

Sunday Forum: We need a federal safety agency for patients

It could save a lot of lives, money and anguish by policing medical errors, argues KAREN WOLK FEINSTEIN of the Pittsburgh Regional Health Initiative

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Item: The newborn twins of actor Dennis Quaid and his wife nearly died after overdoses of heparin, a powerful blood-thinning drug. This occurred due to a mix-up between similarly packaged infant and adult doses (which are 1,000 times stronger). The same error had previously killed or sickened at least 250 newborns. The drug manufacturer had alerted hospitals to potential confusion but not until after the international publicity about the Quaid twins did it clearly differentiate the packaging. The Institute for Safe Medication Practices lists several dozen look-alike medications that cause preventable patient injuries and deaths.

Item: A Pennsylvania man, seriously injured and unconscious after an auto accident, was rushed to a hospital emergency department. A wristband placed on his right wrist denoted an injury. However, at a nearby hospital the same color of wristband meant "do not resuscitate." An ER nurse who worked at both hospitals became confused. Only quick action by other emergency personnel averted a possible death. National research has shown an average hospital wristband identification error rate of 2.2 percent.

Item: Wrong-site surgeries are supposed to be a "never event" in medical parlance. According to the Pennsylvania Patient Safety Authority, wrong-site surgeries in our state average 50-plus each year. Most instances are at least partly attributable to the failure of surgical teams to follow a pre-surgery safety checklist.

It's been 10 years since the Institute of Medicine's groundbreaking patient-safety report, "To Err Is Human." The report estimated that up to 98,000 Americans were dying annually as a result of medical errors and that hundreds of thousands more were suffering serious injuries.

Hopes for dramatic improvement in the wake of the report have not been realized. The federal government's 2008 National Healthcare Quality & Disparities Report asserts there has been virtually no improvement in patient safety in recent years.

Some health-care experts nevertheless believe the stage is set for substantial safety improvements. Others are frustrated after a decade of only marginal improvement through voluntary action; they advocate stronger government intervention.

The Pittsburgh Regional Health Initiative favors government intervention. We propose that Congress create a Federal Patient Safety Agency to identify recurring medical errors and require quick, preventive action.

Federal regulation has been a powerful catalyst for improving safety in other industries, such as aviation. Rather than a large, new federal agency and onerous regulations, PRHI proposes limited federal

intervention that could be implemented rapidly, at modest cost -- intervention that not only would prevent injury and death but also would produce significant savings for taxpayers and private insurers.

Here is an initial outline for a Federal Patient Safety Agency:

- **No new reporting requirements:** The agency could use existing public and private error-reporting systems to identify recurring patient injuries -- the Pennsylvania Patient Safety Authority, for instance, collects and publishes data in Pennsylvania. Other government agencies, such as the Institute of Medicine, already conduct medical-error research. The new safety agency would rely on these resources to develop regulatory recommendations, such as a standardized hospital patient-identification system.
- **Independent evaluation of proposed regulations:** No regulatory action would be taken without the concurrence of a public-private Patient Safety Review Commission. Commission-approved recommendations also would go through the normal federal regulatory review process.
- **Enforcement:** As instances of noncompliance come to the attention of the safety agency, it would be authorized to issue warnings, publicize problems, levy fines or make referrals to federal law enforcement.

When PRHI was founded in 1998, we hoped mistakes in medical settings would be reduced rapidly and dramatically. One of our earliest projects enlisted 30 local hospitals and reduced life-threatening, central line-associated bloodstream infections by more than two-thirds.

That success gave momentum to tackling other infections, medication errors, pathology mistakes and patient falls. But hopes for rapidly spreading and sustaining improvements were naive. We have seen dramatic improvements in certain areas, but not in others. We've learned that quality is not viral.

Part of the problem is that our current health-care payment system rewards errors. If mistakes require further treatment, providers get paid even more for having made them. National exposure of this catastrophic irony played a part in Pennsylvania becoming the first state to require public reporting of hospital-acquired infections.

PRHI vigorously lobbied Medicaid and Medicare officials to withhold reimbursements when egregious errors occur, and it helped to enact new policies. But even negative incentives have produced insufficient patient protections. Observational studies show that most health-care professionals still do not wash their hands appropriately!

Pending federal health-reform legislation would direct Medicare to develop new safety policies to reward hospitals and physicians with good safety records; to penalize providers for high error rates; to publicly report on health-care quality and safety. But none of these promise the gold standard: rapid corrective action.

A Federal Patient Safety Agency of limited scope would not eliminate all medical errors and patient injuries overnight. But by concentrating on the causes of serious, recurring errors -- such as look-alike medications and non-standardized patient identification -- it could expedite significant reductions in preventable patient deaths and injuries. And it could save us all a lot of money.

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