, we are trying to create an organization that's among the safest in the country. I think we can do it." Then he launches into a list of future projects: standardized protocols for infusion pumps, better post-operative pain protocols, and simplified forms to track "near misses" on medication errors. "Some of my colleagues think I'm wasting my education because I'm not 'doing' medicine," says Resar. "But I know I'm just taking care of a larger population of patients."

Making MISTAKES Harder to Make

BY SHELLEY REESE

Like a growing number of hospitals nationwide, staff and administrators at Fairview Health Services, a system of seven hospitals based in Minneapolis, became increasingly aware in the mid-1990s that too many patients were getting the wrong drugs or the wrong dose of a drug. Steve Meisel, assistant director for clinical pharmacy services at Fairview Southdale Hospital, says it was not so much an epiphany as a dawning consciousness and conviction that the problem had to be made a priority.

In 1996, the hospital's leadership launched a program to reduce the risk of drug errors. After three years, the result has been a series of innovations aimed at creating an integrated medications management system with much tighter controls, fewer handoffs, and increased accountability. To do this, Fairview brought together doctors, nurses, pharmacists, and quality improvement experts to focus on the entire continuum of drug delivery.

"The chief thing we had to communicate to people at first was that they may be doing their job very, very well but that the whole process was just not working," says Denise White, a quality consultant at Fairview. "We had to get everyone to step back far enough to see how they work in the whole context."

The first step, both White and Meisel say, was to identify clinical areas, diseases, and medicines where the problems loomed largest and where pilot projects would have the most impact. A multi-disciplinary team ended up creating 15 separate projects. All started off on a small scale so they could be implemented quickly and efficiently. The primary testing ground became Fairview Southdale, a 300-bed hospital in the twin cities suburb of Edina.

The projects involved medications as diverse as anticoagulants, chemotherapy, insulin and sleeping pills. They also explored ways to adjust drug doses for people with abnormal kidney function and took patients out of harm's way by simply removing some of the most dangerous drugs from areas where they were readily available.

All the projects were grounded in a common—and common sense—premise: make it more difficult for staffers at every stage of the process to make a mistake.

A crucial choice was made early on and may well prove a popular model for other hospitals. The hospital system's pharmacy was selected to spearhead and oversee the initiative. The choice is not an obvious one. While pharmacists have long played a key role in hospitals, their expertise has often been underutilized, and some doctors are still reluctant to cede pharmacists control over patient care.

The decision in this case was based on the judgement that pharmacy had both the needed expertise and organizational skills and a strong rapport with various departments throughout the system. Those ties had been forged over 20 years by the

Focusing on the management of a few high-risk drugs, a Minnesota hospital system cut medication errors and sharply improved care

Fairview Health Services
Minneapolis, Minnesota

presence of pharmacists at nursing stations throughout Fairview hospitals—a practice common in Minnesota but not throughout the country.

The Warfarin Project

Among the first changes Fairview Southdale initiated was to reorganize the management of a drug called warfarin among cardiology patients. Warfarin, an anticoagulant, is prescribed for a variety of conditions to prevent and treat blood clots. It's a difficult drug to manage because numerous factors—including diet, alcohol use, and other medications—can affect the amount of drug in the body.

Patients must be carefully educated about warfarin and factors that can affect its use. Frequent monitoring of blood tests is also necessary to assure the drug is working properly and to prevent potential problems. These problems include severe and potentially life-threatening bleeding and clotting.

The warfarin project was prompted in the fall of 1996 when data showed that an average of 1.7 patients per week—almost 90 a year of the roughly 4,000 taking the drug—were being admitted for bleeding. The majority, 70 percent, of the admissions were thought to be due to an error in monitoring or dosing, or to inadequate follow-up. Warfarin was thus an ideal candidate for more intense management.

The project was first launched as a six-month pilot for 135 patients of the Minnesota Heart Clinic, an independent cardiology practice affiliated with the suburban hospital. A Fairview pharmacist was assigned to educate patients on warfarin, oversee dosing, and follow-up with those patients who had been started on the drug in the hospital.

The program yielded benefits from day one. Cardiology patients with insufficient monitoring fell from 22 percent before the pilot to less than one percent. Blood tests showed the share of cardiology patients with the correct dosage of warfarin in their bloodstream increased from 35 percent to 65 percent. As a result, warfarin complications per 100 cardiology patients fell from 12 to two. In addition, patient knowledge about the drug, measured by correct answers on a test, improved from a baseline of 30 percent to over 80 percent.

"The results were dramatic to the point that I almost didn't believe them," says Dr. William Hession, president of the Minnesota Heart Clinic. "It was pretty humbling to see."

The initiative's success is largely attributable, says Meisel, to tracking and follow-up of patients. But he says it's also due to the staff's acceptance and embrace of guidelines that were developed in conjunction with the Minnesota Heart Clinic. Two full-time pharmacists, Melissa Van Holland and Caren Allivato, ran the program from within the Minnesota Heart Clinic. (A third pharmacist has since been added but one is part-time.) Patients are seen face-to-face at each visit to identify potential problems, make adjustments in their therapy, and to provide ongoing education about their drug therapy.

Says Hession: "If you look at why people fail on warfarin, it's because they get lost. Patients figure, 'if I'm not bleeding and the doctor is not bugging me, I must be OK' and they don't get their tests. Now we have a database, and we know who should be coming in for blood studies. Patients are getting watched more closely, and that is really paying off." He says patients also better understand the effects diet and drug interactions can have on them and learn to avoid potentially dangerous situations.

