

parency of the health care industry’s performance and providers’ accountability for improved performance. This more cohesive, bipartisan customer voice has boosted the courage of government players to notch up providers’ accountability, despite the wariness of the health care industry.

Second, the terms “never events” and “preventable serious hospital complications” carry a psychological advantage in congressional deliberations. Nobel Prize-winning research by Kahneman, with Tversky, on “negative framing” and the “availability heuristic” suggests that humans are more strongly inclined to take action when the actions in question are labeled so as to convey the loss avoided rather than the benefit gained and when the consequences of failing to act are mentally vivid. Never events and hospital-acquired infections score well on both counts. Indeed, Kenneth Kizer, who coined the term “never events” when he led the National Quality Forum, built on his intuition that it carried “an extra psychological charge.” (Kizer believes that attention to language’s psychological power was key to his success in leading California’s smoking-cessation ini-

tiative and rapidly improving the performance of Veterans Affairs hospitals.)

Congressional and state legislative pressure on health care providers to be more accountable for the financial consequences of quality problems (see table) and other sources of clinical inefficiency is only going to intensify as more middle-income voters become uninsured or underinsured. Such pressure will inevitably require physicians to learn to systematically reengineer clinical work methods in order to reduce errors and waste — a common approach in other complex service and manufacturing sectors. This trend also portends major revision in physician training, greater collaboration of physicians with systems engineers and other clinical team members, and the adoption of electronic information systems. How these fundamental changes will be facilitated remains an unwritten chapter in the advancement of clinical performance in the United States to a trustworthy level.

For now, physicians should anticipate more urgent requests from hospitals for cooperation in addressing large shortfalls in implementing the National Quality

Forum’s best practices for hospital safety. Some of these practices require substantial changes in physicians’ workflow, such as routine use of procedural checklists and computerized order entry. Postponing such practices, which represents a safety risk for patients, now poses a greater financial risk for hospitals.

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1. Rosenthal MB. Nonpayment for performance? Medicare’s new reimbursement rule. *N Engl J Med* 2007;357:1573-5.
 2. Sack K. Medicare won’t pay for medical errors. *New York Times*. October 1, 2008:A1.
 3. Committee on Redesigning Health Insurance Performance Measures, Payment, and Performance Improvement Programs. Rewarding provider performance: aligning incentives in Medicare. Washington, DC: National Academies Press, 2007.
 4. Medical checks and balances. *Washington Post*. February 26, 2003.
 5. Encinosa WE, Hellinger FJ. The impact of medical errors on ninety-day costs and outcomes: an examination of surgical patients. *Health Serv Res* 2008;43:2067-85.
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Medicare Nonpayment, Hospital Falls, and Unintended Consequences

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In 2005, in response to disturbing and widely cited findings by the Institute of Medicine about the prevalence of life-threatening conditions acquired by patients in U.S. hospitals, Congress authorized the Centers for Medicare and

Medicaid Services (CMS) to implement payment changes designed to encourage the prevention of such conditions. Under an amendment to the Social Security Act that was enacted on January 1, 2007, the secretary of

Health and Human Services was required to identify at least two hospital-acquired conditions by October 1, 2007, that were high-cost, high-volume, or both; that resulted in the assignment of a case to a higher-paying diagnosis-

Strategies Used by the Hospital Elder Life Program (HELP). [*]	
Intervention	Description
Prevention of delirium	Provide orientation and therapeutic activities Make adaptations for vision and hearing impairment Maintain hydration and nutrition Assess and monitor mental status daily
Maintenance of mobility	Avoid physical restraints Remove immobilizing devices (e.g., Foley catheters, intravenous lines, cardiac monitors) Provide physical therapy and early mobilization program
Minimization of psychoactive medications	Avoid standing prescriptions for sleep, anxiety, and agitation Use nonpharmacologic approaches Avoid drugs that are inappropriate for the elderly Review and reduce medications regularly
Scheduled toileting	Have patient walk to toilet every 2 hours during daytime
Lower height of bed	Lower mattress height (to height of mattress at home) to reduce risk of falls and fall-related injuries

^{*} These strategies are recommended for the prevention of hospital falls (<http://hospitalelderlifeprogram.org>).

related group (DRG) when they were present as a secondary diagnosis; and that could reasonably be prevented through the application of evidence-based guidelines.

The CMS worked collaboratively with the Centers for Disease Control and Prevention (CDC) and on October 1, 2008, enacted new payment provisions: Medicare will no longer reimburse hospitals for a higher-paying DRG when one of eight selected hospital-acquired conditions develops during the hospital stay. The CMS heralded this move as an effort to align financial incentives with the quality of care, thereby promoting both quality and efficiency.

