By Donald W. Parsons, MD

Primum Non Nocere:
Safety, Medical Errors and Congressional Intent

Patient safety has emerged as a major health policy issue. Fortunately, several years ago, Kaiser Permanente's Health Policy Committee peered into the crystal ball and made a modest investment in founding the National Patient Safety Foundation (NPSF). This investment was an important first step in taking ownership of a new wave of consumer concern about health care. That wave has now crested with publication of the Institute of Medicine's (IOM) *To Err is Human: Building a Safer Health System*, an effort contributed to substantially by the NPSF and its members.[1]

Authored by a prestigious committee, which included David Lawrence, MD, KFHP CEO, the report[2] summarizes what is known about the toll taken on American life by preventable error in hospitals. The report concludes that most problems are not due to malicious intent or even to individual failure but can be ascribed to failure of systems and processes. Two large, retrospective medical record review studies (one based on 1992 experience in Utah and Colorado[3] and another based on 1985 experience in New York[4]) indicated that, nationwide, as many as 98,000 patients each year lose their lives, most commonly because of medication error or complications of infection. Although these estimates are based on old data, direct observations have suggested that these estimates may be low. Given also that no published studies have described experience in nonhospital settings, the aggregate loss of life may be much higher. We do know that as many as 10% of hospital admissions are occasioned by adverse drug events,[1] suggesting a large-magnitude problem in nonhospital settings. And no solid estimate—only speculation—has been presented to quantify the secondary contribution of medications to fatal car crashes and falls. For example, the sedating antihistamine diphenhydramine may cause driver impairment as severe as that caused by alcohol.

Errors of commission are more easily measured than errors of omission. Among the most vulnerable of our citizens, the frail elderly, noncompliance with medication prescriptions may be high and may account for preventable failure to control acute exacerbation of chronic illness—and this failure can result in fatal complications. In addition, the failure to prescribe or take medications of known efficacy (eg, beta blockers for patients who have had a myocardial infarction) is thought to contribute to many cases of preventable fatal illness.

The magnitude of the patient safety problem is poorly understood. Physicians and other health care professionals are trained—and are expected—to deliver error-free care. When regarded as indicating professional shortcomings, error causes professional blame and shame. Errors can lead to sanctions imposed by regulatory bodies, public embarrassment, and malpractice litigation. The pervasive fear of discovering grounds for lawsuit drives underground the interest of health practitioners and institutions to report errors, even (and especially) those that cause patients no harm.

During a tumultuous election year in which there is considerable restlessness on several fronts about America's flawed health care system, the IOM report's recommendations for mandatory as well as voluntary reporting systems have captured the imagination of both the American public and its Congressional representatives. Consumers are demanding information about specific hospitals and practitioners. Congressional hearings have generated enthusiasm about establishing new federally prescribed mandatory reporting systems for the most severe errors, such as death, permanent disability, and wrong-site surgery. Only the provider trade groups (specifically, the American Medical Association and the American Hospital Association) have voiced strong opposition to public disclosure of specific information, cautioning that this disclosure would invite trial attorneys to file a deluge of lawsuits. Currently, few instances of true negligence result in medical malpractice lawsuits. Many entities, including KP, think that strong federal peer review protections and tort reform must accompany mandatory reporting if such reporting is to be legislated, or else reporting will not occur—a situation experienced in several states that have enacted mandatory error reporting statutes. For example, Pennsylvania has implemented such a system but elicited only a single report from among all Philadelphia hospitals during the most recent reporting cycle. All health care providers and practitioners fear malpractice suits, loss of professional reputation, and media exposure.

A voluntary reporting system in which close calls and "near hits" would be aggregated and analyzed is a more acceptable approach, particularly if reports are stripped of patient and provider identifiers. Congress has heard from the Aviation Safety Reporting System (ASRS), based in NASA, about its 25-year-old system, which elicits up to 30,000 reports annually—all made anonymous after initial verification. Because no plaintiff discovery of that information has ever succeeded, great credibility and trust have been conferred in the ASRS by pilots and by other airline employees. Vastly improved aviation safety over the past two decades is a result of this system; why can't the same thing happen in medicine? After all, the anesthesiologists in this country have shown that concerted action can mitigate damage in a high-risk environment. Operating suites are 90% safer now than they were just ten years ago because of improved patient monitoring, application of professional guidelines, and sharing of information through the Anesthesia Patient Safety Foundation.