Both Fairview and the Minnesota Heart Clinic were so impressed with results that they extended the warfarin program to other patient populations. The hospital made the service available to its orthopedic patients and vascular patients, for example. These patients are often prescribed warfarin after surgery. Results have been similarly promising. After the pharmacists took over the orthopedic patients' warfarin management, the number of blood clot complications for the group fell from an average of 7.6 per year to 4. Today, Van Holland and Allivato, and new colleague Kim Graupe, manage warfarin therapy for about 400 patients.

But warfarin is not the only drug to come under Fairview's microscope. The hospital also established dosing protocols for sleeping pills and for patients with impaired kidney function. And the project team developed a chart with a sliding scale for determining correct insulin dosage. All three programs were piloted

over a period of months and then adopted at some or all of Fairview's hospitals.

Reorganizing drug management of patients with impaired kidney function proved particularly successful. Using dosage guidelines developed by the hospital's Pharmacy & Therapeutics Committee, pharmacists were given permission to independently change physician-prescribed doses of drugs for patients with impaired kidney function. The purpose: to reduce the risk of toxicity associated with too high a dosage, a common problem. About 70 doses now are being changed each month. Physicians are notified.

Fairview Ridges Hospital developed a similar protocol for sleeping pills, such as triazolam (Halcion®) and temazepam (Restoril®), to reduce the risk of overmedication. Too high a dose of such drugs can heighten the risk of falls and accidents. Under the new protocol, if a physician prescribes a dose that is too high for the patient, the pharmacist is empowered to change the dose.

In a related step at Fairview Ridges, all patients considered to be at risk of falling are identified on admission. Nurses then develop plans to prevent falls, for example, by assisting at-risk patients to the bathroom.

Meanwhile, the team at Fairview Southdale tackled the issue of drug errors due to miscommunication. It developed a

Dr. William Hession, *left*, Minnesota Heart Clinic's president, reviews a patient's chart, while Caren Allivato, *above*, a Clinic Pharmacist, works with a patient taking warfarin. *(Photos by Jill Neu)*

pre-printed chart with a sliding scale for insulin dosing and a corresponding pre-printed form for recording medication administration information. The aim was to reduce errors caused by illegible handwriting, improper abbreviations, overlapping blood-sugar ranges, and failure to treat high blood sugar levels in a timely fashion.

The hospital system also sought to tighten controls on drug prescriptions by changing the way information is recorded. For example, at Fairview Southdale chemotherapy order forms were redesigned to prompt practitioners to record the level of detail necessary to safely prescribe, dispense, and administer these powerful drugs. Under the previous system, doctors could place orders verbally or over the telephone. The new template provides consistency and reduces the opportunities for potential errors. Fairview Ridges Hospital has since adopted the system, as well.

"We tried to design the template to reflect exactly the way people thought about dosage," said Paula Welford, a nurse manager formerly in the oncology unit. "So there is no chance of mistaking a one-time only dose for a daily dose."

The same logic was used to develop new procedures for copying information onto patient medication records. By establishing criteria to govern the way information is recorded—such as the use of abbreviations and brand versus generic names—Fairview Ridges reduced the number of places information might be misinterpreted by 60 percent, says Meisel.

Finally, Fairview implemented a key change to reduce the likelihood that high-hazard drugs might mistakenly be administered. At all Fairview hospitals, such medications were simply removed from floor drug carts stock. The move reduced the number of stock items in intensive care units by about 30 percent. In addition, to prevent patients from suffering dangerous reactions to drugs such as astemizole, an antihistamine, and oral ketorolac and metformin, which are used to treat arthritis and diabetes, respectively, they were simply removed from the hospital system's pharmaceutical drug formulary. With the exception of metformin, less hazardous medications were substituted.

So far, the success of Fairview's various programs are confined to distinct pockets of its complex care systems. And there is no single, overarching statistic describing how much patient safety has improved, says Meisel. It is impossible to measure progress in such a tidy way, he says, because there is no baseline figure to show how often mistakes are made.

"If you ask me what's the overall medical error rate in our hospital, I would not have a clue," Meisel says. "It's not like measuring the mortality rate after bypass surgery. You don't always know when an error occurs, and people don't always agree on what constitutes an error."

Fairview's successes have not been without accompanying failures. Some pilot programs have been dropped because of lack of staff support. For example, a measure intended to ensure patients are not being over-medicated would have required doctors to review their orders prior to a patient's transfer from a critical care unit. That initiative was dropped because staff objected to the additional responsibility.

More troubling, the long-term viability of some programs now in place remains uncertain. The warfarin project, for example, relies on tenuous financing. It costs $175,000 a year to run, Meisel says, with expenses comprised almost entirely of the two pharmacists' salaries and a portion of a secretary's salary. Initially, the hospital funded the entire program. But in January 1998, the Minnesota Heart Clinic agreed to begin covering the costs of its increased usage. The cardiology component of the service runs about $100,000 per year.

Still, the doctors, patients and Fairview end up paying for some of the cost: Medicare only pays a portion for face-to-face visits and does not reimburse for phone consults or follow-up. The hospital and Minnesota Heart Clinic bear this cost. "The onus falls on the wrong parties," said Hession. "Right now, none of the insurance companies are willing to come to the table to fully fund this kind of service." He says he hopes insurance companies will eventually come to see the cost effectiveness of warfarin management as a preventive service.

Despite such financial uncertainties, Meisel is brimming with other ways to reduce medical errors. He would like, for example, to expand the more intensive medical management of warfarin to neurology and primary care patients and, eventually, to the entire patient population. And he'd like to apply similar procedures to drugs such as amiodarone, which is prescribed for cardiac rhythm disorders, and digoxin, which is prescribed for heart failure, and other high-hazard drugs.

