



Patient Co-Morbidity and Functional Status Influence the Occurrence of Hospital Acquired Conditions More Strongly than Hospital Factors

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Abstract

Background Never events (NE) and hospital-acquired conditions (HAC) are used by Medicare/Medicaid Services to define hospital performance measures that dictate payments/penalties. Pre-op patient comorbidity may significantly influence HAC development. **Methods** We studied 8,118,615 patients from the NIS database (2002–2012) who underwent upper/lower gastrointestinal and/or hepatopancreatobiliary procedures. Multivariate analysis, using logistic regression, was used to identify HAC and NE risk factors. **Results** A total of 63,762 (0.8%) HAC events and 1645 (0.02%) NE were reported. A total of 99.9% of NE were retained foreign body. Most frequent HAC were: pressure ulcer stage III/IV (36.7%), poor glycemic control (26.9%), vascular catheter-associated infection (20.3%), and catheter-associated urinary tract infection (13.7%). Factors correlating with HAC included: open surgical approach (AOR: 1.25, $P < 0.01$), high-risk patients with significant comorbidity [severe loss function pre-op (AOR: 6.65, $P < 0.01$), diabetes with complications (AOR: 2.40, $P < 0.01$), paraplegia (AOR: 3.14, $P < 0.01$), metastatic cancer (AOR: 1.30, $P < 0.01$), age > 70 (AOR: 1.09, $P < 0.01$)], hospital factors [small vs. large (AOR: 1.07, $P < 0.01$), non-teaching vs teaching (AOR: 1.10, $P < 0.01$), private profit vs. non-profit/governmental (AOR: 1.20, $P < 0.01$)], severe preoperative mortality risk (AOR: 3.48, $P < 0.01$), and non-elective admission (AOR: 1.38, $P < 0.01$). HAC were associated with increased: hospitalization length (21 vs 7 days, $P < 0.01$), hospital charges (\$164,803 vs \$54,858, $P < 0.01$), and mortality (8 vs 3%, AOR: 1.14, $P < 0.01$). **Conclusion** HAC incidence was highest among patients with severe comorbid conditions. While small, non-teaching, and for-profit hospitals had increased HAC, the strongest HAC risks were non-modifiable patient factors (preoperative loss function, diabetes, paraplegia, advanced age, etc.). This data questions the validity of using HAC as hospital performance measures, since hospitals caring for these complex patients would be unduly penalized. CMS should consider patient comorbidity as a crucial factor influencing HAC development.

Keywords Hospital-acquired conditions · Comorbidity · Functional status · Hospital factors · Gastrointestinal surgery

Introduction

Improvements in quality and safety of patient care in hospitals are important aims of the National Quality Forum (NQF) in

the USA.^{1,2} National Quality Forum and Centers for Medicare and Medicaid Services (CMS) have published reports of serious reportable events in hospitals which encompass serious adverse events that are of concern to both the public and to healthcare providers. Such serious events are classified as never events (NE) and hospital-acquired conditions (HAC) and they are presented as serious events that are largely preventable and are thought to be reliable measurements of the quality and safety of patient care.^{1,2} It has been estimated that payments for surgical NE and HAC amounted to over \$1.3 billion from 1990 to 2010.³ To motivate hospitals to accelerate improvements in patient safety by implementation of standardized protocols, in 2008, CMS adopted a non-reimbursement policy for such events. The policy limits the ability of the hospitals to bill Medicare for adverse events and complications.⁴ Reducing NE and HAC is desirable to limit

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harm to patients. Investigating the factors associated with developing NE and HAC can help design the best preventative strategies.

It is unclear whether HACs are truly hospital performance measures. Although some events seem to be unacceptable errors, not all the events are indicative of negligence. In addition, patient conditions and factors may influence the development of this complication.² Patient comorbidity may be a crucial factor influencing development of some HAC. Using a nationwide database, this study aims to investigate predictors of NE and HAC after intra-abdominal operations and investigate influence of patients' factors on developing HAC.

Methods

An analysis of the hospital inpatient discharge data of the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS) database from 2002 to 2012 was used in this study. NIS is the largest publicly available, all-payer inpatient care database in the USA annually compiled of approximately 8 million inpatient stays from approximately 1000 hospitals each year.⁵ Informed consents are obtained from individual patients within the individual hospitals' patient consent forms. NIS captures 20% of all US hospital discharges and weighted data estimates national results.⁵ In this study, we query a subset of 8,118,615 patients who underwent intra-abdominal upper gastrointestinal (GI), lower GI, and hepato-pancreato-biliary (HPB) procedures using the Ninth Revision of the International Classification of Disease (ICD-9-CM) procedure codes (Table 1). NEs and HACs were identified from the database using appropriate ICD-9 diagnosis codes, which were reported as the second to 25th diagnosis of patients in the database (the second to 25th diagnosis can be considered as an in-hospital event or complication, but the first or primary diagnosis is the main reason for hospital admission). Details of the codes used to identify NE and HAC are reported in Table 2. Three HACs were not included in this analysis because they do not pertain to our patient population (deep venous thrombosis or pulmonary embolism after total knee and hip replacements, surgical site infections after coronary artery bypass graft, surgical site infections after certain orthopedic or bariatric surgeries).

