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The Impact of the Medicaid Health Care-Associated Condition Program on Mediastinitis Following Coronary Artery Bypass Graft

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Abstract

Objective—In 2012, the Centers for Medicare and Medicaid Services expanded a 2008 program that eliminated additional Medicare payment for mediastinitis following coronary artery bypass graft (CABG) to include Medicaid. We aimed to evaluate the impact of this Medicaid program on mediastinitis rates reported by the National Healthcare Safety Network (NHSN) compared with rates of a condition not targeted by the program (deep space surgical site infection [SSI] after knee replacement).

Design—interrupted time series with comparison group.

Methods—We included surveillance data from non-federal acute care hospitals participating in NHSN and reporting CABG or knee replacement outcomes from 1/2009–6/2017. We examined the Medicaid program's impact on NHSN-reported infection rates, adjusting for secular trends. Data analysis used generalized estimating equations with robust sandwich variance estimators.

Results—During the study period, 196 study hospitals reported 273,984 CABGs to NHSN, resulting in 970 mediastinitis cases (0.35%); 294 hospitals reported 555,395 knee replacements,

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with 1,751 resultant deep space SSIs (0.32%). There were no significant changes in incidence of either condition during the study. Mediastinitis models showed no effect of the 2012 Medicaid program on either secular trend during the post- vs. pre-program time periods (p-value=0.70) or immediate program effect (p-value=0.83). Results were similar in sensitivity analyses when adjusting for hospital characteristics, restricting to hospitals with consistent NHSN reporting, or incorporating a program implementation roll-in period. Knee replacement models also showed no program effect.

Conclusions—The 2012 Medicaid program to eliminate additional payments for mediastinitis following CABG had no impact on reported mediastinitis rates.

Introduction

Approximately 370,000 patients undergo coronary artery bypass graft (CABG) surgery annually in U.S. hospitals,[1] with 0.3% to 0.6% of patients subsequently developing deep chest surgical site infections, or mediastinitis, following the procedure.[2–4] Patients with mediastinitis experience higher mortality and morbidity, including longer length of stay, need for re-operation, intensive care unit admissions, and hospital readmissions.[3,5–7] Moreover, the estimated additional costs associated with mediastinitis range from $19,000 to $56,000 per case.[3,8]

In 2008, the Centers for Medicare and Medicaid Services (CMS) implemented the "Hospital-Acquired Conditions (HAC) and Present on Admission (POA) Indicator Reporting" program as mandated by the 2005 Deficit Reduction Act.[9] This HAC POA program applies to all hospitals subject to the Inpatient Prospective Payment System (IPPS) and ties its financial penalties to hospital-submitted billing codes. Specifically, it ceases Medicare payments for the additional care required as a result of selected HACs, including mediastinitis following CABG.[10] Prior research on the impact of the 2008 Medicare HAC POA program found that non-payment for multiple healthcare-associated infections (HAIs), including mediastinitis following CABG, was associated with a decrease in billing code-derived HAI rates, while HAI rates based on standardized surveillance data submitted to the National Healthcare Safety Network (NHSN) did not change.[11–13] In 2010, CMS increased the scope of financial penalties tied to hospitals' HAI rates by both expanding the Medicare HAC POA program to include Medicaid patients and developing the Value Based Purchasing (VBP) and HAC Reduction Programs.[14–16] The Medicaid HAC POA program began targeting mediastinitis following CABG for non-reimbursement in 2012, while the VBP and HAC Reduction programs did not introduce any additional financial penalties for this outcome after their implementation in 2014.

The objective of this study was to evaluate the impact of the 2012 Medicaid HAC POA program on reported mediastinitis rates based on prospective surveillance data from the NHSN. We also assessed reported rates of deep space surgical site infection (SSI) after knee replacement as a comparison condition not targeted by the program. We hypothesized that the Medicaid HAC POA program would have minimal to no impact on NHSN-reported rates of mediastinitis following CABG and no impact on reported rates of deep space SSI after knee replacement. This hypothesis was based on the lack of observed impact of the prior

2008 Medicare HAC POA program,[11] along with the rarity of mediastinitis events at baseline and minimal nature of anticipated financial penalties incurred as a result of the program.[17]

