

CONGRESS SHOULD CREATE A FEDERAL PATIENT SAFETY AGENCY

BACKGROUND

There is ample evidence that most medical errors are preventable. Nevertheless, only small increments of progress are occurring to prevent errors and protect patients. Zero tolerance for medical errors is the only acceptable public health goal. Eliminating serious, recurring medical errors would be a substantial step toward that goal. Hundreds of types of repetitive lapses in patient safety are well-known to medical science. In order to assure that patients will be protected against preventable harm, Congress could vest in a federal patient safety agency the authority to require providers to take action when imminent, recurring threats to safety are identified.

THE MAGNITUDE OF THE PATIENT SAFETY CRISIS IS WELL KNOWN

It has been fifteen years since Lucian Leape's seminal work, "Error in Medicine," appeared in the Journal of the American Medical Association, and called attention to the sobering realities about preventable patient deaths and injuries. The subsequent 1998 Institute of Medicine (IOM) report, "To Err Is Human," detailed the extent of the risks to patients, and recommended a national goal of reducing medical errors by 50% over the succeeding five years.¹ Nevertheless, according

to the 2008 National Healthcare Quality Report (NQPR), compiled by the Agency for Healthcare Research and Quality (AHRQ), "(A) clearer picture of trends in healthcare safety is emerging. Distressingly, measures of patient safety in the NHQR indicate not only a lack of improvement but also, in fact, a decline of almost 1 percent in this area."² After more than ten years of unsatisfactory progress, one must ask: "How many more deaths from preventable medical errors are we prepared to countenance?" We believe a timely, appropriate response is establishment of federal authority focused on serious, recurring medical errors. With limited scope, not all aspects of patient safety would be transformed overnight. But creating federal authority to safeguard against frequently repeated, preventable medical errors would be an unequivocal good.

THE OUTLINE OF A LIMITED FEDERAL REGULATORY ROLE

Federal government intervention has been required to achieve safety improvements in other sectors: for example, aviation, mining, food processing and power generation. In each instance, direct federal intervention saved lives, with history and economics demonstrating that the benefits far outweigh the costs. Federal oversight and intervention is needed to save lives in health care, too, as is evident by the lack of progress over the past decade.

In anticipation of concerns about taking this step in health care, our proposal has these advantages:

- Proposed new regulatory authority would be limited to specific, recurring adverse events – in effect, to fill gaps through which



repetitive, preventable patient injuries and deaths occur.

- No new adverse event reporting would be required. Existing public and private reporting systems could be easily adapted to permit identification of repetitive medical errors.
- No new medical research would be required for action. There is already sufficient scientific knowledge to save many lives that are lost to recurring medical errors.

Existing government regulatory authority would not be duplicated. No federal agency is responsible for ordering expedited provider actions to avert recurrences of medical errors.

PATIENT SAFETY SINCE THE IOM REPORT

In 1997, before the initial IOM report, medical errors and patient injuries were accepted as inevitable consequences of delivering healthcare services. In Pittsburgh, the business community created an organization to build value in health care, targeting medical errors as a major source of harm and waste. This organization, the Pittsburgh Regional Health Initiative (PRHI), engaged hospital and healthcare professionals to test the feasibility of averting hospital-acquired infections. Hospitals and healthcare professionals came together in a massive regional effort that reduced deadly central line infections by 68% - a feat once thought to be impossible. This dispelled the conventional wisdom of infections as a sad but necessary corollary of hospital care, but perhaps more importantly it revealed the impact of a creative and effective oversight body in driving transformative change in health care.

One after another, more medical errors were successfully attacked. However, even with tools, new knowledge and techniques available to medical practitioners, a nationwide movement to advance patient safety rapidly has not been realized. Worse still, many serious, well-known medical errors are being repeated, despite efforts to draw attention to them and to the means to avert them.

EXAMPLES OF RECURRING LAPSES IN PATIENT SAFETY

Error-prone medication nomenclature, abbreviations, symbols and dose designations. The Institute for Safe Medication Practices (ISMP), a non-profit organization founded 30 years ago to educate healthcare professionals and consumers about medication safety issues, currently lists approximately 200 medication name-pairs that have been involved in multiple, voluntarily-reported drug errors. ISMP also lists several dozen error-prone medication abbreviations, symbols and dose designations (including heparin) that are "frequently misinterpreted and involved in harmful medication errors."³ ISMP recommends that error-prone terms should "never" be used. The Joint Commission's "do-not-use" list for medication terminology is now embedded in its hospital certification requirements. But dangerous medication mix-ups continue to occur. The Pennsylvania Patient Safety Authority, which under a 2002 state law collects and analyzes safety event data from hospitals, ambulatory surgery centers and nursing homes, has received more than 15,000 reports of "medication error, wrong drug" since 2004, and recommended special attention for two dozen drug-pairs in a 2007 Patient Safety Advisory.⁴ These recommendations, however, do not have the force of law and do not require action.