Discrete patient predictors included demographic data (age, sex, and race), patient diagnosis, comorbidities (hypertension, coagulopathy, diabetes mellitus, etc.), hospitalization length, total hospital charges, and admission type (elective vs. non-elective). Hospital-level variables included bed size (small < 200 beds; medium 201–400 beds; large > 400 beds), teaching status (nonteaching, teaching), and location (urban, rural). The definition of variables was according to ICD-9 diagnosis codes and the classification of the NIS database, which are available online.^{5,6}

We analyzed rates of NE and HAC based on all possible predictors (listed above). We also compared the rates of NE and HAC between two patient populations (based on pre-operative comorbid conditions): (1) high-risk—patients with significant comorbid conditions including: severe loss of function pre-op, diabetes with complications, paraplegia, metastatic cancer, and age > 70 years; and (2) low-risk—patients without these comorbid conditions.

The primary endpoints were estimated national rates of NE and HAC. Secondary endpoints were predictors and outcomes of NE and HAC. Risk-adjusted analysis was performed to investigate predictors and outcomes of NE and HAC.

Statistical Analysis

Data was analyzed using the Statistical Package for Social Sciences (SPSS) software, Version 22 (SPSS Inc., Chicago, IL, USA). Predictors and outcomes of NE and HAC were investigated using multivariate analysis. To compare end points between patients with and without NE and HAC, we used a logistic regression model for categorical end points and a linear regression for cost and length of stay. We compared baseline characteristics between patients with and without NE and HAC using a logistic regression model to investigate predictors of NE and HAC. We included all the variables of the study as covariates in the model. All statistical tests were two-sided with a level of significance set at $p < 0.05$. The estimated adjusted odds ratio (AOR) with a 95% confidence interval (CI) was calculated for each correlation. Weights were applied to each hospitalization per NIS database sets to represent the national hospitalization data.

Results

We identified a total of 8,118,615 patients who underwent HPB, lower GI, and upper GI procedures from 2002 to 2012 within the NIS database. Overall, 46.6% were male and 35.8% of patients were older than 70 years old. The majority of patients were Caucasian (71.8%). Hypertension (49.3%) and diabetes (22.8%) were the most commonly reported comorbid conditions. The median hospitalization length of patients was 4 days. The descriptive statistics, patient demographics, and clinical characteristics of the study populations are summarized in Table 3.

Overall, 1,662,533 patients had HPB procedures, 2,684,019 patients had upper GI, 1,638,327 patients had lower GI procedures, and 2,133,736 patients had mixed procedures. Overall, 1645 (0.02%) had NEs and 63,762 (0.8%) had HAC. A total of 99.9% of NE events were due to retained foreign bodies. The rate of HAC in HPB procedures, upper GI, and lower GI procedures was 0.4%, 1%, and 0.8%, respectively. Upper GI procedures had significantly higher risk of HAC

Table 1 Including procedures in the study according to the Ninth Revision of the International Classification of Disease (ICD-9-CM) procedure codes

Procedure	ICD-9 Procedure Codes ^a
Hepato-pancreato-biliary	50.01–52.99
Upper gastrointestinal	42.09, 42.40–43.19, 43.81–44.03, 44.21–45.01, 45.61–45.63, 45.91, 46.01, 46.02, 46.20–46.41, 46.50, 4.51, 46.60–46.62, 46.71–46.74, 46.93–46.95
Lower gastrointestinal	48.40–49.99, 17.31–17.39, 47.01–47.99, 46.11–46.14, 45.03, 45.41–45.49, 45.52, 45.71–45.83, 45.92–45.95, 46.03–46.04, 46.10–46.14, 46.52–46.63, 46.64, 46.75, 46.76, 46.91, 46.94, 46.96

^a Ninth Revision of the International Classification of Disease (ICD-9-CM) procedure codes

compared to HPB procedures (AOR: 1.49, $P < 0.01$). Also, lower GI procedures had significantly higher risk of HAC compared to HPB procedures (AOR: 1.67, $P < 0.01$). These differences persisted following risk adjustment. Although upper GI procedures had a higher rate of HAC compared to lower GI procedures (1% vs. 0.8%), following risk adjustment, the risk of HAC was higher in lower GI procedures compared to upper GI procedures (AOR: 1.23, $P < 0.01$).

