

Impact of the Hospital-Acquired Conditions Initiative on Falls and Physical Restraints: A Longitudinal Study

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BACKGROUND: The Centers for Medicare & Medicaid Services (CMS) implemented the Hospital-Acquired Conditions (HACs) Initiative in October 2008; the CMS no longer reimbursed hospitals for fall injury. The effects of this payment change on fall and fall injury rates are not well described, nor its effect on physical restraint use.

OBJECTIVE: The aim of this study was to examine the effects of the 2008 HACs Initiative on the rates of falls, injurious falls, and physical restraint use.

DESIGN/SETTING: This was a nine-year retrospective cohort study (July 2006-December 2015) involving 2,862 adult medical, medical-surgical, and surgical nursing units from 734 hospitals.

MEASUREMENTS: Annual rates of change in falls, injurious falls, and physical restraint use during the two years before the payment rule went into effect were compared with one-, four-, and seven-year rates of annual change after implementation, adjusting for unit- and facility-level covariates. Stratified analyses were conducted according to bed size and teaching status.

RESULTS: Compared with prior to the payment change, there was stable acceleration in the one-, four-, and seven-year annual rates of decline in falls as follows: -2.1% (-3.3%, -0.9%), -2.2% (-3.2%, -1.1%), and -2.2% (-3.4%, -1.0%) respectively. For injurious falls, there was an increasing acceleration in the annual declines, achieving statistical significance only at seven years post CMS change as follows: -3.2% (-5.5%, -1.0%). Physical restraint use prevalence decreased from 1.6% to 0.6%. Changes in the rates of falls, injurious falls, and restraint use varied according to hospital bed size and teaching status.

CONCLUSIONS AND RELEVANCE: Since the HACs Initiative, there was at best a modest decline in the rates of falls and injurious falls observed primarily in larger, major teaching hospitals. An increase in restraint use was not observed. Falls remain a difficult patient safety problem for hospitals, and further research is required to develop cost-effective, generalizable strategies for their prevention. *Journal of Hospital Medicine* 2019;14:e31-e36. © 2019 Society of Hospital Medicine

Accidental falls are among the most common incidents reported in hospitals, complicating approximately 2% of hospital stays.¹⁻³ Approximately 25% of falls in hospitalized patients result in injury, and 2% involve fractures.⁴ Substantial costs are associated with falls, including patient care costs associated with increased length of stay and liability.⁵⁻⁷

Beginning October 1, 2008, the Centers for Medicare & Medicaid Services (CMS) stopped reimbursing hospitals for the additional care associated with eight hospital-acquired conditions (HACs), including serious fall-related injury, which were believed to be “reasonably preventable.”^{8,9} Before this change, hospitals recovered the costs of these “never events”

by assigning a higher level MS-DRG (Medicare Severity Diagnosis-Related Group) code for patients experiencing such an event. This is no longer allowed under the revised CMS Prospective Payment System rules.

Although the financial penalty for iatrogenic injury was modest, the payment change placed pressure on hospital staff to decrease falls, and some nurses reported changing practice to be more restrictive of patient mobility.¹⁰ Increased use of physical restraints is a potential unintended consequence of this rule change.¹¹ Restraints are known to cause agitation, delirium, decubiti, deconditioning, strangulation, and death.¹² Not surprisingly, use of restraints is discouraged in hospitals and is a CMS quality of care indicator.^{13,14} Although there is no evidence that restraint use prevents patients from falling,^{15,16} there is a perception among both health professionals and patients that restraints reduce the risk of falling, and they are often used as a “last resort” method of fall prevention.¹⁷⁻¹⁹

The aim of this longitudinal study was to determine whether this payment change was associated with changes in short-

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intermediate-, and long-term rates of falls, injurious falls, and physical restraint use in acute care hospitals. The CMS has included fall-related hip fracture in newer value-based purchasing programs by adding Patient Safety Indicator (PSI) 90 to both the HACs Reduction Program (HACRP)²⁰ and the Hospital Value-Based Purchasing (VBP)²¹ in FY2015. However, the HACs Initiative remains the only Medicare value program that directly penalizes all injurious inpatient falls.