A March 2006 General Accounting Office report criticized the U.S. Food and Drug Administration (FDA) for failing to address post-market confusion about medication names, abbreviations, symbols and dose designations, and look-alike medication packaging.⁵ The FDA has taken steps to improve its procedures for avoiding sound-alike and look-alike medication names, but there are, as indicated above, literally hundreds of look-alike, sound-alike, confusing drug pairs that are responsible for medication errors. A federal patient safety regulatory agency with direct authority to resolve obvious threats and recurring medication errors quickly could save many lives and avert thousands of serious patient

injuries, as further illustrated by the next example.

Neo-natal heparin errors. In 2007, the twin infant children of actor Dennis Quaid and his wife nearly died after receiving adult doses of heparin (1,000 times the prescribed heparin dosage for babies), a mix-up that resulted from nearly identical manufacturer packaging of adult and infant heparin, and the failure of hospital staff to recognize and adjust for this problem.⁶ The story attracted global attention, and Mr. Quaid spoke publicly about the need for action to avoid a repetition of the harm that befell his children.

The publicity of this unfortunate event revealed the true scope of the problem on a national level. Similar heparin mix-ups that injured newborns occurred at least 250 times before the Quaid twins were overdosed.⁷ A 2006 tragedy at an Indianapolis hospital saw six infants in intensive care receive adult doses of heparin, three of whom subsequently died. Two other infants were administered similar heparin overdoses at the same hospital in 2001.⁸

The Joint Commission issued a heparin safety alert in September 2008,⁹ and heparin overdoses have been out of the news recently. But hundreds of heparin overdoses administered to sick newborns could have been prevented if there had been federal authority to order immediate separation and clear differentiation of infant and adult heparin by hospitals, and rapid replacement of look-alike heparin packaging.

Wrong-site surgery.

Wrong-site surgery is a classic example of a system problem. Wrong-site surgery is prevented by surgical team training and rigorous adherence to proven safety precautions, including written checklists and protocols, standardized pre- and post-

operative communications handoffs, patient participation, surgeon-led timeouts, and real-time error/near miss reporting and analysis. Systematic prevention of wrong-site surgery is detailed by a number of authoritative sources, including the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™.¹⁰ The Pennsylvania Patient Safety Authority's Preventing Wrong-Site Surgery Project has made significant progress toward sustaining zero wrong-site surgeries among 30 participating Pennsylvania hospitals, but hospital-reported data in Exhibit 1 demonstrate that wrong-site surgeries continue to occur.¹¹

The criticality of surgical teams consistently following safety procedures to the letter was illustrated vividly two years ago, when three wrong-site brain surgeries – by three different surgeons – took place in less than one year at Rhode Island Hospital, the teaching hospital for Brown University. As with virtually all wrong-site surgeries, there was a different, critical deviation from the Universal Protocol™ in each of the three cases. Zero wrong-site surgeries could become an attainable goal if adherence to the Universal Protocol™ was required by federal regulation and if additional