The overall mortality was 2.6%. Following risk adjustment, patients who developed HAC had significantly higher mortality (8% vs. 2.6%; AOR: 1.14, $P < 0.01$). HAC were significantly associated with an increased mean length of stay (21 vs. 7 days; $p < 0.01$) and mean total hospital charges (\$166,324 vs. \$54,868; $p < 0.01$).

Overall, 63,762 (0.8%) patients developed HAC, of which stages III and IV pressure ulcers were the most common (36.7%), followed by poor glycemic control (26.9%), vascular catheter-associated infection (20.3%), catheter-associated urinary tract infection (13.7%), falls and trauma (4.5%), and ABO incompatible blood transfusion (0.006%). The incidence of HAC was stable (0.3–0.4%) from 2002 to 2007 and then increased starting in 2008 and plateaued at a significantly higher rate from 2009 to 2012 (1.3–1.4%, $P < 0.0001$, 2002–2007 vs 2008–2012, Chi-squared) (Fig. 1).

On multivariate analysis, several factors were associated with HAC. The strongest predictor of HAC was severe loss of function before surgery and major mortality risk before surgery (Table 4). Distribution of hospital-acquired conditions after intra-abdominal operations in high-risk vs low-risk patient groups is shown in Fig. 2. Using multivariate analysis of factors associated with HAC, we selected factors that had highest adjusted odd ratio which had strongest associations with HAC to divide the patients to two groups of high-risk patient. High-risk patients, with severe comorbid conditions pre-operatively, had an exponentially higher risk of HAC compared to low-risk patients (Fig. 2).

The overall utilization of MIS approaches was 13% with conversion rate of 10.5%. Patients who underwent open operations had a significantly higher risk of HAC (0.9% vs. 0.3%, AOR: 1.25, $P < 0.01$). Although there was a steady increase in utilization in MIS approaches in abdominal GI operations during 2002–2012, this did not correlate with a decrease in the rate of HAC during 2002–2012 (0.3% in 2002 vs. 1.3% in 2012).

Sub-group analysis was done to determine factors significantly associated with each HAC. The strongest predictors of falling were: diabetes with chronic complications (AOR: 4.18, $P < 0.01$), severe loss of function before surgery (AOR: 3.68, $P < 0.01$), and major mortality risk before surgery (AOR: 2.02,

Table 2 Hospital-acquired conditions and never events identification codes

Diagnosis	ICD-9 Diagnosis Codes ^a
Hospital-acquired conditions (HAC)	
Air embolism	999.1
Blood incompatibility	999.60, 999.61, 999.62, 999.63, 999.69
Pressure ulcer stages III and IV	707.23, 707.24
Falls and trauma	800–829, 830–839, 850–854, 925–929, 940–949, 991–994
Catheter-associated urinary tract infection (UTI)	996.64
Vascular catheter-associated infection	999.31, 999.32, 999.33
Poor glycemic control	250.10–250.13, 250.20–250.23, 251.0, 249.10–249.11, 249.20–249.21
Never events (NE)	
Retained foreign body	E871.0, E871.9, 998.4, 998.7
Wrong operation on correct patient	E876.5
Wrong operation intended for another patient	E876.6
Correct operation on wrong body part/site	E876.7

^a Ninth Revision of the International Classification of Disease (ICD-9-CM) diagnosis codes

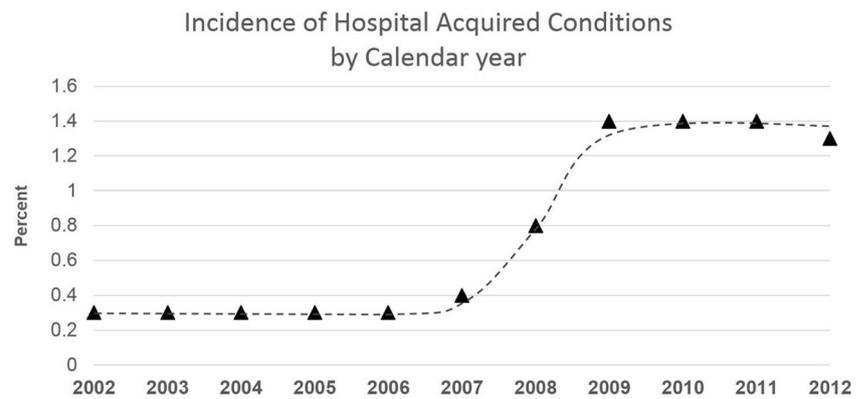
Table 3 Demographics and clinical characteristics of patients of the study

