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Patient Safety: A Data-Driven Prescription

by Heather Burns and Charles Beever

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Medical mistakes kill almost 100,000 Americans each year and cost the country as much as $29 billion annually. The right prescription could be a nationwide information system modeled on the FDA's adverse drug reaction network.

by Heather Burns and Charles Beever

Medical mistakes are a persistent blight on the U.S. health-care system. Although the United States spends more per capita on health care than any other country in the world, as many as 98,000 Americans die each year from preventable medical errors during hospitalization, according to a 1999 report by the Institute of Medicine. And a 2002 study by the Harvard School of Public Health and the Kaiser Family Foundation found that 35 percent of physicians and 42 percent of the public said they had experienced errors in their own or in a family member's care.

Beyond the obvious societal toll of medical mistakes, there are also serious and far-reaching consequences for the American economy and corporations. The cost associated with these errors in lost income, disability, and health-care expenses is as much as $29 billion annually, according to the National Academy of Sciences Institute of Medicine. Preventable medication errors alone are estimated to increase hospital costs by about $2 billion nationwide.

In fact, the costs of medical errors have become so alarming to companies that more than 120 large U.S. employers and insurers, representing about 33 million health-care consumers, have formed a collective called the Leapfrog Group to tackle the problem. Among a wide set of initiatives, including a plan that would attempt to assign patients to hospitals that specialize in their specific conditions, Leapfrog is supporting federal legislation to decrease health-care mistakes by requiring hospitals and physicians to report errors in patient care to a centralized database. Under the proposed law, the job of monitoring and analyzing this computerized information would go to the Center for Quality Improvement and Patient Safety, a new agency yet to be created within the Department of Health and Human Services. This agency would identify national trends, provide feedback to health-care providers about safe and effica-

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cious treatments as well as alternatives that should be avoided, and, overall, encourage best practices in the medical profession.

Although it has much of corporate America on its side, and backing from influential lawmakers like Senators Edward Kennedy (D-Massachusetts), William Frist (R-Tennessee), and James Jeffords (I-Vermont), this bill's future is far from certain. In the last Congress, it never made it out of committee in either the Senate or the House.

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A patient safety database could be a credible repository of treatment options for people bewildered by the array of good and bad medical information on the Web.

A Database Template

If patient safety legislation does pass, a model already exists for how it can be implemented. It's called the Adverse Event Reporting System (AERS), developed in 1998 by Booz Allen Hamilton for the Food and Drug Administration (FDA). This is a national database that has become the centerpiece of the FDA's safety surveillance program for drugs and therapeutic products. Prior to AERS, the FDA primarily used paper records to keep track of adverse drug reactions reported by pharmaceutical companies, health-care providers, or consumers. Because the data wasn't automated, it was virtually impossible for the FDA to analyze and correlate the information. That, in turn, made it difficult to uncover, for instance, regional or condition-specific drug-reaction phenomena. Also, the FDA was frustrated by the haphazard way that the information was provided. Officials wanted a more standardized process for drug safety reporting and information sharing among health authorities and pharmaceutical companies worldwide.

Designed to fulfill these needs, AERS automatically codes adverse reaction terms using a new international coding schema; critical adverse event reports are routed directly to the appropriate FDA staff's electronic inboxes; flexible query tools let the agency identify potential drug risks and explore various drug safety hypotheses online; and tools, screens, tables, and reports present adverse event data in summarized or detailed formats. The output from AERS is evaluated by clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The results may lead to further epidemiological studies; regulatory action to improve product safety, such as updated labeling; regular correspondence with health-care professionals alerting them to the proper use of the drug; or the reevaluation of an approval decision.

With some modifications, AERS

could be used as a template for a patient safety reporting system, because medical treatment specialists in the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC), the Veterans Administration, and the Department of Defense's Military Health System face many of the same data shortcomings as the FDA did a few years ago. Currently there is no standard, automated mechanism for collecting details about incidents in which patients receive less than ideal treatment because of diagnosis failure, ignorance, or misinformation. Hospitals and physicians operate in a litigious culture in which mistakes are not addressed openly or shared for their learning value. Consequently, most of these errors are never recorded, analyzed, or corrected.

