Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation

Mary S. Vaughan-Sarrazin, PhD
Edward L. Hannan, PhD
Carol J. Gormley, MA
Gary E. Rosenthal, MD

Context Certificate of need regulation was designed to control health care costs by preventing health care facilities from expanding unnecessarily. While there have been several studies investigating whether these regulations have affected health care investment, few have evaluated the relationship between certificate of need regulation and quality of care.

Objective To compare risk-adjusted mortality and hospital volumes for coronary artery bypass graft (CABG) surgery in states with and without certificate of need regulation.

Design, Setting, and Participants Retrospective cohort study of 911 407 Medicare beneficiaries aged 65 years or older, who underwent CABG surgery between 1994 and 1999 in 1063 US hospitals.

Main Outcome Measures States (and the District of Columbia) with continuous (n=27), none (n=18), or intermittent (n=6) certificate of need regulation; mortality (in-hospital or within 30 days of CABG surgery) rates; and mean annual hospital volumes for CABG surgery.

Results Unadjusted mortality was 5.1% in states without certificate of need regulation compared with 4.4% in states with continuous regulation, and 4.3% in states with intermittent certificate of need regulation ($P<.001$ for each comparison). Adjusting for demographic and clinical factors, mortality remained higher in states without certificate of need regulation compared with states with continuous certificate of need regulation (odds ratio [OR], 1.22; 95% confidence interval [CI], 1.15-1.28; $P<.001$). Using the same groups for comparison, the mean annual hospital volume for CABG surgery was 84% lower in states without certificate of need regulation (104 vs 191; $P<.001$) and more patients underwent CABG surgery in low-volume hospitals (<100 procedures annually) (30% vs 10% for states with continuous certificate of need programs; $P<.001$). Following the repeal of certificate of need regulation in states categorized as intermittent, the percentage of patients undergoing CABG surgery in low-volume hospitals tripled.

Conclusions Mortality rates for Medicare patients undergoing CABG surgery were higher in states without certificate of need regulation. Repeal of certificate of need regulations during the study period was associated with declines in hospital volume for CABG surgery.

JAMA. 2002;288:1859-1866

www.jama.com

CERTIFICATE OF NEED REGULATION began in 1974 under federal guidelines that were designed to control health care costs by preventing health care facilities from expanding unnecessarily. Certificate of need laws also were intended to ensure quality of care and clinical proficiency by limiting the number of health care facilities performing complex medical procedures. However, opponents of certificate of need regulation argued that it may limit competition and give unfair economic advantage to established facilities. In 1984, opponents to certificate of need regulation successfully worked to enact legislation that abolished the federal government's role. This legislation allowed each state to determine whether to have certificate of need regulation.[1] With the enactment of public policies in the mid-1980s to deregulate many sectors of the economy and the emergence of competition in health care, many states, in turn, have significantly reduced certificate of need regulation or eliminated it altogether.

At the heart of the certificate of need regulation debate are concerns about whether elimination of the regulation may adversely affect the quality of care or result in excess use of services. While

Author Affiliations: Division of General Internal Medicine, Department of Medicine, VA Medical Center and University of Iowa College of Medicine, Iowa City (Drs Vaughan-Sarrazin and Rosenthal); School of Public Health, State University of New York, Albany (Dr Hannan); and Florida Hospital Association, Tallahassee (Ms Gormley).
Corresponding Author and Reprints: Gary E. Rosenthal, MD, Division of General Internal Medicine, University of Iowa Hospitals and Clinics, SE618 GH, 200 Hawkins Dr, Iowa City, IA 52242 (e-mail: gary-rosenthal@uiowa.edu).

there have been several studies investigating whether certificate of need regulation has affected health care investment,[2-5] few studies have evaluated the relationship of certificate of need regulation with quality of care.[6,7]

Our study examines associations between state certificate of need regulation and outcomes of patients undergoing coronary artery bypass graft (CABG) surgery. The analysis used claims data for Medicare beneficiaries from all 50 states for a 6-year period (1994-1999) to compare risk-adjusted hospital mortality rates and the proportions of patients undergoing CABG surgery in low-volume hospitals in states with and without certificate of need regulation. Although the validity of using Medicare claims data to adjust for case-mix and severity of illness has been questioned in analyses of hospital mortality, it is likely that state-level differences in patient-mix are less than hospital-level differences. Moreover, Medicare data are available for all states, making it feasible to compare outcomes across states with and without certificate of need regulation.

While the cross-sectional design of the analysis may limit the ability to infer a causal relationship between the repeal of certificate of need regulations and patient outcomes, we nonetheless hypothesized that states without certificate of need regulation would have more low-volume hospitals and higher proportions of patients receiving CABG surgery at low-volume hospitals. We further hypothesized that states without certificate of need regulation would have higher mortality rates.