Variables		Patients with hospital-acquired conditions <i>N</i> (%) total = 63,762	Patients without hospital-acquired conditions <i>N</i> (%) total = 8,054,853	<i>P</i> Value	
Age	Mean (\pm standard deviation)	62 (\pm 18) years	61 (\pm 19) years	< 0.01	
	Median	64 years	63 years	< 0.01	
Sex	Female	31,699 (49.7%)	4,293,475 (53.4%)	< 0.01	
Race	White	33,723 (60.8%)	4,675,960 (71.9%)	< 0.01	
	Black or African American	12,829 (23.1%)	804,429 (12.4%)	< 0.01	
	Asian	5710 (10.3%)	652,578 (10%)	< 0.01	
	Other	3233 (5.1%)	368,519 (5.7%)	< 0.01	
	Predicted mortality risk before surgery	Major Mortality Risk before Surgery	36,192 (56.8%)	808,072 (26.6%)	< 0.01
Function before surgery	Severe loss of function before surgery	41,040 (64.4%)	1,241,965 (40.8%)	< 0.01	
	Paraplegia	8515 (13.4%)	165,203 (2.1%)	< 0.01	
	Diabetes mellitus with chronic complications	8913 (14%)	285,795 (3.6%)	< 0.01	
	Diabetes mellitus without chronic complications	22,339 (35.1%)	1,516,160 (19%)	< 0.01	
	Weight loss	19,108 (30.1%)	546,671 (6.8%)	< 0.01	
	Congestive heart failure	11,051 (17.4%)	666,471 (8.3%)	< 0.01	
	Neurological disorders	9148 (14.4%)	464,908 (5.8%)	< 0.01	
	Fluid and electrolyte abnormalities	35,115 (55.2%)	1,902,461 (23.8%)	< 0.01	
	Lymphoma	596(0.9%)	50,341 (0.6%)	< 0.01	
	Drug abuse	1912 (3%)	137,339 (1.7%)	< 0.01	
	Deficiency anemia	19,523 (30.7%)	1,301,755 (16.3%)	< 0.01	
	Obesity	5690 (9%)	635,416 (8%)	< 0.01	
	Liver disease	3082 (4.8%)	342,776 (4.3%)	< 0.01	
	Psychosis	3363 (5.3%)	218,819 (2.7%)	< 0.01	
	Coagulopathy	6619 (10.4%)	372,347 (4.7%)	< 0.01	
	Arthritis	1617 (2.5%)	183,433 (2.3%)	< 0.01	
	Peripheral vascular disease	6337 (10%)	500,134 (6.3%)	< 0.01	
	End stage renal failure on dialysis	13,658 (21.5%)	699,565 (8.8%)	< 0.01	
	Chronic pulmonary disease	11,068 (17.4%)	1,372,666 (17.2%)	0.13	
	Hypertension	31,536 (49.6%)	3,940,783 (49.3%)	0.18	
	Cancer with metastatic disease	2333 (3.7%)	301,463 (3.8%)	0.16	
	Type of the procedure	Hepato-pancreato-biliary (HPB)	6950 (10.9%)	1,655,583 (20.6%)	< 0.01
		Upper gastrointestinal	27,487 (43.1%)	2,656,532 (33%)	< 0.01
Lower gastrointestinal		11,153 (17.5%)	1,627,174 (20.2%)	< 0.01	
Hospital Factors	Teaching hospital	21,560 (50.6%)	1,498,693 (49.8%)	< 0.01	
	Large bed size hospitals	27,172 (63.8%)	1,965,687 (65.4%)	< 0.01	
	Private, non-profit	4751 (11.2%)	328,962(4.1%)	< 0.01	
	Government, nonfederal	2993 2(70.3%)	2,255,169 (75%)	< 0.01	
	Private, investment-owned	7890 (18.5%)	422,434 (14.1%)	< 0.01	
Surgical approach	Open	61,429 (96.3%)	7,110,901 (88.3%)	< 0.01	
	Minimally invasive	2333 (3.7%)	943,952 (11.7%)	< 0.01	
Other factors	Non-elective admission	54,916 (86.3%)	5,754,530 (71.6%)	< 0.01	
	Admission during weekend	14,125 (22.2%)	1,404,342 (17.4%)	< 0.01	

$p < 0.01$). Among patients who developed catheter-related urinary tract infection, a significantly higher risk of the event was seen in patients who had paraplegia (AOR: 4.24, $P < 0.01$), severe loss of function before surgery (AOR: 7.06, $p < 0.01$),

and patients older than 70 years (AOR: 1.68, $p < 0.01$). Factors associated with vascular catheter-associated infection were: severe loss of function before surgery (AOR: 3.15, $p < 0.01$) and major mortality risk before surgery (AOR: 14.42, $p < 0.01$).

