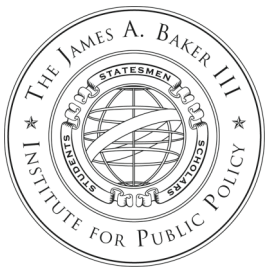

James A. Baker III Institute for Public Policy
Rice University

Cardiac CON Regulations and the Availability and Use of Revascularization Services

BY

Vivian Ho, Ph.D.
James A. Baker III Institute for Public Policy and Department of Economics, Rice University
Houston, Texas
Department of Medicine, Baylor College of Medicine
Houston, Texas

Joseph S. Ross, M.D., M.H.S.
Department of Geriatrics and Adult Development, Mount Sinai School of Medicine
New York, New York
Geriatrics Research, Education & Clinical Center, James J. Peters VA Medical Center
Bronx, New York

Brahmajee K. Nallamothu, M.D., M.P.H.
Health Services Research and Development Center of Excellence
Ann Arbor VA Medical Center
Ann Arbor, Michigan

Harlan M. Krumholz M.D., S.M.
Section of Cardiovascular Medicine and
the Robert Wood Johnson Clinical Scholars Program, Department of Medicine
New Haven, Connecticut
Section of Health Policy and Administration, Department of Epidemiology and Public Health
Yale University School of Medicine
New Haven, Connecticut
Center for Outcomes Research and Evaluation, Yale-New Haven Hospital,
New Haven, Connecticut

April 11, 2008

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This research was supported by a grant awarded to Dr. Ho by the National Heart, Lung, and Blood Institute (R01 HL073825-01A1). Dr. Ross was a scholar in the Robert Wood Johnson Clinical Scholars Program at Yale University sponsored by the Robert Wood Johnson Foundation at times during his involvement in the project. The Robert Wood Johnson Foundation had no role in the design or conduct of the study; collection, management, analysis or interpretation of the data; or preparation, review or approval of the manuscript.

ABSTRACT

Background: Many states enforce Certificate of Need (CON) regulations for cardiac procedures, but little is known about how CON affects utilization. We assessed the association between cardiac CON regulations, availability of revascularization facilities, and revascularization rates.

Methods: We determined when state cardiac CON regulations were active and obtained data for Medicare beneficiaries ages 65 and older who received coronary artery bypass graft surgery (CABG) or a percutaneous coronary intervention (PCI) between 1989 and 2002. We compared the number of hospitals performing revascularization and patient utilization in states with and without CON regulations, and in states which discontinued CON regulations during 1989-2002.

Results: Each year, the per capita number of hospitals performing CABG and PCI was higher in states without CON (3.7 per 100,000 elderly for CABG, 4.5 for PCI in 2002), compared with CON states (2.5 for CABG, 3.0 for PCI in 2002). Multivariate regressions that adjusted for market and population characteristics found no difference in CABG utilization rates between states with and without CON (p=.7). However, CON was associated with 19.2 percent fewer PCIs per 1,000 elderly (p=.01), equivalent to 322,526 fewer PCIs for 1989-2002. Among most states that discontinued CON, the number of hospitals performing PCI rose in the mid 1990s, but there were no consistent trends in the number of hospitals performing CABG or in PCIs or CABGs per capita.

Conclusions: CON restricts the number of cardiac facilities, but its effect on utilization rates may vary by procedure.

INTRODUCTION

Policy makers, healthcare providers, and payers are debating whether our healthcare system requires more competition or more regulation.(1;2) The U.S. is overwhelmed by rising numbers of uninsured citizens and escalating health care costs. Despite calls for government intervention, evidence is lacking on how several aspects of existing government regulation have affected practice.