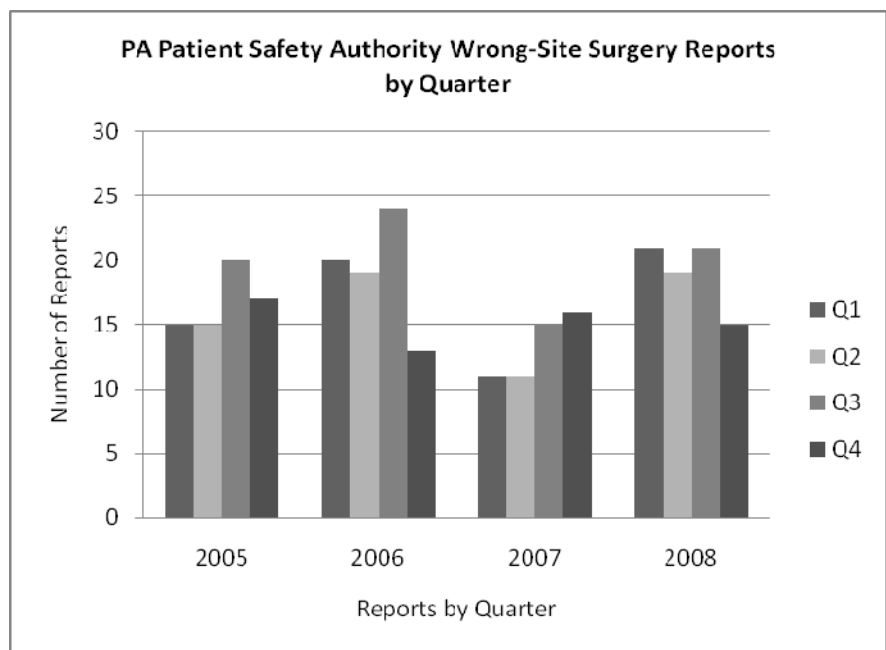


Exhibit 1: Wrong-Site Surgery Reports in Pennsylvania

safety steps were mandated (e.g., one national standard – placement, color, size and type of mark – for surgical site marking).

Patient misidentification. Patient misidentification is a frequent cause of medical errors, including but not limited to wrong-site surgeries. Studies indicate patient wristband error rates of up to 5%.¹² The Joint Commission has issued several sentinel event reports about patient misidentification, and in 2003 embedded accurate patient identification in its National Patient Safety Goals, with a recommendation that healthcare workers use at least two patient identifiers before undertaking treatments or procedures on a patient.¹³

Use of bar codes to assure accurate patient identification has shown promise, but few hospitals have implemented this technology. Some hospitals and ambulatory surgery centers have voluntarily adopted standard wristband color codes, too. The risks posed by ad hoc color code schemes were illustrated by an event report to the Pennsylvania Patient Safety Authority. Clinicians nearly failed to rescue a patient who was in cardiopulmonary arrest because a nurse incorrectly placed a yellow wristband on the patient, which signified in that hospital that the patient should not be resuscitated. The nurse made the mistake because she also worked at another, nearby hospital in which a yellow wristband denoted "restricted extremity," i.e., do not use this arm for drawing blood or an IV.¹⁴

Standardization could eliminate such errors. Hospitals should be required to adhere to a nationally standardized wristband identification system, and bar code identification systems should be a required element of hospital health information technology standards.

Seasonal patient safety risks. A PRHI-sponsored, central line-associated bloodstream infection project at Pittsburgh's Allegheny General Hospital (AGH) produced and sustained MICU and CCU central line infections of nearly zero.¹⁵ The AGH infection team, however, discovered that the infection rate

began to creep up when new trainees arrived at the hospital. As a countermeasure, formal training modules in central line insertion and maintenance were created for all new physicians and nurses who care for patients with central lines: written practicum, computerized segments, and hands-on mannequin simulations. In the aftermath of these actions, infection rates returned to zero. The broader lesson is obvious. All new staff involved in patient care should complete training in infection prevention and patient safety at the outset of their service.

Inappropriate use of hydrogen peroxide for wound cleaning. The incidence of lower extremity wounds and infections has been increasing.¹⁶ Higher frequencies of lower extremity wounds and amputations among the elderly have been documented. Not only does aging affect wound healing negatively, the presence of underlying diseases, particularly diabetes, is directly related to both impaired wound healing and higher frequencies of lower extremity limb amputations.¹⁷

Hydrogen peroxide has many appropriate uses, but it is toxic to specialized cells that are essential to wound healing. Hydrogen peroxide use for debriding and cleansing open wounds not only can interfere with healing, it poses a particular risk among elderly patients whose wound healing capabilities may already be compromised by age and pre-existing illness.

AHRQ's Clinical Guideline for Treatment of Pressure Ulcers¹⁸ addresses certain uses of hydrogen peroxide and antiseptics with similar properties in the care of pressure ulcer wounds, abscesses, and closed body cavities from which oxygen cannot escape. Routine use of hydrogen peroxide for general wound care is not widely recommended. At the least, there should be specific precautions against use of full-strength hydrogen peroxide for debriding and cleansing lower extremity wounds among elderly patients.

BUILDING ON THE KNOWLEDGE WE ALREADY HAVE

There is already an infrastructure of public and private medical error reporting, as well as knowledge to inform the actions of a federal agency charged with safeguarding patients against the most dangerous, recurring medical errors. Unfortunately, the current system is one of often overlapping state and federal authorities, many operating under voluntary reporting guidelines, and only a few submitting reports electronically. By consolidating, standardizing and streamlining a national adverse event reporting system, we see the potential actually to lessen administrative burdens on providers.