METHODS

Data

The study used Medicare Provider Analysis and Review Part A public use data files, which were purchased from the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration). The Part A files contain data available on the UB-92 hospital discharge abstract for a 100% sample of Medicare patients discharged from acute care hospitals and have been extensively used in health services research.[8] Data elements include demographic information; patients' state of residence; primary and secondary diagnoses and procedures (classified by the *International Classification of Diseases, Ninth Revision, Clinical Modification* system); the diagnosis related group; admission source (eg, transfer from another hospital, emergency department); admission and discharge dates; disposition at the time of hospital discharge; and a 6-digit unique hospital identifier. In addition, Part A files are matched quarterly to the Medicare Enrollment database to obtain dates of death for Medicare beneficiaries who died after hospital discharge.

Patients who underwent CABG surgery between 1994 and 1999, and who were 65 years or older were identified (N=911 740) on the basis of specific diagnosis related groups (106, 107, and 109). The 109 group became effective in October 1998. Patients discharged from hospitals with 5 or fewer CABG surgery procedures in the Medicare Provider Analysis and Review data (n=333; 0.04% of total cases) were assumed to represent procedure coding errors and were excluded from the analysis, leaving a final sample of 911 407 patients in 1063 US hospitals. Analyses including these patients yielded nearly identical findings.

Information on the number of Medicare beneficiaries aged 65 years or older with either Medicare hospital or supplemental insurance in each state was obtained from the Centers for Medicare and Medicaid Services Web site at http://www.hcfa.gov/stats/. Information regarding the percentage of the population aged 65 to 74 years, 75 to 84 years, and 85 years or older by sex was obtained from the US Census 2000 Summary File at http://factfinder.census.gov.

Information about states' certificate of need regulation was obtained from the American Health Planning Association's National Directory of Health Planning, Policy, and Regulatory Agencies for 1993 through 2000.[9] Individual states (and the District of Columbia) were categorized according to whether they had certificate of need regulation regarding open heart surgery in effect from 1994 through 1999. Three certificate of need categories were defined. Twenty-seven states had *continuous* certificate of need regulations for open heart surgery from 1994 through 1999. Eighteen states terminated certificate of need regulation for open heart surgery prior to 1994 and had *no* (without) regulation during the study period. Six states had terminated and/or reinstated certificate of need regulation for open heart surgery between 1994 and 1999 and had *intermittent* regulation during the study period. Of the states in the no regulation category, 8 states had regulation for services other than open heart surgery (Arkansas, Indiana, Louisiana, Minnesota, Montana, Oklahoma, Oregon, and Wisconsin) from 1994 through 1999, and 10 states had no regulation for any services (Arizona, California, Colorado, Idaho, Kansas, New Mexico, South Dakota, Texas, Utah, and Wyoming). Of the states in the intermittent category, Pennsylvania repealed regulations in 1996; Nebraska, Nevada, North Dakota, and Delaware repealed regulations in 1997; and Ohio repealed regulations in 1998.

Analysis

Demographic variables and primary and secondary diagnosis and procedure codes that represented potential patient risk factors were identified in the Medicare Provider Analysis and Review data. These variables included race, sex, age, admission type, and several comorbid conditions previously identified by Hannan et al[10,11] as risk factors for post-CABG surgery mortality using administrative data. The prevalence of demographic variables and clinical risk factors, mean predicted risk of death, and mortality rates of patients in states in all 3 certificate of need regulation categories were compared using analysis of variance or the χ^2 test. Mortality was defined as deaths that occurred within 30 days of CABG surgery or during hospitalization for CABG surgery.

A risk-adjustment model was developed by entering candidate variables associated ($P<.05$) with mortality in bivariate analyses into a stepwise logistic regression. Variables independently related to mortality were identified using a statistical criterion of $P<.01$. In the risk-adjustment model, age was expressed as 1 of 5 indicator variables (70-74 years, 75-79 years, 80-84 years, 85-89 years, or ≥90 years), with a referent category of 65 to 69 years. Race was expressed using 2 indicator variables for patients who were classified in the database as either having black or other nonwhite race. Surgical priority was expressed using 2 indicator variables for emergent and urgent admissions, relative to elective admissions. Admission source was expressed as indicator variables for patients transferred to the hospital from another acute care facility and patients admitted through the emergency department, with a referent category that primarily included patients referred by a physician.

Model discrimination was evaluated using the *c* statistic,[12] and calibration was assessed using the goodness of fit statistic.[13] The coefficients from the risk adjustment model were then used to determine a predicted risk of death (0%-100%) for each patient as a measure of overall patient severity.

