

Financial Incentives to Promote Healthcare Quality The Hospital Acquired Conditions Nonpayment Policy

Kevin T. Kavanagh, MD, MS, FACS
Board Chairman Health Watch USA
www.healthwatchusa.org

Contact:

3396 Woodhaven Dr.
Somerset, KY 42503

Cell: 606-875-3642

E-Mail: kavanagh.ent@gmail.com

**Manuscript has been submitted to the
Journal of Social Work in Public Health on June 1, 2010**

Abstract: Over a decade ago it was estimated that in the United States 98,000 patients die each year from Hospital Acquired Conditions (HAC). Recently it has been reported that this many patients now die annually from Hospital Acquired Infections (HAI) alone. Currently, HAI afflicts 1.7 million United States citizens each year. Although these conditions are often called "preventable errors," some are associated with particular hospital and physician cultures and many of these conditions, such as pressure ulcer formation and infections, may be a sign of low facility staffing levels.

Protocols have been developed that have been shown to lower the incidence of many HAC, but these have been slow to be adopted. Voluntary reporting mechanisms to assure healthcare quality are reported as having reduced effectiveness by both the Joint Commission and Dept. of HHS OIG reports. Transparency and public education have also met with resistance, but in the case of infections, now have the support of major national medical organizations.

As a further initiative to promote quality, financial incentives have been implemented by the Centers for Medicare and Medicaid Services. Surgeons have lived under stringent financial incentives since the mid-1980s when they were placed under global surgical fees. Medicare currently must make expenditure reductions since it is at risk of becoming insolvent within the decade.

Implementation of financial incentives should depend upon a balance between the nonpayment of providers for non-preventable HAC verses the promotion of healthcare quality and patient safety, the reduction in patient morbidity and mortality, the spurring of mechanisms to further reduce HAC, and the recouping of taxpayer dollars for HAC that could have been prevented.

Introduction:

Concern over the safety of medical care in the United States was brought to the public's attention in 2000 with the publication of the Institute of Medicine's report that approximately 98,000 patients die each year from Hospital Acquired Conditions. (1) To help address this problem, the Centers for Medicare and Medicaid Services (CMS) and the Agency for Health Research and Quality (AHRQ) have initiated policies to promote healthcare transparency that are designed to educate and guide consumers in their healthcare choices, and CMS has implemented a nonpayment policy for certain largely preventable adverse outcomes.

Beginning Oct. 1, 2008, Medicare stopped paying for care related to certain Hospital Acquired Conditions (HAC) – See Table 1. (2) These conditions are very costly, both in lives lost and in actual dollars (3) (See Table 2). Current Medicare payment to facilities is based on Diagnostic Related Groups (DRG), and each DRG has between one and three levels of payment. The HAC in Table 1 are comorbidities that can no longer be used to justify the higher payment level. However, other comorbidity may exist that would justify the higher level of payment. Medicare's list is not the same as the National Quality Forum's (NQF) adverse event list that contains additional Hospital Acquired Conditions and does not include acquired infections (HAI).(4)

Although HAC are often referred to as "medical errors," only a small portion of them, such as wrong-site surgery or leaving a foreign object in a patient during surgery, are true errors. The others represent adverse outcomes that are not universally preventable but may reflect both the inertia in the medical culture to adopt new protocols and the type of culture that is driving both the physician and institution's healthcare delivery system. As described by Gawande (5), there are two conflicting cultures, one patient-centered and the other profit-driven. He observed that, unfortunately, the latter appeared to be winning.

In 2009, The Leapfrog Group reported that patient fatalities could be reduced by approximately two to four times, depending on the high-risk procedure, if a hospital meets Leapfrog standards, and that more than 3,000 deaths per year could be prevented if Leapfrog standards were adopted in all hospitals.(6) Of the HAC that are largely but not universally preventable, the two most controversial categories are Hospital Acquired Infections and advanced (Stage III and IV) bed ulcers. The incidence of both categories of conditions is sensitive to facility staffing levels. (7-14).