METHODS

Study Units

As previously described,²² the National Database of Nursing Quality Indicators (NDNQI) is a data collection project initiated by the American Nurses Association (ANA). The NDNQI provides national comparative data at the unit and facility levels on nursing-sensitive indicators endorsed by the National Quality Forum. More than 2,000 hospitals voluntarily participate in the NDNQI, including virtually all ANA Magnet-recognized hospitals, and more than 90% of nursing units participate in the fall measures (NDNQI, personal communication). At the start of study data collection, the project was administered by the School of Nursing at the University of Kansas Medical Center. In 2014, the ownership of the NDNQI was transferred from the ANA to Press Ganey Associates, Inc. In addition to standardized data on unit, facility, and staffing characteristics, the NDNQI member hospitals can elect to submit monthly data on falls and quarterly data on physical restraint use prevalence.

We examined the data collected from adult medical, medical-surgical, and surgical units in United States acute care hospitals that elected to participate in the fall and physical restraint use data collection within the NDNQI for the 27 months before and the 87 months after the implementation of the CMS rule change. Eligible units contributed at least one fall and physical restraint use data point during both the 27 months preceding October 1, 2008, and the 87 months immediately after. The Institutional Review Board at the University of Kansas Medical Center reviewed and approved the study before its implementation.

Endpoints

Fall Events

The NDNQI defines a patient fall as an unplanned descent to the floor, regardless of whether the fall results in injury and regardless of whether the patient was assisted to the floor by a member of the hospital staff. Events in which a patient lands on a surface where one would not expect to find a patient (eg, on a mat next to a low bed) are also counted as falls.

Using internal data sources (eg, medical records, incident reports), participating hospitals report the number of inpatient falls each month to the NDNQI. We analyzed the falls data for the period July 1, 2006, through December 31, 2015. Thus, each unit could contribute 114 months (27 months before the rule change and 87 months after the rule change) of falls data.

Hospitals classify the injury level of each fall as none, minor (resulting in bruise, pain, abrasion, wound cleaning, or limb elevation, or in the use of ice, dressing, or topical medication), moderate (resulting in suturing, splinting, muscle or joint strain,

or application of steri-strips or skin glue), major (resulting in surgery, casting, traction, any type of fracture, consultation for neurological or internal injury, or receipt of blood products for patients with coagulopathy), or death (resulting from injuries sustained from falling). For this study, a fall resulting in any injury (including minor) was considered as an injurious fall. The NDNQI data have been validated for falls and fall injury.^{23,24}

Based on patient counts from unit censuses and/or internal data on actual patient hours on the unit, hospitals also report to the NDNQI the monthly number of patient days for each unit for which falls data are reported. The NDNQI uses these data to calculate each unit's total and injurious fall rate per 1,000 patient days.

Physical Restraint Use

The NDNQI follows the CMS definition of restraint, which is "any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely".¹³ The NDNQI restraint use data are collected quarterly. Participating hospitals choose one day each quarter to conduct a restraint use prevalence survey on participating units. On the selected day, designated RNs within these hospitals visually assess each patient on the unit for restraint use. Based on this survey, hospitals report to the NDNQI the total count of patients surveyed and whether each was restrained. For restrained patients, hospitals also report the type of restraint as limb, vest, or other (eg, four side rails, net beds, mitts not attached to the bed).

We analyzed the restraint use data for the period October 1, 2006, through December 31, 2015. Thus, 37 quarters of data (eight pre- and 29 postrule change) were available. For this study, we computed for each unit the quarterly proportion of surveyed patients who were physically restrained by dividing the total count of restrained patients (regardless of the type of restraint) on the day of the survey by the total count of surveyed patients.