Differences in risk-adjusted mortality were determined by including 2 indicator variables for CABG procedures performed in states with intermittent or without certificate of need regulations in the patient-level multivariable risk-adjustment model that also included patient-specific risk factors. The regression coefficients were exponentiated to provide the adjusted odds of death of patients in these 2 groups, relative to patients in states with continous certificate of need regulations. This analysis was then repeated using an indicator variable for each state without or with intermittent certificate of need regulations to determine the odds of death for individual states, relative to all states with continuous certificate of need regulations. To account for the clusters of patients within hospitals and for heterogeneity in the odds of death across individual states in each group, robust methods of determining the 95% confidence intervals (CIs) around the odds ratios (ORs) were used.[14,15]

Mean age-adjusted CABG surgery rates and annual hospital CABG surgery volumes in states with continuous, intermittent, and without certificate of need regulations were compared using analysis of variance. Surgery rates for each state were standardized directly by determining the observed rate in each age-sex stratum and then applying those rates to a standard distribution of patients (ie, the age-sex distribution of the entire sample).[16] In addition, the proportion of low-volume hospitals and the proportions of patients undergoing CABG surgery in low-volume hospitals were compared using the χ^2 statistic. These analyses used the following thresholds to define low-volume hospitals: less than 50 procedures performed for Medicare patients per year or less than 100.

Analyses were performed using SAS statistical sofware (Version 8.0; SAS Institute, Cary, NC), except for the logistic regression analysis with robust variance estimates, which was performed using STATA statistical sofware (Version 7; STATA Corp, College Station, Tex).

RESULTS

The mean (SD) age of patients was 73 (5.3) years and was nearly identical in all 3 certificate of need categories (continuous, intermittent, and none) (TABLE 1). Of 911407 Medicare patients, 34.8% were women and 93.0% were white. The 3 certificate of need categories varied ($P<.001$) according to sex and race, although the magnitude of the differences was relatively small. Patients in states without certificate of need regulations had a somewhat lower prevalence of diabetes, chronic obstructive lung disease, congestive heart failure, cerebrovascular disease, and peripheral vascular disease compared with patients in states with continuous or intermittent certificate of need regulations. Although patients in states without regulations were less likely ($P<.001$) to be classified as undergoing emergent procedures, they were more likely ($P<.001$) to undergo CABG surgery on the same day as a cardiac catheterization or on the same day as a percutaneous transluminal coronary angioplasty (PTCA). Patients in states without regulations were less likely ($P<.001$) to be transferred from another acute care hospital.

Unadjusted 30-day or in-hospital mortality rates in states without certificate of need regulations were higher than in states with either continuous or intermittent certificate of need regulations (5.1% vs 4.4% and 4.3%, respectively; $P<.001$ for each pairwise comparison). Differences in mortality were similar in analyses limited to just in-hospital mortality (4.2% vs 3.6% and 3.6%, respectively; $P<.001$) or to just 30-day mortality (5.0% vs 4.2% and 4.2%, respectively; $P<.001$). These differences were consistent across individual years (data not shown).

Risk-Adjusted Mortality

Fourteen risk factors met criteria for inclusion in the multivariable risk-adjustment model: age (expressed as 5 indicator variables); female sex; race (expressed as 2 indicator variables); primary diagnosis of acute myocardial infarction; secondary diagnoses of congestive heart failure, cerebrovascular disease, diabetes mellitus, peripheral vascular disease, or chronic obstructive pulmonary disease; surgical priority (expressed as 2 indicator variables); admission source (expressed as 2 indicator variables); PTCA on the same day as CABG surgery; cardiac catheterization on the same day as CABG surgery; and use of an intra-aortic balloon pump prior to CABG surgery. The ORs associated with each risk factor are shown in TABLE 2. The *c* statistic of the model was 0.72. The proportion of patients with a predicted risk of death of less than 2% (based on the risk-adjustment model) was somewhat higher ($P<.001$) in states without certificate of need regulations (Table 1).

Using the multivariable model, the odds of death was 22% higher for patients in states without certificate of need regulations for open heart surgery, relative to patients in states with continuous certificate of need regulations (OR, 1.22; 95% CI, 1.15-1.28; $P<.001$) during the entire 6-year period of analysis. Results were similar in analyses limited to deaths within 30 days (OR, 1.23; 95% CI, 1.17-1.30; $P<.001$) and in-hospital deaths (OR, 1.20; 95% CI, 1.13-1.27; $P<.001$). Results were similar in an analysis that examined the odds of death separately for the 10 states without certificate of need regulations for any clinical service relative to states with continuous regulations (OR, 1.23; 95% CI, 1.15-1.31; $P<.001$). Results were also similar in an analysis of the 8 states with intermittent certificate of need regulations for some services, but not open heart surgery (OR, 1.20; 95% CI, 1.12-1.27; $P<.001$). The odds of death for patients receiving CABG surgery in states with intermittent certificate of need regulations were similar to states with continuous regulations (OR, 0.99; 95% CI, 0.92-1.07; $P=.78$).