Determining and mandating proper staffing levels and uniform protocols to prevent HAC is often almost an impossible task, both from the standpoint of justification and political implementation. It is more effective to look at outcomes and use free-market incentives to motivate enactment of known interventions that work and to spur the development of new interventions to further reduce HAC.

Healthcare Workforce and Hospital Acquired Conditions:

Reductions in facility staffing have always been a concern but are even more so during a period of economic turmoil and budgetary restraint. At a time when Hospital Acquired Infections are a major concern to both medicine and the public, the Association for Professionals in Infection Control and Epidemiology reported in 2009 that 41% of acute care facilities had cut their infection control budget.(15)

Many of the HAC are nursing-sensitive and associated with reduced hospital staffing. (7, 16, 17) In August 2002, the Joint Commission found that inadequate hospital staffing was a factor in 24% of all reported sentinel events.(8) "Higher acuity patients plus fewer nurses to care for them is a prescription for danger."(8) In an AHRQ summary report, it was concluded that, "There is strong evidence that leaner nurse staffing is associated with increased length of stay, nosocomial infection (urinary tract infection, postoperative infection, and pneumonia), and pressure ulcers."(9)

The "nursing shortage" has been blamed for over a decade for hospitals' difficulty staffing their facilities, but the cause of this "shortage" has been called into question. The Robert Wood Johnson Foundation(18) found that 26.2% of new nursing graduates are leaving hospital employment within the first two years, many because of poor working conditions. The American Nurses Association also reported in 2008 and 2009 that seven of every ten nurses believe their units were understaffed, 52.7% of nurses were considering leaving their positions (19) and "that staffing problems drive nurses from positions."(20)

Two different approaches have been tried by nursing organizations to address this problem. In 2006, the American Nurses Association launched an unsuccessful lawsuit alleging that the Department of Health and Human Services was not assuring adequate nursing staffing by using the Joint Commission which used its own "minimal standards."(21) This "shortage" has also been the impetus behind a growing national nursing labor movement that has observed the prompt restaffing of hospitals during strikes despite the "shortage" and a rapid increase in licensed registered nurses after mandatory nurse-to-patient ratios were mandated in California.(22)

However, with the exception of California, few states have been willing to mandate hospital staffing levels. An AHRQ's report concluded that although lower nursing staffing levels were associated with a higher incidence of adverse events, this relationship was not always causal and "must be tempered by provider characteristics including hospital commitment to higher quality care not considered in most studies."(23) Thus, in facilities with a low nurse-to-patient ratio, there may be a general disregard for quality, and this brings into question the cause of the "nursing shortage."

Monetary incentives can also be used to promote quality and financially penalize adverse outcomes in institutions. This would be expected to be very effective in profit-driven

medical cultures. Institutions are starting to respond to this financial pressure with a cost-of-care versus the cost-of-a-nurse analysis.(24, 25)

Staffing Sensitive HAC – Pressure Ulcers and Hospital Acquired Infections

There is a growing consensus that severe pressure sores should rarely occur. The Leapfrog Group and The National Quality Forum (NQF) consider severe pressure ulcers (Stage III and IV) as a Serious Reportable Adverse Event. Nancy Foster, Vice President of Quality and Patient Safety Policy for the American Hospital Association, has stated that the AHA encourages hospitals not to bill for NQF Serious Adverse Events.(4) The LeapFrog Group also encourages a hospital policy of not charging for care attributed to Serious Adverse Events.(26) In addition, the Colorado Hospital Association has also adopted a set of principles which encourages facilities not to seek payment for care related to the treatment of NQF Serious Reportable Events that occurred during the initial and any **previous** hospitalizations.(27)

There is, however, not as large a consensus among providers regarding Hospital Acquired Infections being classified as a serious reportable adverse event. Medicare considers many types of HAI as serious events that are not eligible as comorbidity factors and thus cannot be used to increase the payment of the base DRG.