Finally, Meisel would like to see the hospital invest in technology to automate and streamline drug dispensing with computers and lower the risk of errors with a bar-coding system that tracks all drug orders. Having witnessed the results a handful of small-scale initiatives can yield, he's eager to tackle more ambitious measures. "When you think of the contribution pharmacy can make to improving safety and how far things can go, it's enormous," Meisel says. "There are several hundred more things we'd like to try. We'd like to get to the point where no patient again would be the victim of a medication error."

A Dummy HELPS PAVE THE WAY TO Better Medicine

Simulation technology, like that used to train pilots, can help doctors learn from their mistakes

VA/Stanford Simulation Center
Palo Alto, California

BY LISA KRIEGER

In the operating room, things are not going well. An electronic monitor recording a patient's heart rate registers a sharp rise from 70 to 100 and then to 160 beats per minute. His blood pressure is crashing. His airways spasm. Warning lights flash red. Alarms sound.

All in a few minutes, routine knee surgery has turned lethal. The anesthesiologist reaches for a syringe, fumbles, then drops the vial. Time is running out. The doctors scramble to figure out what is going wrong. They are acutely aware that the combination of rapid heart rate and plummeting blood pressure could kill a person in minutes.

But fortunately, not this patient. Lying before this medical team is literally a dummy, a simulated emergency care patient made of plastic, wires and computer chips. His formal name is "PatientSim," but he usually goes by Sam, Johnny, or Jessica (add a wig and some other features and he becomes a she). Even if Sam's doctors made all the wrong decisions, he would survive; a simple touch of a "reset" button brings him back to life.

But the doctors who are tending to Sam are keenly aware that they'll not have that luxury with a flesh and blood human being. They are "practicing" on the simulated patient to learn how to avoid and overcome medical errors and to respond in crisis situations—where studies consistently show the risk of medical errors is particularly high.

Since its creation in 1986, based on work by Dr. David M. Gaba, Director of the Patient Safety Center of Inquiry at the VA Medical Center in Palo Alto, CA, and a professor of anesthesia at Stanford, the PatientSim simulator has become a central learning tool at the VA/Stanford Simulation Center for Crisis Management Training in Health Care. Both PatientSim and the Center were inspired by Gaba's firm belief that the failure of doctors to learn to cope with urgent crises and react in a systematic, timely way is a major factor in preventable anesthesia and operating room medical mishaps.

Early forerunners of PatientSim at the VA/Stanford Center were the nation's only hi-tech human simulators until just a few years ago. But PatientSim now has some 150 "friends" in hospitals around the world made by two competing manufacturers. The growing number has occurred because simulator-based training has gradually gained an important foothold in medical education. And with interest in reducing medical errors and improving safety rising rapidly, medical safety experts predict medical simulation training to spread more widely in coming years.

The technology is modeled to a large degree on the experience in aviation. After World War II, the rapidly expanding commercial airline industry knew it had a safety and liability problem on its hands. Simulators were one way the industry sought to enhance training and reduce the risk of pilot error—which had risen sharply as planes got more and more complex. Today, airline pilots are required to learn to fly in a simulator before they take the controls of a real plane. Hours of additional simulator time are required to keep skills sharp. And pilots frequently learn to use new equipment and fly unfamiliar planes in a simulator.

Simulators are credited with playing a key role in the enormous reduction in air crashes and fatalities over the past few decades. Simulation-based training is also used in automobile driving, shipping, military command and control, and the operation of nuclear power plants. Gaba believes simulator training in health care can and should play a similar role.

Like pilots, he says, surgeons and anesthesiologists can face crisis events that are infrequent but potentially lethal. Both pilots and doctors must absorb a prodigious amount of technical knowledge. And the bias in their education and training leans heavily towards mastering a defined and complex set of skills. But unlike today's pilots, doctors are often poorly trained in "crisis management"—how to respond when something goes wrong, sometimes terribly wrong, Gaba says.

Many anesthesia mistakes, for example, are caused by technical problems, such as incorrect administration of a drug. But many others are caused by behavioral problems and poor communication among doctors, nurses, and technicians. For example, a doctor barking an order into thin air in an operating room could go unheeded if it is not addressed to a specific individual.

Gaba also thinks the system trains doctors poorly to do new tasks. It is not uncommon for a doctor performing a new technique or using a new piece of technology to try it out for the very first time on a real patient. That, Gaba says, is unwise.

In the practice of anesthesia, Gaba notes that deaths from errors have declined sharply over the last 30 years (see story page 26). But "we need to, and can, make it even safer," he says. Deaths from anesthesia errors have declined to as low as one per 100,000 to 200,000 "healthy" patients (those whose physical condition can not have contributed to the death). But the risk of dying in a domestic commercial jet flight in the U.S. is far, far lower—about one in 8 million.

Gaba says the idea for the patient simulator came to him when he was reading the 1985 book *Normal Accidents* by Yale sociologist Charles Perrow. The book analyzes the social and human side of technological risk. It concluded that system complexity, and the human response to emergency, make error and failure inevitable in many high-risk industries.

The relevance to anesthesia and medicine was clear to him immediately, Gaba says. "I wanted to test how anesthesiologists respond to unexpected events. And it dawned on me that we could build something to measure and monitor this."

But building a patient simulator posed challenges for Gaba not faced by the designers of flight simulators. An artificial environment that mimics the human body is enormously more complicated than simulating flight. The human body presents thousands of variables that make even fickle weather conditions seem easy.

The first electromechanical anesthesia simulator had been developed in the late 1960s. Though ahead of its time, the machine was flawed and drifted into oblivion. In 1986, Gaba and a colleague began developing the first generation of realistic simulators, using new computer capabilities to provide signals to actual clinical instruments. This model was improved with a modified mannequin which allowed mask ventilation, intubation and monitoring of breath sounds. But it was still relatively crude, with no pulse, spontaneous breathing or human-like physiology.

