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Contemporary Impact of State Certificate-of-Need Regulations for Cardiac Surgery

An Analysis Using the Society of Thoracic Surgeons' National Cardiac Surgery Database

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Background**—**Prior research using administrative data associated certificate-of-need (CON) regulation for open heart surgery with higher hospital coronary artery bypass grafting (CABG) volume and lower CABG operative mortality rates in elderly patients. It is unclear whether these findings apply in a general population and after controlling for detailed clinical characteristics and region.

Methods and Results**—**Using the Society of Thoracic Surgeons' (STS) National Cardiac Surgery Database, we examined isolated CABG surgery volume, operative mortality, and the composite end point of operative mortality or major morbidity for the years 2000 to 2003. The presence of CON regulations for open heart surgery was ascertained from the National Directory of the American Health Policy Association and by contacting CON administrators. Results were analyzed nationally, by state, and by region (West, Northeast, Midwest, South) and were adjusted for clinical factors and both population density and region with mixed-effects hierarchical logistic regression models. During 2000 to 2003, there were 314 710 isolated CABG surgeries performed at 294 STS hospitals in CON states ($n=27$, including Washington, DC) and 280 512 procedures at 343 STS hospitals in non-CON states ($n=24$). Patient clinical characteristics were similar among CON and non-CON hospitals. States with CON regulations tended to have higher population densities and had significantly higher median hospital annual CABG volumes in each of the years 2000 to 2003 ($P<0.005$). This difference remained significant after adjustment for region and population density. Operative mortality was 2.52% for CON versus 2.62% for non-CON states ($P=0.32$). There was a significant association between CON law and operative mortality in the South. After adjustment for patient risk factors and region, there was a marginally significant reduction of mortality risk in states with CON regulation (adjusted OR 0.92, 95% CI 0.86 to 1.00). However, this difference was not statistically significant when a revised model accounted for random state effects. Similar volume and outcomes results were seen when the analysis was repeated with data from the national Medicare database.

Conclusions**—**CON states have significantly higher hospital CABG surgery volumes but similar mortality compared with non-CON states. CON regulation alone is not a sufficient mechanism to ensure quality of care for CABG surgery. **(*Circulation*. 2006;114:2122-2129.)**

Key Words: coronary disease ■ morbidity ■ mortality ■ surgery

Multiple stakeholders have a significant interest in using legislation or other regulatory means to ensure high-quality medical care. This is especially true for treatments like coronary artery bypass grafting (CABG), in which differences in procedural quality can have a direct impact on patient outcomes. New York[1] and Pennsylvania[2] were the first states to require all hospitals and practitioners performing CABG surgery to report case volumes and outcomes annually. Other states have followed. Although the results of these surveys are available to the public, their effects on quality of care have been difficult to measure.[3–5] Other stakeholders such as the Center for Medicaid and Medicare Services (CMS) and industry consortia of high-volume purchasers of healthcare services (the Leapfrog Group, for example) have proposed volume and/or outcome criteria for

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certification of and payment for expensive services such as CABG surgery.

One of the oldest forms of governmental controls is represented by state certificate-of-need (CON) programs. The purpose of CON regulations is to concentrate expensive healthcare services within a limited number of institutions by requiring prior approval before these services can be offered. This control has been applied to critical care beds, cardiac surgery programs, and other resource-intense areas of care delivery. Such CON laws affecting cardiac surgery presently are in effect in 26 states in the United States and in the District of Columbia.

The value of CON as a means of ensuring quality of care has been a matter of debate.[6] A recent study by Vaughan-Sarrazin and colleagues[7] supported the contention that CON laws have beneficial effects both on increasing CABG procedural volumes and improving patient outcome. This analysis was limited to elderly patients, did not control for regional factors, and due to its reliance on an administrative database, did not adjust fully for clinical factors.

The purpose of the present study was to assess the impact of state CON regulation using contemporary, clinically rich, age-inclusive data available from the Society of Thoracic Surgeons' National Cardiac Surgery Database (STS NCD). We sought to test the hypothesis that states with CON regulations had higher CABG procedural volumes and to examine whether this was associated with lower operative mortality and morbidity. We further assessed whether any associations remain after adjustment for baseline patient clinical factors, hospital features, and state and regional factors. We also repeated our analyses using Medicare claims files obtained from the CMS.