Hospital falls and trauma were included as one of the eight conditions that, the CMS argues, “should not occur after admission to the hospital.” There is little argument that hospital falls fulfill the first two criteria outlined by Congress — they are high-cost and high-volume, and they result in the assignment of a case to a higher-paying DRG. Some 3 to 20% of inpatients fall at least once

during their hospital stay; these falls result in injuries, increased lengths of stay, malpractice lawsuits, and more than \$4,000 in excess charges per hospitalization. Thus, hospital falls represent a major patient-safety problem and may complicate a patient’s care and treatment. Yet we believe that the inclusion of falls and trauma in this initiative is misguided: it implies both that hospital falls occur as the result of lapses in the health care system and that they can reasonably be prevented through the application of evidence-based guidelines. Most important, their inclusion may have unintended consequences that may cause greater harm than the falls that the initiative is meant to prevent.

Unlike other hospital-acquired conditions that were selected by the CMS, falls are often the result not of medical errors but of diseases, impairments, and appropriate uses of medications and other treatments. Falls and injuries can occur even when hospitals provide the best possible care.

Each year, about one third of persons who are 65 years of age or older living in community settings fall at least once; the percentage is 50% among those 80 years of age or older. The CMS’s statement that the selected conditions should not occur after admission to the hospital presumes that the conditions were not present before hospitalization — which is not true in the case of falls.

There is no evidence that hospital falls “can be consistently and effectively prevented through the application of evidence-based guidelines.” The authors of the CMS rule acknowledge this fact. In the final rule, as recorded in the Federal Register on August 22, 2007, they note that “although we have not identified specific prevention guidelines for the conditions . . . we believe these types of injuries and trauma should not occur in the hospital and we look forward to working with CDC and the public in identifying research that has or will occur that will assist hospitals in following the appropriate steps to prevent these conditions from occurring after admission.” Although clinical trial results suggest that certain strategies may reduce the risk of falling in community settings, fall prevention in the hospital has been much less studied. What little evidence is available is not encouraging. A recent systematic review suggested that, at best, about 20% of hospital falls can be prevented.¹ Moreover, no intervention has yet been shown to reduce the risk of serious injury, the outcome of clinical relevance.

Of greatest concern is that the heightened focus on fall prevention will probably have unintended consequences. If hospitals are

scrutinized for the occurrence of falls, the natural tendency will be to focus on such events even at the expense of competing (and perhaps more important) outcomes. Unintended consequences are likely to include a decrease in mobility and a resurgence in the use of physical restraints in a misguided effort to prevent fall-related injuries. Physical restraints have long been used because they are believed to prevent falls. Studies have shown, however, that not only do they not reduce the risk of falls or related injuries, but they are associated with increased rates of complications, including immobility, functional loss, delirium, agitation, pressure sores (which are themselves one of the nonreimbursible hospital-acquired conditions), asphyxiation, and death.² Moreover, accumulating evidence suggests that restraints may actually increase the risk of falling or sustaining an injury from a fall.³

Manufacturers are taking advantage of the increased interest in fall prevention by marketing new devices. Chairs that are difficult to get out of, enclosed beds, and a wide array of bed alarms — even sock alarms — are meant to circumvent guidelines against the use of traditional restraints. But as devices intended to inhibit free movement, they should be subjected to the same regulations that apply to any other restraints.

We are not advocating that the CMS and hospitals ignore falls; rather, we are sounding a warning for health care providers and policymakers to avoid the temptation to address a complex problem with a simple but wrong solution. As a first step, the CMS should recognize that the goal is ensuring safe mobility, not merely preventing falls, and thus ex-

PLICITLY acknowledge the inherent tradeoff between safety and mobility. Mobility should be considered a vital sign — much as pain now often is, thanks to efforts

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to heighten care providers' awareness of it and to improve its treatment.

Hospitals must recognize that given the burden of illness, multiple risk factors, and the short duration of hospital stays, multifaceted approaches will most likely be required to prevent falls while maintaining patients' mobility. Indeed, available studies on fall prevention in the hospital suggest that multicomponent interventions implemented by an interdisciplinary team (such as physicians, nurses, rehabilitation therapists, and volunteers or aides) are likely to be the most effective strategies.

Mental-status change has consistently been shown to be a significant contributor to falls in the hospital setting. Therefore, strategies such as the Hospital Elder Life Program (HELP), which has proved to be effective in preventing delirium (a condition that was itself proposed for inclusion on the no-pay list but was eliminated during the public-comment stage), might also be applied success-

fully to fall prevention.⁴ Preliminary evidence suggests that the HELP protocols — which address orientation, therapeutic activities, early mobilization, vision and hearing, oral volume repletion, and sleep enhancement — are effective in reducing falls (see table). Unpublished data from hospitals that use HELP reveal a reduction in falls from 11.4 to 3.8 per 1000 patient-days at one site and from 4.7 to 1.2 per 1000 patient-days at a second site. At 29 hospitals implementing HELP, 95% of staff members reported a reduction in the rate of falls.⁵ This finding is not surprising: delirium and falls share common risk factors, such as cognitive and functional impairment and immobility.