Covariates

Unit- and facility-level covariates were included in several model specifications to determine whether patient or facility characteristics affected the results. The unit-level covariates included the type of nursing unit (medical, medical and surgical, or surgical), monthly rates of total nursing hours per patient day, and nursing skill mix (percent registered nurses/total nursing personnel). The three facility-level variables included urban-rural location (defined as metropolitan [located in an area containing an urban core with a population of at least 50,000], micropolitan [located in an area containing an urban core with a population of 10,000-49,999], or neither), bed size (<300 beds or ≥300 beds), and teaching status (academic health center, major teaching hospital, or nonteaching hospital).

Because larger, academically affiliated hospitals are overrepresented in the NDNQI, we conducted stratified analyses of these variables to explore how change in the rates of falls and restraint use in the entire sample might differ between hospitals according to bed size (<300 beds, ≥300 beds) and teaching status (nonteaching versus teaching and academic health center).

Statistical Methods

We compared the mean annual rates of change in falls, injurious falls, and physical restraint use prevalence during the two years before the HACs Initiative went into effect (October 2006–September 2008) with the mean annual rates of change following the implementation of the payment rule. Short-term (one-year) change was the slope from October 2008 to September 2009, intermediate-term (four-year) change was the slope from October 2008 to September 2012, and long-term (seven-year) change was the slope from October 2008 to September 2015.

Monthly rates of falls and injurious falls over the 114-month period were modeled using negative binomial models with a random intercept to account for heterogeneity between units. Each base mean model included the preimplementation intercept and slope (over time), the postimplementation intercept, and slope (both linear and quadratic). We also fit the models that included the terms in the base model and facility-level covariates, unit-level covariates, both individually and combined. All models included terms for seasonality.

Quarterly prevalence rates of restraint use over the 37 quarters were modeled using beta-binomial models with a random intercept to account for heterogeneity between units. Each base mean model included the preimplementation intercept and slope (over time), the postimplementation intercept, and slope (both linear and quadratic). Similar to the one specified for falls, models were also fitted that included facility- and unit-level covariates as described above.

To adjust for multiple comparisons of the three postimplementation slopes, all confidence intervals were Bonferroni corrected.

RESULTS

Nursing Units

We included nursing units with one or more months of falls data and one or more quarters of restraint use data before and after the rule change. Of the 11,117 nursing units that submitted data to the NDNQI, 2,862 units (983 medical, 1,219 medical-surgical, and 660 surgical) with the requisite demographic, falls, and restraint use data were considered for inclusion in the study. The characteristics of the nursing units (ie, the type of unit, total nursing hours per patient day, and nursing skill mix) and hospitals (ie, location, bed size, teaching status) included in the study were similar to those of the overall NDNQI member units.

Baseline Characteristics

In the first study month (July 2006), 1,941 sample nursing units reported 5,101 falls during 1,401,652 patient-days of observation. Of these, 1,502 (29%) resulted in injury (1,281 minor, 144 moderate, 75 major, and two deaths). Across falls, the median (interquartile range [IQR]) patient age was 70 (55–80) years, with males accounting for 51% of falls. Most of the falls, 4,328 (85%), were documented as unassisted. A total of 209 (4%) falls occurred while physical restraints were in use.

In the first quarterly restraint use prevalence survey (October 2006), the 829 participating nursing units surveyed 19,979 patients (median [IQR] = 23 [20–23] patients per nursing unit). The median (IQR) age was 66 (51–78) years, and 54% of them

were females. At the time of the survey, restraints were in use for 326 (1.6%) patients. Restrained patients were older than unrestrained patients (median age: 78 vs 65 years) and more likely to be male (56% vs 46%). Limb restraints were used for 139 patients, vest restraints for 66, both limb and vest restraints for 24, and other restraint types were used for 113 patients (including 11 in limb restraints and 5 in limb and vest restraints).

Change in Endpoints after Implementation of the HACs Initiative

Monthly crude fall and injurious fall rates, defined as falls/patient days contributed by all nursing units, are displayed in Figure 1. Figure 2 shows the quarterly crude restraint use prevalence, defined as the number of patients restrained/number of patients present on nursing units during quarterly restraint use prevalence surveys across all nursing units.