Despite the controversy, Hospital Acquired Infections (HAI) are a large and growing category of Hospital Acquired Conditions. The CDC estimates that each year 1.7 million patients develop HAI, and they cause nearly 100,000 fatalities.(28, 29) The average additional cost of each infection ranges from \$32,000 (30) to \$38,656 (31), totaling an annual cost to our healthcare system of \$28 billion to \$33 billion. (32)

Two of the most common HAI are caused by Methicillin-resistant Staphylococcus aureus (MRSA) and C. Difficile.(33) Infection rates for MRSA have increased eight times more than expected (34) and C. Difficile has increased at a rate of 10 to 20 times more than expected.(35) MRSA is a common cause of surgical site infections. Postoperative infections are occurring at a higher than expected rate. An article in the American College of Surgeons' Surgery News reports a higher than 10% rate of infection for open abdominal and thoracic aortic aneurysm repair and almost a 9% postoperative infection rate after aortic-iliac bypass. (36)

Despite this deadly and growing public health problem of infections, the healthcare industry has been slow to respond by not adopting known protocols that have been researched extensively and proven to reduce infection rates. Protocols for the prevention of Central Line-Associated Bloodstream Infections (CLABSI) have been reported to reduce infection rates from 10.5 to 1.2 per 1,000 catheter days, and mortalities from 51% to 16%.(37) These rigid protocols were first introduced by Berenholtz et al. in 2004 (38) and perfected and popularized by Pronovost in 2006, who reported an 82% reduction in CLABSI ($p < 0.002$). (39) Although time-tested and effective, these protocols have not been universally adopted by the healthcare industry.

MRSA surgical site infections and MRSA septicemia have been extensively studied, but there is little consensus on implementation of protocols to prevent this infection. The incidence of an MRSA carrier state in the general population has been reported to be 3% (40, 41), 6% (42) and as high as 10%. (43) In addition, Hitt (2010) reported a colonization rate in healthcare workers of 4%. (44)

The risk of the MRSA carrier state to develop Hospital Acquired Infections is significant. (41, 45) Two independent large studies, the Pittsburgh Veterans Administration Healthcare System (46) and the Northwestern University study, both reported a 70% drop in the incidences of MRSA infections with the incorporation of surveillance **testing** into their infection control protocols (47). The New Mexico MRSA Collaborative also reported a 48% reduction in MRSA bloodstream infections by the use of active surveillance testing and appropriate MRSA control measures. (40)

Finally, a recent congressional inquiry reported the findings from the national VA initiative which was based upon the Pittsburg VA protocol for the reduction of MRSA infection. "Bundled" interventions were used, including the use of universal surveillance **testing**, contact precautions and **stringent** hand hygiene.(48) There was a 76% reduction in MRSA rates in the ICU setting (from 1.62/1,000 bed days of care to 0.39/1,000 bed days) and a reduction in the non-ICU setting of 28% (from 0.46/1,000 bed days of care to 0.33/1,000 bed days of care).

In the one article that is widely quoted as non-supporting universal screening (49), however, only 30% of the MRSA positive group that underwent surgery received preoperative systemic antibiotics, and carriers were placed in "flagged side or single rooms whenever available." The study did observe that 5.1% of patients admitted to the institution were MRSA positive and that these patients accounted for 41% of all MRSA infections (Chi Square $p < 0.0001$). (49)

Catheter-Associated Urinary Tract Infections (CAUTI) are the most common cause of secondary nosocomial septicemia, causing 17% of all cases with a fatality rate of approximately 10% (50). There is little doubt that CAUTI rates cannot be brought to zero. However, the use of and number of days urinary catheters are in place can be reduced, resulting in a lower infection rate(51) as can the use of lecithin/silver-coated catheters to reduce bio-films.(52)

The policies regarding nonpayment of Catheter-Associated Urinary Tract Infections are controversial.(53, 54) It has been argued that CAUTI are almost ubiquitous in certain groups of patients and the differentiation between colonization and a low-grade infection is fraught with error. In view of the \$1,000 average cost of treatment (55) and difficulty in defining an infected patient, it could be argued that CAUTI should not be a comorbidity under any circumstance because the cost of treatment does not justify the increase in DRG payment **level**.