Certificate of Need (CON) regulations are one of the government's most prominent forms of healthcare oversight and intervention over the past four decades. In 1978 the federal government introduced CON regulations for cardiac care, requiring hospitals to obtain approval from a designated state agency before building capacity for coronary revascularization services. Separate CON regulations exist for open heart surgery, which includes coronary artery bypass graft (CABG) surgery, and cardiac catheterization. Some states impose CON regulations for both diagnostic cardiac catheterization and percutaneous coronary intervention (PCI), while other states regulate PCI only. The federal law mandating CON expired in 1986, leading many states to discontinue their CON programs in the mid-1980's.(3) Although 27 states maintained CON for open heart surgery through 2002, preservation of these regulations has been hotly debated in some states.(4)

CON was first introduced in an attempt to control costs.(3;5) Regulators in the late 1950's were concerned that increasing availability of health insurance contributed to Roemer's law: a bed created is a bed used.(3) However, except for a case study of Pennsylvania's experience with CON for open-heart surgery,(6) the ability of CON to control the number of facilities performing revascularization has not been assessed. Moreover, cost control suggests that utilization of services should be lower in CON regulated states. Surprisingly, cardiac CON regulators never explicitly stated an intent to restrict overall use of revascularization, nor has the possibility of lower use of cardiac services in CON states been investigated.

This study uses data from all 50 states to examine the association of state cardiac CON

regulations with cardiovascular services, measured in terms of number of hospitals performing revascularization and the number of cardiovascular procedures performed. Prior population-based studies of cardiac CON and procedure use had data from at most two states (6;7). We also distinguish between CABG and PCI when examining the association between CON and procedure use. CABG is a major procedure that has substantial risk of morbidity and mortality, while PCI is less invasive and may be more sensitive to service availability. The potential for CON regulations to influence the use of each of these procedures may depend upon the role that these other factors play in procedure choice.

We examine states that have been with or without cardiac CON since the mid 1980's. We then examine states that discontinued CON in the mid 1990's. Thus, we are able to study the long-term effects of government intervention, as well as the experience of states that recently chose to relax the role of regulation in the healthcare sector.

METHODS

Data

We obtained data for Medicare beneficiaries ages 65 and over who received CABG surgery or PCI between 1989 and 2002. Inpatient data for 1991 through 2002 were drawn from Center for Medicare and Medicaid Services (CMS) MedPAR files, and data for 1989 and 1990 came from comparable inpatient files collected by CMS. PCI (including stents) was defined based on ICD-9-CM codes 36.0, 36.00, 36.01, 36.02, or 36.05 and CABG based on ICD-9-CM codes 36.1x in any field of the inpatient claim. Patients were counted once for both PCI and CABG if they received both during a hospital stay, but multiple occurrences of the same type of revascularization during the same hospital stay were not counted.

We computed the number of Medicare beneficiaries age 65 and over who received either CABG or PCI and the number of hospitals performing each of these procedures by state. We excluded hospitals with fewer than 3 procedures a year because of miscoding concerns. Sensitivity analyses using a cutoff of 5 or more procedures yielded virtually identical results.

We standardized our results for differences in population size across states with U.S. Census information on the population age 65 and over for each state and year between 1989 and 2002.(8) We controlled for other population and market characteristics that have been associated with revascularization rates in previous studies.(9-11) We included the percent uninsured,(12) per capita personal income,(13) the annual share of the population enrolled in an HMO (14), and smoking and obesity rates (15) by state and year. We identified states reporting risk-adjusted mortality rates for CABG and/or PCI by searching websites of state health departments and follow-up emails and phone calls. We determined the first full year that these "report cards" were available in participating states.

The American Health Planning Agency (AHPA) surveys state regulatory agencies to obtain information on state CON programs and health planning activities. This information is has been analyzed in previous cardiac CON studies(4;16) However, the survey lacks detailed data on cardiac CON extending back to expiration of federal CON regulations in 1986. We contracted with the AHPA to collect a detailed history of cardiac CON regulations.

