ORIGINAL ARTICLE

Patient Characteristics and the Occurrence of Never Events

Donald E. Fry, MD; Michael Pine, MD, MBA; Barbara L. Jones, MA; Roger J. Meimban, PhD

Objective: To determine whether the occurrence of "never events" after major surgical procedures is affected by patient and disease characteristics and by the type of operation performed.

Design: Epidemiological analysis.

Interventions: Derivation and assessment of predictive equations for postoperative infectious events and decubitus ulcers using Healthcare Cost and Utilization Project Nationwide Inpatient Sample administrative claims data for patients hospitalized between 2002 and 2005.

Main Outcome Measures: C statistics for each predictive equation with and without hospital dummy variables.

Results: Predictive equations for 6 of 8 complications had C statistics greater than 0.65 without hospital variables, while 2 had C statistics of less than 0.55. All equations had C statistics greater than 0.75 when hospital dummy variables were included.

Conclusions: Patient characteristics and type of operative procedure are important predictors of complications of surgical care evaluated in this study, undermining the rationale for their current classification as "never events." Variations in risk-adjusted complication rates among hospitals support the influence of quality of care on their occurrence. Development and use of warranties to cover costs associated with caring for the unavoidable components of potentially avoidable complications is proposed as a means of rewarding high-quality providers without creating unrealistic expectations or perverse financial incentives.

Arch Surg. 2010;145(2):148-151

Author Affiliations: Michael Pine and Associates (Drs Fry, Pine, and Meimban, and Ms Jones); Department of Surgery, Northwestern University Feinberg School of Medicine (Dr Fry); and Department of Medicine, University of Chicago School of Medicine, Chicago, Illinois (Dr Pine).

THE DEFICIT REDUCTION ACT of 2005 required the Secretary of Health and Human Services to eliminate Medicare payments for complications of patient care deemed to be "never events."[1] Accordingly, on October 1, 2008, the Centers for Medicare & Medicaid Services (CMS) began denying payment for costs associated with treatment of select complications of hospital care.[2] Many commercial insurers also have stated their intention to deny payment for these complications.[3,4] Additional complications have been proposed as never events to be added to CMS's list of complications for which payment is denied.[5]

CME available online at www.jamaarchivescme.com and questions on page 119

Use of the term *never event* and denial of payment for all such events imply that these complications result entirely from avoidable clinical errors. This clearly is true for rare complications such as wrong-site surgery or retained surgical sponges. However, CMS's list of current and proposed never events includes medical and surgical complications that may occur even when the highest current standards of care are met. Occurrence of these complications is related, in part, to external factors beyond a provider's control such as the complexity and severity of a patient's current medical conditions and the nature of required interventions.

See Invited Critique at end of article

If recognizable external factors influence the occurrence of never events, denial of payment for treatment of these complications will create an incentive to avoid treating high-risk patients. This study explores the effect of recognizable external factors on the occurrence after major surgery of 8 infection-related complications, each of which has been designated as a never event by CMS.

METHODS

Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample administrative claims data[6] from 2002 through 2005 were screened to identify hospitalized patients aged 18 years and older who had 1 of 5 operations

included in the Surgical Infection Prevention Project.[7] Patients who had colon resection, coronary artery bypass graft (CABG) surgery, total hip replacement, abdominal hysterectomy, or aortofemoral bypass surgery at hospitals that performed at least 100 of these procedures during the 4-year study period were included in the analytic database.

The 7 postoperative infectious complications studied were *Clostridium difficile* enterocolitis, methicillin-resistant *Staphylococcus aureus* infection, mediastinitis after CABG surgery, surgical site infection, postoperative pneumonia, intravascular device infections, and catheter-associated urinary tract infection. An eighth never-event complication, decubitus ulcer, was added as a potentially infection-associated event.

As described previously,[8] a predictive equation for the occurrence of each adverse outcome was derived using stepwise logistic regression[9] to select independent variables and the Schwarz criterion[10] combined with clinical judgment to determine which variables to retain. Equations were derived using all patients who had CABG surgery for mediastinitis and all study cases for catheter-associated urinary tract infection because the index events were few in number (n=280). Twenty-five percent of random samples of cases with and without each of the other 6 never-event complications were used for the design of predictive equations because the large number of cases made analysis problematic with the entire data set. Potential predictive variables for the development of a postoperative complication included age, sex, emergency admission, chronic conditions coded as secondary diagnoses, type of operation, and dummy variables for each hospital included in the study. Because implantation of internal thoracic arteries is associated with sternal infections after CABG surgery,[11] this procedure was included among potential risk factors for mediastinitis. Present-on-admission codes, admission laboratory data, and other clinical data (eg, timing of antibiotics) were not in the HCUP database. Final predictive equations were created by removing hospital variables and recalibrating intercepts without changing the coefficients of predictive variables so that the total numbers of observed and predicted complications were equal.

