

Federal Legislation Efforts To Improve Patient Safety

The problem of patient safety was recognized and a patient safety philosophy was developed long before the Institute of Medicine (IOM) report or the Harvard Medical Practice Study. Early in the century, Dr. Ernest A. Codman, a Boston surgeon, pioneered the discipline of methodical scrutiny of surgical outcomes and complications. He attempted to collect data, learn from experience, shed light on systematic causes of bad results, and improve care by prevention of error and standardization of hospital techniques.¹ His innovations included anesthesia records, tumor registries, the founding of the American College of Surgeons Committee of Hospital Standardization (forerunner of the Joint Commission on Accreditation of Healthcare Organizations²), and increased accountability for surgical outcomes through end-result reporting and process improvement techniques. Codman was a visionary whose contributions were not appreciated in his own time.¹

In its March 1998 report, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry presaged the IOM report by including in its recommendations a national effort to study the issue of patient safety.³ This led to the establishment of the Quality Interagency Coordination Task Force,⁴ which recommended an ambitious patient safety agenda among all federal agencies delivering or contracting for health care. The National Forum for Health Care Quality Measurement and Reporting (NQF),⁵ an organization that involves the public and private sector and has a charter to develop standards for patient safety, is also an outgrowth of the Advisory Commission. The Veterans Administration, under the leadership of Kenneth Kizer, MD, who was then Undersecretary for Health and is now President of the NQF, has developed a system-wide program to promote patient safety that is based on medical error analysis and reporting (see "Developing a Culture of Safety in the Veterans Health Administration" in this issue).

In the private sector, the founding of the Anesthesia Patient Safety Foundation (APSF) in 1984⁶ and the National Patient Safety Foundation (NPSF) in 1997⁷ anticipated the current interest in addressing these problems. The APSF, under the direction of Dr. Ellison "Jeep" Pierce, former chair of anesthesia at Massachusetts General Hospital in Boston, can take great credit for promoting oximetry and other monitoring devices in the operating room. These innovations have dramatically improved safety during the past 15 years. The NPSF brings together diverse stakeholders from professional, academic, purchaser, regulatory, consumer, and manufacturing perspectives to address patient safety concerns across a broad front, emphasizing research funding and education. In the purchaser community, the Leapfrog Group has taken the initiative to establish standards for contracting with health plans and providers (see "Improving the Safety of Health Care: The Leapfrog Group" in this issue). These standards were developed based on evidence showing that safer care is provided at hospitals that perform high volumes of technically complex surgery, have hospital-based physicians who are trained in critical care medicine, and provide computer entry for physician orders.⁸

Current Legislation Efforts

Against this backdrop of increasing interest in patient safety, the IOM's November 1999 report, "To Err Is Human: Building a Safer Health System,"⁹ presented decade-

This paper is available at ecp.acponline.org.

old data in a fashion that has captured the attention of the media, policymakers, and all who are connected to the health care enterprise. As if a sleeping giant had awakened and stretched, the American public finally grasped the meaning of information that has been available in peer-reviewed medical literature since at least 1991.^{10,11} It is astonishing that as many as 98,000 Americans may die each year in hospitals because of preventable medical errors. The methodology by which this number was derived has been criticized^{12,13}; however, since so much of medical care now occurs in ambulatory settings outside of hospitals and considering the inaccuracies of hospital records with significant underreporting of errors, the overall number of preventable deaths and injuries may be much larger.¹⁴ Regardless of the question of accuracy of counting, the IOM report has exposed a truth long maintained in professional circles: that preventable complications account for unacceptably high levels of patient morbidity and mortality.

On Capitol Hill, reaction to the IOM report has been substantial. Proposals to address the issues raised in the report surfaced within 2 weeks of its release, during hearings held even while Congress was in recess in December 1999. Senator Arlen Specter, chair of the Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee, held hearings to explore the pros and cons of federally authorized mandatory versus voluntary reporting systems. He entertained suggestions for increasing the funding of the Food and Drug Administration to improve post-marketing surveillance of drugs and establishing a National Center for Patient Safety within the Department of Health and Human Services as well as an ambitious research agenda. Specter's bill (S 2038), the first of many introduced this year, calls for several federal demonstration projects to compare the effectiveness of voluntary and mandatory reporting of adverse events in hospitals. Other hearings in both chambers during the spring led to the introduction of additional bills calling for some version of federal reporting. As shown in **Table 1**, these bills have many similarities. The main differences among them relate to whether the reporting system should be mandatory or voluntary. As the bills have evolved over time, there seems to be a crystallization of the view that both systems might serve useful purposes. Mandatory reporting of serious errors that harm patients might be supplemented by voluntary reporting of close calls and less serious errors that do not result in injury.

The 106th Congress has not acted on these bills, and they are not likely to do so in the lame duck session. Remarkably, however, just before the July 4th recess, without any previous committee action, the Senate passed an amendment to the Departments of Labor,

Health and Human Services, Education, and Related Agencies Appropriation Bill (HR 4577), incorporating a version of the Jeffords proposal (S 2738). The Patient Safety and Errors Reduction Act (HR 4577¹⁵) would, if adopted, establish a Center for Quality Improvement and Patient Safety, foster research into the causes of error, and promote patient safety. A confidential national patient safety database, protected from access by any outside entity, would allow the aggregation of data from reporting systems in the federal, state, and private sectors. The legislation includes explicit confidentiality and peer review protections and states that certified entities will collect and analyze information on medical errors and close calls. These entities will follow recommendations on a common set of core measures for reporting developed by the National Forum for Health Care Quality Measurement and Reporting.