The AHPA surveyed states in the first quarter of 2005 and determined whether cardiac CON rules were in place, and if not, when they were removed. We grouped states according to whether they maintained cardiac CON through 2002 for either PCI or open heart surgery (continuous CON states), states that had dropped cardiac CON for either procedure prior to the beginning of our sample period in 1989 (states without CON), and states that dropped CON between 1989 and 2002 (discontinued CON states). States with CON regulation for PCI only, or for both PCI and diagnostic catheterization were classified as states with PCI CON regulations.

Analysis

For both CABG and PCI, we computed the number of hospitals in each state and year

performing 3 or more of each procedure per 100,000 residents 65 years or older. We also computed the number of Medicare beneficiaries receiving each procedure per 1,000 residents 65 years or older by state and year. We graphed these rates for continuous CON states and states without CON.

We graph the experience of each individual state that discontinued CON during the sample period and perform qualitative comparisons. The number of states that discontinued CON during the sample period is too small to make summary statistics reliable. Missouri did not drop open heart surgery CON until the end of the sample period (2002) and is thus excluded from the figures.

We used multivariate regression analyses to examine revascularization rates and availability of hospitals, controlling for differences in population and market characteristics across states. The CON indicator variable in the regressions provides the adjusted difference in the number of hospitals or procedures per capita in CON versus non-CON states. Discontinued CON states were classified as CON states in the regressions for the years when CON was active. An indicator variable for years and states with report cards was included in the utilization regressions, but not the facility regressions. Almost all states introduced report cards recently, and thus they were unlikely to affect the number of hospitals during the sample period.

We used the natural log of the number of patients per 1,000 population receiving CABG or PCI in each state and year as the dependent variable to control for skewness in the distribution of revascularization rates. The coefficients for these regressions therefore measure percentage differences.(17) State per capita income and smoking rates were excluded from the final regressions, because preliminary analysis revealed that these variables added little explanatory power beyond the other explanatory variables. All regressions were estimated with Stata 9.0 and included indicator variables for each sample year. We applied Stata's robust option to obtain heteroskedasticity-robust standard errors. We also specified the cluster option to account for the correlation of observations across years within states.

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

RESULTS

Our sample contained 2,254,685 CABGs and 2,685,500 PCIs performed between 1989 and 2002. Figure I categorizes states according to their CON status during our sample period. If a state had removed cardiac CON regulations, the figure lists the year in which this event occurred. Altogether 26 states maintained continuous CON for CABG, and 27 states maintained continuous CON for PCI. Prior to 1989, 16 states had dropped cardiac CON and were therefore without CON regulations during the sample period. Between 1989 and 2002, 8 states discontinued CON for open heart surgery, and 7 states discontinued CON for PCI.

Continuous CON versus non-CON

Figure II shows the number of hospitals by CON status performing CABG procedures on Medicare beneficiaries per 100,000 persons age 65 and older. In 1989, continuous CON states had fewer CABG hospitals per capita than states without CON (2.2 versus 3.5 hospitals per 100,000; $p<.001$). This pattern persisted throughout the entire sample period. By 2002, continuous CON states had 2.5 CABG hospitals, versus 3.7 hospitals per 100,000 population in states without CON ($p=.002$).

Figure III provides information for PCI procedures. Like the results for CABG, continuous CON states had fewer PCI hospitals per capita in 1989 than states without CON (2.3 versus 3.7 hospitals per 100,000; $p=.001$). This pattern persisted throughout the sample period. By 2002, continuous CON states had 3.0 PCI hospitals per 100,000 population as compared with 4.5 PCI hospitals per 100,000 population in states without CON ($p=.004$).

Figure IV shows that rates of CABG procedures among Medicare beneficiaries per 1,000 elderly were similar for continuous CON and non-CON states throughout the sample period. The rate of CABG per 1,000 elderly in CON versus non-CON states in 1989 was 3.4 versus 3.6 ($p=0.6$). CABG utilization rose for both CON and non-CON states through 1996 and declined

through 2002. By the end of the sample period, CABG rates in continuous CON and states non-CON states were 4.8 versus 4.5 respectively (p=0.8).