Methods

Data Sources

The STS NCD is a voluntary registry of cardiac surgical patients sponsored by the STS. The database captures clinical information from nearly two thirds of all United States CABG procedures performed at more than half of all centers doing adult cardiac surgery.[8,9] Sites enter patient data using uniform definitions (available online at http://www.sts.org) and certified software systems. A series of quality checks are performed before a site's data are aggregated into the national sample. Although participation in the STS database is voluntary, data completeness is high, with preoperative risk factors missing in fewer than 5% of cases.[10] The accuracy of data has been confirmed in independent comparisons of hospital CABG volume and mortality rates reported to STS with those reported to CMS.

A second series of analyses was performed with Medicare Provider Analysis and Review (MedPAR) data files, obtained from CMS. The MedPAR data include all Medicare fee-for-service hospitalizations and patient and hospital identifiers; demographics; dates of admission, discharge, and death; admission acuity; codes for diagnoses and procedures as classified by the *International Classification of Diseases,* 9th Revision, Clinical Modification (*ICD*-9-CM); and discharge disposition.

Patient Population/Outcomes

We examined data from the STS NCD on 595 222 patients undergoing isolated CABG procedures from January 1, 2000, to December 31, 2003. Patients having concomitant procedures were excluded. The primary outcome for this analysis was operative mortality (death during the same hospitalization as surgery, or after discharge but within 30 days of surgery). Other end points were reoperation for any reason, prolonged ventilation (for 48 hours or longer), permanent stroke (deficit persisting >72 hours), renal failure, deep sternal wound infection, and prolonged postoperative stay (>14 days after surgery). We also considered a composite end point of mortality and/or major morbidity.

Analysis of Medicare patients included all Medicare fee-for-service patients aged 65 years and older undergoing isolated CABG during 2001. Patients were identified by *ICD*-9-CM procedure codes (n=163 393). Patients undergoing concurrent valve surgery were excluded (n=20 882).

The presence of CON regulations for open heart surgery was ascertained from annual reports for the years 2000, 2001, 2002, and 2003 published by the National Directory of the American Health Policy Association[11] and by contacting CON administrators. No state changed its CON status during the study period. State-level demographic and economic variables were obtained from the US Census 2000 Summary File 1 100-Percent Data through the Web site http://factfinder.census.gov. States were grouped into geographic regions (West, Northeast, Midwest, and South) according to Census Bureau definitions. For analyses that included random state effects, Washington, DC, was combined with Virginia.

Statistical Analysis

The frequency of patient-level risk factors and adverse outcomes was tabulated for states with and without CON regulation. Differences were assessed with mixed-effects regression models to account for clustering (lack of independence) of outcomes within hospitals. State-level explanatory variables were also compared by CON status to investigate potential confounding by these variables. Differences in the distribution of state-level census variables by CON status were assessed with the Wilcoxon rank sum test.

We used hierarchical models to assess the association between CON status and annual hospital CABG volumes while treating state as a random effect and adjusting for covariates. We first analyzed hospital volumes as a continuous variable, using a mixed-effects linear regression model. We repeated the analysis using a dichotomous end point, low hospital volume, defined as fewer than 60 CABG procedures per year. Approximately 5% of STS hospitals were classified as low volume. To assess sensitivity, we varied the definition of low hospital volume using a threshold of 200 cases. State-level explanatory variables were population density (based on the 2000 census) and region.

Hierarchical logistic regression models were developed to compare operative mortality and complication rates in CON and non-CON states with adjustment for differences in patient case mix. Several models were developed with patient-level data for each outcome. The simplest model included CON status as a fixed effect plus hospital as a random effect. These models were used to assess the unadjusted association between CON status and each outcome in a manner that accounted for clustering (nonindependence) of outcomes measured on patients within the same hospital. The models were modified by the addition of preoperative characteristics, such as age, race, gender, diabetes mellitus, myocardial infarction, and year of surgery. Additional explanatory variables were chosen based on previous STS risk-adjustment models (online-only Data Supplement, Appendix I).[12] Hospital-level characteristics (such as annual CABG volume) were not included in any model because these variables may lie in the causal pathway between CON status and outcomes of interest. The models were modified by the addition of indicator variables for geographic region. Finally, analyses were repeated by fitting the models separately within each geographic region.