Over the 9-year study, the raw falls rate decreased from 3.9 to 3.0 per 1,000 patient days. Injurious falls rate decreased from 1.0 to 0.6 per 1,000 patient days, and restraint use prevalence decreased from 1.6% to 0.6%. The rates of falls, injurious falls, and restraint use showed a decreasing trend before the CMS payment change. Compared to the two years before the payment change, there was a stable acceleration in the one-, four-, and seven-year annual rates of decline in falls as follows: -2.1% (-3.3%, -0.9%), -2.2% (-3.2%, -1.1%), and -2.2% (-3.4%, -1.0%), respectively. For injurious falls, there was an increasing acceleration in declines, achieving statistical significance at seven years as follows: -3.2% (-5.5%, -1.0%). However, the decline in restraint use slowed, with a statistically significant deceleration in the seven-year annual change in restraint use prevalence = +9.7% (1.6%, 17.8%; Table 1). The addition of unit- and hospital-level covariates alone or in combination had little effect on these estimates (Table 2).

Stratified Analysis

At baseline, fall rates and restraint use prevalence were slightly higher, whereas the rate of injurious falls was slightly lower, among teaching and academic medical centers compared to those in nonteaching hospitals. Declines in falls rate and restraint use prevalence were higher in teaching hospitals than in nonteaching hospitals (data not included).

Injurious fall rates were slightly lower and restraint use prevalence was slightly higher at baseline in larger hospitals. Declines in falls rate and restraint use prevalence were much higher in larger hospitals, but restraint use prevalence declined faster in smaller hospitals (data not included).

CONCLUSIONS

We examined the rates of falls and fall injuries among 2,862 hospital units before and after the implementation of the HACs Initiative. Implementation of the CMS payment change was associated with a modest improvement in the rate of decrease for falls; a statistically significant effect on the rate of decrease for injurious falls was detectable only at seven years postchange. Fall reductions were the greatest among teaching and larger hospitals. These findings are consistent with our