Figure V compares rates of PCI procedures among Medicare beneficiaries per 1000 residents age 65+ by CON status. In 1989, the number of PCIs per 1000 elderly persons was lower in continuous CON states than in non-CON states (2.1 vs. 2.8; p=0.01). By 2002, PCI rates had risen substantially in all states. However, the difference in the number of PCIs per 1000 elderly persons was no longer statistically significant between continuous CON states and non-CON states (8.5 versus 9.3, p=0.3).

The results in Column I of Table I indicate that, after adjustment for potential confounders, states with open heart surgery CON had 1.2 fewer hospitals performing CABG per 100,000 elderly residents when compared with states without CON (p<.001). Similarly, states that enforced PCI CON had 1.3 fewer hospitals per 100,000 elderly residents performing PCI than states without CON (p<.001). We found no association between open heart surgery CON and the number of CABGs per capita performed in a state (p=.7) However, states with PCI CON had 19.2 percent fewer Medicare patients per 1,000 elderly residents receiving PCI each year relative to states without CON (p=.01). Based on these regression estimates, states with CON had 322,526 fewer PCIs between 1989 and 2002 than if their utilization had been similar to non-CON states.

Discontinued CON

Figures II through V show the experience of each state that discontinued CON. A vertical line indicates the year of CON repeal. For Ohio and Pennsylvania, the rate of increase in the number of hospitals per capita performing CABG rose after CON repeal. However, no such pattern appears for the other 5 states.

For those states that dropped CON for PCI during the sample period, there is some indication that lifting of CON coincided with a relative increase in the availability of hospitals

performing PCI. For Pennsylvania and Nebraska, the rate of increase in the number of PCI hospitals per capita appears to rise when CON was lifted. This increase appears 2 years prior to the lifting of CON in Ohio. Nevada's availability of PCI hospitals per capita was declining until 1995 when CON was lifted; after which the number of PCI hospitals began to increase.

CABG utilization differed across states that dropped CON for open heart surgery during the sample period, even though these states dropped the regulations within a relatively narrow time frame (between 1995 and 1998). After the 7 states discontinued CON, patterns varied from sharp to moderate dropoffs, to no change, and even an increase for one state in CABG rates. There also was no systematic trend in PCI utilization rates for states that dropped CON for PCI during the sample period. Utilization rates rose for all 6 states. However, the growth in utilization rates for PCI appeared to slow for some states, yet remained constant or increased in other states.

DISCUSSION

We found that the presence of continuous CON regulations was associated with fewer hospitals per capita performing CABG and PCI. Continuous CON and non-CON states had similar utilization rates for CABG in the elderly population. However, multivariate regressions indicated that the presence of CON regulations was associated with 19.2 percent fewer PCIs per 1,000 elderly in the population, which translated to 322,526 fewer PCIs between 1989 and 2002.

Past studies of cardiac CON have examined either CABG or PCI alone, or the combined event of revascularization.(6;7;16;18) In contrast, we distinguish between CABG and PCI procedures, and we find important differences in trends for CON and non-CON states for these two interventions. Prior population-based studies of cardiac CON and procedure use had data from two states at most (6;7) Our findings are consistent with a case study of Pennsylvania, where the number of open-heart surgery programs rose 25%, but there was no significant

increase in the number of CABGs performed after it lifted CON in 1996.(6) However, we find that the Pennsylvania case study does not generalize to all states that discontinued CON in the 1990's, and that the experience of states that discontinued CON in the last decade differs from those states that maintained CON for this entire time period.

Our findings are also consistent with a recent study that found greater revascularization rates for AMI patients in non-CON versus CON states, and indirect evidence of fewer facilities performing revascularization in CON states.(4) Our study differs, in that we directly compare the number of providers performing revascularization by CON status, because regulators explicitly aimed to control facility numbers. We go beyond past research by performing a population-based study. Although regulators did not express an intent to control the total number of procedures performed, it is crucial for patient welfare that we understand whether CON regulations are associated with differential revascularization rates in the population.