Methods

Study Population

We obtained prospective NHSN surveillance data from non-federal acute care hospitals subject to the Inpatient Prospective Payment System (IPPS) rule and enrolled in the Preventing Avoidable Infectious Complications by Adjusting Payment (PAICAP) study.[18] We included any enrolled hospital reporting mediastinitis following CABG or deep space SSI after knee replacement to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) using standardized CDC/NHSN surveillance definitions from January 1, 2009 through June 30, 2017.[19] For CABG, we included all reported SSI cases classified as mediastinitis. For deep space SSI after knee replacement, which functioned as our comparison condition, we included all reported SSI cases classified as osteomyelitis, peri-prosthetic joint infection, or infection of the joint space or bursa.[20] To minimize potential confounding in comparison condition analyses, we explicitly excluded hospitals in states participating in a campaign to improve adherence to evidence-based SSI prevention bundles after knee or hip replacement that was ongoing during the study period.[21]

To understand whether the NHSN hospitals included in our study are representative of the general population of hospitals performing CABG in the United States, we compared the characteristics of NHSN study hospitals with those reporting CABG outcomes into the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database.[22] The STS Adult Cardiac Surgery Database is the world's premier clinical registry for cardiac surgery, representing approximately 95% of the centers that perform CABG in the United States and capturing 98% of CABG procedures billed to Medicare in 2012.[23] For the comparison, we included STS hospitals subject to the IPPS rule that reported CABG procedures into the registry between 2013 and 2016 (all available years). We compared hospital characteristics for STS and NHSN study hospitals by linking to the 2011 American Hospital Association Annual Survey Database.[24]

Study Design

We used a quasi-experimental interrupted time-series design with comparison group to examine the impact of the Medicaid HAC POA program on reported rates of mediastinitis and deep space SSI after knee replacement before and after the program, adjusting for secular trends. Inclusion of a comparison condition that affects a similar population but is not anticipated to change in response to program implementation is an accepted method in quasi-experimental study design to combat threats to study validity.[25] In the primary analysis, we assessed the level and the slope of quarterly rates of both mediastinitis and deep space SSI of the knee per 1,000 procedures before and after a program implementation "roll-in period." Given that hospitals may have initiated their response to the program soon after publication of the CMS Final Rule on June 6, 2011,[14] we considered the year prior to the

program's enforcement date (July 1, 2011 through June 30, 2012) to be the roll-in period and did not assess risk of infection during this time in the primary analysis.[26] Correspondingly, the pre-program period ranged from January 1, 2009 to June 30, 2011 and the post-program period ranged from July 1, 2012 through June 30, 2017.

Statistical Analysis

We used generalized estimating equations with robust sandwich variance estimators to assess whether there was a change in both level and trend for quarterly rates of infection after program implementation. Our models included time (to adjust for secular trends), an indicator of the post-program implementation period (after July 1, 2012, allowing for evaluation of an immediate program effect), and a two-way interaction term to determine whether the program resulted in a change in the trend. Finally, for the mediastinitis outcome, we performed a series of sensitivity analyses that 1) treated the Medicaid HAC POA program implementation as a single time point without a preceding roll-in period, 2) limited the analysis to hospitals reporting data to NHSN in both the first and last year of the study period, 3) included effect modification by hospital safety-net status or hospital teaching status, and 4) adjusted for hospital characteristics, including bed size, hospital ownership, and teaching status. When considering program implementation as a single time point, we defined the pre-program period to be January 1, 2009 through June 30, 2012 and the post-program period to be July 1, 2012 through June 30, 2017. For the deep space SSI after knee replacement outcome, we performed two sensitivity analyses that 1) limited the analysis to hospitals that also reported CABG outcomes, and 2) limited the analysis to hospitals that reported knee replacement outcomes in both the first and last year of the study period. We considered p-values of <0.05 to be statistically significant and did not adjust for multiple comparisons. All analyses were performed in SAS (version 9.4; SAS Institute).

IRB Approval

This study was approved by the Harvard Pilgrim Healthcare Institute institutional review board.

Results

Study Population

Among the 622 hospitals participating in the PAICAP study between January 1, 2009 and June 30, 2017 and meeting IPPS criteria, 196 hospitals from 35 states reported CABG data to the NHSN. These hospitals reported 273,984 CABG procedures to NHSN during the study period, with mediastinitis occurring following 970 procedures (3.5 cases per 1,000 procedures). One hundred eight (55%) hospitals reported mediastinitis surveillance data to NHSN in both the first and last year of the study period. Table 1 shows the characteristics of hospitals included in the study compared to IPPS hospitals reporting CABG outcomes to the STS Adult Cardiac Surgery Database. Compared to STS Database hospitals, a higher proportion of NHSN study hospitals were located in the Northeast and were major teaching centers or safety-net hospitals. The two groups of hospitals were otherwise generally comparable.