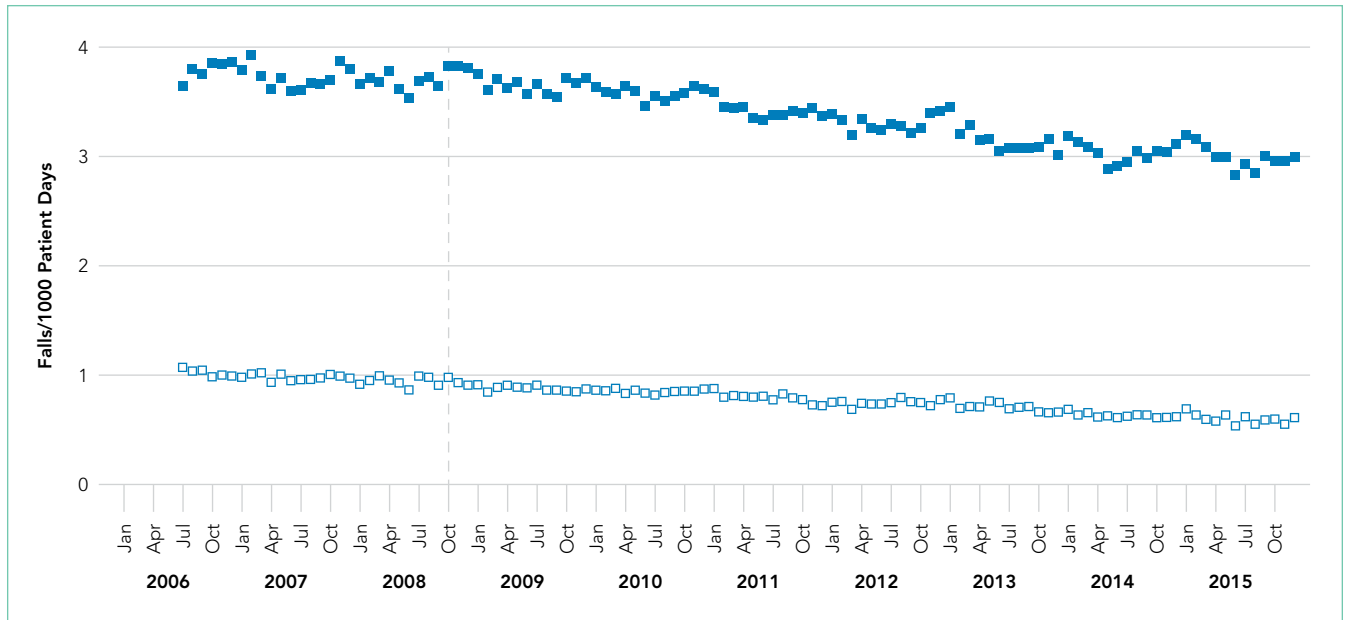


FIG 1. Monthly Crude Total Fall Rates (Filled) and Injurious Fall Rates (Open) before and after the Implementation of the CMS Nonpayment for Iatrogenic Injury Rule on October 1, 2008.

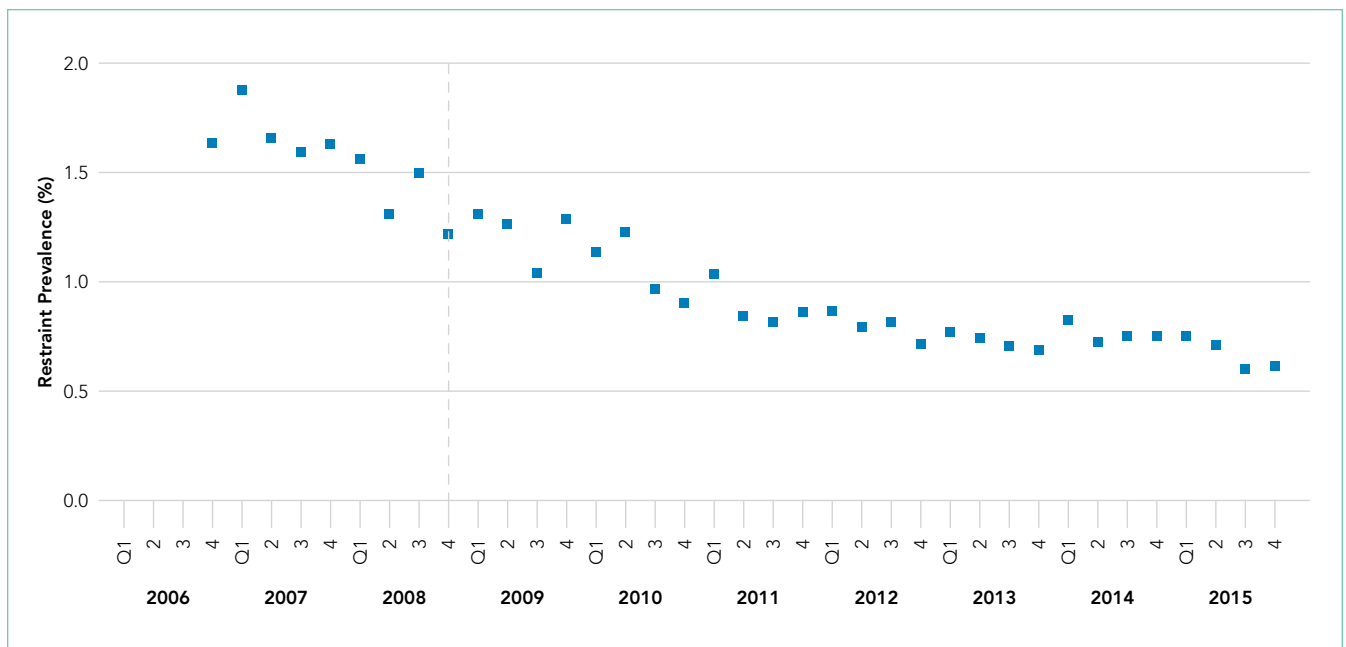


FIG 2. Quarterly Crude Restraint Use Prevalence before and after the Implementation of the CMS Nonpayment for Iatrogenic Injury Rule on October 1, 2008.

previous analysis of NDNQI data that found no short-term effect of the rule change on the rate of injurious falls.²⁵

We found no evidence indicating that restraint use prevalence increased because of this payment change. Physical-restraint use prevalence showed a rapidly decreasing trend before 2008, and although the rate of decline was attenuated seven years after the rule change, the overall physical restraint use prevalence in these units in 2015 was less than half of that in 2006. Unlike falls, the steepest declines in restraint use prevalence occurred in smaller hospitals.