Why was CON associated with fewer PCIs per capita, but not fewer CABGs? We suggest two hypotheses. First, CABG is a major procedure that has substantial risk of morbidity and mortality. It may be that the greater availability of hospitals in non-CON states exerts only a small effect on the use of this procedure. Prior studies have shown that within hospital referral regions there is a strong association between supply of services and utilization,(19) but the magnitude of difference by CON status may not have been sufficient to create a gradient in CABG use. In contrast, PCI is a much less invasive procedure that may be more sensitive to service availability. Fewer PCI facilities in CON states may have deterred some physicians from recommending a procedure which influences quality of life more than survival.(20)

Second, we documented the rapid growth in PCI during the 1990's, relative to slower growth and the eventual decline in CABG rates over this same period. There may be a limit to the speed at which individual PCI facilities can increase capacity. Therefore, the lower number of PCI facilities in CON states may have prevented the rapid increase in the use of this procedure that more plentiful facilities in non-CON states could achieve. In contrast, the slower

growth and eventual dropoff in use of CABG may have been more easily accommodated in CON states.

The seven states with discontinued CON dropped cardiac CON in the mid 1990's, so that we could compare several years of experience both before and after CON regulations were dropped. States that dropped CON during the sample period experienced differing changes in the number of facilities and revascularizations per capita, so that they remained different from states that were continuously without cardiac CON. For these states, there is some indication that lifting CON coincided with a relative increase in the availability of hospitals performing PCI, although there were no systematic trends in utilization rates of either PCI or CABG.

The discontinued CON states may have differed in the strictness of their CON regulations. The states may have also differed in the availability of interventional cardiologists who perform PCI, or in the potential financial gains to hospitals of opening new facilities. Some states may have faced pressure to lift CON from potential new providers, while other states may have discontinued the regulations after noting an absence of interest from potential providers. With only seven states and a wide range of factors potentially influencing the number of providers and procedures, further qualitative analysis of the experience of discontinued CON states would be beneficial.

How successful have CON regulations been in controlling the use of costly cardiac interventions? Both open heart surgery facilities and cardiac catheterization labs require substantial investment in capital and equipment, so that fewer facilities in CON states implies lower fixed costs per capita for revascularization. In addition, because CABG rates were similar in CON and non-CON states, average CABG volume was higher in hospitals in CON states. The fixed costs of CABG were therefore spread over more patients, so that the average cost per patient in CON states should be lower.

The results in this study should be interpreted in the context of the following limitations. The associations between CON regulation and revascularization services in this study can

suggest, but cannot prove a causal effect of CON on the delivery of cardiac care. It is possible that factors other than CON may explain the observed differences in availability and use of revascularization identified in this study. However, the multivariate regressions controlled for a range of health and market-related factors.

The descriptive statistics indicated lower PCI utilization in CON versus non-CON states in 1989, although this difference became statistically indistinguishable by 2002. Therefore, the association between CON and lower PCI use in the multivariable model may be driven largely by pre-2002 data. However, we interacted CON status with each year indicator in a sensitivity analysis and could not reject the hypothesis that the association between PCI utilization and CON status was constant through the sample period ($p=0.15$).

We lack information on the prevalence of diabetes, hypertension, and hypercholesterolemia, all of which may influence the need for revascularization. No existing database contains information on these variables by state for our study period. However, past research finds no association between cardiac revascularization and admission rates for AMI for Medicare patients across different parts of the United States.(19) These findings suggest that heart disease risk factors are not the principal cause of variability in PCI rates between CON and non-CON states.