Hospitals' procedure volume ranged from 1 to 243 CABGs per quarter (median: 41; interquartile range: 22 to 70). One hundred sixty-eight hospitals (86%) had an average annual surgical volume of ≥50 CABG procedures, which is NHSN's threshold for inclusion in the calculation of the Standardized Infection Ratio (SIR), the primary summary measure used for public reporting of HAIs.[27] Mediastinitis is a rare outcome; among the 5,361 hospital-quarters during the study period, 4,615 (86%) reported zero cases and 577 (11%) reported a single case. The majority of mediastinitis cases were identified on hospital readmission (729; 75%) or post-discharge surveillance (25; 3%), rather than the index surgical admission (216; 22%).

Within the study period, 347 hospitals participating in the PAICAP study met IPPS criteria and reported deep space SSI after knee replacement outcomes to the NHSN. To reduce confounding in comparison group analyses, we excluded 53 hospitals from states participating in a campaign to improve adherence to evidence-based SSI prevention bundles after knee or hip replacement.[21] After exclusion of campaign state hospitals, 294 study hospitals remained and were included in comparison group analyses. Included study hospitals reported 555,395 knee replacement procedures during the study period, with 1,751 resulting in deep space SSI of the knee (3.2 cases per 1,000 procedures). Just over half of the hospitals reporting knee replacement outcomes also reported mediastinitis after CABG (167; 57%) and 43% of the hospitals reported knee replacement outcomes in both the first and last year of the study period (126/294). Forty hospitals (14%) had an average annual surgical volume of ≥50 knee replacement procedures. Like mediastinitis after CABG, the majority of deep space SSI after knee replacement cases were identified on hospital readmission (1,565; 89%) or post-discharge surveillance (160; 9%), rather than the index surgical admission (26; 1%).

Impact of the Medicaid HAC POA Program on Reported HAI Rates

Figure 1A shows a plot of quarterly mediastinitis rates for study hospitals reporting CABG data to NHSN, demonstrating no visible effect of the Medicaid HAC POA program on reported rates of mediastinitis in NHSN study hospitals. Our model showed no measurable effect of the Medicaid HAC POA program on either trend in the post- vs. pre-program time period (odds ratio 1.01, 95% confidence interval [CI]: 0.96 – 1.07) or immediate program effect (odds ratio 1.06, 95% CI: 0.64 – 1.75) (Table 2). The risk of mediastinitis remained constant throughout the study period; the odds ratios for the time trend were 0.98 (95% CI: 0.94–1.03) during the pre-program time period and 0.99 (95% CI: 0.97–1.02) during the post-program period.

When we examined deep space SSI after knee replacement (Figure 1B), we similarly found no measurable change in trend in the post- vs. pre-program time period (odds ratio 1.00, 95% CI: 0.95 – 1.05) or immediate decrease in infections coincident with implementation of the Medicaid HAC POA program (odds ratio 0.91; 95% CI: 0.62 – 1.36) (Table 2). Likewise, risk of deep space SSI after knee replacement remained constant throughout the study period, with no significant trends in the pre- or post-program implementation time periods (odds ratio 1.00 [95% CI: 0.96 – 1.05] and odds ratio 1.00 [95% CI: 0.99 – 1.02], respectively).

Sensitivity Analysis

The results of sensitivity analyses performed for mediastinitis following CABG were consistent with the primary analysis. When we treated Medicaid HAC POA program implementation as a single time point rather than incorporating a roll-in period, mediastinitis models showed no measurable effect of the program on either trend in the post- vs. pre-program time period (odds ratio 0.99, 95% CI: 0.96–1.04, p-value 0.79), immediate program effect (odds ratio 0.94, 95% CI: 0.69–1.28, p-value 0.68), or secular trend in either the pre- or post-program period (odds ratio 1.00 [95% CI: 0.97–1.03] and odds ratio 0.99 [95% CI: 0.97–1.01], respectively). There continued to be no measurable effect of the program and no significant secular trend when we restricted our analysis to hospitals reporting in both the first and last year of the study period, incorporated effect modification by hospital safety-net or teaching status, or when we adjusted for hospital size, teaching status, and type of ownership (data not shown).