The CMS decision to include falls with injury among the “reasonably preventable” HACs was controversial.¹¹ Inpatient falls are largely attributable to individual patient risk factors and are unusual among HACs in the extent to which patient behavior plays a role in their occurrence. Although hospital fall prevention guidelines have been published, only a few controlled trials have been conducted, with little evidence supporting the recommendations.^{1,26} A quantitative review found no evidence of benefit in published hospital fall prevention studies using concurrent controls (internal rate of return = 0.92; 95% CI: 0.65-

TABLE 1. Annual Percent Rate of Change in Falls, Injurious Falls, and Physical Restraint Use Prevalence Pre and One, Four, and Seven Years Post Centers for Medicare & Medicaid Rule Change

	Annual Percent Change	Difference Compared to Pre
Total falls (/1,000 patient days)		
Pre: July 2006-September 2008	-1.46 (-2.48, -0.44)	Referent
1-year post: October 2008-September 2009	-3.55 (-4.16, -2.93)	-2.09 (-3.27, -0.90)
4-year post: October 2008-September 2012	-3.61 (-3.80, -3.41)	-2.15 (-3.19, -1.11)
7-year post: October 2008-September 2015	-3.66 (-4.31, -3.02)	-2.20 (-3.42, -0.99)
Injurious falls (/1,000 patient days)		
Pre: July 2006-September 2008	-4.51 (-6.38, -2.64)	Referent
1-year post: October 2008-September 2009	-5.00 (-6.21, -3.79)	-0.49 (-2.71, 1.73)
4-year post: October 2008-September 2012	-6.38 (-6.76, -5.99)	-1.87 (-3.77, 0.04)
7-year post: October 2008-September 2015	-7.73 (-9.01, -6.45)	-3.22 (-5.50, -0.95)
Restraint use prevalence		
Pre: July 2006-September 2008	-12.72 (-19.36, -6.07)	Referent
1-year post: October 2008-September 2009	-16.62 (-19.93, -13.31)	-3.90 (-11.29, 3.49)
4-year post: October 2008-September 2012	-10.08 (-11.32, 8.84)	+2.63 (-4.11, 9.38)
7-year post: October 2008-September 2015	-3.03 (-7.65, 1.62)	+9.71 (1.59, 17.79)

TABLE 2. Difference in Mean Annual Rate of Change before the Implementation of the Centers for Medicare & Medicaid Nonpayment Regulation. Base Model and Adjusted for Facility-Level and Unit-Level Covariates

Model	Base Model	Facility-Level Covariates ^a	Unit-Level Covariates ^b	Facility- and Unit-Level Covariates
Total falls (/1,000 patient days)				
October 1, 2008-September 30, 2009	-2.09 (-3.27, -0.90)	-2.13 (-3.32, -0.94)	-2.11 (-3.29, -0.92)	-2.13 (-3.32, -0.94)
October 1, 2008-September 20, 2012	-2.15 (-3.19, -1.11)	-2.18 (-3.22, -1.14)	-2.16 (-3.20, -1.12)	-2.17 (-3.21, -1.14)
October 1, 2008-September 30, 2015	-2.20 (-3.42, -0.99)	-2.22 (-3.43, -1.00)	-2.22 (-3.43, -1.00)	-2.22 (-3.43, -1.01)
Injurious falls (/1,000 patient days)				
October 1, 2008-September 30, 2009	-0.49 (-2.71, 1.73)	-0.19 (-2.40, 2.02)	-0.69 (-2.91, 1.54)	-0.33 (-2.55, 1.88)
October 1, 2008-September 20, 2012	-1.87 (-3.77, 0.04)	-1.63 (-3.50, 0.24)	-2.01 (-3.93, -0.09)	-1.83 (-3.74, 0.08)
October 1, 2008-September 30, 2015	-3.22 (-5.50, -0.95)	-3.04 (-5.25, -0.83)	-3.32 (-5.60, -1.03)	-3.30 (-5.57, -1.02)
Restraint use prevalence				
October 1, 2008-September 30, 2009	-3.90 (-11.29, 3.49)	-4.39 (-11.50, 2.73)	-4.21 (-11.53, 3.10)	-4.32 (-11.63, 2.99)
October 1, 2008-September 20, 2012	+2.63 (-4.11, 9.38)	+2.30 (-4.28, 8.88)	+2.23 (-4.47, 8.93)	+2.42 (-4.27, 9.11)
October 1, 2008-September 30, 2015	+9.71 (1.59, 17.79)	+9.56 (1.53, 17.59)	+9.18 (1.12, 17.26)	+9.74 (1.65, 17.79)