A major redesign in 1989 incorporated a physiologic model of the cardiovascular system. Then in 1992, the CAE Link Corporation, a manufacturer of military aviation and space flight simulators, licensed the technology from Gaba's team to develop a commercial patient simulator. Its mannequin contained a complete model of cardiovascular, pulmonary, fluid, acid-base electrolyte and thermal physiology. It includes computer-controlled electromechanical lungs, heart and breath sounds, changeable airway anatomy, and a palpable pulse.

HOW THE SIMULATOR WORKS

The VA/Stanford Simulation Center, opened in 1995, looks and feels like a fully functional operating room, complete with assorted high tech medical equipment, surgical lights, and tension in the air. An adjacent control room contains a computer that executes all Sam's "physiologic" functions—from the cardiovascular and pulmonary systems, to metabolism, fluid and electrolyte balance, and thermal regulation. For example, the system moves "mathematical blood" from one heart chamber to the next and from blood vessel to blood vessel—a process requiring thousands of computations every second.

The simulator can mimic dozens of complex and realistic clinical crisis scenarios. And instructors can modify these scenarios in hundreds of ways. Thus, Sam can be programmed to act like a healthy young truck driver or a frail 80-year-old woman. Instructors can induce a heart attack, respiratory trouble, an allergic reaction to medicines, and other kinds of distress. For each event, myriad settings are possible to mimic severity and responsiveness to treatment. And reactions to drugs and procedures vary with each computer-programmed change in physiology.

The simulator is programmed to show the same distress symptoms as a human patient. For example, a working blood pressure band is strapped to Sam's biceps and an IV is placed in one arm. His pulse can be felt at both wrist and neck. The heart beat can be heard with a stethoscope and the heart rhythm can be made to be abnormal. Inside Sam's mouth are teeth, tongue, uvula and windpipe. Electromechanical, computer-controlled lungs are embedded in its chest; they "breathe" spontaneously, as well as by hand or mechanical ventilation. Incoming gases are detected and quantified and their concentrations fed to the physiologic and pharmacological computer models. Oxygen sensors ensure that if Sam quits breathing, alarms go off.

Most amazingly, Sam is programmed to respond as a healthy human would to more than 70 medications. When he gets an anesthetic, for example, his eyelids stop moving and his breathing slows; doctors must quickly stick a tube down his windpipe to give him air. If the tube does not go down correctly and he fails to get enough oxygen, his heartbeat speeds up and carbon dioxide makes his blood pressure rise. By mimicking an actual patient during surgery as much as possible, doctors know quickly if they've injected the wrong drug, erroneously interpreted vital signs, or made other errors.

After every simulator session, doctors and nurses can watch their performance on video monitors in a debriefing room. These sessions, Gaba says, provide profound insight into glitches in the system that can lead to patient harm.

"It's not about finding bad doctors," Gaba says. "It's about helping doctors learn to work together better to prevent problems and errors."

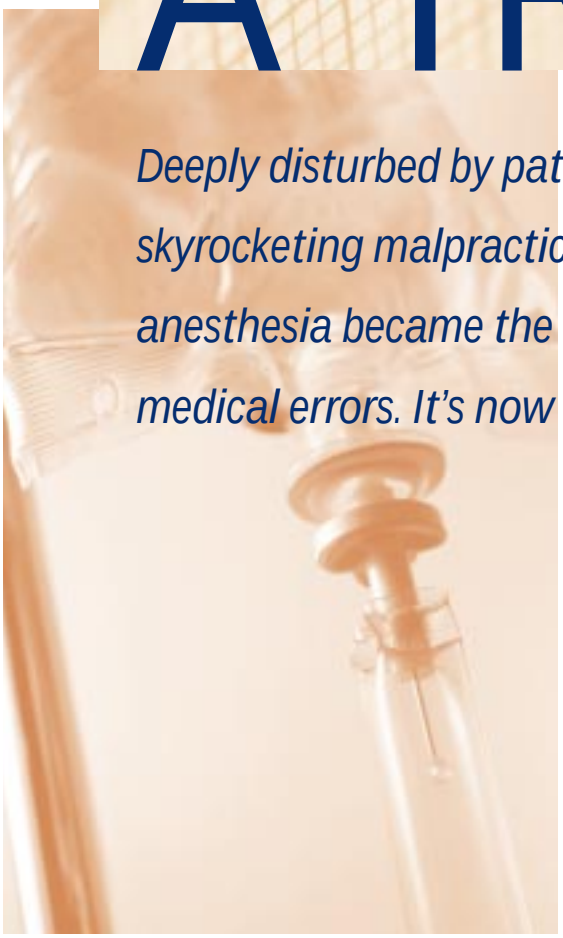
The simulator also is being used for research. Gaba and his team have studied decisions made by intensive care unit clinicians, comparing their responses to those of a prototype computer-based decision support system. They also are measuring the influence of fatigue on cognition.

"Within the next few years, we can expect to see continued, incremental improvement of simulator technology," Gaba says. Beyond that—in 10–20 years—the next generation of simulators will likely use virtual reality technology to replicate the operating room's environment. And beyond that...well, anything is possible. It's likely that simulators will be used broadly in training and perhaps even become so commonplace that they allow doctors to practice particularly tricky operations before they do them.

Already the crisis management training pioneered in anesthesiology has been extended to delivery room crisis and neonatal resuscitation, emergency room and trauma care, intensive care medicine, cardiac arrest response ("code") teams, and other health care settings. Although Gaba believes that simulators will improve medical safety, he's quick to say they are complementary to, not a replacement for, conventional means of medical education. After all, for all his marvelous technical sophistication, Sam is still just a dummy.