Table 1. Patient Characteristics According to State Certificate of Need Regulation Status

	State Certificate of Need Regulation Status, %			
	Continuous (n = 509 679)	None (n = 278 611)	Intermittent (n = 123 117)	P Value*
Women	35.0	33.8	36.2	<.001
Age, mean (SD), y	73 (5.35)	73 (5.38)	73 (5.25)	<.001
65-69	29.0	29.2	28.6	<.001
70-74	32.4	32.3	33.0	
75-79	25.1	24.9	25.7	
80-84	10.9	10.9	10.4	
85-89	2.4	2.4	2.1	
≥90	0.2	0.3	0.2	
Race				
White	93.0	91.8	95.1	<.001
Black	4.4	2.8	3.1	
Other	2.6	5.4	1.8	
Surgical priority				
Emergent admission	30.1	22.5	32.0	<.001
Urgent	31.3	35.6	28.3	<.001
Elective	38.2	41.6	39.1	<.001
Admission source				
Transferred from other facility	22.1	14.4	23.4	<.001
Emergency department	19.0	19.7	17.4	<.001
Comorbid conditions				
Diabetes mellitus	10.6	9.4	10.1	<.001
Chronic obstructive lung disease	14.3	14.0	14.5	.003
Congestive heart failure	19.3	18.3	19.3	<.001
Cerebrovascular disease	10.2	9.5	10.2	<.001
Peripheral vascular disease	8.6	8.0	8.7	<.001
High-risk clinical conditions				
Primary diagnosis of acute myocardial infarction	20.4	20.0	20.2	<.001
Cardiac catheterization on same day as coronary artery bypass graft (CABG) surgery	7.8	9.6	7.8	<.001
Percutaneous transluminal coronary angioplasty on same day as CABG surgery	1.2	1.7	1.2	<.001
Intra-aortic balloon pump prior to day of CABG surgery	3.4	3.1	3.2	<.001
Predicted risk of death, %				
Mean (SD)	4.7 (4.1)	4.5 (4.0)	4.6 (4.0)	<.001
<2	15.9	16.8	16.2	<.001
2-5	55.5	56.0	55.3	
5-10	20.9	20.0	21.0	
>10	7.8	7.3	7.5	
Observed deaths				
30-day or in-hospital	4.4	5.1	4.3	<.001
30-day only	4.2	5.0	4.2	<.001
In-hospital only	3.6	4.2	3.6	<.001

*The P value tests the null hypothesis that the 3 groups are equivalent.

Further analyses (FIGURE 1) found that the adjusted odds of death of patients in states without certificate of need regulations were higher in each of the 6 years, when examined individually, ranging from 16% to 26%. Differences in risk-adjusted odds of death in states with intermittent certificate of need regulations were generally similar to states with continuous regulations, with the exception of 1994, during which mortality was higher in states with intermittent regulations (OR, 1.14; 95% CI, 1.02-1.28; $P=.02$).

The odds of death of patients in individual states without or with intermittent certificate of need regulations for open heart surgery were also determined, relative to patients in states with continuous regulations. These analyses found a higher ($P<.05$) odds of death for 10 of 18 states without regulations: Arizona (OR, 1.56; 95% CI, 1.39-1.76); Arkansas (OR, 1.22; 95% CI, 1.06-1.40); Colorado (OR, 1.18; 95% CI, 1.04-1.35); Idaho (OR, 1.42; 95% CI, 1.07-1.89); Indiana (OR, 1.14; 95% CI, 1.04-1.23); Louisiana (OR, 1.36; 95% CI, 1.16-1.59); Oklahoma (OR, 1.26; 95% CI, 1.11-1.43); Oregon (OR, 1.10; 95% CI, 1.02-1.19); Texas (OR, 1.45; 95% CI, 1.35-1.57); and Wisconsin (OR, 1.14; 95% CI, 1.01-1.29). South Dakota, which had no certificate of need regulation, had lower odds of death (OR, 0.64; 95% CI, 0.55-0.74). Of the 6 states with inter-

mittent certificate of need regulations, the odds of death were higher for Nebraska (OR, 1.28; 95% CI, 1.04-1.59) and Nevada (OR, 1.57; 95% CI, 1.37-1.81); and lower for Pennsylvania (OR, 0.87; 95% CI, 0.80-0.95) and Delaware (OR, 0.92; 95% CI, 0.88-0.96).

Hospital Volume

The mean (SD) annual hospital volume for Medicare beneficiaries in states with continuous certificate of need regulations was 84% higher than in states without regulations (191 [155] vs 104 [97]; $P<.001$), but was similar ($P=.16$) to the mean (SD) annual hospital volume in states with intermittent regulations (173 [130]). However, mean annual hospital volume in states with intermittent regulations (ie, states that repealed certificate of need regulations during the study period) decreased by 23% from 201 to 154 between 1994 and 1999, while mean volumes decreased only by 1% from 191 to 189 for states with continuous regulation and 7% from 105 to 98 for states without regulations. Additionally, the number of hospitals performing CABG surgeries increased 22% in states with intermittent certificate of need regulations, while the increase was 4% both in states with continuous and without regulations.