Critical examination of the available body of literature pertaining to medical conditions and collaboration with medical associations that are already establishing treatment protocols in their fields can help a governing organization set guidelines for a standard of care. These guidelines, governing what physicians are compelled to do under specific medical circumstances, can then be coded in a database that is constantly updated with information from health-care providers and hospitals describing their actions — and the results — during patient encounters. (Patients' names would be withheld to protect confidentiality.)

The databank would automatically modify these standard treatment guidelines when certain protocols proved to be more successful. Errors would be highlighted and analyzed for any underlying trends. All of this data would then be available to health-care providers via computer to use as a means of improving the level of their performance. In a simplified format, it could be provided to patients via the Internet.

A system like this offers several advantages. For one thing, a computerized, searchable source of best medical practices could benefit millions of patients under the care of rural physicians, who face many unfamiliar complaints and conditions and may lack a single, reliable, up-to-date source of the best and most effective treatment courses. And in a health-care landscape that is increasingly patient-focused, this database could be a credible repository of treatment options for people bewildered by the array of good and bad medical information on the Web.

Hurdles and Incentives

Some physicians oppose a patient safety databank, because they fear that such an information network would bring about more malpractice suits amid further monitoring of their practices. But for the best doctors, the opposite could occur: Physicians whose pattern of performance meets or exceeds the clinical benchmarks detailed in the safety databank could avoid malpractice suits because they would have evidence that their level of patient care matches or goes beyond minimum national health-care standards. In addition, these physicians could be rewarded for consistent adherence to patient safety guidelines with lower malpractice premiums.

There are also potential economic incentives for hospitals to

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eliminate errors. Health-care mistakes often severely undercut a hospital's reputation, such that additional financial resources are needed to reestablish its public image. Furthermore, in the most dire cases, poor patient safety may lead to high-ticket litigation, poor employee morale, and even loss of the customer base. Accreditation organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), can encourage increased use of clinical standards and enhanced reporting of physician/patient encounters by assigning a designation of excellence to hospitals that meet the highest safety standards. Hospitals can then use this designation to attract more patients.

Business Takes Action

Corporate America, bearing the brunt of the high cost of medical mistakes, doesn't need any additional encouragement to support patient safety — and some companies are not waiting for legislation or the development of a national database to do something about it. General Motors Corporation is a good example. The automaker is the largest private purchaser of health care in the U.S.; its medical plan covers 1.2 million people, and its yearly contribution to employee health insurance is about $4 billion. To cut down on medical errors, GM has begun to provide physicians with Palm PDAs that have a preinstalled drug database and prescription-writing program. Using this software, physicians can access current information about thousands of drugs and receive alerts about newly discovered drug interactions. GM made the decision to supply the PDAs and software after a Harvard study revealed that prescription drug errors decline by 55 percent when doctors use electronic prescription systems.

Pfizer Inc. has begun a hospital patient safety program as well. Recently, the pharmaceutical giant launched a program to print bar codes on packaged pills that identify the medicine, its dosage, its lot number, and its expiration date. The main purpose is to ensure that patients get the right medicine in the right strength, but it would also help in recalls. Overall, it could leave Pfizer less open to litigation over medication errors in hospitals.

Just a few years ago, the issue of patient safety wasn't on the agenda for most policymakers and healthcare experts. It was a slippery problem with few easy solutions, so getting companies and legislators to focus on it was difficult. But skyrocketing costs linked to medical mistakes have changed all of that; suddenly it's in everyone's financial and social interest to do something before the costs in dollars and lives are completely out of control. The timing couldn't be better for this renewed attempt to eliminate medical errors, because proven technology finally offers a way to track patient safety and respond to mistakes. That's a significant achievement — and it means the last obstacle left is opposition from physicians and hospitals. +

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