Reporting adverse events. We will always need more data and research to prevent many thousands of patient deaths from recurring medical errors. But we do not need more data to get started on what we know should be regulated.

Twenty-six states and the District of Columbia already have adverse event reporting programs.¹⁹ State programs differ widely in the types of facilities from which reporting is required, in the types of patient safety events that are to be reported and in the rigor with which solutions to problems are analyzed. Reporting under all but one of the 27 reporting programs is mandated by law, but there are huge differences in numbers of reported adverse events among states. Some of this variation is attributable to new state programs that are still ramping up for full reporting. But an even more important reality is that all but a handful of the responsible state agencies lack authority to validate and enforce accurate reporting.

Definitions of reportable adverse events in 12 states are based on the National Quality Forum standards; individual state-developed standards are used for the other 15 programs.^{20,21}

Near-miss reporting is required in just four states (Kansas, New York, Oregon and

Pennsylvania). Washington's program includes voluntary near-miss reporting.²¹

In all but four states (California, Massachusetts, Ohio and South Carolina) the confidentiality of reported adverse events is fully protected under state law.^{19,21}

Notwithstanding the differences in scope and gaps in reporting among the state programs, the combined results generate useful information for providers and consumers about adverse event frequencies, trends and prevention that could be synthesized and acted upon. None of the responsible state agencies, however, have broad authority to respond to statewide patterns of medical errors by ordering preventive actions.

A number of private, non-profit organizations also receive and analyze voluntarily submitted patient safety data from hospitals, as well, including the Institute for Safe Medication Practices, National Coordinating Council for Medication Error and Prevention, National Quality Forum, Partnership for Patient Safety and National Patient Safety Foundation. These organizations and others like them, including a number of federally-recognized Patient Safety Organizations, identify sentinel events, develop preventive recommendations and disseminate information to consumers and providers. None have authority to require providers to act on the basis of their findings and recommendations, but individually and collectively they contribute significantly to understanding of the incidence, causes and prevention of patient injuries.

The Joint Commission has adopted patient safety standards as a key part of its accreditation process. Annually updated National Patient Safety Goals are the foundation of work in this area, and the Patient Safety Advisory Group established in 2002 assists with their development. Nearly one-half of all Joint Commission accreditation standards are safety-related, including the Joint Commission's Universal Protocol™. Another key part of accreditation is required

investigation to root cause of every sentinel event. Knowledge gained through these investigations is reported voluntarily to the Joint Commission and shared with other institutions, and constitutes another excellent source of information about patient safety issues.²² Converting this information into immediate or expedited action when dangerous practices are identified could prevent the recurrence of sentinel events.

Preventing medical errors. PRHI was among the first to apply industrial process improvement methodologies to health care, deriving its Perfecting Patient CareSM methodology from the principles of the Toyota Production System. PRHI has trained thousands of healthcare professionals in the use of Perfecting Patient CareSM methods to achieve previously unimagined improvements in quality and safety. Parallel adaptations of the Toyota system and other industrial process improvement approaches have been used in other regions and by individual healthcare systems to drive improvements, ranging from projects undertaken by frontline caregivers in individual hospitals to the Institute for

Healthcare Improvement's national Five Million Lives Campaign – all of which create a continuously expanding base of clinically validated information to feed into a national effort to address recurring threats.

The accumulated evidence about specific harm and, then, lifesaving practices from these quality and safety improvement demonstrations has fundamentally altered the context in which patient safety issues should be considered. We know what prevents many hospital-acquired infections, medication errors, patient falls, etc. But it is not mandatory today to implement preventive systems and adhere to safety protocols in hospitals, ambulatory surgery centers, skilled nursing facilities, and other healthcare settings. The IOM found that it takes 17 years for scientific knowledge to be routinely incorporated into everyday clinical practices across the nation.²³ Without federal intervention, it will take many years for best safety practices to become standard practice and save thousands of lives.