Higher proportions ($P<.001$) of hospitals performing CABG surgeries in states without certificate of need regulations were classified as being of lower volume than in states with continuous or intermittent regulations (FIGURE 2). For example, 32% of the 474 hospitals that performed CABG surgeries in states without regulations had mean annual volumes for Medicare beneficiaries of 50 or less, while 62% of hospitals had mean annual volumes of 100 or less. In contrast, 12% and 33% of hospitals in states with continuous certificate of need regulations had mean annual volumes of 50 or less and 100 or less, respectively, and 10% and 40% of hospitals in states with intermittent regulations had mean annual volumes of 50 or less and 100 or less, respectively.

Similarly, proportions of patients undergoing CABG surgery in low-volume hospitals were higher ($P<.001$) in states without certificate of need regulations (Figure 2). In states without regulation, 9% of CABG surgeries occurred in hospitals that performed 50 or fewer procedures and 30% of CABG surgeries occurred in hospitals that performed 100 or fewer procedures annually. In contrast, in states with continuous certificate of need regulations, the respective percentages were 2% and 10%.

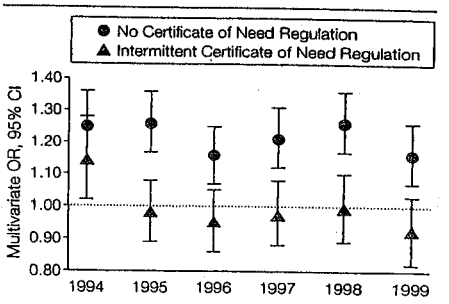
For states with intermittent regulations, the proportion of patients treated at low-volume hospitals increased during the study period to a greater degree than in states with either continuous or intermittent certificate of need regulations (particularly after 1996, which was the first year during the study period in which a repeal occurred). For example, the proportion of patients treated in hospitals that performed fewer than

Table 2. Risk Factors Included in the Logistic Regression Risk-Adjustment Model*

Risk Factor	Unadjusted Mortality, %†	OR (95% CI)	P Value
All	4.6		
Women	5.7	1.27 (1.23-1.28)	<.001
Age, y‡			
70-74	4.0	1.22 (1.18-1.25)	<.001
75-79	5.3	1.55 (1.50-1.60)	<.001
80-84	7.2	2.04 (1.97-2.11)	<.001
85-89	9.4	2.56 (2.42-2.70)	<.001
≥90	12.7	3.39 (2.95-3.90)	<.001
Race§			
Black	5.6	1.18 (1.11-1.25)	<.001
Other nonwhite	5.0	1.15 (1.08-1.23)	<.001
Comorbid conditions			
Diabetes mellitus	5.4	1.10 (1.06-1.14)	.003
Chronic obstructive pulmonary disease	5.8	1.24 (1.20-1.28)	<.001
Congestive heart failure	9.0	2.14 (2.08-2.19)	<.001
Cerebral vascular disease	9.2	2.31 (2.24-2.39)	<.001
Peripheral vascular disease	6.4	1.41 (1.36-1.46)	<.001
Surgical priority‖			
Emergent procedure	6.0	1.17 (1.12-1.23)	<.001
Urgent procedure	4.8	1.12 (1.07-1.17)	<.001
High-risk clinical conditions			
Primary diagnosis of acute myocardial infarction	7.1	1.33 (1.30-1.37)	<.001
Cardiac catheterization on same day as coronary artery bypass graft (CABG) surgery	7.8	1.64 (1.58-1.71)	<.001
Percutaneous transluminal coronary angioplasty on same day as CABG surgery	12.4	2.61 (2.46-2.77)	<.001
Intra-aortic balloon pump prior to day of CABG surgery	15.0	3.05 (2.86-3.24)	<.001
Admission source			
Transferred from other facility	5.5	1.12 (1.07-1.16)	<.001
Emergency department	6.4	1.13 (1.08-1.18)	<.001

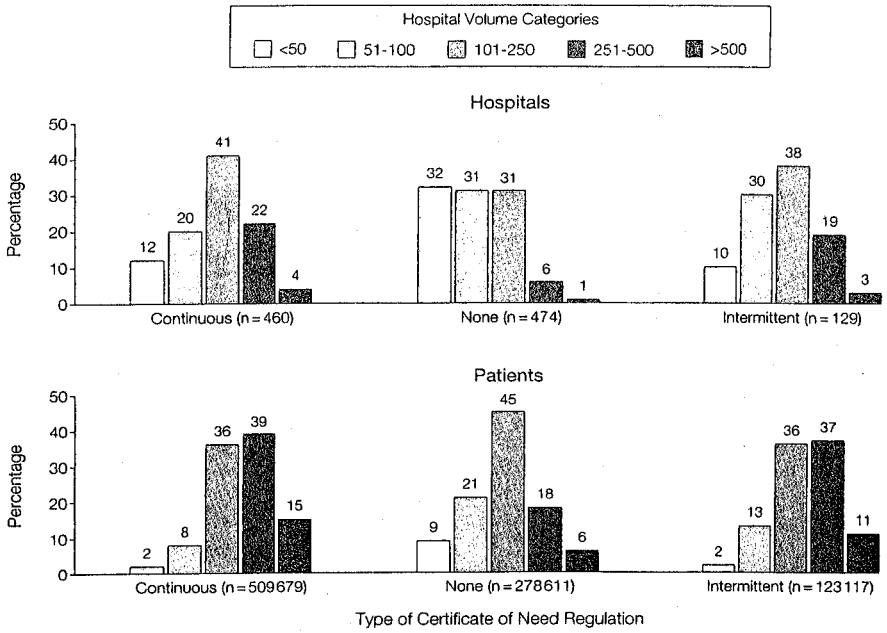
*OR indicates odds ratio; CI, confidence interval.
†The unadjusted mortality rate was higher ($P<.001$) for patients with each of the variables listed than in patients without the variable or included in the referent group.
‡The ORs are relative to patients aged 65 to 69 years.
§The ORs are relative to white patients.
‖The ORs are relative to elective procedures.