Negotiation in the House and Senate conference committee on the Departments of Labor, Health and Human Services, Education, and related agencies Appropriations bill removed the Senate's language on patient safety. The same committee has expanded the budget for the Agency for Healthcare Research and Quality by \$50 million for the specific purpose of funding research into patient safety and medical error reporting. This infusion of research funds indicates that continued federal attention will be paid to an issue that has also found expression in the election platforms of the two major political parties. Politicians (e.g., Newt Gingrich) are publishing editorials calling for congressional action.¹⁶ Adding fuel to the fire are findings that the problem may be much bigger than suggested in the IOM report.^{17,18}

The National Aeronautics and Space Administration's Aviation Safety Reporting System (ASRS)¹⁹ has informed Congress about the elements of an error-reporting system that embraces many of the features that would be required in a national voluntary system of reporting medical errors. By combining incentives to report—including protection from regulatory punishment, analysis of root causes, anonymity of the data, absolute protection of reports from outside discovery, and feedback and education to the entire aviation industry—the ASRS has supported a nonpunitive contribution to sustained improvement in aviation safety over the past 25 years. At least one large medical system (the Veterans Administration) has turned to the ASRS for assistance in managing error reporting.²⁰

Prognosis for the Future

In addition to federal activity, the National Academy for State Health Policy reports that 18 states have enacted

TABLE 1

Overview of Bills Related to Reducing Medical Errors*

BILL	SPONSOR	DATE INTRODUCED	SUMMARY	ACTION
The Medical Error Reduction Act of 2000 (S 2038)	Sen. Arlen Specter (R-PA)	2/8/00	Health Care Financing Administration to establish medical error demonstration projects	Referred to Senate Committee
The Patient Safety Act of 1999 (HR 1288; S 966)	Rep. Maurice Hinchey (D-NY); Sen. Harry Reid (D-NV)	3/25/99; 5/5/99	Requires providers under the Medicare program to publicly disclose nursing staff levels and outcomes data	Referred to House Ways and Means and Commerce Health Subcommittees; referred to Senate Finance Committee
The Medical Error Prevention Act of 2000 (HR 3672)	Rep. Constance Morella (R-MD)	2/16/00	Provides for the voluntary reporting of medication errors	Referred to House Commerce Health Subcommittee
Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000 (S 2378)	Sen. Charles Grassley (R-IA)	4/6/00	Requires providers to report sentinel events to a new reporting system, to establish patient safety systems; reported data protected from discovery	Referred to Senate Finance Committee
Voluntary Error Reduction and Improvement in Patient Safety Act of 2000 (S 2743)	Sen. Edward Kennedy (D-MA)	6/15/00	Establishes voluntary reporting system with confidentiality protections; establishes Center for Quality Improvement to conduct research	Referred to Senate Health, Education, Labor, and Pension Committee
Patient Safety and Errors Reduction Act (S 2738)	Sen. James Jeffords (R-VT)	6/15/00	Establishes voluntary confidential reporting system, a national database, provisions for research	Referred to Senate Health, Education, Labor, and Pension Committee
Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act of 2001 (HR 4577)	Sen. Don Nickles (R-OK), by amendment	6/29/00	Establishes voluntary reporting systems with confidentiality protections, a national database, provisions for research	Passed Senate, 6/29/00

*D= Democrat; IA= Iowa; MA= Massachusetts; MD= Maryland; NV= Nevada; NY= New York; OK= Oklahoma; PA= Pennsylvania; R= Republican; Rep.= Representative; Sen.= Senator; VT= Vermont.

mandatory reporting statutes or regulations, 7 states have voluntary systems in place, and 6 states have pending medical error–patient safety legislation.²¹ When these systems have succeeded in eliciting reports, they have done so because of protections put in place to maintain the confidentiality of the information reported.²² Presumably because institutions fear that a plaintiff's attorney might discover any sensitive information reported to third parties, these and other reporting systems have failed to elicit much of the information avail-

able in hospitals.²³ Without these data, however, it will be difficult to improve patient safety.

The stage is set for the 107th Congress, the first full Congress of the new millennium. The IOM report and the much earlier work by Drs. Codman, Berwick, Leape, Brennan, and others have begun an avalanche of interest in patient safety. The private sector is involved through purchasers (the Leapfrog Group), insurers,²⁴ and professional organizations (NPSE, the American Hospital Association,²⁵ and U.S. Pharmacopeia,²⁶

among others). There is new federal research money in the wings for the next fiscal year. Politicians in both parties have called for action. The NPSF and others are collecting and defining the best practices from around the country, and several legislative proposals will be molded into bills for introduction in early 2001. This entire prologue will accelerate research, dialogue, and progress in a field long neglected. We will see legislative activity in earnest on both state and federal levels. With legislated barriers to ensure that information remains confidential and that physicians and their colleagues are protected from professional embarrassment, blame, and punishment for system malfunctions, we can hope that the health care establishment will develop safer systems quickly. It is likely that such legislated protection on the federal level will be approved by the next Congress.

Perhaps we can achieve the goal of the Advisory Commission: a 50% reduction in errors in 5 years. Let's hope so. Physicians, other health professionals, and especially patients are sure to benefit as a result.

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