Correct assessment of the association between CON status and outcomes is complicated by the presence of unexplained heterogeneity in risk-adjusted mortality and complication rates at the level of individual states. Such heterogeneity may be caused by unmeasured state-level factors that affect outcomes through mechanisms unrelated to CON regulation. To perform a more conservative assessment of the effect of CON regulations, we repeated the analyses using a model that included random effects for each state. To make such an

TABLE 1. Hospital Isolated CABG Volume: Median Hospital Volumes for Non-CON vs CON

		Median Hospital Volume		Hierarchical Model *P* Value		
Year	n	Non-CON	CON	Unadjusted	Adjusted*	Adjusted†
2000	431	224	302	0.0039	0.0202	0.0943
2001	479	214	298	0.0033	0.0309	0.1474
2002	549	198	273	<0.0001	0.0006	0.0163
2003	564	176	258	<0.0001	0.0010	0.0348

n indicates number of hospitals.

*Adjusted for state population density.

†Adjusted for region and state population density.

analysis computationally feasible, it was necessary to omit random hospital effects from these logistic regression models.

Because participation is voluntary, hospitals that submit data to the STS are likely to differ from those that do not participate. To validate our findings, the analyses described were repeated in the inclusive CMS data set. Hospitals in this data set were classified as low volume if they performed 30 or fewer CABG surgeries in Medicare patients during 2001. The association between CON status and designation as a low-volume hospital was analyzed by fitting logistic regression models identical to the ones used to analyze the STS data. The association between CON status and mortality was assessed by fitting patient-level logistic regression models with random effects for hospitals. These models were similar but not identical to the models used for analysis of the STS data. Individual patient risk factors were defined according to previous studies with administrative data[1–3] and included sociodemographic factors, patient comorbid conditions (defined by *ICD*-9-CM secondary diagnosis codes[2,3]), and indicators of disease severity (eg, surgical priority, primary diagnosis of acute myocardial infarction and location of myocardial infarction, and previous CABG). These analyses were performed in the overall CMS population and repeated in the subset of CMS hospitals that also participate in the STS database.

The authors had full access to the data and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results

Twenty-six states and the District of Columbia reported having CON regulations for cardiac surgery during 2000 to 2003 (online Data Supplement, Appendix II). The presence of CON regulations varied by geographic region ($P=0.004$). Whereas 8 of 9 Northeastern states had CON regulations for cardiac surgery, only 1 of 11 mainland Western states had such CON regulations (3 of 13, including Alaska and Hawaii). Thus, CON status was highly confounded with region. The CON states generally had higher state population densities (median 142 versus 44 people per square mile, $P=0.0005$.), higher state percentages of blacks (median 6.4% versus 3.3%, $P=0.027$), and higher state per capita incomes (median $21 557 versus $19 946, $P=0.024$). During 2000 to 2003, a total of 314 710 isolated CABG surgeries were performed at 294 STS-participating hospitals in CON states. In non-CON states, 280 512 CABG procedures were reported at 343 STS-participating hospitals.

CABG Volumes

Between 2000 and 2003, average annual hospital CABG volume in CON states was significantly higher than that in non-CON states (median 271 versus 188, $P=0.0001$; Table 1). Over the 4-year period, however, CABG volume declined in both CON and non-CON states. In non-CON states, volume fell from a median of 224 to 176 per year (21.4% decline), whereas in CON states, this change was from 302 to 258 per year (14.6% decline). The tendency for hospitals in CON-regulated states to have larger CABG volumes was statistically significant (Table 2) before adjustment for covariates and was still significant for 2 of the 4 years examined (2002 and 2003) after adjustment for region and population density.

In non-CON states, the prevalence of low-volume hospitals (fewer than 60 procedures per year) increased from 6.7% (16/240) in 2000 to 7.4% (22/299) in 2003. In contrast, the prevalence of low-volume hospitals in CON states decreased from 4.7% (9/191) in 2000 to 3.0% (8/265) in 2003. The association between the presence of CON laws and low-volume status persisted after adjustment for region and population density, and results were similar whether or not the model included a random state effect (Table 2). Results were also similar when low-volume status was defined with a threshold of 200 instead of 60 cases (Table 3).