Figure 1. Risk-Adjusted Odds of Death



Reference group is states with continuous certificate of need regulations (dotted line). OR indicates odds ratio; CI, confidence interval.

Figure 2. Differences in the Distributions of Mean Annual Hospital Volumes and in the Proportions of Patients Undergoing CABG Surgery Between 1994 and 1999



Volumes reflect procedures performed in Medicare beneficiaries aged 65 years or older. CABG indicates coronary artery bypass graft.

100 procedures annually increased 3-fold from 6% in 1996 to 19% in 1999.

CABG Surgery Use

Overall age and sex-adjusted use was lower in states without certificate of need regulations (4.23 procedures/1000 Medicare beneficiaries aged ≥65 years) compared with states with continuous (4.75 procedures/1000 Medicare beneficiaries aged ≥65 years) and intermittent (4.97 procedures/1000 beneficiaries) regulations. Results were similar in analyses that only included patients who had CABG surgery performed in hospitals in their state of residence (use rates of 3.83 procedures/1000 Medicare beneficiaries for states without regulations, 4.16 procedures/1000 Medicare beneficiaries for continuous regulations, and 4.59 procedures/1000 Medicare beneficiaries for intermittent regulations). Differences in CABG surgery use were smaller when the age- and sex-adjusted use rates in individual states were averaged (4.66 procedures/1000 Medicare beneficiaries for states without regulations, 4.57 procedures/1000 Medicare beneficiaries for continuous regulations, and 4.84 procedures/1000 Medicare beneficiaries for intermittent regulations). This largely reflected the lower use rate in California (3.20 procedures/1000 Medicare beneficiaries), which is a state without a certificate of need regulation, and the "unweighting" of the state's large CABG surgery volume in the latter calculation.

COMMENT

This analysis represents the first large-scale evaluation of the potential impact of certificate of need regulation on hospital outcomes and use of CABG surgery in the United States. Using Medicare claims data for patients undergoing CABG surgery during 1994 to 1999, a period in which US health care delivery experienced substantial change, the study found that risk-adjusted mortality was 22% higher in the 18 states that had no certificate of need regulation for open heart surgery than in the 26 states and the District of Columbia that had continuous certificate of need regulations. The higher mortality in states without a certificate of need regulation was observed in all 6 years of the study period. In addition, mean patient volume in states with continuous certificate of need regulations was 84% higher than in states without regulation. A substantially higher proportion of patients in states without a certificate of need regulation underwent CABG surgery in low-volume hospitals.

These findings confirm our a priori hypotheses that the absence of certificate of need regulations would be associated with higher mortality and more low-volume hospitals providing CABG surgery. While factors other than certificate of need status may explain the differences in hospital volume (eg, differences in population density or managed care penetration), the higher proportions of patients treated at low-volume hospitals in states without certificate of need regulation provides a plausible explanation for the higher risk-adjusted mortality in such states, given the well-documented relationship between hospital volume and mortality for CABG surgery and other surgical procedures.[17-20]

While mortality was similar in states with continuous and intermittent certificate of need regulations, the number of hospitals performing CABG surgery in states that repealed regulations (intermittent) increased to a greater degree than in states with continuous regulations, as did the proportion of patients undergoing CABG surgery in low-volume hospitals.

The study also found that somewhat higher proportions of patients undergoing CABG surgery in states without certificate of need regulations (vs continuous or intermittent regulations) underwent cardiac catheterization or PTCA on the same day as surgery. Since cardiac catheterization and PTCA are also generally regulated in states that have certificate of need regulations for open heart surgery, outcomes of these procedures in states without certificate of need regulations

may be worse for the same reasons that outcomes of CABG surgery are worse in states without regulations. The higher incidence of cardiac catheterization and PTCA on the same day as CABG surgery may reflect higher complication rates for those procedures, rather than greater patient presurgical risk. If this is the case, then use of these variables as risk factors in the mortality model biases results in favor of states without certificate of need regulations. When these variables were not included in the mortality risk-adjustment models, the relative odds of death increased slightly to 1.24 in states without regulations.