A MEDICAL SPECIALTY BLAZES A TRAIL

Deeply disturbed by patient deaths and facing skyrocketing malpractice premiums, the field of anesthesia became the first to seriously tackle medical errors. It's now a model for others.



BY JAN ZIEGLER

It's just a small device, resembling a plastic clothespin with some wires that connect to a monitor about the size of a portable phone. Without looking closely you might think it was part of an electronic game. But the elegantly simple device is among the most important in medicine. It determines whether a patient under general anesthesia is receiving enough oxygen—oxygen that will keep the patient alive through the procedure and, if all goes as expected, permit her to awaken in the recovery room with no ill effects.

Oxygen, of course, is vital to all living tissue. In decades past, oxygen deprivation while a patient was under anesthesia was one of the most common errors in medicine. Lack of oxygen, or hypoxia, occurred most frequently because the tube that was supposed to deliver the precious gas through the trachea to the lungs was placed by mistake into the esophagus. It's an "operator error," and when it happens, irreversible brain damage and death can occur in minutes. In the past, by the time the mistake was detected, it was usually too late. But the clothespin-like device, developed in the early 1980s, discerns the levels of oxygen circulating in the patient's bloodstream.

The oxygen pulseoximeter, as the device is called, is one of dozens of important advances in the field of anesthesiology in the past 20 years. What makes the field unique is that many of the advances were either specifically aimed at reducing the risk and rate of errors, or did so as an important secondary benefit. As a result, undergoing anesthesia has gone from being one of the most notoriously dangerous procedures in medicine to one of the safest.

In the 1950s, the death rate from anes-

thesia was roughly one in 3,000 to 4,000. By the 1970s, it had come down to roughly one in 10,000, says John Eichhorn, M.D., professor and chairman of anesthesiology at the University of Mississippi Medical Center. But by 1990, Eichhorn's own meticulous research among patients in Boston found just one non-fatal mistake among 392,000 patients undergoing anesthesia. Other recent data indicate a rate of one death per 200,000 to 300,000 anesthetics administered.

"It has been a true revolution in health care," says Eichhorn.

That revolution and the field of anesthesia is now being held up as an example for other medical specialties, and medicine in general.

Most notable, say experts, is that anesthesiologists—led by their professional groups—went about making the necessary changes themselves. They set strict internal standards and organized initiatives. No outside government body—state or federal health authorities, Congress, or the American Medical Association—made them do it. There was of course another, baser motive: malpractice liability. And eventually, some in the profession also pushed for state regulations.

The early years

Among the early leaders of this effort, Ellison "Jeep" Pierce is widely considered to have been particularly indispensable. His Spencer Tracy-like appearance and manner inspired allegiance and trust. His occasional gruffness hid compassionate commitment to the improvement of medical practice. What's more, Pierce is still involved in the fight. He serves today, at 71, as executive director of the Anesthesia Patient Safety Foundation based in Boston.

Pierce began his residency in 1954 at the Hospital of the University of Pennsylvania. "Our practices back then were abysmal," he says. "I can remember we had one cardiac arrest a week as a direct result of the anesthesia. We would go to the family and say, `We're sorry, old Joe just couldn't take it.' That was it. They accepted it."

Pierce says it was common in those days, for example, for anesthetists to be allowed to leave the operating room for a cup of coffee after the patient was "under." Ether was the primary agent used, despite the availability of other gases. They monitored the patient by simply observing signs such as breathing rate and pulse. "It was really very rudimentary," Pierce says.

In 1960, Pierce became vice-chairman of anesthesia at Peter Bent Brigham Hospital in Boston. "As I collected cases over the next 10 years," he says, "it became obvious there were a lot of deaths that could be prevented."

The public was beginning to surmise that as well. No longer willing to accept the "old Joe" explanation, people began to sue anesthesiologists for malpractice in record numbers in the late 1970s and early 1980s. As a result, malpractice premiums for anesthesiologists skyrocketed, becoming among the most expensive in medicine.

The media poured fuel on this fire. The risks of anesthesia became a common story in print media, and television was not far behind. In 1982, the ABC newsmagazine show *20/20* aired a now-famous segment highlighting shoddy anesthesia practices at several institutions. The show warned viewers that 6,000 would die or experience brain damage that year because of avoidable anesthesia error.

Pierce and others knew a major effort was now in order or the speciality would suffer long-lasting damage. In 1983 Pierce became the vice-president of the American Society of Anesthesiologists (ASA). He used his position there—bolstered by the gathering outrage over malpractice premiums—to establish the ASA Committee on Patient Safety and Risk Management. The group set standards of care and safety and used every means available to get the word out—including the production of a series of educational videos that remain popular. Two years later in 1985, Pierce and other leaders organized the first International Symposium on Preventable Anesthesia Mortality and Morbidity. The meeting was a turning point for the wider adoption of more sophisticated patient safety measures in the field. The creation in 1984, of the Anesthesia Patient Safety Foundation also added momentum.

At the same time, outside forces were impinging. Malpractice insurers were taking a proactive stance towards anesthesia errors. Eichhorn says the major malpractice carrier for the nine Boston hospitals affiliated with Harvard Medical School made the rounds of anesthesia department chiefs in the mid-1980s. Their message was simple and blunt, he says: "You guys are costing us too much money."

Spurred by the insurer's warning, Pierce, Eichhorn and others helped form the Harvard Department of Anaesthesia Risk Management Committee. The group embarked on creating a comprehensive set of practice standards for the field. They would be the first ever. The standards were issued in 1985 and published in the *Journal of the American Medical Association* in 1986. They quickly gained broad currency and remain today the core set of practice standards in the field—widely adhered to. Regular updates have taken place. For example, pulse oximetry, the mechanism that uses a small clip or bandage-like device on fingertip, ear, nose or toe to measure oxygen in the blood, became part of the standards in 1990. Capnography, a companion device that measures blood levels of carbon dioxide, was added to the standards in 1991.