Mortality and Morbidity

Unadjusted mortality for CABG was 2.52% for states with CON and 2.62% for states without CON regulations (OR, 0.97; 95% CI, 0.90 to 1.03; $P=0.32$). Mortality rates for Medicare patients aged 65 years or older were 3.60% in CON states and 3.61% in non-CON states. All unadjusted nonfatal morbidity end points tended to be lower in CON states than in non-CON states (Table 4; stroke [OR, 0.97; 95% CI, 0.90 to 1. 04], renal failure [OR, 0.84; 95% CI, 0.77 to 0.93], prolonged ventilation [OR, 0.97; 95% CI, 0.89 to 1.07], deep sternal infection [OR, 1.00; 95% CI, 0.87 to 1.14], reopera-

TABLE 2. Association Between CON Status and 2003 Low-Volume (<60 Cases) Hospital Status Based on Hierarchical Logistic Regression

	Percent Low-Volume Hospitals (n/N)		OR (95% CI) Comparing CON vs Non-CON		
Year	Non-CON	CON	Unadjusted	Adjusted*	Adjusted†
2000	6.7 (16/240)	4.7 (9/191)	0.73 (0.30–1.77)	0.74 (0.29–1.88)	0.47 (0.17–1.28)
2001	6.0 (16/266)	3.8 (8/213)	0.63 (0.26–1.55)	0.71 (0.29–1.71)	0.43 (0.16–1.16)
2002	7.7 (23/298)	2.0 (5/251)	0.30 (0.10–0.91)‡	0.36 (0.11–1.16)	0.16 (0.05–0.46)‡
2003	7.4 (22/299)	3.0 (8/265)	0.38 (0.17–0.89)‡	0.43 (0.18–1.01)	0.33 (0.13–0.87)‡

*Adjusted for state population density.

†Adjusted for state population density and region.

‡$P<0.05$.

TABLE 3. Association Between CON Status and 2003 Low-Volume (<200 Cases) Hospital Status Based on Hierarchical Logistic Regression

	Percent Low-Volume Hospitals (n/N)		OR (95% CI) Comparing CON vs Non-CON		
	Non-CON	CON	Unadjusted	Adjusted*	Adjusted†
2000	42.5 (102/240)	25.7 (49/191)	0.46 (0.27–0.80)‡	0.56 (0.32–0.98)‡	0.49 (0.28–0.88)‡
2001	46.2 (123/266)	31.5 (67/213)	0.51 (0.29–0.91)‡	0.62 (0.35–1.12)	0.68 (0.36–1.28)
2002	51.0 (152/298)	31.9 (80/251)	0.40 (0.25–0.65)‡	0.46 (0.28–0.75)‡	0.48 (0.29–0.82)‡
2003	57.5 (172/299)	35.5 (94/265)	0.37 (0.23–0.61)‡	0.44 (0.28–0.80)‡	0.51 (0.30–0.86)‡

*Adjusted for state population density.
†Adjusted for state population density and region.
‡$P<0.05$.

tion [OR, 0.93; 95% CI, 0.86 to 1.00], and any morbidity or mortality [OR, 0.95; 95% CI, 0.89 to 1.01]). Of these, only renal failure reached statistical significance ($P<0.001$). In contrast, the frequency of postoperative length of stay >14 days was slightly higher in CON states (5.49% versus 5.14%; OR, 1.09; 95% CI, 1.01 to 1.18; $P=0.02$).

Patient clinical characteristics were similar in CON and non-CON hospitals (Table 5) except that CON states had a higher proportion of black patients, as noted above. The use of hierarchical logistic regression to adjust for patient characteristics did not change these OR estimates (Table 6). After regional factors and patient characteristics were added to the model, 2 end points were significantly lower in CON states: stroke (OR, 0.93; 95% CI, 0.89 to 0.97) and renal failure (OR, 0.81; 95% CI, 0.72 to 0.90). In this analysis, the association between the presence of CON laws and a reduction in risk of operative mortality was marginally significant (OR, 0.92; 95% CI, 0.86 to 1.00; $P=0.05$). The increased frequency in CON states of postoperative stay longer than 14 days was no longer significant ($P=0.23$). Results were similar when the analysis was restricted to patients aged 65 years or older.

Regional Analyses

There was a suggestion that the impact of CON laws on procedural volume and outcomes varied by geographic region. For example, after adjustment for covariates, there was no association between CON status and low-volume status in the Midwest ($P=0.239$), Northeast (0.963), or West (0.993); however, there was a significant association between the presence of CON regulations and a reduced prevalence of low-volume hospitals in the South (OR, 0.18; 95% CI, 0.04 to 0.89; $P=0.035$; Table 6). Similarly, the association between CON status and operative mortality during 2003 varied within each of the 4 geographic regions. There was no significant association between CON status and operative mortality in the Midwest ($P=0.4739$), Northeast ($P=0.1532$), or West ($P=0.6366$) regions after adjustment for covariates; however, CON status was associated with lower operative mortality in the South (OR, 0.78; 95% CI, 0.67 to 0.90; $P=0.0007$; Table 7).