In 2007, the Leapfrog Group surveyed 1,256 hospitals and found that 87% reported that they did not consistently follow recommendations to prevent Hospital Acquired infections (HAI) (56). The General Accounting Office (GAO) noted that “a few of (CDC’s strongly recommended practices) were required by CMS or the accrediting organizations’ standards” but that it was “not reasonable to expect CMS or accrediting organizations to require additional practices without a prioritization.” The GAO concluded that the “lack of department-level prioritization of CDC’s large number of recommended practices had hindered efforts to promote their implementation.”(57)

In view of the worsening of HAI in U.S. Institutions and the wide diversity of protocols used by U.S. hospitals in an attempt to curb HAI, it is good policy to implement interventions based upon outcomes. Nonpayment of certain classes of infections should serve to spur adoption of protocols that work and research on additional protocols to further lower the infection rates at our institutions. Table 3 lists five categories of Hospital Acquired infections.(55) Only the first two categories and certain surgery site infections are currently on the Medicare nonpayment list.(2)

Additional Paradigms that use Free Market Principles to Promote Quality:

In addition to the nonpayment of largely preventable Hospital Acquired Conditions, two other paradigms have been implemented that use market principles and financial incentives to promote quality: Pay-For-Performance and public disclosure of Hospital Acquired Conditions.

Initial data regarding Pay-For-Performance protocols is encouraging. The Hospital Quality Incentive Demonstration (HQID) project, a Pay-For-Performance initiative, was reported by the Premier Alliance to have an aggregate improvement in hospital quality measures by 18.6%. (58)

Public disclosure of adverse hospital outcomes, specifically Hospital Acquired Infections, was elevated to mainstream medical policy by a letter of support for the public reporting provisions in the 2009 House Healthcare Reform Bill (HR 3200) from national epidemiology and infection control organizations, including The Association for Professionals in Infection Control, the Infections Disease Society of America, the Society for Healthcare Epidemiology of America, the Council of State and Territorial Epidemiologists and the Trust for America's Health. (59) Currently, 26 states have passed laws requiring public reporting of HAI, and on Feb. 2, 2010 the CDC issued a statement in support of Public Reporting of Hospital Acquired Infections (60).

A concern with sole dependence on the above interventions is that they rely to a large degree on self-reporting. Questions have arisen regarding the accuracy and efficacy of self-reporting protocols in quality assurance oversight.

According to a recent Dept. of HHS OIG report, the effectiveness of major healthcare quality oversight entities that rely on self-reporting and policing has come into question by healthcare stakeholders.(61, 62) The poor state of voluntary facility reporting was documented in a March 8, 2010 OIG Report which found that in surveyed hospitals, patient diagnosis codes were inaccurate or absent for 7 of the 11 Medicare Hospital Acquired Conditions identified by physician reviewers and reviewed hospitals did not generate incident reports for 93% of the events.(62)

Even when mandatory reporting is required, there is little active enforcement. (61) Several disturbing observations may have prompted stakeholders and government to look for other avenues of quality assurance. An observation included in this report was from officials at the Joint Commission who estimated that only 0.1% of sentinel (severe) events are reported.(61) In addition, a March 2010 Joint Commission report stated that only 4,590 reports of sentinel events from general hospitals and 298 reports of sentinel events from emergency rooms had been received since January 1995.(63) Only 64.6% of these reports were identified by self-reporting.(63) An AHRQ survey found similar results with 48% of 614 facilities (with 143,052 respondents) that did not report any adverse events (sentinel or otherwise) at their institution.(64) Finally, the AMA News reported that as of 2007, approximately half of U.S. hospitals had never reported a physician to the National Practitioner Data Bank that was established in 1986.(65)

All of this sets the stage for poor quality and the non-recognition of serious adverse events. Protocols that use nonpayment for largely preventable Hospital Acquired Conditions are effective regardless of whether or not the HAC are reported. Either way, they are not paid and the institution is penalized.