We did not compare patient outcomes or procedure appropriateness in CON and non-CON states. One study found that CON was associated with lower mortality rates for CABG (16), but a later study using more detailed clinical data and controls for regional confounding found no such effect (18). Lower revascularization rates among AMI patients have been identified in CON states compared with states without CON, but 30-day mortality rates were the same.(4) A recent study also found that CON was associated with lower rates of equivocally and weakly indicated cardiac catheterization after admission for AMI.(21) These studies suggest that lower PCI use in CON states identified in this study may represent reduced provision of procedures that have little marginal benefit.

We performed our analysis over a time period when PCI was increasingly used as a substitute for CABG (22). There may be concern that our results are attributable to this substitution effect rather than an association with CON. All cardiac CON states in our sample except Delaware maintained regulation of both CABG and PCI simultaneously. Therefore, the differences between CON and non-CON states that we identified are not likely to result from an overall substitution away from CABG and towards PCI. All states with cardiac CON also have acute care CON regulations, which likely limit the number of acute care hospitals. Thus, the association between cardiac CON regulations and number of facilities may in part be due to the presence of acute care CON regulations.

States with cardiac CON may differ in their enforcement, and states without cardiac CON may regulate cardiac procedures through other means. Delaware and Missouri have cardiac CON, but the law as written makes the regulations relatively ineffective. Ohio and Pennsylvania eliminated CON, but they still regulate PCI and open heart surgery under licensing programs. We conducted a sensitivity analysis reclassifying Delaware and Missouri as states without CON, and Ohio and Pennsylvania as continuous CON. The regression estimates are very similar in both magnitude and precision.

Despite these caveats, the results have important policy implications for the ongoing debate regarding the benefits of regulation for cost control. Past research has concluded that CON has been unsuccessful in controlling aggregate healthcare costs.(3;5) Our analysis of CON regulations suggests that these effects may vary across cardiac procedures. CON regulators focused on whether or not new facilities should be allowed to open, which is a crude method of cost control.

Neither do our results suggest that unconstrained competition aids in cost control. The number of facilities and utilization of revascularization in states without CON was always greater than or equal to that observed in states with CON. States that removed cardiac CON during the sample period did not experience a decline in revascularization rates, and the number of PCI

facilities appeared to rise.

These results suggest that future efforts to control costs should consider both capital investment and service utilization. Hospital quality reports are now available,(11) and these data could be used by future CON regulators to directly monitor quality in addition to access and utilization. Regulators should also consider the treatment appropriateness and the potential effect of regulations on patient outcomes. Ideally future regulatory efforts would be accompanied by evaluations that allow us to learn from these actions and generate evidence to refine our policy interventions. Policy makers may conclude that one cannot effectively regulate costs, treatment appropriateness, and patient outcomes simultaneously. However, future attempts to identify optimal regulations are imperative for improving patient welfare.

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Table I. Regression Estimates of Determinants of Hospitals per Capita and Procedures per Capita for CABG and PCI*