THE EFFECTS OF FEDERAL SAFETY REGULATION

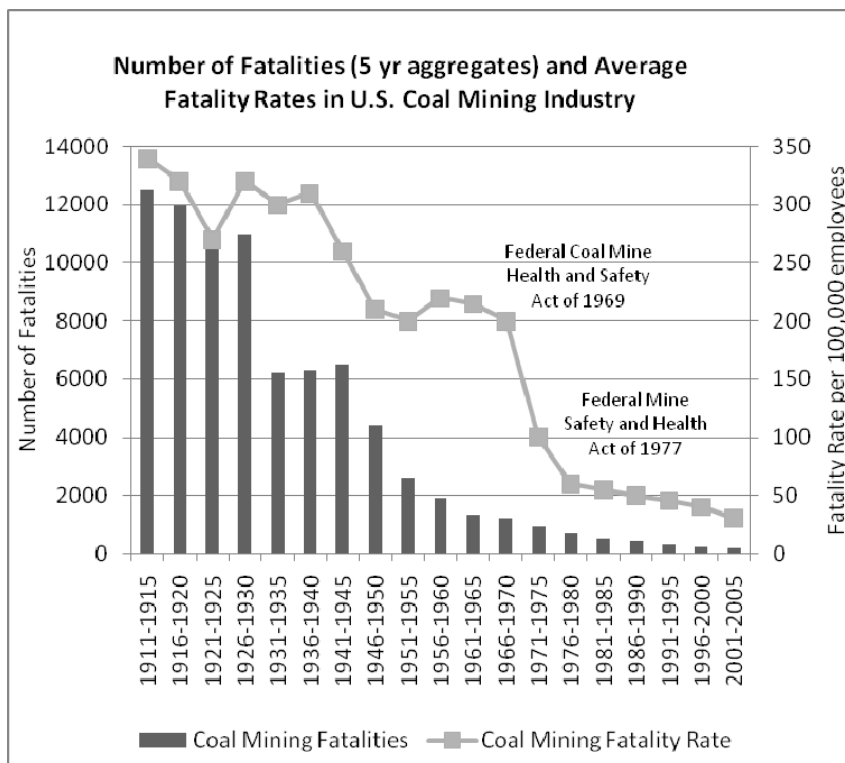


Exhibit 2: Number of Fatalities and Fatality Rate in U.S. Coal Mining Industry

In retrospect, hopes for a rapid revolution in health care may have been unrealistic. Fortunately, we know what will accelerate change. In many sectors in which there have been serious safety problems, significant improvement has been accompanied by federal regulatory intervention (e.g., transportation, consumer products, construction, manufacturing, food, etc.).

Aviation. Strong federal regulation and enforcement have been the foundation for improvements in aviation safety. Under Congressional mandates, the National Transportation Safety Board (NTSB) thoroughly investigates all aviation accidents and incidents, and the Federal



Exhibit 3: Workplace Safety at ALCOA

Coal Mining. More than 100,000 coal miners lost their lives to mining accidents during the last century, and nearly one million were injured. Mine Safety & Health Administration (MSHA) records date back to 1931, and reflect 1,463 fatalities during that year. Public outrage over a series of mining tragedies impelled a succession of Presidents and Congresses to bring mining safety incrementally under federal control. Although initial federal authority was limited to issuing notices of violation, full federal power to enforce mine safety regulations occurred in 1969, and MSHA was established as a freestanding enforcement agency in 1977.^{26,27}

Aviation Administration (FAA) actively regulates carriers in order to assure commercial aviation safety. Based on NTSB findings and other sources of information, the FAA carries out an ongoing aircraft inspection program, orders special inspections and repairs, assesses fines and other sanctions against carriers for safety lapses, and even grounds aircraft when it finds an imminent safety threat. Aviation safety policies succeed because they are designed for rapid responses to acute safety issues, demand systems solutions to identified problems, and require adherence to safety protocols.^{24,25}

Nonetheless, the aviation industry has been committed to build on past successes in a drive for safety perfection. In 1998, it established a new federal program – the Commercial Aviation Safety Team (CAST) – which was charged with further reducing the air-travel accident rate by an additional 80% over 10 years by rapidly implementing modern, evidence-based strategies. The initiative not only met but exceeded that goal.

The parallels between aviation and health care are strong. Provonost et al (Health Affairs Web Exclusive, 2009; 28(3). W479-89) has proposed creation of a public-private healthcare safety advisory commission in the image of CAST, a concept we endorse.

By 1990, coal mining deaths had dropped to 66, progress that moved U.S. Secretary of Labor Lynn Martin to set a goal of zero fatalities by 2000. In 2008, there were 30 coal mining deaths²⁸ – continuing, incremental progress but still far short of Secretary Martin's zero goal. Coal mining safety has come a long way, as Exhibit 2 illustrates.²⁹ But perhaps Secretary Martin or one of her successors should have created a new program, like CAST, to further the drive to perfection.