Redesigning the machinery

Even as doctors were finding better and safer ways to use the technology at their disposal, engineers like Peter Schreiber and Jeffrey Cooper were trying to make the technology more user-friendly.

Schreiber, who moved to the U.S. from Germany in 1970 to start his own company, says the equipment even in the 1970s was "very imperfect." It left too much room for operator error and machine failure. The machines consisted of a metered gas cylinder and a vaporizer for the other gas or gases that would be administered concurrently, such as nitrous oxide or oxygen. There was no way to measure the patient's responses to the anesthesia. Anesthetists simply observed their breathing and appearance and took their pulse, much as as they had in the 1850s.

Schreiber knew that monitors were needed to keep track of cardiac, lung and other functions. But he says there was tremendous initial resistance to this idea. Anesthetists at the time considered what they did an art form. Many, he says, flatly told him: "I do not trust any mechanism or electrical equipment that is between me and my patient."

Schreiber's most important insight—and one that resounded later through much of medical equipment design—was that humans were not wired well to monitor "boring events" for hours at a time. And he defined surgery as a boring event—from the anesthetists point of view at least. Attention can easily slip during hours of watching a patient.

His argument slowly began in the 1970s to make a dent. Manufacturers rolled out a plethora of monitors that would provide information on bodily functions. Then, realizing the sheer number of these devices was impractical, they designed a system that contained all the necessary monitoring components.

Cooper, meanwhile, was focused on another element of anesthesia technology. As a bio-engineer at Massachusetts General Hospital in the 1970s, he began to use a method popular in the field of aviation safety—called critical incident technique—to evaluate the interface between machine and human in anesthesia. He did not like what he saw.

"The equipment was no longer the biggest problem; it was all this other stuff," says Cooper, now chairperson of bio-engineering at Massachusetts General Hospital and Brigham and Women's Hospital in Boston. The "other stuff" was the human error involved in using the technology. His research demonstrated that inadequate experience and familiarity with equipment were major factors in anesthesia errors. His ground-breaking papers, published in 1978 and 1984, led to training programs that are widely believed to have played a major role in anesthesia error reduction.

It's the law

The latest step in this evolution began a decade ago. Even as anesthesiologists were eagerly embracing the new equipment and adhering to voluntary standards, some felt more was needed. One of these people was Ervin Moss, M.D., a practicing anesthesiologist in New Jersey and New York for 45 years. Moss believes voluntary standards are commendable and useful, but lack the teeth needed to go the rest of the way towards reducing anesthesia errors.

He began lobbying heavily for state rules in the mid-1980s. His first opportunity came when his own state of New Jersey set about changing its medical licensing regulations in 1988. Moss insisted that anesthesiology be governed separately. The result was passage of the Anesthesia Regulation Bill. The new law, which covered any facility with two or more surgical operating rooms, had swift impact. Three hospital chiefs of anesthesiology were forced to resign because one new rule in the law required board certification for the post. Hospitals were given six months to junk out-of-date machines. If they didn't, they had to close the operating room. All anesthesia-related deaths and other adverse events had to be reported to the state health department by hotline immediately, and in writing in 30 days. Failure to comply carried a number of penalties, including loss of license.

But Moss did not stop there. In the early 1990s, he pushed for regulations in New Jersey that would govern hospitals and facilities—primarily doctor's offices—with just one operating room. "They were hiding behind the idea that they were simply offices," Moss says. "But a lot of surgical procedures are done in a doctor's office."

It was a long fight but Moss, again, ultimately prevailed. The New Jersey legislature in June 1998 passed a law regulating office-based anesthesia and surgery.

But New Jersey is so far the only state with such a law on the books. California has regulations but they are not nearly as strong, Moss says. A few other states are looking at the issue. Moss believes a major push from anesthesiologists and consumers will be needed to get the issue on to the front burner.

Meanwhile, the anesthesia profession continues to wage an aggressive campaign to further reduce errors. One initiative has yielded important data. It's called the "Closed Claims Study." It originated at the University of Washington in Seattle in 1985. The project uses data from settled malpractice claims to analyze anesthesia accidents. Among its findings to date are that death and brain damage represent a declining proportion of malpractice claims—31 percent in the late 1990s, down from 56 percent in the 1970s. Inadequate ventilation represented 22 percent of all claims in the 1970s but just seven percent in the 1990s. Pierce says the data are more concrete documentation that the most serious, and fatal, kinds of anesthesia accidents have declined.

That these event still occur at all though, is very disturbing, Pierce says. "We can not rest on our laurels. That's the bottom line," he says. "There will always be room for more improvement, and we simply must achieve it."

Resources and Suggested Reading

SELECTED ORGANIZATIONS

National Patient Safety Foundation (NPSF)
515 N. State Street, 8th Floor
Chicago, IL 60610
PHONE 312-464-4848
FAX 312-464-4154
EMAIL npsf@ama-assn.org
WEBSITE www.ama-assn.org

The NPSF maintains a website that provides links to a variety of sites with information on patient safety.

Institute for Safe Medication Practices (ISMP)
300 West Street Road
Warminster, PA 18974
PHONE 215-956-9181
FAX 215-956-9266

ISMP provides an independent review of medication errors that have been voluntarily submitted by practitioners to a national Medication Errors Reporting Program (MERP) operated by the U.S. Pharmacopeia (USP).