Fig. 1 Incidence of hospital-acquired conditions (HAC) by calendar year. HAC increased significantly after 2008 ($P < 0.00001$, 2002–2007 vs 2008–2012, Chi-squared)



Strongest risk factors of stages III and IV pressure ulcers were: severe loss of function before surgery (AOR: 8.07, $p < 0.01$), major mortality risk before surgery (AOR: 9.78, $p < 0.01$), and paraplegia (AOR: 4.90, $P < 0.01$). Finally, poor glycemic control was significantly associated with: diabetes with complications (AOR: 254.2, $P < 0.01$), diabetes without complications (AOR: 238.3, $P < 0.01$), severe loss of function before surgery (AOR: 5.01, $p < 0.01$), and non-elective admission (AOR: 3.12, $p < 0.01$).

Discussion

In October 2008, the Centers for Medicare and Medicaid Services (CMS) discontinued additional payments for certain hospital-acquired conditions (HAC) that were deemed preventable. The results of this study question the validity of such a policy and we documented strong correlations between the development of hospital-acquired conditions (HAC) and inherent patient characteristics, present pre-operatively, among patients undergoing gastrointestinal procedures. We identified 13 inherent patient factors and two situation factors (non-elective admission, weekend admission), which were significantly associated with increased risk of HAC. These non-modifiable patient factors were far more significantly associated with HAC than the evaluated hospital characteristics. Specifically, we found that the rate of HAC was significantly higher in with patients with certain co-morbidities. Thus, avoidance of HAC might be difficult in high-risk patients with multiple risk factors. One factor that was particularly important was loss of function before surgery. Patients with major or extreme loss of function before surgery had more than six times that the risk of HAC compared to those with minor or moderate loss of function. In addition, patients with paraplegia, diabetes (with or without complications), and weight loss had 2–3 times the risk of HAC. This group of patients needs special attention for avoidance of HAC. Although preventive strategies are important, most of these inherent patient risk factors are not modifiable. Inability to modify comorbidity is particularly true for non-elective admissions, and we found that the rate of HAC

was increased in cases with non-elective and weekend admissions. Thus, our study documents that hospitals taking care of these sicker patients and more emergent cases had a higher rate of HAC that significantly correlated with patient, *not* hospital, factors. This data argues for the addition of a patient risk adjustment model to the CMS Hospital Quality determination.

Several studies have reported the importance of patient factors to the development of HAC.^{7–13} Wen et al.⁸ studied the influence of patient factors on NE and HAC occurrence following cerebrovascular surgery; they noted that age and the presence of ≥ 2 comorbidities were strong independent predictors of HACs. They also advocated for development of risk-adjusted models. Similarly, Lidor et al.,¹⁰ who studied bariatric patients, Shah et al.,¹² who studied open vascular procedures, reported the importance of patient factors to surgical outcomes. In addition, numerous studies have documented increased HAC occurrence among non-elective cases and weekend admissions.^{9,12,13}

The importance of patient comorbidity factors to surgical outcomes is well validated. An excellent example of this is the NSQIP program. [14, 15] Initially developed in the VA, the NSQIP program utilized risk-adjusted models to predict surgical outcomes based on pre-operative patient factors (and procedural factors). This robust model has now been validated in both the VA and American College of Surgeons (ACS) programs. The use of risk-adjusted outcomes as measures of quality of surgical care allows for comparisons of hospital factors such as variations in structure and processes of care. Not only does this program reliably document the quality of surgical care, but, with implementation of NSQIP, there has been a steady decrease in both risk-adjusted and actual mortality rates tracked annually within the VA and ACS programs.^{14,15} The same cannot be said of the outcome of the CMS payment/penalty policies.

Numerous studies have highlighted the inaccuracy of administrative Medicare Claims data. Several studies have compared it to NSQIP or chart review data.^{16–19} Lawson, Liu, and Ko et al. reported poor-to-moderate correlation between hospital complication rates comparing Medicare and ACS-NSQIP data, as well as poor hospital outlier status classification using