The adjusted odds of mortality varied considerably by state, even within regions. To adjust for unexplained between-state variation, the hierarchical logistic regression analyses were repeated by introducing random effects at the level of individual states. This more conservative analytic strategy was used to assess whether there was no causal association between CON status and outcomes. After the inclusion of random state effects in the model, no differences in risk-adjusted mortality or morbidity between CON and non-CON states were found to be statistically significant (CON versus non-CON: mortality [OR, 0.95; $P=0.46$], stroke [OR, 0.90; $P=0.105$], renal failure [OR, 0.94; $P=0.542$], prolonged ventilation [OR, 1.06; $P=0.623$], sternal infection [OR, 0.99; $P=0.912$], reoperation [OR, 1.02; $P=0.84$], major morbidity or mortality [OR, 1.00; $P=0.97$], and length of stay >14 days [OR, 1.08; $P=0.38$]).

TABLE 4. Operative Mortality and Morbidity Prevalence (%) and Unadjusted ORs Comparing CON States vs Non-CON States

	Prevalence, %			
Variable	Non-CON	CON	OR (95% CI)	*P*
Operative mortality	2.6	2.5	0.97 (0.90–1.03)	0.32
Stroke	1.6	1.5	0.97 (0.90–1.04)	0.39
Renal failure	3.8	3.3	0.84 (0.77–0.93)	<0.001
Prolonged ventilation	7.3	7.2	0.97 (0.89–1.07)	0.58
Deep sternal infection	0.5	0.5	1.00 (0.87–1.14)	0.97
Reoperation	6.3	6.1	0.93 (0.86–1.00)	0.05
Any major morbidity/mortality	14.1	13.6	0.95 (0.89–1.01)	0.12
PLOS >14 days	5.1	5.4	1.09 (1.01–1.18)	0.02

PLOS indicates patient length of stay in hospital.

Analysis of CMS Data

In general, findings from analysis of the Medicare data set were similar to those derived from the STS database. The percent of hospitals in the CMS data set that performed fewer than 30 CABG procedures on Medicare patients in 2001 was 14.2% in non-CON states compared with 4.6% in states with CON laws ($P<0.0001$). After adjustment for population density and random state effects, the presence of a CON law was associated with a 46% reduction in the odds of being a low-volume hospital (OR, 0.54; 95% CI, 0.29 to 0.98; $P=0.041$). These estimates are consistent with the analyses on STS data reported in Table 3 (OR for low-volume status defined as fewer than 60 CABG cases in 2001=0.43; 95% CI, 0.16 to 1.16).

The existence of a CON law also was associated with a 9% reduction in the unadjusted risk of mortality in Medicare patients (OR, 0.91; $P=0.005$). Unlike in the analysis of STS

TABLE 5. Patient Demographic and Clinical Data

Demographic	Non-CON (n=280 512)	CON (n=314 710)
Age, y		
20–57	24.7	26.6
58–66	25.8	26.4
67–73	23.2	22.7
>74	26.2	24.3
Gender		
Male	72	71
Female	28	29
Race		
White	87	87
Black	3.3	6.4
Other	8.8	4.6
Year of surgery		
2000	25	24
2001	26	24
2002	26	26
2003	23	26
Risk factors		
Smoking	59	62
Dialysis	1.4	1.3
Diabetes mellitus	34	35
Hypertension	73	74
Reoperation	9.6	8.6
Stroke	6.6	6.6
Ejection fraction <0.40	16	16
Left main disease	24	24
Myocardial infarction		
1–7 d	19	18
>7 d	19	18
Shock	1.9	1.7
Surgery status, %		
Elective	53	54
Urgent	43	41
Emergency	4.2	4.0
Salvage	0.2	0.3
Predicted mortality	3.2	3.0

All values are percentages. Percentages in each category do not necessarily total 100 because some data are missing in some patients. Predicted mortality is mean based on STS NCD risk stratification algorithm.

data, the association between CON and mortality in the Medicare patients was still significant after adjustment for patient characteristics and region (OR, 0.90; $P=0.004$). This finding is consistent with a prior study of CMS data.[7] Although the association between CON status and risk of death was not significant in the STS data, the estimates of ORs calculated in the STS and Medicare data sets are of similar magnitude (OR=0.90 in Medicare versus OR=0.92 in STS). The association between CON status and mortality was no longer significant when the model was adjusted to include random state effects (OR, 0.94; $P=0.28$).