The results of sensitivity analyses performed for deep space SSI after knee replacement were also consistent with the primary analysis for this outcome. There continued to be no measurable effect of the Medicaid HAC POA program and no significant secular trend for deep space SSI after knee replacement when we restricted our analysis to only those hospitals also reporting CABG outcomes or when we restricted our analysis to hospitals reporting in both the first and last year of the study period (data not shown).

Discussion

In this study, we evaluated the impact of CMS' 2012 extension of the 2008 HAC POA program from Medicare to Medicaid on rates of mediastinitis following CABG using prospectively collected surveillance data from 196 hospitals reporting to CDC's NHSN. We found that the Medicaid program did not have an impact, either positive or negative, on mediastinitis rates or rates of a comparison condition not targeted by the program. Our results were robust to multiple sensitivity analyses, including adjustment for hospital characteristics, restriction of hospitals to those with more consistent participation in NHSN during the study period, and incorporation of a policy implementation roll-in period.

While elimination of additional payment for preventable complications occurring during hospitalization may improve the value of inpatient care by reducing unnecessary spending, the Medicare and Medicaid HAC POA programs have failed to demonstrate any direct influence on reductions in preventable harm.[11,13,28] For mediastinitis following CABG, there are a number of possible explanations for why the HAC POA programs did not lead to demonstrable decreases in reported rates of this complication. First, both the Medicare and Medicaid HAC POA programs targeted mediastinitis for non-reimbursement during the index surgical admission for CABG. However, our analysis and prior work suggest that the majority of cases of mediastinitis following CABG are identified on readmission, when a hospital would continue to receive full reimbursement for the costs related to treatment of this complication.[11] Second, the HAC POA program attempts to align quality and payment by linking financial penalties to a hospital's submission of a billing code for a complication that would allow for higher level of reimbursement. While the HAC POA programs may lead to elimination of additional payments for HACs, it does not align incentives for a

hospital to re-design care delivery given the incomplete overlap between billing and surveillance rates of complications.[11] This disconnect allows hospitals caring for the highest risk patients with the most comorbid conditions to avoid incurring a net negative financial effect due to non-payment for mediastinitis following CABG, as more complex patients who develop mediastinitis will have additional billable attributes that allow hospital coders to achieve equivalently high billing groups even when they are unable to be reimbursed for mediastinitis.

In addition, the highly variable nature of prevalence estimates for extremely rare outcomes like mediastinitis also calls into question their appropriateness as value-based incentive policy targets. Depending on surgical volume, a hospital's rate of a rare outcome in any given reporting period may not be an accurate representation of the quality of care provided. For example, a rate of 0 mediastinitis cases per 1,000 CABGs is much more meaningful for the surgical center performing 1,000 procedures per year as compared to the center performing 100 procedures per year. Moreover, longitudinal analyses of hospital claims data for rare HAI outcomes, including mediastinitis following CABG, demonstrate that hospital performance rankings based on the tracking of these outcomes may be highly unstable from year to year.[29] As pay-for-performance and value-based payment policies proliferate, these rankings yield increasing reputational and financial repercussions for hospitals and should be chosen for their reliability and demonstrated association with overall quality of care.

This study has several potential limitations. First, the PAICAP hospitals included in the study represent a subset of all U.S. hospitals performing CABG and reporting mediastinitis outcomes to NHSN. However, our PAICAP hospitals were generally similar to the hospitals reporting into the STS Adult Cardiac Surgery Database, with the exceptions of region of the country and major teaching status. Furthermore, sensitivity analyses including adjustment for hospital characteristics did not influence model results. Second, NHSN does not capture information about insurance status for individual patients, or patient-level information for surgical procedures that do not result in an HAI. Therefore, we were unable to conduct analyses to determine potential HAC POA program impact within the Medicaid population alone, risk-adjust infection rates, or assess for unintended consequences of non-reimbursement, such as avoidance of Medicaid or other clinically high-risk patients as surgical candidates. Finally, the rare nature of mediastinitis following CABG presents a challenge in interpreting a negative study on the impact of reimbursement changes, as we may not have had sufficient power to detect small changes over time. In addition, the lack of impact of the program we studied may not be generalizable to more common conditions, which hospitals may deem higher priority for prevention efforts. When monitoring for improvements or complications within hospitals, infection control units often adopt measurement approaches that allow for increased power to detect change over time, such as G charts to track the number of CABG surgeries between rare mediastinitis events.[30] Due to limitations in the type of data collected by NHSN, we were unable to alter our study design in order to increase power to detect small changes in infection rates.

