

Enforceable Regulations for Patient Safety

The Institute of Medicine (IOM) report, *To Err Is Human* (2000), recommended a national goal of reducing medical errors by 50% within 5 years. To say that we haven't met this goal would be an understatement. In its latest *National Healthcare Quality Report*, the Agency for Healthcare Research and Quality (AHRQ) asserts that, "measures of patient safety ... indicate not only a lack of improvement but also, in fact, a decline of almost 1 percent in this area." In retrospect, this shouldn't be surprising. Dramatic safety improvements in other sectors have occurred only after direct federal regulatory intervention. That is what is needed in healthcare—creation of a federal patient safety regulatory agency, with authority to require healthcare providers to take steps in order to prevent serious, recurring errors.

Medical errors and patient injuries were once accepted as inevitable consequences of delivering healthcare services. Clinical demonstration projects have shown otherwise. In one of the first, the Pittsburgh Regional Health Initiative engaged 30 local hospitals 10 years ago in a combined, regional project that yielded a 68% reduction in deadly, hospital-acquired central line infections—a feat once thought to be impossible.

Succeeding projects successfully attacked other infections, medication errors, pathology errors, wrong-site surgeries, and more. However, even with tools, new knowledge, and techniques available to medical practitioners, broad advances in patient safety haven't been realized. Even worse, many preventable medical errors occur repeatedly.

Premature babies in intensive care require tiny IV catheters that must be flushed with heparin, an anticoagulant, to prevent clotting. In November 2007, the prematurely born, twin infant children of actor Dennis Quaid and his wife nearly died after hospital staff mis-

takenly used adult dosages of heparin—1,000 times more concentrated than the dosage for infants.

The Quaid's discovered, to their dismay, that their babies' ordeal wasn't a one-in-a-million mistake. Similar heparin overdoses had already injured or killed at least 250 newborns at other U.S. hospitals, including a 2006 incident at an Indianapolis hospital in which six infants in intensive care were overdosed with heparin, three of whom subsequently died—5 years after two other infants suffered similar heparin overdoses at the same hospital.

These overdoses were caused by look-alike packaging of adult and infant versions of the drug, a problem that wasn't fixed until late 2007. Similar problems still haven't been fixed. The Institute for Safe Medication Practices (ISMP) lists several dozen error-prone medication abbreviations, symbols, and dose designations (including heparin) that are "frequently misinterpreted and involved in harmful medication errors."

Wrong-site surgery ought to occur "never," too. Nevertheless, the Pennsylvania Patient Safety Authority reports 50 to 65 wrong-site surgeries annually. A litany of anecdotal information from around the country includes an instance of three wrong-site brain surgeries in 1 year—performed by three different surgeons at Rhode Island Hospital.

Virtually all wrong-site surgeries can be traced to deviations from recommended pre-op procedures. In fact, failure to follow known preventive measures is the common thread in millions of medical errors. Many private and public organizations collect and analyze patient safety information and develop and disseminate prevention recommendations, including 26 state agencies, ISMP, The Joint Commission, and others. None, however, have authority to insist that all healthcare providers comply with safety steps.

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Voluntary action by hospitals isn't protecting patients from harm. If we are to avert tens of thousands of patient deaths, hundreds of thousands of serious patient injuries and wasting tens of billions of dollars, stronger steps—in the form of direct federal safety regulation—are needed.

More than 100,000 coal miners lost their lives to mining accidents during the last century, and nearly one million were injured. From a peak of 1,463 coal-mining fatalities in 1931, Mine Safety & Health Administration (MSHA) records show a drop to fewer than 50 per year. Huge decreases in mining accidents occurred quickly, as soon as federal safety regulations were implemented.

Safety improvements of similar magnitude have resulted from federal regulatory authority in other areas: e.g., aviation, railroads, automobiles, food safety, manufacturing, and construction. In healthcare, however, there is no federal authority to protect patients, even in the face of recurring, preventable medical errors.

Substantial safety gains could be achieved by congressional creation of a federal patient safety agency, which would require relatively modest resources and have limited authority. The agency's responsibilities could include:

Identification of recurring serious, recurring medical errors. No new provider reporting would be required. Patient safety agency staff would review

publicly available information collected by existing public and private organizations. Agency staff would cull instances of apparent repetitive errors that resulted in patient injury, analyze the existing medical and safety literature for effective preventive actions, and draft recommended preventive actions for affected providers.

Independent evaluation of apparently recurring medical errors and recommended preventive actions. Staff-generated information and recommendations would be evaluated by a new public-private committee of medical and safety experts appointed by the Secretary of Health and Human Services. The committee would have two core responsibilities: 1) ascertain that each staff-proposed recommendation pertained to recurring error that posed serious, continuing risks for patients; and 2) evaluate staff-recommended preventive actions and concurrence/disagreement/modification.

Publication of regulations. Once the public-private committee ratified a staff recommendation, it would be converted into a proposed federal regulation (e.g., required physical separation of look-alike medications on pharmacy shelves and a further distinguishing marking for infant doses). Public comments would be invited and considered, and final regulations would then be published.

Dissemination and enforcement. The patient safety agency staff would be responsible for disseminating timely information about new regulatory requirements to relevant professional and health- and safety-related publications. Staff would not have authority to monitor provider compliance or investigate possible violations of requirements. In instances in which provider non-compliance came to the attention of agency staff, the patient safety agency would be authorized to refer individual matters to federal law enforcement and levy fines.

A federal patient safety agency of this scope would not eliminate all medical

errors and patient injuries overnight. But by concentrating on the most serious kinds of recurring medical errors, it could have a substantial and immediate impact in areas like confusing medication labeling and wrong-site surgeries.

In a report issued earlier this year, *To Err Is Human—To Delay Is Deadly*, Consumers Union took the initial IOM estimates of patient injuries and asserted, “Ten years later, a million lives lost, and billions of dollars wasted. Ten years later, we don’t know if we’ve made any real progress, and efforts to reduce the harm caused by our medical care system are few and fragmented.”

The status quo is clearly unacceptable. As has been proven in other sectors, a federal patient safety agency could make a big difference. **IPSQH**

Karen Wolk Feinstein is president and chief executive officer of the Jewish Healthcare Foundation (JHF) and its two supporting organizations, the Pittsburgh Regional Health Initiative (PRHI) and

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Health Careers Futures (HCF). Appointed the Foundation's first CEO in 1990, she initially focused on health issues endemic to aging, women's health, and underserved populations. She has since made JHF and PRHI leading voices in patient safety, healthcare quality, and workforce issues. Feinstein may be contacted at info@prhi.org.



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