Hospitals that participated in the STS database tended to have larger CABG volumes among Medicare patients than hospitals that did not participate. In 2001, the median CABG volume in the Medicare data set was 121 (interquartile range, 67 to 192) for STS participants and 67 (interquartile range, 21 to 136) for nonparticipants. Although STS database participants reported larger average volumes than nonparticipants, the selection of STS database participants was similar in CON and non-CON states. The proportion of hospitals that participated in the STS database was 49.9% (221/443) in CON states and 46.5% (267/574) in non-CON states. The frequency of STS database participation among CMS providers with fewer than 30 cases was also similar (41/102 [40.2%] versus 79/215 [36.7%]). Moreover, CON status was not a significant predictor of participation in the STS database after we controlled for hospital volume ($P=0.77$). The association between CON status and mortality in the Medicare analysis did not change substantially when Medicare data were restricted to hospitals that were also participants in the STS database (OR, 0.87; $P=0.01$).

Discussion

Our analysis demonstrates that state CON regulations have been generally effective in concentrating bypass surgery procedural volumes, increasing mean and median annual procedure volumes, and decreasing the likelihood that there are hospitals with very low volumes of cardiac surgery. This association, however, does appear to vary by region, with greater apparent impact in the South relative to other areas of the country. Despite this relationship, however, CON alone appears to have little impact on procedural quality as assessed by differential rates of mortality and major morbidities. Hospitals in states with CON had generally similar operative mortality and morbidity as those without CON. The present data suggest that state CON laws are not a sufficient mechanism to ensure quality of care for CABG surgery. CON regulations can have an impact on the allocation and location of resources but cannot ensure the skills, judgment, and evidence-based practice applied in the delivery of care.

These conclusions differ somewhat from those of Vaughan-Sarrazin and colleagues[7] based on their study using the CMS database. There are several potential explanations for these differences. First, the impact of CON on outcomes could be limited to elderly patients. The present analysis did not find, however, that patient age played a modifying role on the impact of CON status. Alternatively, the present analysis may have accounted more fully for patient clinical features and both state and regional characteristics. Third, an important limitation of the CMS MedPAR data is the lack of patients covered under managed care (MedPAR files include fee-for-service patients only), which in 2001 was ≈15% of the Medicare population nationally. Fourth, the present study used more recent data, and it is possible that the impact of CON regulations is changing over time. Finally, the present analysis was based on selected sites that voluntarily submit data to a national database. Although the STS NCD represents the majority of hospitals doing CABG surgery in the United States, it is possible that these participants constitute a nonrepresentative sample. However, the CMS findings based

TABLE 6. Adjusted ORs (95% CIs) Comparing CON States vs Non-CON States Based on Hierarchical Logistic Regression Analysis

	Adjusted for Patient Risk Factors		Adjusted for Risk Factors and Region	
Outcome Variable	OR (95% CI)	*P*	OR (95% CI)	*P*
Operative mortality	0.98 (0.91–1.05)	0.52	0.92 (0.86–1.00)	0.05
Stroke	0.96 (0.89–1.03)	0.28	0.93 (0.89–0.97)	0.001
Renal failure	0.83 (0.75–0.92)	$<$0.001	0.81 (0.72–0.90)	$<$0.001
Prolonged ventilation	0.97 (0.88–1.07)	0.50	0.98 (0.88–1.09)	0.66
Sternal infection	0.98 (0.85–1.12)	0.74	0.98 (0.84–1.14)	0.76
Reoperation	0.93 (0.86–1.00)	0.06	0.93 (0.85–1.01)	0.08
Any major	0.94 (0.88–1.01)	0.08	0.95 (0.88–1.02)	0.14
PLOS $>$14 d	1.09 (1.01–1.18)	0.02	1.05 (0.97–1.15)	0.23

PLOS indicates patient length of stay in hospital.

on data from all US hospitals yielded similar estimates. Furthermore, analysis of CMS data limited to STS hospitals gave findings similar to those seen in the CMS data overall.

The present analysis also revealed an absence of concordance between volume and quality. A number of previous studies have demonstrated an apparent linkage between outcome and hospital case volumes in cardiac surgery and other specialties.[4,13–22] On the other hand, this association has been questioned by data that suggest that minimum-volume thresholds may not be useful or at least may be set considerably lower than previously considered. The adoption of evidence-based treatment algorithms and guideline-based clinical best practices may be responsible for the decreasing importance of volume effects on outcomes.[23–27] CON regulations appear to concentrate procedural volume yet fail to improve hospital outcomes. These findings are consistent with the recent observations that CABG volume is a relatively poor discriminator of hospital quality as assessed by risk-adjusted mortality.[23] The present data support the inference that case volume is not a primary determinant of the quality of outcome after CABG.