US Pharmacopeia (USP)
12601 Twinbrook Parkway
Rockville, MD 20852
PHONE 800-4-USP-PRN (800-487-7776)
WEBSITE www.usp.org

USP Medication Errors Reporting Program
PHONE 800-23-ERROR (800-233-7767)

National Coordinating Council for Medication Error Reporting and Prevention
PHONE 800-822-8772

USP has a Medication Errors Reporting Program. USP's Practitioner Reporting Network (PRN) publishes the USP Quality Review, which often discusses medication error topics.

National Patient Safety Partnership
Office of the Under Secretary for Health
Department of Veterans Affairs
810 Vermont Avenue NW
Washington, DC 20420
PHONE 202-273-5807
FAX 202-273-7090

VHA National Center for Patient Safety
2215 Fuller Road
Ann Arbor, MI 48105
PHONE 734-930-5890
FAX 734-930-5899

BOOKS

Bogner, M.S., ed. *Human Error in Medicine*. (Hillsdale, NJ: Lawrence Erlbaum) 1994.
This collection of presentations from a symposium on errors in medicine provides a good overview of many aspects of health care errors. A number of the key contributors to current thought concerning error in medicine are represented.

Cohen, M. *Medication Errors*. (Washington, DC: The American Pharmaceutical Association Foundation) 1999.
This book provides an overview of the types of medication errors, processes that lead to errors, research on medication errors, and suggestions for minimizing the potential for future errors.

Corrigan, J.; Kohn, L.; and Donaldson, M., eds. *To Err Is Human: Building a Safer Health System*. Committee on Quality of Health Care in America, Institute of Medicine. (Washington, DC: Institute of Medicine) 1999.
The report lays out a comprehensive strategy for government, industry, consumers, and health providers to reduce medical errors, and it calls on Congress to create a national patient safety center to develop new tools and systems needed to address persistent problems. Each chapter of the report contains a reference list, allowing the reader to select additional material based on a specific area of interest.

Kahneman, D.; Slovic, P.; and Tversky, A., eds. *Judgment Under Uncertainty: Heuristics and Biases*. (New York, NY: Cambridge University Press) 1982.
The classic collection of studies of how humans make judgments under (usual) conditions of uncertainty. The authors coined some of the key terms in behavioral science.

Leape, L. L.; Kabcenell, A.; Berwick, D.M.; and Roessner, J. *Reducing Adverse Drug Events: Breakthrough Series Guide*. (Boston, MA: The Institute for Healthcare Improvement) 1998.
Institute for Healthcare Improvement Guides are based on the real-life experiences of health care organizations that have made dramatic changes while participating in a Breakthrough Series Collaborative. Each contains a synopsis of the Collaborative goals and results, the model for accelerating improvement, change concepts that Collaborative participants used successfully, additional resources, key contacts and a bibliography. The book is based on a 1996-97 Collaborative.

Perrow, C. *Normal Accidents*. (New York, NY: Basic Books) 1984.
A fascinating book that opens the world of complex systems and introduces the reader to concepts of human error. The contrasts between the effectiveness of error prevention in aviation and the merchant marine are striking.

Reason, J. *Human Error*. (New York, NY: Cambridge University Press) 1990.
The "bible" of error theory, written by the leading authority. Reason reviews the literature and establishes a theoretical framework for understanding error. A treasury of important concepts.

ARTICLES

Alibhai, S.M.H.; Han, R.K.; and Naglie, G. "Medication education of acutely hospitalized older patients." *J Gen Intern Med*, 1999, 14:610-616.
The results of this study indicate that even though patients perceive the education they receive from their physician or pharmacist to be satisfactory, many patients still make errors when they take their medications.

Bates, D. W.; Cullen, D. J.; Laird, N.; Petersen, L. A.; Small, S.; Servi, D.; Laffel, G.; Sweitzer, B.; Shea, B. F.; Hallisey, R.; Vander Vliet, M.; Nemeskal, R.; and Leape, L. L. "Incidence of adverse drug events and potential adverse drug events: Implications for prevention." *JAMA*, 1995, 274:29-34.
A study of 4301 inpatient admissions of medical and surgical intensive care units at two tertiary care hospitals. The authors concluded that adverse drug events (ADEs) were common and often preventable and that serious ADEs were more likely to be preventable.

Bates, D.W.; Leape, L.L.; Cullen, D.J.; et al. "The impact of a physician computerized order entry system on prevention of serious medication errors." *JAMA*, 1998, 280:1311-1316.
To evaluate the impact of computerized physician order entry (POE), patients admitted to three medical units were studied for seven-to ten-week periods in four different years. The baseline period was before implementation of POE, and the remaining three were after implementation. During the study, the non-missed-dose medication error rate fell 81 percent.

Bates, D.W.; Spell, N.; Cullen, D.J.; et al. "The costs of adverse drug events in hospitalized patients." *JAMA*, 1997, 277:307-311.
Analysis of the costs of adverse drug events identified in Adverse Drug Event Prevention Study (see Bates et al., JAMA 1995 above), using a case-control methodology. Preventable ADEs cost twice as much as nonpreventable ADEs and averaged $4,685 each at one teaching hospital. Authors estimate that hospitals in the study are losing $2.8 million each year on preventable ADEs.

Bedell, S.E.; Deitz, D.C.; Leeman, D.; and Delbanco, T.L. "Incidence and characteristics of preventable iatrogenic cardiac arrests." *JAMA*, 1991, 265:2815-2820.
Landmark study that demonstrates that most cardiac arrests that occur in hospitals are caused by misuse of drugs and are, therefore, potentially preventable.

Bordage, G. "Why did I miss the diagnosis? Some cognitive explanations and educational implications." *Acad Med*, 1999, 74(10):S138-S143.
A review article that has several purposes: 1) to describe diagnostic errors in general; 2) present details about two specific types of diagnostic error; and 3) apply lessons learned to the educational process so medical students will learn how to avoid similar errors.