To determine the discriminatory power of predictive equations, C statistics[12] were computed for predictive equations for each never-event complication with and without hospital variables included. The SAS software (version 9.1.3; SAS Institute, Cary, North Carolina)[13] was used for all analyses.

RESULTS

A total of 887 189 cases from 1368 hospitals met the criteria for inclusion in the analytic database (**Table 1**). Numbers of operations ranged from 18 734 aortofemoral bypass procedures to 295 077 abdominal hysterectomies. Complication rates ranged from 0.03% for catheter-associated urinary tract infections to 2.35% for postoperative pneumonias (**Table 2**). Significant predictive variables and their odds ratios are shown in **Table 3** for each of the 8 never-event complications.

C statistics for equations with and without hospital variables are shown in Table 2. All of the never-event complications had C statistics greater than 0.75 when hospital variables were included in predictive equations. Removal of hospital variables from predictive equations resulted in substantial decreases in C statistics, but 6 of the 8 predictive equations had C statistics greater than 0.65 when hospital variables were removed. Only urinary tract infection and mediastinitis had C statistics of less than 0.55 when hospital variables were removed.

Table 1. Type and Number of Major Surgical Procedures

Procedure	*ICD-9-CM* Code	Cases, No.
Colon resection	45.7[1-9], 45.8, 48.62, 48.63	153 073
Coronary artery bypass graft	36.1[1-9], 36.2	269 656
Total hip replacement	81.51, 81.52, 81.53	150 649
Abdominal hysterectomy	68.41, 68.49	295 077
Aortofemoral bypass	39.25	18 734

Abbreviation: *ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification.*

COMMENT

This study demonstrates that patient characteristics and procedural interventions are important predictors of the occurrence of 6 of the 8 never-event complications analyzed. Because predictive equations for these postoperative complications have substantial discriminatory power (ie, have C statistics substantially greater than 0.50), risk factors beyond the control of providers affect the occurrence of these adverse events. Calling these complications never events and refusing to pay for their treatment may advantage high-quality caregivers, but it also will penalize providers that care for the most vulnerable patients or that perform procedures with higher-than-average risk. On the other hand, predictive equations for catheter-associated urinary tract infection and for mediastinitis after CABG surgery had only marginal discriminatory power after hospital variables were removed. But because important information about potential risk factors beyond the control of providers was not available in the administrative claims data used in this study, further analyses are needed to establish that patient and procedural factors do not influence the rates at which these 2 complications occur.

The discriminatory power of predictive equations for all 8 never-event complications increased substantially when hospital variables were included in predictive equations. This finding supports the contention that achievable improvements in quality of care can reduce the incidence of these complications and that creating financial incentives to reward hospitals with better outcomes is good public policy.

Our findings suggest that CMS's policy of denying payment for a wide variety of never events will be counterproductive in many cases because most hospital-acquired complications cannot be eliminated entirely by adherence to current best practices. To recognize this fact, payment to cover the cost of caring for potentially avoidable complications should be based on empirically derived rates and costs of complications for providers who deliver documented high-quality care. To avoid denial of care to high-risk patients, payments should be adjusted to reflect the predicted incidence and cost of complications based on patient and disease characteristics and on planned procedural interventions. Both of these goals can be achieved readily through the use of risk-adjusted warranties that link financial rewards and penalties to the

Table 2. Frequency of Complications in Study Patients and C Statistics for Predictive Equations for Each Complication With and Without the Inclusion of Hospital Variables

Complication	*ICD-9-CM* Code	Frequency, No. (%)	C Statistic	
			With Hospitals	Without Hospitals
Clostridium difficile enterocolitis	008.45	3256 (0.37)	0.892	0.783
Methicillin-resistant *Staphylococcus aureus* infection	V09.0	1064 (0.12)	0.924	0.695
Mediastinitis after coronary artery bypass graft surgery	519.2	208 (0.08)	0.844	0.535
Surgical site infection	998.59	11 444 (1.29)	0.824	0.744
Postoperative pneumonia	481, 482, 485, 486, 507	20 876 (2.35)	0.838	0.799
Intravascular device infection	996.62	2712 (0.31)	0.875	0.755
Catheter-associated urinary tract infection	996.64	280 (0.03)	0.754	0.536
Decubitus ulcer	707	5220 (0.59)	0.902	0.839