Last, CABG surgery use was somewhat lower in states without certificate of need regulations when compared with states with either continuous or intermittent regulations. While this finding was somewhat unexpected, most of the lower use was explained by the low rates of CABG surgery in California, a state with a high presence of managed care and with low use of hospital services and other surgical procedures.[21]

Taken together, these findings suggest that repeal of certificate of need regulations may have adverse effects on patient outcomes and may promote the development of low-volume surgical programs. Although underlying factors responsible for the direct relationship between volume and outcomes in CABG surgery (eg, better presurgical evaluations, anesthesia practices, surgeon skill, postoperative care, nursing care) have yet to be elucidated, surgical volume has become an important proxy for quality in recent initiatives to measure quality and reward high-quality clinicians.[22]

However, in interpreting the current findings in this report, it is important to recognize that the observational, cross-sectional design can only infer, but not prove, a cause and effect relationship between certificate of need status and CABG surgery outcomes. In addition, several other potential methodological limitations should be considered.

First, the analysis was limited to Medicare beneficiaries and, thus, only includes roughly half of all patients undergoing CABG surgery. However, it is likely that if patterns of care were different for Medicare patients relative to other patients, these differences would be similar across states and would not necessarily bias study findings.

Second, any associations between certificate of need regulations and post-CABG surgery mortality, hospital procedure volumes, and surgery use may represent confounding due to other factors that may differ according to certificate of need status. These factors may include managed care penetration; regional physician practice variation; efforts to report and disseminate post-CABG surgery outcomes data to hospitals, clinicians, third-party payers, and the public; and differences in population and physician density and specialty mix, although the degree to which certificate of need status is related to these factors has not been established. Furthermore, alternative study designs to more definitively determine causality (ie, randomization to certificate of need) are not feasible.

Third, the analysis may also be confounded by regional differences in the use of PTCA as an alternative treatment for coronary insufficiency. Differences in PTCA use may directly affect CABG surgery use and lead to selection bias in analyses comparing post-CABG surgery mortality rates. The direction of such bias is difficult to estimate, given that PTCA may be preferentially used in patients with less severe forms of coronary artery disease or in patients with severe disease, but at high operative risk.

Fourth, there is likely to be heterogeneity in the character of certificate of need regulations for open heart surgery across individual states, which may lead to differences in the scope and stringency of regulation. In addition, specific regulations within a given state can vary from year to year, and certain aspects of certificate of need regulation may be phased out over time. Furthermore, states without certificate of need regulations may have other types of health care regulatory mechanisms, such as licensure or limits on capital diffusion.

Last, the risk-adjustment models based on administrative data are subject to limitations. The reliability of individual diagnoses coded in administrative data may vary across hospitals, and important prognostic variables (eg, left ventricular ejection fraction, vital signs, functional status) cannot be ascertained from administrative data. However, in the absence of a national clinical database of patients undergoing CABG surgery, which exists for patients undergoing CABG in Veterans Affairs hospitals[23,24] or in New York State,[25,26] administrative databases represent the only vehicle for examining the potential impact of state-level differences in certificate of need regulation.

Despite these limitations, the current study has several important implications for health services research and policymakers. First, this analysis provides evidence that post-CABG surgery mortality may be higher in states without certificate of need regulation than in states with such regulations. The analysis found no systematic differences in the prevalence of individual risk factors or in the overall predicted risk of death that would account for mortality differences. In addition, the analysis found that average hospital volumes in states without certificate of need regulation were substantially lower and that patients in such states were substantially more likely to undergo CABG surgery in low-volume hospitals. Furthermore, states that recently repealed certificate of need regulations experienced large decreases in hospital volume in the years following the repeal. The higher proportion of patients undergoing CABG surgery in low-volume hospitals may underlie the higher risk-adjusted mortality in states without certificate of need regulations. While there are limitations to the study, this analysis suggests that policymakers should carefully consider the potential adverse effects of repeal of certificate of need regulations. In a time when patient safety, medical errors, and patient outcomes are coming under greater

scrutiny, certificate of need regulations may be an important and effective regulatory mechanism for ensuring higher quality care and better patient outcomes.

Author Contributions: *Study concept and design:* Vaughan-Sarrazin, Hannan, Gormley, Rosenthal. *Acquisition of data:* Vaughan-Sarrazin. *Analysis and interpretation of data:* Vaughan-Sarrazin, Hannan, Rosenthal. *Drafting of the manuscript:* Vaughan-Sarrazin, Rosenthal. *Critical revision of the manuscript for important intellectual content:* Vaughan-Sarrazin, Hannan, Gormley, Rosenthal. *Statistical expertise:* Vaughan-Sarrazin, Hannan. *Obtained funding:* Gormley, Rosenthal. *Administrative, technical, or material support:* Gormley, Rosenthal. *Study supervision:* Rosenthal.

Funding/Support: This research was supported by a contract with the Florida Hospital Association and by grant ACC 97-004 from the Health Services Research and Development Service, Veterans Health Administration, Department of Veterans Affairs.

Disclaimer: The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs or the Florida Hospital Association.