Chassin, M.R.; Galvin, R.M.; et al. "The Urgent Need to Improve Health Care Quality." *JAMA*, 1998, 280:1000-5.
This article explained the framework of health care quality defined as "underuse, overuse, and misuse," and concluded that these problems exist in large and small health care organizations in all regions of the country.

Classen, D.C.; et al. "Adverse Drug Events in Hospitalized Patients." *JAMA*, 1997, 277:301-6.
This study examined the excess length of stay, extra costs, and mortality attributable to adverse drug events (ADEs) in hospitalized patients. The authors found that ADEs are associated with a significantly prolonged length of stay, increased economic burden, and an almost two-fold increased risk of death.

Classen, D.C.; Pestotnik, S.L.; Evans, R.S.; and Burke, J.P. "Computerized surveillance of adverse drug events in hospital patients." *JAMA*, 1991, 266:2847-51.
Description of the continuous monitoring system at LDS Hospital in Salt Lake City, Utah. This is an impressive system that integrates clinical, laboratory, drug, and cost information to identify ADEs both prospectively and retrospectively.

Cullen, D.J.; Bates, D.W.; Small, S.D.; et al. "The incident reporting system does not detect adverse drug events: A problem in quality assurance." *Jt Com J Qual Improv*, 1995, 21:541-548.
The yield of spontaneous reporting of ADEs by the hospital incident reporting system was compared to intensive, confidential data collection by means of self-report and daily record review. Ninety-four percent of ADEs discovered by record review and confidential report were not reported as incident reports.

Dansky, K.H.; Gamm, L.D.; Vasey, J.J.; and Barsukiewicz, C.K. "Electronic medical records: are physicians ready?" *J Healthcare Manage*, 1999, 44:440-455.
Electronic medical records are often presented as one solution for reducing medical error. This article outlines some of the barriers in successful acceptance of this mode of operation within the clinical setting.

Ko, R. "Adverse reactions to watch for in patients using herbal remedies." *West J Med*, 1999, 171:181-186.
This review article looks at patient safety issues regarding the use of alternative medicines and offers several advisory lists for clinicians whose patients use herbal remedies.

Kronz, J.D.; Westra, W.H.; and Epstein, J.I. "Mandatory second opinion pathology at a large referral hospital." *Cancer*, 1999, 86:2426-2435.
Johns Hopkins Medical Center was the site of this study. A mandatory second opinion program was put in place, and it was found that a significant portion of initial diagnoses reviewed within the study had discrepancies with the conclusions drawn through the second review.

Leape, L. L.; Bates, D. W.; Cullen, D. J.; Cooper, J.; Demonaco, H. J.; Gallivan, T.; Hallisey, R.; Ives, J.; Laird, N.; Laffel, G.; Nemeskal, N.; Petersen, L. A.; Porter, K.; Servi, D.; Shea, B. F.; Small, S.; Sweitzer, B.; Thompson, B. T.; and Vander Vliet, M. "Systems analysis of adverse drug events." *JAMA*, 1995, 274:35-43.
The landmark article on systems ananlysis of adverse drug events. The authors define the underlying problems and identify the "proximal causes" of medication errors.

Leape, L.L.; Cullen, D.J.; Clapp, M.D.; Burdick, E.; Demonaco, H.J.; Erickson, J.I.; and Bates, D.W. "Pharmacist participation on physician rounds and adverse drug events in the intensive care unit." *JAMA*, 1999, 282:267-270.
To measure the effect of pharmacist participation on medical rounds in the ICU on the rate of preventable ADEs caused by ordering errors, the authors compared between phase 1 (baseline) and phase 2 (after intervention implemented) and phase 2 comparison with a control unit that did not receive the intervention. The rate of preventable ordering ADEs decreased by 66 percent from 10.4 per 1000 patient-days before the intervention to 3.5 after the intervention. In the control unit, the rate was essentially unchanged during the same time periods: 10.9 and 12.4 per 1000 patient-days.

Lesar, T.S.; Briceland, L.L.; Delcoure, K.; et al. "Medication prescribing errors in a teaching hospital." *JAMA*, 1990, 263:2329-34.
One of the first descriptions of prescribing errors in hospitals.

Lesar, T.S.; Briceland, L; and Stein, D.S. "Factors related to errors in medication prescribing." *JAMA*, 1997, 277(4):312-7.
This study quantified the type and frequency of identifiable factors associated with medication prescribing errors. Systematic evaluation of every third prescribing error over a one-year period at a tertiary care teaching hospital revealed total errors of 2103, with 696 errors meeting a study criteria of errors with the potential for adverse patient effects.

McDonald, C.J. "Protocol-based computer reminders, the quality of care and the non-perfectibility of man." *N Eng J Med*, 1976, 295:1351-55.
Pioneering paper on the potential use of computerized reminders to aid medical decision-making.

McNally, K.M.; Page, M.A.; and Sunderland, V.B. "Failure mode and effects analysis in improving a drug distribution system." *Am J Health-Syst Pharm*, 1997, 54:171-177.
Description of use of such analysis in pharmacy practice.

Melmon, K.L. "Preventable drug reactions—causes and cures." *Sem Med Beth Israel Hosp*, 1971, 284:1361-7.
One of the earliest papers on preventable adverse drug events. A classic.

Thomas, E. J.; Studdart, D.M.; Newhouse, J.P.; et al. "Costs of medical injuries in Utah and Colorado." *Inquiry*, 1999, 36(3):255-64.
The authors estimate the direct and indirect costs of adverse events. Extrapolation to all hospital admissions in the U.S. indicates national costs for preventable adverse events of $17 billion.

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