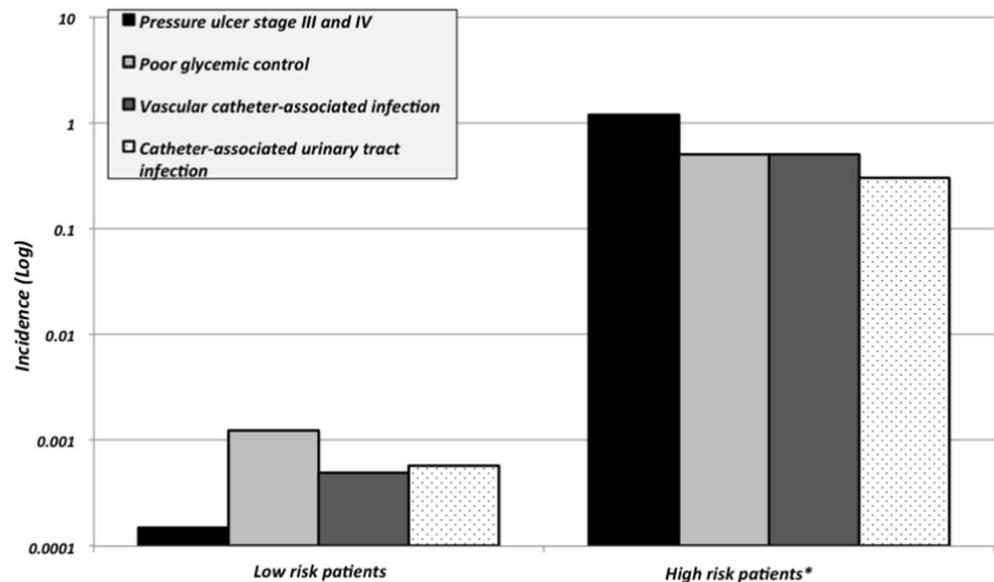
Table 4 Multivariate analysis of factors associated with hospital-acquired conditions, NIS 2002–2012

Variable			Adjusted odd ratio	95% confidence interval	P value	
Patient factors	Age	Age > 70 years	1.09	1.07–1.12	< 0.01	
	Sex	Sex (female vs. male)	1.03	1.01–1.05	< 0.01	
	Function before surgery	Severe loss of function before surgery	6.65	6.33–6.99	< 0.01	
	Predicted mortality risk before surgery	Major mortality risk before surgery	3.48	3.37–3.58	< 0.01	
	Co-morbidity	Paraplegia		3.14	3.05–3.23	< 0.01
		Diabetes mellitus with chronic complications		2.40	2.32–2.48	< 0.01
		Diabetes mellitus without chronic complications		2.05	2.006–2.10	< 0.01
		Weight loss		2	1.95–2.04	< 0.01
		Lymphoma		1.36	1.23–1.51	< 0.01
		Neurological disorders		1.33	1.29–1.37	< 0.01
		Psychosis		1.18	1.13–1.23	< 0.01
		Fluid and electrolyte abnormalities		1.13	1.11–1.16	< 0.01
		Deficiency anemia		1.13	1.10–1.15	< 0.01
		Drug abuse		1.09	1.03–1.16	< 0.01
		Congestive heart failure		1.04	1.01–1.07	0.01
		End stage renal failure on dialysis		0.93	0.90–1.01	0.11
		Cancer with metastatic disease		0.92	0.87–1.01	0.11
		Obesity		0.85	0.82–1.01	0.12
		Coagulopathy		0.83	0.80–1.01	0.13
	Arthritis		0.95	0.90–1.01	0.16	
	Chronic pulmonary disease		0.75	0.73–1.01	0.12	
	Peripheral vascular disease		1.01	0.97–1.04	0.51	
Hypertension		0.73	0.71–1.01	0.13		
Liver disease		0.67	0.64–1.02	0.12		
Operative factors	Surgical approach	Laparoscopic	–	–	–	
		Open	1.25	1.18–1.33	< 0.01	
Hospital factors	Hospital teaching status	Teaching hospital	–	–	–	
		Non-teaching hospital	1.10	1.08–1.12	< 0.01	
	Hospital type	Private, non-profit	–	–	–	
		Government, nonfederal	1.06	1.02–1.09	< 0.01	
	Hospital bed size	Private, investment-owned	1.20	1.17–1.24	< 0.01	
		Large bed size hospitals	–	–	–	
Other factors	Type of the admission	Small bed size hospitals	1.07	1.05–1.08	< 0.01	
		Elective	–	–	–	
	Admission day	Non-elective	1.38	1.34–1.42	< 0.01	
		Admission during week days	–	–	–	
	Hospitalization length	Admission during weekend	0.99	0.96–1.01	0.042	
	Hospitalization length	1.017	1.016–1.017	< 0.01		

Medicare data.^{16–19} This same group documented the poor accuracy of the Medicare claims data compared to NSQIP in identifying complications.^{17,18} Winters et al. utilized systematic chart review to examine the accuracy of Medicare data; they found limited validity HAC measures compared against the standard of medical chart review.¹⁹ In addition, several studies documented inherent bias in the CMS Hospital-Acquired Condition Reduction Program (HACRP), reporting different