Abbreviation: *ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification.*

Table 3. Predictive Variables Included in Each Equation and Their Associated Odds Ratios

Complication	Age, y	OR	Preexisting Conditions	OR	Operative Procedures	OR
Clostridium difficile enterocolitis	>75 y	2.7	Malnutrition/weight loss	3.0	Aortofemoral bypass	6.5
			Chronic renal failure	2.7	Colon resection	5.5
			Emergency admission	1.8	CABG surgery	3.5
Methicillin-resistant *Staphylococcus aureus* infection			Diabetic complications	3.3	Colon resection	21.3
			Weight loss	2.9	Aortofemoral bypass	11.9
			Chronic lung disease	2.4	CABG surgery	6.5
			Emergency admission	2.3		
Mediastinitis after CABG surgery			Malnutrition/weight loss	5.3		
			Chronic renal failure	5.2		
Surgical site infection			Malabsorption	2.9	Colon resection	5.2
			Malnutrition/weight loss	2.5		
			Congestive heart failure	2.2		
			Chronic renal failure	2.0		
Postoperative pneumonia	>85	5.2	Malnutrition/weight loss	2.8	Aortofemoral bypass	5.3
	75-84	3.7	Chronic renal failure	2.5	CABG surgery	3.8
	65-74	2.8	Chronic lung disease	2.2	Colon resection	2.6
			Emergency admission	2.1		
			Alcohol abuse	2.0		
			Congestive heart failure	2.0		
			Malnutrition/weight loss	2.8		
Intravascular device infection	>85	1.8	Malnutrition/weight loss	16.4	Aortofemoral bypass	2.3
			Chronic renal failure	4.3		
Catheter-associated urinary tract infection	>85	5.8	Urinary tract obstruction	5.8	CABG surgery	2.2
	75-84	3.7	Malnutrition/weight loss	5.1		
	65-74	2.2				
Decubitus ulcer	>85	10.4	Diabetic complications	5.3	Aortofemoral bypass	3.8
	75-84	7.7	Chronic renal failure	4.7	CABG surgery	3.3
			Malnutrition/weight loss	3.8	Colon resection	2.4
			Peripheral vascular disease	2.3		
			Emergency admission	2.0		

Abbreviations: CABG, coronary artery bypass graft; OR, odds ratio.

degree of control providers have over the occurrence and cost of potentially avoidable complications.

Using analytic techniques such as those in this study, and with the use of refined data sets that include present-on-admission coding and available clinical information,[14] providers with low risk-adjusted complication rates can be identified. Predictive equations for potentially avoidable complications can be standardized using only data from these high-quality providers. The price of a warranty to cover the cost of caring for designated complications in a hospitalized patient can be derived by multiplying the probability that a complication will occur by the predicted average cost of treating this complication. This fee will cover the costs of treating complications that occur when a high standard of care is provided, eliminating financial incentives for cherry-picking patients.

In return for these warranty payments, providers will take responsibility for the cost of caring for all designated complications. Providers who have fewer, less costly complications than predicted will profit from these warranties; providers with high rates of expensive-to-treat complications will have complication-related costs in excess of their warranty payments. Successful investments in reducing the incidence and cost of complications will be rewarded financially without incorrectly labeling these complications as never events or placing blame for any single adverse event.

In contrast to denial of payment for never events, properly calibrated risk-adjusted warranties will not create financial incentives to deny care to high-risk patients and to specialize in low-risk procedures. Properly administered, these warranties can reward high-quality providers while protecting safety-net institutions that care for the most vulnerable patients and centers of excellence that perform high-risk interventions.

Accepted for Publication: March 5, 2009.
Correspondence: Donald E. Fry, MD, Michael Pine and Associates, 5020 S Lake Shore Dr, Ste 304, Chicago, IL 60615 (dfry@consultmpa.com).
Author Contributions: Dr Fry had access to all of the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis. *Study concept and design:* Fry, Pine, and Meimban. *Acquisition of data:* Fry, Pine, Jones, and Meimban. *Analysis and interpretation of data:* Fry, Pine, Jones, and Meimban. *Drafting of the manuscript:* Fry and Pine. *Critical revision of the manuscript for important intellectual content:* Fry, Pine, Jones, and Meimban. *Statistical analysis:* Pine and Meimban. *Administrative, technical, and material support:* Pine and Jones.
Financial Disclosure: None reported.