^aFacility-level covariates: Location (metropolitan population $\geq 50,000$; micropolitan population 10,000-49,999; or neither), bed size (<300 beds, ≥ 300 beds), teaching status (academic health center, major teaching hospital, nonteaching hospital).

^bUnit-level covariates: Type of nursing unit (medical, medical-surgical, surgical), total nursing hours per patient day, and nursing skill mix (percent registered nurses/total nursing personnel).

1.30),²⁶ and a recent, well-executed, cluster randomized trial of multifactorial fall prevention interventions found no change in fall rates compared with controls.²⁷ Current hospital fall prevention guidelines are limited to unproven and time-consuming nursing-level (eg, toileting schedules and use of alarms) or organizational-level strategies (eg, changing staff attitudes regarding the inevitability of falls or "leadership support").^{1,28}

Despite the large sample size and the use of nurse-reported data that include patient falls from all age groups and not subject to bias due to the regulation itself (eg, ICD coding changes), our findings should be interpreted taking into account several limitations.

First, hospitals participating in the NDNQI self-select to participate and are larger and disproportionately urban compared with nonparticipating hospitals.²⁹ Although our findings were unchanged when hospital-level covariates were included in modeling, analyses stratified by teaching status and bed size demonstrated important differences. Larger teaching hospitals experienced greater fall reductions, whereas restraint use prevalence decreased more rapidly in smaller hospitals.

Second, the absence of a control group prevents us from conclusively attributing changes in falls rate and restraint use prevalence to the 2008 CMS payment change.³⁰ Our findings may have been influenced by other policy changes. For ex-

ample, in October 2014, the CMS implemented the Hospital-Acquired Condition Reduction Program (HACRP)²⁰ and the Hospital Value-Based Purchasing (VBP)²¹ Program. Under these programs, falls with hip fractures were an indicator that could alter hospital payment.

Third, we did not ascertain the use of all available fall prevention measures such as companions, bed rails, very low beds, bed alarms, and restricted activity.³¹ Nor could the study address changes in patient functional status or discharge location. In a before- and after-study of four hospitals in a single hospital system, we found that bed alarm use increased, restraint orders decreased, and the use of room change or sitters remained stable after the implementation of the CMS payment.³²

Nevertheless, we believe that these findings are consistent with the hypothesis that the HACs Initiative increased the cost of patient falls to hospitals, and, in response, some hospitals were able to modestly reduce the rate of falls. We found no evidence that physical restraint use prevalence increased.

In summary, our findings suggest modest impact of the HACs Initiative on falls and injurious falls, but no unintended impact on restraint use. These results highlight the importance of ensuring that pay-for-performance initiatives target outcomes where there are evidence-based approaches to prevention. The creation or identification of prevention tools and guidelines does not make an outcome preventable. Despite interval improvement in these self-selected hospital units in fall rates and physical restraint use prevalence, falls remain a difficult patient safety problem for hospitals, and further research is required to develop cost-effective, generalizable strategies for their prevention.

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