In conclusion, we found no impact of the 2012 Medicaid program that eliminated additional payments for mediastinitis following CABG on rates of mediastinitis as reported to NHSN. The advent of public reporting of HACs and their linkage to hospital rankings and

reimbursement has increased national awareness of these potentially preventable conditions. Despite the intent by policymakers to improve care value and reduce preventable harm, our findings provide additional evidence that employing claims-based measures to align quality and payment has yet to translate effectively to decreasing HACs at the hospital-level. In addition, our findings highlight the importance of considering the rarity of the outcome targeted for reduction when developing value-based incentive policy, as well as whether the targeted outcome and the metric directly linked to the policy typically occur within the same hospital admission.

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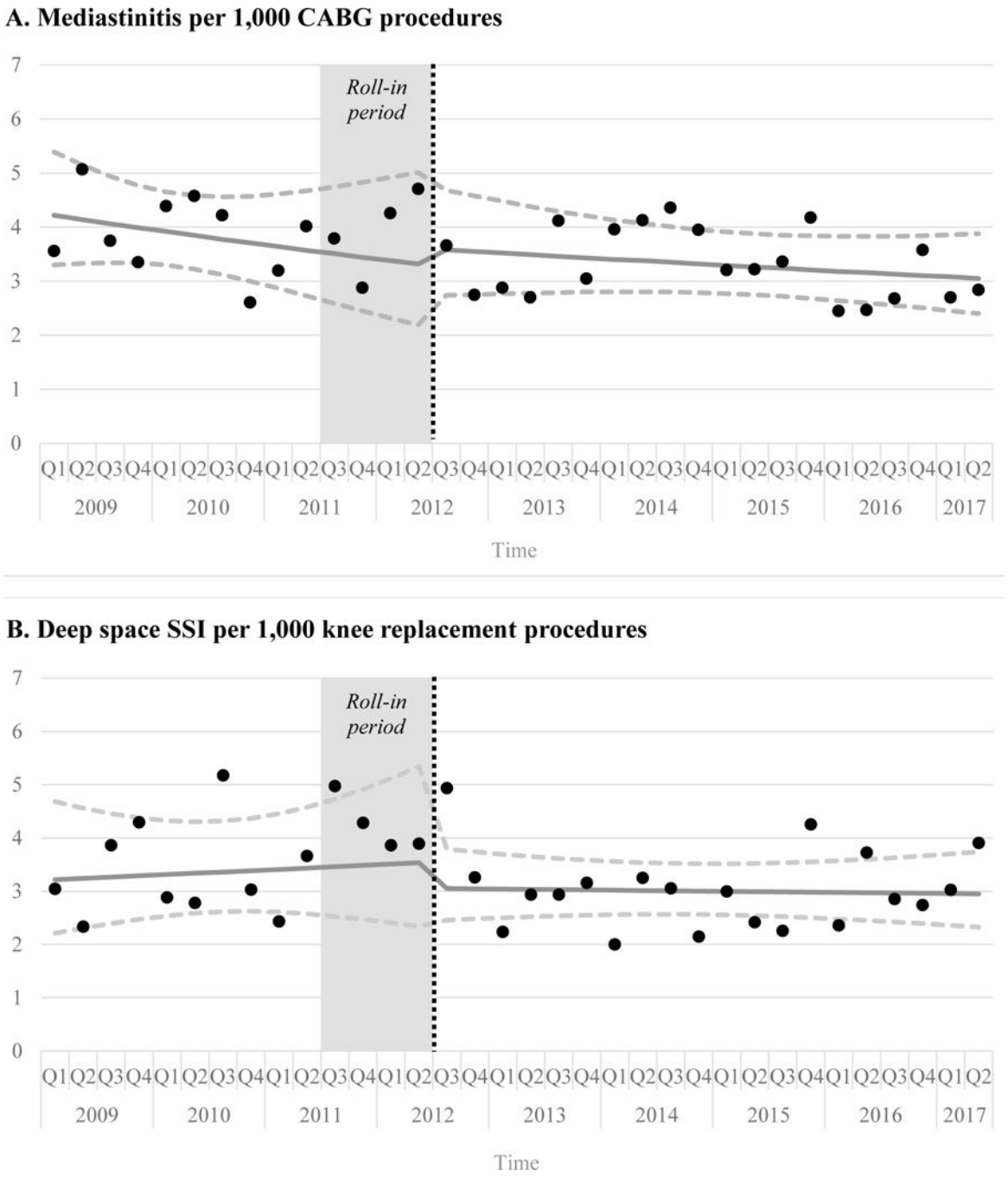

Figure 1.