REFERENCES

1. Altman SH, Ostby EK. Paying for hospital care: the impact on federal policy. In: Ginzberg E, ed. *Health Services Research: Key to Health Policy.* Cambridge, Mass: Harvard University Press; 1991:46-68.
2. Sloan F, Steinwald B. Effects of regulation on hospital costs and input use. *J Law Econ.* 1980;23:81-109.
3. Conover CJ, Sloan FA. Does removing certificate of need regulations lead to a surge in health care spending? *J Health Polit Policy Law.* 1998;23:455-481.
4. Harrington C, Swan JH, Nyman JA, Carrillo H. The effect of certificate of need and moratoria policy on change in nursing home beds in the United States. *Med Care.* 1997;35:574-588.
5. Howell JR. Evaluating the impact of certificate of need regulation using measures of ultimate outcome: some cautions from experience in Massachusetts. *Health Serv Res.* 1997;19:587-613.
6. Shortell SM, Hughes EF. The effects of regulation, competition, and ownership on mortality rates among hospital inpatients. *N Engl J Med.* 1988;318:1100-1107.
7. Robinson JL, Nash DB, Moxey E, O'Connor JP. Certificate of need and the quality of cardiac surgery. *Am J Med Qual.* 2001;16:155-160.
8. Mitchell JB, Bubolz T, Paul JE, et al. Using Medicare claims for outcomes research. *Med Care.* 1994; 32(suppl):38-51.
9. *National Directory of Health Planning, Policy, and Regulatory Agencies, 1993-2000.* Falls Church, Va: American Health Planning Association; 2000.
10. Hannan EL, Racz MJ, Jollis JG, Peterson ED. Using Medicare claims data to assess provider quality for CABG surgery: does it work well enough? *Health Serv Res.* 1997;31:659-678.
11. Hannan EL, Kilburn H Jr, Lindsey M, Lewis R. Clinical versus administrative databases for CABG surgery: does it matter? *Med Care.* 1992;30:892-907.
12. Ash AS, Schwartz M. Evaluating the performance of risk-adjustment methods: dichotomous measures. In: Iezzoni LI, ed. *Risk Adjustment for Measuring Health Care Outcomes.* 2nd ed. Chicago, Ill: Health Administration Press; 1997:427-470.
13. Lemeshow S, Hosmer DW Jr. A review of goodness of fit statistics for use in the development of logistic regression models. *Am J Epidemiol.* 1982;115: 92-106.
14. Huber PJ. The behavior of maximum likelihood estimates under non-standard conditions. In: *Proceedings of the Fifth Berkeley Symposium on Mathematical Statistics and Probability.* Berkeley: University of California Press; 1967:221-233.
15. White H. A heteroskedasticity-consistent covariance matrix estimator and a direct test for heteroskedasticity. *Econometrica.* 1980;48:817-830.
16. Feinstein AR. *Clinical Epidemiology: The Architecture of Clinical Research.* Philadelphia, Pa: WB Saunders Co; 1985:441-445.
17. Hannan EL, O'Donnell JF, Kilburn H Jr, Bernard HR, Yazici A. Investigation of the relationship between volume and mortality for surgical procedures performed in New York State hospitals. *JAMA.* 1989; 262:503-510.
18. Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized: the empirical relation between surgical volume and mortality. *N Engl J Med.* 1979; 301:1364-1369.
19. Luft HS, Junt SS, Maerki SC. The volume-outcome relationship: practice makes perfect or selective referral patterns? *Health Serv Res.* 1987;22: 157-182.
20. Showstack JA, Rosenfeld KE, Garnick DW, Luft HS, Schaffarzick RE, Fowles J. Association of volume with outcome of coronary artery bypass graft surgery. *JAMA.* 1987;257:785-789.
21. Escarce JJ, Van Horn RL, Pauly MV, Williams SV, Shea JA, Chen W. Health maintenance organizations and hospital quality for coronary artery bypass surgery. *Med Care Res Rev.* 1999;56:340-362.
22. Milstein A, Galvin RS, Delbanco SF, Salber P, Buck CR. Improving the safety of health care: the Leapfrog initiative. *Effective Clin Pract.* 2000;3:313-316.
23. Grover FL, Hammermeister KE, Burchfiel C. Initial report of the Veterans Administration preoperative risk assessment study for cardiac surgery. *Ann Thorac Surg.* 1990;50:12-28.
24. Grover FL, Johnson RR, Marshall G, Hammermeister KE. Factors predictive of operative mortality among coronary artery bypass subsets. *Ann Thorac Surg.* 1993;56:1296-1306.
25. Hannan EL, Kilburn H Jr, O'Donnell JF, Lukacik G, Shields EP. Adult open heart surgery in New York State. *JAMA.* 1990;264:2768-2774.
26. Hannan EL, Kilburn H Jr, Racz M, Shields E, Chassin MR. Improving the outcomes of coronary artery bypass surgery in New York State. *JAMA.* 1994;271: 761-766.