The inclusion of hospital falls in the new Medicare initiative appears to be premature, at best; at worst, it may be harmful to the very patients it is intended to protect and may ultimately increase the costs of Medicare because of its unintended consequences. In their desire to promote the quality and efficiency of care, the CMS and hospitals must avoid strategies that cause more harm than good. As H.L. Mencken put it, "There is always an easy solution to every human problem — neat, plausible, and wrong."

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1. Oliver D, Connelly JB, Victor CR, et al. Strategies to prevent falls and fractures in

hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses. *BMJ* 2007;334:82.

2. Frank C, Hodgetts G, Puxty J. Safety and efficacy of physical restraints for the elderly: review of the evidence. *Can Fam Physician* 1996;42:2404-9.

3. Park M, Tang JH. Changing the practice of physical restraint use in acute care. *J Gerontol Nurs* 2007;33:9-16.

4. Inouye SK, Bogardus ST Jr, Charpentier PA, et al. A multicomponent intervention to prevent delirium in hospitalized older patients. *N Engl J Med* 1999;340:669-76.

5. Bradley EH, Webster TR, Schlesinger M, Baker D, Inouye SK. Patterns of diffusion of evidence-based clinical programmes: a case study of the Hospital Elder Life Program. *Qual Saf Health Care* 2006;15:334-8.

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The Global Burden of Tuberculosis — Combating Drug Resistance in Difficult Times

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According to the 13th annual tuberculosis report of the World Health Organization (WHO) — published on World TB Day, March 24, 2009 — there were an estimated 9.27 million new cases of tuberculosis worldwide in 2007.¹ Although this figure represents an increase from 9.24 million in 2006, the world population has also grown, making the number of cases per capita a more useful measure of the problem; this figure peaked in 2004 at 142 per 100,000 and fell to 139 per 100,000 in 2007. An estimated 1.32 million people who were not infected with the human immunodeficiency virus (HIV) died of tuberculosis in 2007, as did an estimated 456,000 people who were HIV-positive. Prevalence and mortality rates appear to be falling in all six WHO regions. Thus, the Americas, the eastern Mediterranean, and Southeast Asia appear likely to meet the Millennium Development Goals target, set in conjunction with the Stop TB Partnership and the World Health Assembly, of halving tuberculosis prevalence and tuberculosis-related mortality between 1990 and 2015. This target will probably not be met by the African and European regions. Nevertheless, do the new statistics, at last, represent the turn of

the tuberculosis tide and provide reason for cautious optimism?

Some 22 high-burden countries collectively account for 80% of the global tuberculosis burden. In 2007, the countries with the highest prevalence were India (with 2.0 million cases), China (1.3 million), Indonesia (530,000), Nigeria (460,000), and South Africa (460,000); of the estimated 1.37 million cases in HIV-positive persons, 79% were in Africa and 11% in Southeast Asia. Disturbingly, there were an estimated 500,000 cases of multidrug-resistant (MDR) tuberculosis in 2007 (including 289,000 new cases); of these, 131,000 were in India, 112,000 in China, 43,000 in Russia, 16,000 in South Africa, and 15,000 in Bangladesh; 55 countries had reported cases of extensively drug-resistant (XDR) tuberculosis by the end of 2008. These last figures are reason for considerable concern and highlight a potential threat to our ability to treat tuberculosis, both in individual patients and in the context of a treatment program.

In early April in Beijing, at a ministerial meeting of countries with a high burden of MDR or XDR tuberculosis, it was forecast that to achieve the target set out in the Global Plan to Stop TB, treatment of 1.4 million cases of

MDR or XDR tuberculosis will be required in the 27 countries with the highest burden between 2009 and 2015. The cost of diagnosing and treating these cases was estimated at \$16.9 billion, with annual costs increasing from \$700 million in 2009 to \$4.4 billion in 2015; the latter figure is 61 times the funding that is available in 2009. In higher-burden regions, the proportion of tuberculosis cases that are multidrug-resistant may range from 1 to 14% or more.² Of these cases, the proportion that are extensively drug-resistant may be as high as 21%.³ Even in the United States, where the number of MDR cases appears to be declining, the number of XDR cases is increasing. Although countries in Eastern Europe, the former Soviet Union, and China have a large number of MDR cases, reporting suggests that sub-Saharan Africa has a relatively low proportion of drug-resistant cases. However, the incidence of primary drug-resistant cases indicates that these areas may have the highest rates of transmitted MDR tuberculosis in the world.² Furthermore, we know that reinfection and multiple infection are common in high-incidence areas, and thus that many so-called recurrent cases are the result of a new infection and should be add-