REFERENCES

1. Deficit Reduction Act of 2005. Sec 5001: Hospital Quality Improvement. Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/LegislativeUpdate/downloads/DRA0307.pdf. Accessed December 7, 2009.
2. Centers for Medicare and Medicaid Services. CMS improves patient safely for Medicare and Medicaid by addressing never events. http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3224&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date. Accessed January 9, 2009.
3. Smith S. Medical mistakes no longer billable: bold steps taken by state to reduce hospital errors. *The Boston Globe*. June 19, 2008. http://www.boston.com/news/local/articles/2008/06/19/medical_mistakes_no_longer_billable?mode=PF. Accessed January 9, 2009.
4. Promoting patient safety: CIGNA to stop reimbursing hospitals for never events. *Reuters*. April 17, 2008. http://www.reuters.com/article/pressRelease/idUS160249+17-Apr-2008+BW20080417. Accessed January 9, 2009.
5. Department of Health and Human Services. Center for Medicare and Medicaid: preventable hospital-acquired conditions (HACs), including infection. Fed Register. 2008;73(84):23547-23562. http://edocket.access.gpo.gov/2008/pdf/08-1135.pdf. Published April 30, 2008. Accessed November 30, 2009.
6. Overview of the Nationwide Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP) Web site. http://www.hcup-us.ahrq.gov/nisoverview.jsp. Accessed January 9, 2009.
7. Bratzler DW, Houck PM, Richards C, et al. Use of antimicrobial prophylaxis for major surgery: baseline results from the National Surgical Infection Prevention Project. *Arch Surg*. 2005;140(2):174-182.
8. Pine M, Jordan HS, Elixhauser A, et al. Enhancement of claims data to improve risk adjustment of hospital mortality. *JAMA*. 2007;297(1):71-76.
9. Hosmer DW, Lemeshow S. *Applied Logistic Regression*. 2nd ed. New York, NY: John Wiley & Sons; 2000:116-128.
10. Schwarz G. Estimating the dimension of a model. *Ann Stat*. 1978;6:461-464.
11. Nakano J, Okabayashi H, Hanyu M, et al. Risk factors for wound infection after off-pump coronary artery bypass grafting: should bilateral internal thoracic arteries be harvested in patients with diabetes? *J Thorac Cardiovasc Surg*. 2008;135(3):540-545.
12. Hanley JA, McNeil BJ. The meaning and use of the area under a receiver operating characteristic (ROC) curve. *Radiology*. 1982;143(1):29-36.
13. SAS Institute Inc. Statistics: powerful statistical software for both specialized and enterprise analytical needs. http://www.sas.com/technologies/analytics/statistics/index.html Accessed January 9, 2009.
14. Fry DE, Pine M, Jordan HS, et al. Combining administrative and clinical data to stratify surgical risk. *Ann Surg*. 2007;246(5):875-885.

INVITED CRITIQUE

Broadening Never Events

Is It a Plausible Road to Improved Patient Safety?

The Institute of Medicine's landmark article on patient safety provided a new lens through which medical errors are viewed.[1] Consequently, improvements in patient safety have become paramount to improving patient outcomes. The CMS, in their desire to respond to the need for increased patient safety and reduction of costly complications, have introduced the concept of "never events." Never events, according to the CMS, are "serious, preventable, and costly medical errors."[2] Never events come from the National Quality Forum list of serious reportable adverse events and, for the most part, would be considered by anyone, health care worker or not, to be avoidable, such as infant abduction and wrong-site surgery. State-mandated reporting and payment reductions for never events has been promoted by CMS to assure hospitals' active role in reduction of these medical errors. Despite this punitive approach in a time of rising health care costs, few surgeons would disagree with eliminating never events such as a wrong surgical procedure on the wrong side of the wrong patient. Indeed, it is every surgeon's nightmare to envision being involved in such an error. Therefore, never events have spawned valuable research into systemwide team approaches to finding solutions in a fashion not traditionally seen in surgery. For example, the implementation of preoperative surgical checklists has been found to significantly improve patient outcomes.[3]

However, the CMS's never events also include hospital-acquired infections and, in its most recent 2008 report, will increase further to include other nosocomial infections and postoperative complications such as deep vein thrombosis.[4] As the list of errors to be eliminated grows, so does concern over the ability to absolutely avoid many of these errors. Fry and colleagues analyzed the contribution of external factors to the occurrence of 8 of these never events. They challenge us with data that highlights patient- (age, sex, chronic conditions) and proce-