Two of these paradigms (Transparency of HAI and Nonpayment of Certain HAC) refrain from micromanaging hospitals with a myriad of mandatory protocols. The institution, itself, can determine how best to proceed. These initiatives support the principles of outcome-based evaluation and free- market principles to promote quality and patient safety.

Additional Social Reasons for Implementation of Nonpayment Policy for HAC:

The American Hospital Association, The Leapfrog Group and The Colorado Hospital Association all encourage facilities not to bill for serious reportable events as defined by The National Quality Forum (4, 26, 27). Medicare does not reimburse for many of the NQF adverse events, plus it has a nonpayment policy for certain Hospital Acquired Infections.

The most controversial Medicare nonpayment policy is that regarding Catheter-Associated Urinary Tract Infections. However, there is ample evidence that even CAUTI can be lowered by adhering to rigid protocols and having proper staffing at facilities. Clearly, most of the Central Line-Associated Bloodstream Infections can be prevented.(37-39) However, just because all

occurrences of a Hospital Acquired Condition category cannot be prevented is not enough reason for all occurrences in the category to be paid. One must weigh the unfair nonpayment to the healthcare provider for treating conditions that could not have been prevented versus the unfair payment burden on the American taxpayer and Medicare for conditions that could have been prevented. In addition, nonpayment may result in motivation for the development of better protocols to prevent adverse outcomes(53), not to mention the hiring of additional infection control staff and better staffing of facilities along with a reduction in patient morbidity and mortality.(24, 25)

The motivational effect of monetary inducements (both positive and negative) was illustrated in an article published in the American Medical News that reported on a session at the 2009 Patient Safety Congress entitled, "Making the Business Case for Patient Safety," where phrases such as "Cost Effectiveness" and "Return on Investment" were heard. In a presentation on Never Events, it was stressed that resources had to be placed into the promotion of quality because, "You just can't afford not to do it."(25)

Medicare is facing budgetary shortfalls in historic proportions and without intervention will become insolvent in 2017.(66) Even the 2010 Healthcare Reform Bill will just postpone, not correct, the situation. Medicare must cut somewhere. It only makes sense to cut in areas which can also be expected to promote quality.

Surgeons have been living under global fee rules since the mid-1980s and receive nonpayment (except for reduced payment for a return to the operating room) for any related adverse occurrence after surgery. Surgeons have not abandoned their patients and other sectors of medicine have viewed this as good policy. The vast majority (98% to 99%) of Central Line-Associated Bloodstream Infections are not related to the initial line placement but to post-procedural care rendered at the facility.(67) One must wonder, why would surgeons argue for facility payment of CLABSI when the surgeon does not get paid for treating these infections?

The argument that hospitals will not admit patients with severe and complicated illnesses under these rules is not valid. Doctors, not hospitals, admit patients, and the sicker the patient is, the more likely the patient will be charged the **maximum** level DRG from additional comorbidities regardless of whether or not the patient develops a comorbidity from an HAC.

In addition, at least 30 states have enacted I'm Sorry Laws, allowing a physician to say that they are sorry and barring this apology from being used in court.(68) Saying "I'm sorry" has been shown to decrease the filing of malpractice claims.(69, 70) But one must ask in the case of Never Events and Hospital Acquired Conditions, are we now to say, "I'm sorry, here is your bill"?

Finally, there is the argument of holding medicine to the same standard as other sectors of the US Economy. A survey conducted by the American Medical News found that almost 80%

of more than 50 employers said other healthcare purchasers and insurance plans should stop paying for Hospital Acquired Conditions as defined by Medicare. (71)

Conclusion: Credibility is lost when physicians from profitable healthcare systems plead the argument that a policy of nonpayment for Hospital Acquired Conditions should not be implemented because it is too costly and will **adversely** affect patient access. Implementation depends upon the balance between the nonpayment of providers for non-preventable HAC versus the promotion of healthcare quality and patient safety, the facilitation of new research to prevent HAC and the recouping of taxpayer dollars for HAC that could have been prevented.