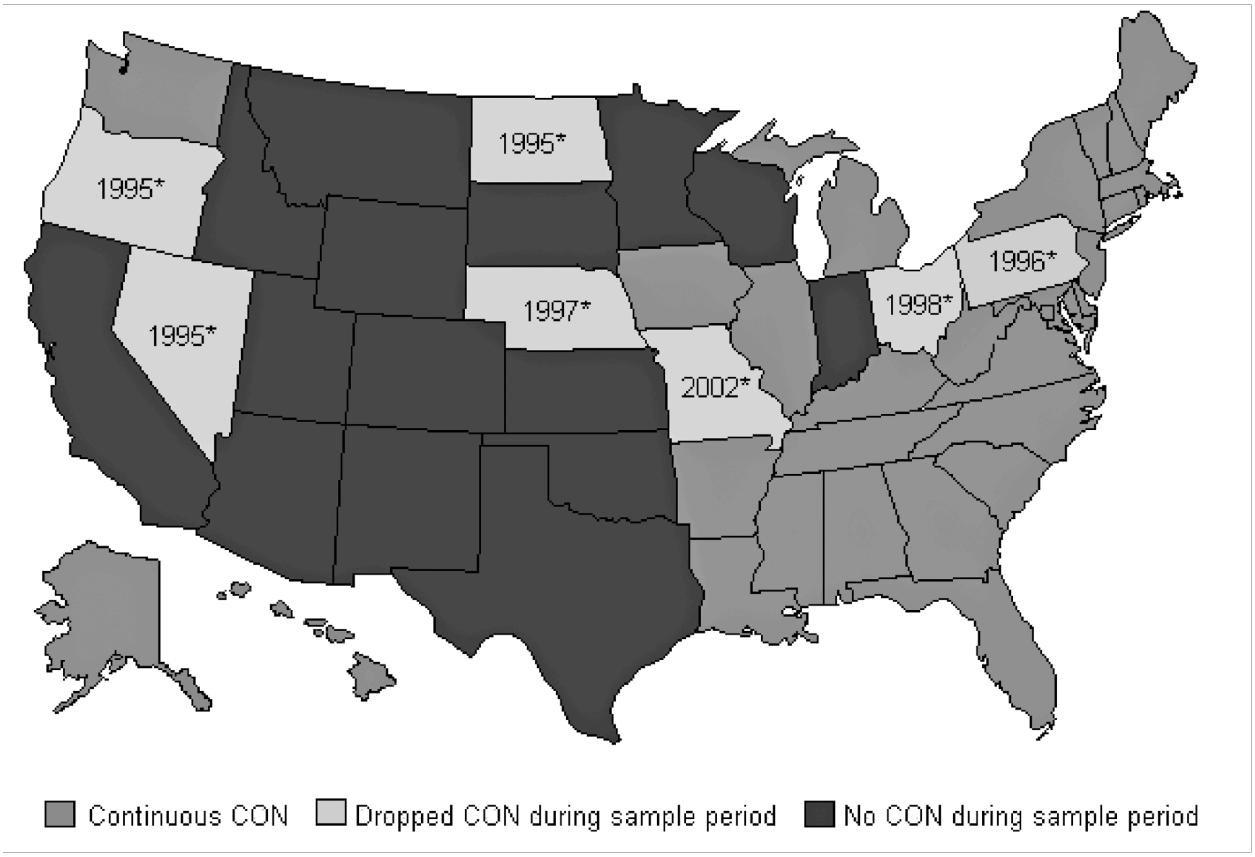
	CABG				PCI			
	Hospitals per Capita		ln(CABGs per Capita)		Hospitals per Capita		ln(PCIs per Capita)	
	Coef†	CI‡	Coef†	CI‡	Coef†	CI‡	Coef†	CI‡
CON in force	-1.194	(-1.762– -0.626)	-0.025	(-0.152– 0.101)	-1.313	(-1.976– -0.650)	-0.192	(-0.343– -0.041)
Report Card	–	–	-0.073	(-0.182– 0.035)	–	–	-0.110	(-0.266– 0.045)
uninsured %	0.015	(-0.050– 0.079)	-0.016	(-0.030– -0.002)	0.004	(-0.066– 0.074)	-0.011	(-0.026– 0.003)
HMO penetration rate	-0.028	(-0.057– 0.002)	-0.004	(-0.010– 0.003)	-0.029	(-0.059– 0.001)	-0.005	(-0.012– 0.003)
Obesity rate	0.118	(-0.004– 0.239)	0.037	(0.014– 0.061)	0.105	(-0.025– 0.236)	0.033	(0.005– 0.060)
constant	2.307	(0.298– 4.315)	1.116	(0.703– 1.529)	2.852	(0.691– 5.013)	0.781	(0.325– 1.238)

