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

Authoring a prestigious committee, which included David Lawrence, MD, KFHP CEO, the report 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 Colorado3 and another based on 1985 experience in New York4) 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,5 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 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 care.
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 Biley (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 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