In 1926, at Jefferson Medical College, Cushing, one of the founders of modern surgery, challenged the graduating medical class to always place the patient's good above self-interest.(72) Certainly, the support of nonpayment of Hospital Acquired Conditions falls under this concept. As data is being produced on efforts to reduce HAC and improved outcomes are observed, all healthcare providers should embrace this policy to promote healthcare quality and patient safety.

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Table 1: Health Care Acquired Conditions (2)

1. Foreign Object Retained After Surgery
2. Air Embolism
3. Blood Incompatibility
4. Stage III and IV Pressure Ulcers
5. Falls and Trauma
 - * Fractures
 - * Dislocations
 - * Intracranial Injuries
 - * Crushing Injuries
 - * Burns
 - * Electric Shock
6. Manifestations of Poor Glycemic Control
 - * Diabetic Ketoacidosis
 - * Nonketotic Hyperosmolar Coma
 - * Hypoglycemic Coma
 - * Secondary Diabetes with Ketoacidosis
 - * Secondary Diabetes with Hyperosmolarity
7. Catheter-Associated Urinary Tract Infection (UTI)
8. Vascular Catheter-Associated Infection
9. Surgical Site Infection Following:
 - * Coronary Artery Bypass Graft (CABG) - Mediastinitis
 - * Bariatric Surgery
 - o Laparoscopic Gastric Bypass
 - o Gastroenterostomy
 - o Laparoscopic Gastric Restrictive Surgery

* Orthopedic Procedures

- o Spine
- o Neck
- o Shoulder
- o Elbow

10. Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)

* Total Knee Replacement

* Hip Replacement

Table 2 Estimated Cost of Healthcare Acquired Conditions (Medicare Data For Year 2007) (3).

Condition	Number	Cost/Incident	Total
Foreign Object Left at Surgery	750	\$63,631,	\$47,723,250
Air Embolism	57	\$71,636,	\$4,083,252
Blood Incompatibility	24	\$50,455	\$1,210,920
Stage III & IV Pressure Ulcers	257,412	\$43,180	\$11,115,050,160
Falls and Trauma	193,566	\$33,894	\$6,560,726,004
Failure of Diabetic Control			
Diabetic Ketoacidosis	11,469	\$42,974	\$492,868,806
Nonketotic Hyperosmolar Coma	32,248	\$35,215	\$1,135,613,320
Diabetic Coma	1,131	\$45,989	\$52,013,559
Hypoglycemic Coma	212	\$36,581	\$7,755,172
Deep Vein Thrombosis	140,010	\$50,937	\$7,131,689,370
Catheter-Associated Urinary Tract			
Infections	12,185	\$44,043	\$536,663,955
Vascular Catheter Associated Infections	29,536	\$103,027	\$3,043,005,472
Surgical Site Infections			
Mediastinitis after CABG	69	\$299,237	\$20,647,353
Total Knee Replacement	539	\$63,135	\$34,029,765
Laparoscopic Gastric Bypass and			
Gastroenterostomy	208	\$180,142	\$37,469,536
Ligation and Stripping of Varicose Veins	3	\$66,355	\$199,065

Table 3. Estimated Costs of Prevalent Hospital Acquired Infections (Cost data is from 2007 and adjusted by the CPI for Inpatient Hospital Services and Urban Consumers) – From Scott RD (55).

Total	Low Est.	High Est.	
Catheter-Associated Urinary Tract Infections (CAUTI)	449,334	\$862	\$1007
Total Cost between \$387,325,908 to \$452,479,338			
Central Line-Associated Bloodstream Infections (CLABI)	92,011	\$7,288	\$29,156
Total Cost between \$670,576,168 to \$2,590,661,716			
Surgical Site Infections	290,485	\$11,874	\$34,670
Total Cost between \$3,449,218,890 to \$10,071,114,950			
Clostridium difficile-associated disease	178,000	\$6,408	\$9,124
Total Cost between \$1,140,624,000 to \$1,624,072,000			