Individual members of Congress have staked out turf in this debate already. Rep Bill Thomas (R-CA), Chairman of the House Ways and Means Committee's Health Subcommittee, has indicated that there can be no greater protection of patients than safe medical care. Therefore, the subject of patient safety can logically be introduced into the ongoing debate on managed

DONALD W. PARSONS, MD, is the Permanente Federation's Associate Executive Director for Health Policy Development.
E-mail: don.parsons@kp.org

care reform and patient protection. Others have called for newly commissioned demonstration projects to test the concepts of mandatory and voluntary reporting. Sen Arlen Specter (R-PA), who chairs the Senate Health and Human Services (HHS) Labor Appropriations Subcommittee, wants to make new money available to the FDA for more intense oversight of medication errors. Sen Bill Frist (R-TN), the Senate's lone physician—who led the push to redefine the newly named Agency for Health Research and Quality (AHRQ) in last year's Congressional session—would like to establish a new center for patient safety within that agency. This recommendation has also been espoused by the Administration; indeed, the President has called on all federal agencies responsible for health care programs to build patient safety expectations into all systems (the Veterans Administration and the Department of Defense) and into all contracts administered by the Health Care Financing Administration (HCFA) and the Federal Employees Health Benefit Program (FEHBP). Senators Lieberman, Grassley, and Bryan have introduced legislation to set up a national center for patient safety and a national mandatory reporting system for all Medicare and Medicaid contracting providers. Patient safety is a "motherhood-and-apple-pie" issue that no legislator standing for reelection will oppose. Tom Bliley (R-VA), who chairs the House Commerce Committee, has taken the argument one step further by supporting Sen Ron Wyden's (D-OR) call for public disclosure of malpractice and disciplinary reports on physicians contained in the National Practitioner Data Bank.

The private sector is jumping in front of the parade. The largest is the "Leapfrog Group," which includes leaders from several large purchasers of health care, including General Motors, General Electric, GTE, the Pacific Business Group on Health, the federal Office of Personnel Management, and others. This group has developed and disseminated three standards for patient safety that have been considered by General Motors and by some large purchasers, including the "V-8" group of eight purchasing coalitions, in forming health plan contractual performance expectations for the year 2000 and beyond (Pat Salber, MD, personal communication). First, the group wants health plans to influence their contracted hospitals to adopt computerized physician order entry for medications, a technique available in only a small percentage of hospitals now but which has reduced medication errors by two thirds in the VA hospital system. Second, the group is calling for improved training and staffing for intensive care units. Third, the group is setting volume standards for hospitals where highly technical procedures, such as open-heart surgery, are done. All these new standards are evidence-based and are tied to improved patient outcomes through reduction of preventable complications, according to the Leapfrog Group's Executive Director, Suzanne del Banco (who can be reached at (202) 973-2953 or e-mail sdelbanco@hotmail.com).

As the IOM has cautioned, medical errors and patient safety are not problems of managed care. Instead, these problems pervade American medicine.[1] The good news for Kaiser Permanente is twofold: First, we have an enviable track record and have been examining our own data for some time; second, as David Lawrence is eager to point out, correcting such systemic problems requires an integrated medical care delivery system based on patient focus, professional and administrative collaboration, and excellent information technology.[2] In the area of patient safety, the private sector is likely to develop innovations before Congress can act. We at KP are moving ahead with our own efforts to promote patient safety and report errors.[5,6]

Our new Health Policy Institute, directed by Senior Vice President Bob Crane, has convened national experts who have developed policy suggestions to guide legislative activity. We are calling for a nationwide, voluntary reporting system modeled on the Aviation Safety Reporting System and including additional protections to safeguard the information from discovery intended solely to encourage civil legal action. We also recommend State-mandated reporting of near-miss events, postmarketing drug and device surveillance, and funding for a new national center for patient safety.

With the high current level of public interest in patient safety, we can be sure Congress will take action soon. ❖

References
1. Kohn LT, Corrigan J, Donaldson MS, editors; Committee on Quality of Health Care in America, Institute of Medicine. To err is human: building a safer health system. Washington DC: National Academy Press; Mar 2000, 312 p.
2. Lawrence D. Is Medical Care Obsolete? Speech for National Press Club, Washington DC, July 14, 1999.
3. Thomas EJ, Studdert DM, Newhouse JP, Zbar BI, Howard KM, Williams EJ, et al. Costs of medical injuries in Utah and Colorado. Inquiry 1999 Fall;36(3):255-64.
4. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. N Engl J Med 1991 Feb 7;324(6):370-6.
5. Tolbert LD. The risk management approach at Kaiser Permanente Los Angeles Medical Center. Permanente J 1998 Summer; 2(3):69-72.
6. Stajer R, Pate B. Kaiser Permanente's response to JCAHO's Sentinel Event Standards: Our Significant Event Root-Cause Analysis Program Leads To Preventing Medical Errors (this issue, The Permanente Journal).