The STS NCD provides clinical and outcome information that is not available in administrative databases and that can be used to provide risk-adjusted outcomes data. Such data can be applied to process and performance improvement in care delivery. This is a difference from analysis of data derived from administrative sources such as CMS MedPAR. The STS database has the advantages of years of peer-reviewed development, refinement, and validation of its risk models, as well as national scope of representation.[8,9] One major concern regarding the STS database is that at present, participation is voluntary. The centers that contribute data to the STS, therefore, are self-selected and may not be representative of practice in general.

The additional analysis of Medicare data, specifically that restricted to hospitals that also participate in the STS database, attempted to address such issues of potential selection bias. Consideration of this subset of Medicare- and STS database–participating hospitals yielded results that were consistent with those derived from the STS data alone. This supports the conclusion that inferences drawn from the STS database are applicable to all hospitals, not just to those that participate in the STS database. In other words, the supplementary CMS analysis makes it less likely that there was important selection bias related to the fact that participation in the STS database is voluntary and not universal. This finding is supported by a recent study using CMS data that demonstrated an inverse relationship between early use of coronary revascularization and CON laws but no association with mortality after acute myocardial infarction.[28] Given both CMS and STS data, the conclusion appears supportable that CON laws regulate the volume of services but do not by themselves have a consistent effect on the quality of outcomes after revascularization procedures for coronary artery disease.

The present analysis has also uncovered some epiphenomena. One is the progressive decline in CABG case volumes throughout the country during the first years of the 21st century. This probably reflects the expanding application of new drugs (such as the statins) and catheter-based treatment

TABLE 7. Hierarchical Analysis of CON vs 2003 Low-Volume Status (<60 Surgeries) by Region

	Percent Low-Volume Hospitals (n/N)		Adjusted OR (95% CI), CON vs Non-CON	*P*
	Region	Non-CON		
Midwest	6.7 (7/104)	3.2 (3/95)	0.44 (0.11–1.74)	0.239
Northeast	2.9 (1/34)	3.0 (1/33)	0.89 (0.01–120.7)	0.963
South	14.5 (8/55)	2.5 (3/121)	0.18 (0.04–0.89)	0.035
West	5.7 (6/106)	6.3 (1/16)	0.99 (0.11–9.24)	0.993

*Adjusted for state population density.

TABLE 8. Adjusted ORs Comparing CON States vs Non-CON States Based on Hierarchical Logistic Regression Analysis

	Mortality, %			
Region	Non-CON	CON	Adjusted OR (95% CI)	*P*
Midwest	2.5	2.6	1.04 (0.93–1.16)	0.4739
Northeast	2.3	2.2	0.86 (0.70–1.06)	0.1532
South	3.1	2.4	0.78 (0.67–0.90)	0.0007
West	2.7	2.8	1.06 (0.83–1.35)	0.6366

*Isolated CABG only. Random intercepts hierarchical logistic regression model with random hospital effects. Patient risk factors are the same as those included in the respective STS morbidity model.

approaches to established coronary artery disease. It will be interesting to observe whether the introduction of drug-eluting stents in 2003 accelerates this trend. Furthermore, the prevalence of CON regulations in certain regions of the country also appears to be associated with demographic differences in these areas. These observations emphasize the importance of recognizing these and other regional and within-state variables and correcting for them in analysis of the impact of factors such as CON laws. This has important implications for policy makers.

Study Limitations:

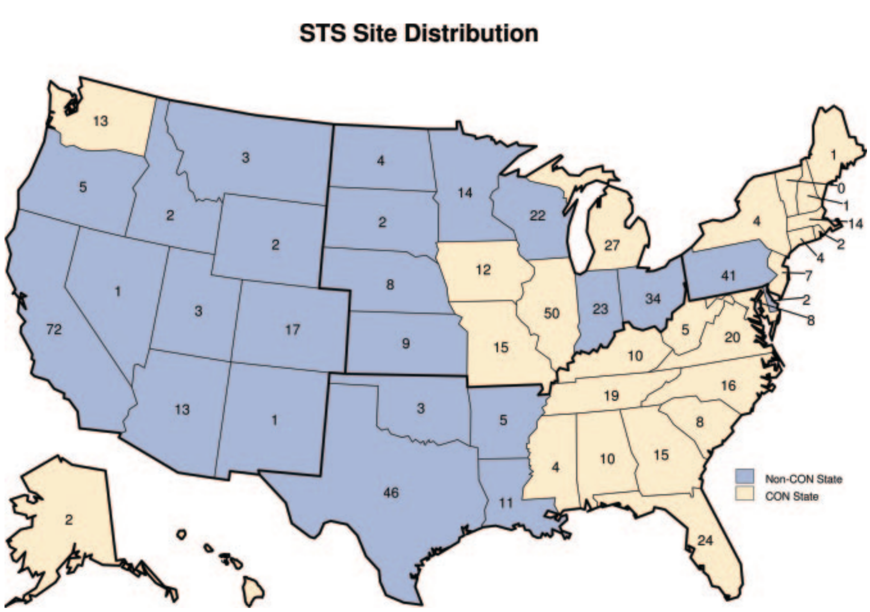
A main limitation of the present study was the fact that participation in the STS NCD is voluntary and thus lacked full representation of all CABG hospitals. This limitation was mitigated in part by the supplemental analyses from the inclusive Medicare claims file. Second, the present study did not consider an evaluation of costs, an important component of the value equation. Although charge data are readily available, cost information has been notoriously hard to come by, although progress is being made. The merging of STS data with cost analyses, especially if the STS data were national, would help to address the value questions now assuming increasing importance. Third, we did not consider functional assessment or long-term rehabilitation, outcomes that will take on growing importance in the assessment of the quality, value, and overall impact of care provided. Fourth, although we attempted to adjust for regional differences, the power of such analyses is limited by the fact that the states in a given region were either predominantly CON or predominantly non-CON; therefore, the association between CON status and outcomes is largely confounded by regional effects. The map in the Figure indicates the extent to which CON status is determined by region. In the South, where CON appears to have the most impact on outcomes, comparing CON versus non-CON states is equivalent to comparing Southeast versus Southwest subregions. The potential for confounding by region is shared by all previous observational studies that examined the impact of CON on outcomes. Finally, the present study represents a snapshot of regulatory activity in states over a finite period of time and therefore may not reflect the past or future impact of CON regulations.

Conclusions

The present analysis does not support the conclusion that CON laws alone are a sufficient mechanism to ensure better outcomes for CABG surgery in contemporary medical practice. Although CON laws do appear to concentrate procedure volume at certain sites, their impact on procedural mortality or morbidity appears marginal. Alternative mechanisms may be needed to improve CABG outcomes. Programs that monitor results, exchange information about best practices, and provide feedback to hospitals and practitioners have been shown to improve the quality of care after CABG surgery. Such programs include the cardiac surgery database of the Veterans Administration[8] and the Northern New England Cardiovascular Disease Study Group, as well as the STS NCD.[29,30] It is likely that the most significant advances in the care of patients having CABG procedures will come from dissemination of best practices, active and ongoing exchange of clinical information, and wide participation in validated and comprehensive clinical databases such as the STS NCD.

Disclosures

None.



US map of CON and non-CON states; numbers indicate number of STS NCD–participating hospitals.

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CLINICAL PERSPECTIVE

Using contemporary, clinically rich, age-inclusive data available from the Society of Thoracic Surgeons' National Cardiac Surgery Database (STS NCD), this study tested the hypothesis that states with certificate-of-need (CON) regulations had higher coronary artery bypass grafting (CABG) procedural volumes and associated lower operative mortality and morbidity. Further assessed was whether any associations remained after adjustment for baseline patient clinical factors, hospital features, and state and regional factors. To ensure the absence of significant selection biases in the STS NCD, the analyses were repeated with Medicare claims files obtained from the Centers for Medicare and Medicaid Services. The analysis did not support the conclusion that CON laws alone are a sufficient mechanism to ensure better outcomes for CABG surgery in contemporary medical practice. Although CON laws do appear to concentrate procedure volume at certain sites, their impact on procedural mortality or morbidity appears marginal. Alternative mechanisms may be needed to improve CABG outcomes. These might include programs that monitor results, exchange information about best practices, and provide feedback to hospitals and practitioners that have been shown to improve the quality of care during and after CABG surgery. It is likely that the most significant advances in the care of patients having surgical myocardial revascularization procedures will come from dissemination of best practices, active and ongoing exchange of clinical information, and wide participation in validated and comprehensive clinical databases like the STS NCD.