Industrial Manufacturing. Federal safety standards can make patient safety a higher priority, but striving for the only acceptable goal – zero errors – requires that safety be embedded in the culture of health care. Motivated individuals and organizations can reach for and achieve seemingly unattainable safety goals. Former Treasury Secretary Paul H. O'Neill was for 12 years chairman and CEO of Alcoa, a company with 140,000 employees in 36 countries, most of which lack meaningful government oversight of workplace safety. Nevertheless, under his leadership Alcoa established an unmatched safety record. "I was prepared to accept the consequences of spending whatever it took to become the safest company in the world," O'Neill said.³⁰

O'Neill required that every incident be reported and resolved to root cause, with preventive measures to be implemented worldwide. This commitment was put to the test when one of

Alcoa's most highly regarded plant managers was discovered to have withheld information about workers falling ill due to carbon monoxide. After considering the facts, O'Neill discharged the manager for failure to report these safety events and, therefore, for putting lives at risk.³¹ Embedding these values at Alcoa enabled the company to become the safest employer in the world. As shown in Exhibit 3, the corporation's safety record improved from 1.86 lost workday incidents per year (or accidents per 100 employees that led to days lost from work) to 0.2 – a 90% improvement in safety.^{32,33}

The example set by Alcoa shows that even across diverse workplaces, assertive leadership with an unwavering goal of safety perfection can succeed. Translating these concepts beyond the microsystem of a single company, and applying them to a national healthcare system, could not happen without federal oversight.

THE ARGUMENT FOR A FEDERAL PATIENT SAFETY AGENCY

As a co-founder of PRHI, O'Neill brought the same commitment and ethic to health care in western Pennsylvania. In 2000 Congressional testimony, O'Neill reiterated principles for patient safety that have become broadly accepted:

Goals should be placed at the theoretical limit of performance - perfect patient care. In the case of patient safety problems, the goal should be perfect patient care -- zero incidents resulting from medical errors.³⁴

Fragmented, largely voluntary efforts to improve patient safety, however, have not brought the U.S. much closer to the goal of zero adverse incidents. In response to evidence of safety risks in other sectors, Congress endowed one (or more) federal agencies with specific powers to reduce injuries and deaths: mandatory safety reporting systems, required remedial actions, and civil and criminal penalties for non-compliance. Medical errors are one of the nation's leading causes of death and a significant contributor to

rising healthcare costs. We believe, therefore, it is in the national interest for Congress to create federal regulatory powers to protect against serious, recurring medical errors. This new federal authority should be risk-based: sufficient to respond to clear evidence of recurring, significant threats to patient safety for which a countermeasure is proven reliably across the full spectrum of healthcare settings, but not so expansive as to assert total federal regulatory control over health care, undertake additional research or establish a centralized medical error reporting system.

Whether as an independent agency or embedded within an existing federal agency (e.g., the Agency for Healthcare Research and Quality), a federal patient safety agency that concentrated on serious, recurring medical errors would require relatively modest resources and limited authority:

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 from general acute care hospitals, specialty hospitals, ambulatory surgery centers, laboratories, pharmacies, long-term care facilities and rehabilitation facilities. 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 apparent recurring medical errors and recommended preventive actions. Staff-generated information and recommendations would be evaluated by a new public-private patient safety committee of medical and safety experts that would be appointed by the Secretary of Health and Human Services (i.e., the CAST model described above that was established to boost aviation safety). The committee would have two core responsibilities: (a) ascertain that each staff-proposed recommendation pertained to

recurring error that posed serious, continuing risks for patients; and (b) evaluate staff-recommended preventive actions and concur/disagree/modify.

Publication of regulations. Once the public-private patient safety 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 (e.g., Mickey Mouse sticker 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, patient safety agency would be authorized to refer to 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. It would rely on existing research and adverse event reporting resources to inform its priorities and actions. For instance, a brief scan of states' adverse event reporting yields a series of issues to which to which this new agency could turn its attention immediately: wrong-site surgeries, wristband patient identification label synchronization, medication labeling and packaging, retained foreign bodies after surgeries, non-standardized crash carts and defibrillators, sharing of multi-dose medication vials among patients. By focusing its attention on such serious, recurring lapses, a federal patient safety agency could have a substantial, immediate impact on the number of lives lost and money wasted on preventable medical errors.

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.

Authors: Cliff Shannon, John Rice, JD and Karen Wolk Feinstein, PhD

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