Reported quarterly rates of infections per 1,000 procedures based on prospective National Healthcare Safety Network surveillance data in all study hospitals.

Black circles depict observed infection rates aggregated for all hospitals by quarter. The dark grey solid line shows predicted values based on models, with 95% upper and lower confidence limits depicted with lighter grey dashed lines. The vertical black dotted line indicates the start of Medicaid HAC POA program enforcement in July 2012, and is

preceded by a shaded area depicting the program “roll-in period” between the month following program announcement in July 2011 and enforcement.

Abbreviations: CABG: coronary artery bypass graft; Q: quarter; SSI: surgical site infection; HAC: hospital-associated condition; POA: present on admission

Table 1

Characteristics of STS Adult Cardiac Surgery Registry Hospitals and NHSN Hospitals Performing Coronary Artery Bypass Graft in Our Study Population

Characteristic	STS Hospitals (n = 577)[a]	NHSN Hospitals (n = 196)
Region		
Midwest	184 (32%)	47 (24%)
Northeast	86 (15%)	77 (39%)
South	185 (32%)	34 (17%)
West	122 (21%)	38 (19%)
Location		
Metro	553 (96%)	185 (94%)
Micro	23 (4%)	11 (6%)
Rural	1 (0%)	0
Bed Size		
<100	17 (3%)	3 (2%)
100-399	328 (57%)	98 (50%)
≥400	232 (40%)	95 (48%)
Type of ownership		
For-profit	87 (15%)	24 (12%)
Not-for-profit	449 (78%)	154 (79%)
Public	41 (7%)	18 (9%)
Teaching status[b]		
Graduate	159 (28%)	51 (26%)
Major	131 (23%)	79 (40%)
Minor	46 (8%)	7 (4%)
Non-teaching	241 (42%)	59 (30%)
Full-time equivalent nurses, No. per 100 patient-days		
Median	0.8	0.8
Interquartile range	0.6 – 0.9	0.6 – 0.9
Medicare admissions, %		
Median	49.0	48.6
Interquartile range	42.8 – 57.8	39.7 – 55.6
Medicaid admissions, %		
Median	16.4	18.2
Interquartile range	11.6 – 22.2	12.8 – 24.9
Safety-net hospital[c]	105 (18%)	56 (32%)

Note: Data are number (%) unless otherwise noted.

[a] Of the 588 hospitals reporting CABG outcomes to the STS Adult Cardiac Surgery Registry, 577 met IPPS criteria.

[b] All hospitals were placed into 1 of 4 categories based on their response to the AHA survey: major teaching hospitals (those that are members of the Council of Teaching Hospitals [COTH]), graduate teaching hospitals (non-COTH members with a residency training program approved by the

Accreditation Council for Graduate Medical Education), minor teaching hospitals (non-COTH members with a medical school affiliation reported to the American Medical Association), and nonteaching hospitals (all other institutions).

[c]Safety-net hospitals are defined as those with Disproportionate Share Hospital (DSH) index in the highest quartile out of all U.S. IPPS hospitals reporting into the Centers for Medicare and Medicaid Services 2014 Historic Impact File. Hospital safety-net status was not available for 69 of the STS hospitals and 21 of NHSN study hospitals.

Table 2

Changes in reported quarterly rates of mediastinitis following coronary artery bypass graft and deep space surgical site infection after knee replacement over time.

Estimated change in reported infection rate	Odds Ratio (95% CI)	P value
Targeted healthcare-associated infection: mediastinitis following CABG		
Slope in pre-program period	0.98 (0.94 – 1.03)	0.49
Slope in post-program period	0.99 (0.97 – 1.02)	0.63
Change at time of program implementation	1.06 (0.64 – 1.75)	0.83
Change in slope (post- vs. pre-program period)	1.01 (0.96 – 1.07)	0.70
Non-targeted healthcare-associated infection: deep space SSI after knee replacement		
Slope in pre-program period	1.00 (0.96 – 1.05)	0.95
Slope in post-program period	1.00 (0.99 – 1.02)	0.67
Change at time of program implementation	0.91 (0.62 – 1.36)	0.66
Change in slope (post- vs. pre-program period)	1.00 (0.95 – 1.05)	0.96

Note: Deep space SSI after knee replacement includes infections of the joint or bursa, osteomyelitis, or periprosthetic joint infection.