HACRP scores based solely on hospital size or use of surveillance (e.g., DVT surveillance), in situations with identical complication rates.^{20,21} Finally, and ironically, Rajaram et al. reported that the CMS non-payment policy, as currently designed, actually penalized the highest-performing hospitals; those that were accredited by the Joint Commission, offered advanced services, were major teaching institutions, and had better performance on process and outcome measures.²² These

Fig. 2 Distribution of hospital-acquired conditions (HAC) by patient risk group. *High-risk patients included: diabetes with complication, paraplegia, severe loss of function before surgery, severe risk of mortality on admission, disseminated cancer patients. Note that the vertical axis is a Log plot



authors recommended re-evaluation and reform of the CMS policy. CMS may use risk-adjusted data in analyzing HAC. Also, considering our results of differences in HAC risk for upper GI, lower GI, and HPB procedures, the risk-adjusted model should include type of the procedure. The problems with Medicare non-payment policies become even more evident when their influence on the funding of safety-net hospitals is examined.^{23–26} Several studies have examined their impact on safety-net hospitals and reported that these crucial hospitals are not only more likely to be penalized, but they also incurred larger payment penalties, despite having comparable mortality rates.^{23–26} Penalties on these hospitals are more serious since they are likely to run on a tight budget, have less resources for resilience, and provide care for an underserved patient group. Thus, the CMS policy penalizes the most vulnerable patient populations.

The current study reports a significant increase in mortality, morbidity, hospitalization length, and hospital charges among cases with HAC. This agrees with other reports regarding the association between NE and HAC with patient outcomes, increased hospital charges, and length of hospital stay.^{7–11} With this administrative data, however, we cannot determine whether HACs represent a causative factor on morbidity, mortality, and hospital charges; the data can only identify a correlation. And, since HAC most strongly correlated with high patient comorbidity, present preoperatively, it is possible that patient morbidity is the primary factor driving morbidity, mortality, hospital charges, and HAC development. Given these findings, patient comorbidity factors represent an area to focus on prevention strategies, with specific standardization of preoperative care, tracking events in each hospital, and follow-up of the clinical effectiveness of preventive strategies. But, even with robust strategy development, it is unlikely that *all* HAC will be prevented in patients with existing high morbidity.

Advancement in surgical techniques, such as laparoscopic surgery, could decrease risk of postoperative HAC.¹⁰ We found a significant decrease in HAC following minimally invasive approaches compared to open approach, which is in line with previous studies.¹⁰ Molena et al. reported a decrease in HAC over time by utilization of minimally invasive approaches in bariatric procedures.¹⁰ Shorter hospitalization times with the use of MIS approaches for abdominal GI procedures been reported multiple times in the literature.^{27–29}

However, despite increased utilization of laparoscopic techniques, the rate of HAC did not decrease during the 11 years of our study. Instead, our data demonstrated that the incidence of HAC *increased* significantly after 2008, following institution of Centers for Medicare and Medicaid Services (CMS) non-payment policy. This indicates that this policy was ineffective in reducing these outcomes. Others have reported the ineffectiveness of the CMS non-payment program in reducing infections.³⁰ The increase in HAC coinciding with initiation of the CMS non-payment policy likely reflects increased surveillance. This surveillance bias has been previously reported. Shackford et al. compared VTE incidence between trauma medical centers that did or did not use routine duplex DVT screening and noted that while the incidence of PE was identical (0.4%) at both centers, the odds of a DVT diagnosis were 5.3 times higher in the center using routine DVT surveillance.²¹

Several risk factors for HAC were particularly important. The risk of HAC in patients with major or extreme loss of function before surgery was greater than six times compared to patients with minor or moderate loss of function before surgery. Major mortality risk before surgery more than tripled the risk of HAC. And, patient factors of paraplegia, diabetes, and age more than 70 years old also strongly influenced the development of HAC. Unfortunately, these risk factors are not

modifiable. These high-risk patients may benefit from development of specific protocols to reduce complication risks, but even with robust protocols, it is unlikely that HAC can be completely eliminated in these high-risk patient groups.

In our analysis, catheter-related urinary tract infections were significantly associated with paraplegia, severe loss of function before surgery, and age more than 70. This is in line with previously published articles.^{11,31,32} Appropriate preventive strategies such as the removal of the catheter as soon as possible or avoidance of its use may be helpful.^{32–35} Saint et al. reported that 38% of physicians were not aware of the status of urinary catheter use for their patients, so reminder systems involving staff nurses and virtual reminders involving the use of electronic devices may help decrease the risk of catheter-related urinary tract infection.³⁵ But, the characteristics of the highest risk patients with catheter-related urinary tract infection suggest that many had chronic indwelling catheters. This, of course, presents a much higher risk for urinary infections. The presence of a chronic indwelling catheter needs to be considered when analyzing urinary HAC.

In our study, poor glycemic control was the second most common HAC after intra-abdominal operations. We found significant associations between poor glycemic control and diabetes with or without chronic complications, severe loss of function before surgery, and non-elective admission. Hyperglycemia (glucose ≥ 150 mg/dl) has been reported as an adverse outcome predictor in surgical patients, even in the non-diabetic population.^{36,37} Checking the blood glucose in the morning of surgery in patients with and without a history of diabetes is recommended in the literature.³⁶ Unfortunately, prospective study protocols, utilizing strict perioperative blood glucose management, were associated with a higher incidence of hypoglycemia episodes.³⁸

Vascular catheter-associated infections were the third most common HAC in the current study. Multiple studies investigated catheter-related bloodstream infections in literature.^{39,40} There is an estimate of 15 million central vascular catheter days for patients hospitalized at intensive care units each year in the USA.^{39,40} Recognition of risk factors and identifying high-risk patients will help design preventive programs. Factors of duration of catheterization and use of a semipermeable transparent dressing have been reported to be associated with positive cultures of catheters.⁴¹ We found severe loss of function before surgery and major mortality risk before surgery as risk factors of vascular catheter-associated infection after intra-abdominal operations. Preventive strategies of educating and designating trained healthcare personnel and assessing their knowledge and adherence to guidelines, correcting selection of catheters and sites, hand hygiene and aseptic techniques, maximal sterile barrier precautions, and appropriate catheter site dressing regimens could be helpful.⁴⁰

Falling is one of the preventable HAC after operations.⁴² Fall represents a failure of multiple physiological systems and

it is also a marker for increased perioperative mortality, morbidity, and postoperative delirium.^{39,42–45} We found a higher risk of fall among patients with diabetes with chronic complications, severe loss of function before surgery, and major mortality risk before surgery. Factors like older age, functional dependence, and lower albumin levels have been reported to be associated with falls.⁴² Diabetes with peripheral neuropathy can increase risk of fall after surgery. Preventive strategies such as minimizing poly-pharmacy and avoiding medications that increase the risk of delirium, increasing the presence of family members or sitters at the bedside, minimizing environmental hazards, and occupational and physical therapy training in high-risk patients, especially in diabetic patients with peripheral neuropathy, may be helpful.

Study Limitations

There are some limitations to the current study. First, this study is limited by its retrospective nature and we are unable to draw causal conclusions and suggested preventive strategies would need to be confirmed by clinical trials. Detection of HAC in the NIS database is limited to the ICD-9-CM coding system and coding error is possible.^{46,47} Despite our attempts to adjust for all possible confounders, we could not capture some potentially important explanatory variables that may contribute to patient outcomes, such as anatomic or laboratory data and length of use of urinary catheter. Also, The NIS has no ability to follow patient outcomes after discharge. Although this study evaluated hospital factors regarding HAC, the types of hospital factors evaluated were limited to those present in the NIS database. Due to NIS limitations, we could not investigate HAC in all types of hospital systems. Because of this, individual HAC hospital performance could not be stratified by high performing (upper decile/quartile) versus low performing (lower decile/quartile) hospitals. Despite these limitations, the advantage of using the NIS database is the broad national geographic representation across all regions of the country and also the possibility of reporting weighted results as national outcomes.

Conclusion

HAC and NE impacted outcomes following intra-abdominal GI operations were evaluated. HAC incidence after intra-abdominal GI operations was 0.8%, and they were associated with increased mortality, hospitalization length, and hospital charges. But, the incidence of HAC was higher among patients with severe comorbid conditions. While small, non-teaching, for profit hospitals, and open operations were associated with increased HAC events, the strongest HAC risk factors were non-modifiable patient factors (preoperative loss of function,

severe risk of mortality after surgery, paraplegia, diabetes, advanced age, and non-elective admission). This data questions whether HAC are truly hospital performance measures and suggests that hospitals caring for these complex patients could be unduly penalized. CMS should consider patient comorbidity as a crucial factor influencing HAC development.

Author's Contribution Moghadamyeghaneh Z: Conceived and designed the analysis; collected the data; contributed data or analysis tools; performed the analysis; wrote the paper, approval of final version, accountable for all aspects of the work.

Stamos MJ: Contributed to design of analysis, critical revision, edited paper, approval of final version.

Stewart L: Conceived and designed the analysis, critical revision, co-wrote and edited paper, approval of final version, accountable for all aspects of the work.

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