* *Regressions include indicator variables for each sample year.*

† *Coef = Coefficient*

‡ *CI = Confidence Interval*

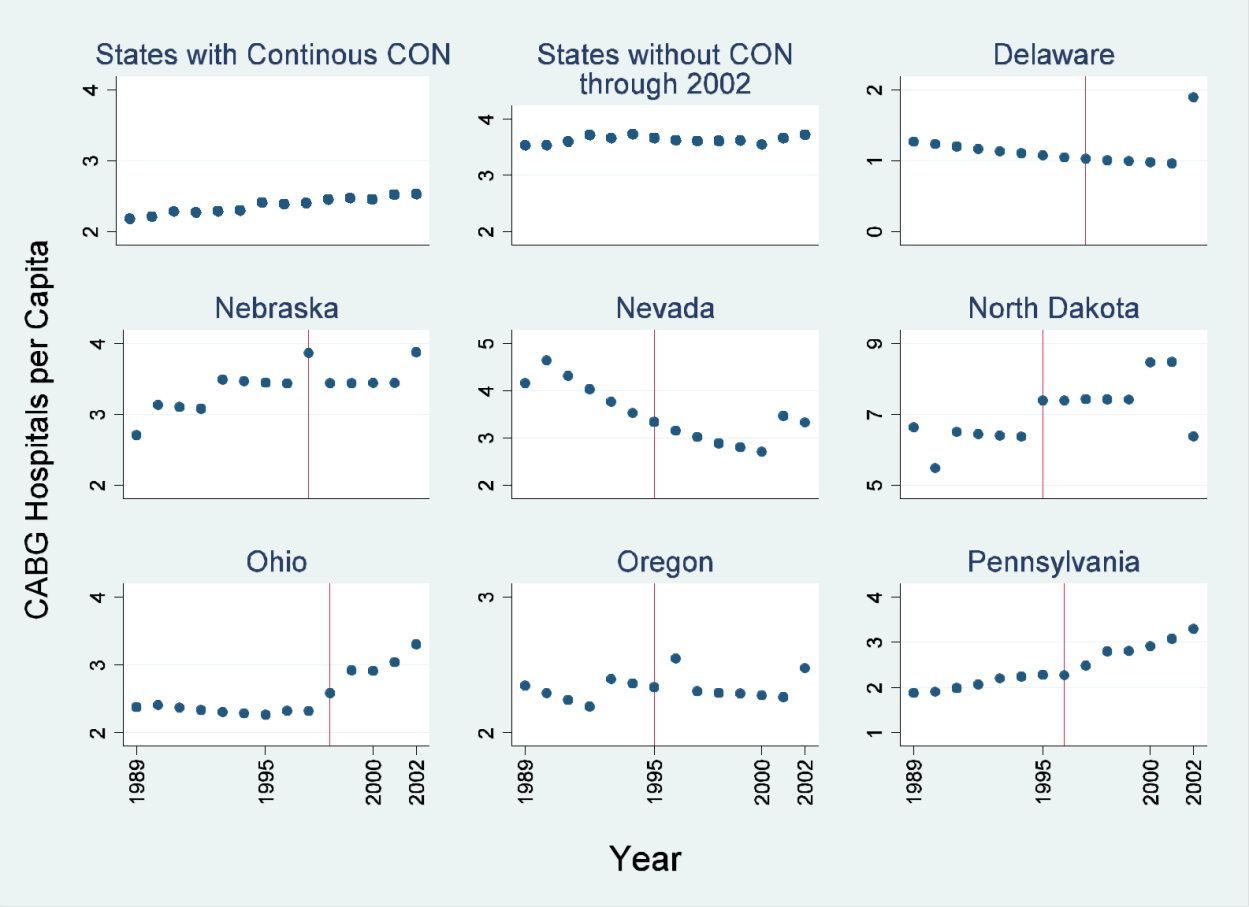
Figure I. Status of Cardiovascular CON Regulation during Sample Period 1989-2002



* Year cardiac CON was removed

† Delaware had cardiac CON for percutaneous coronary intervention only.

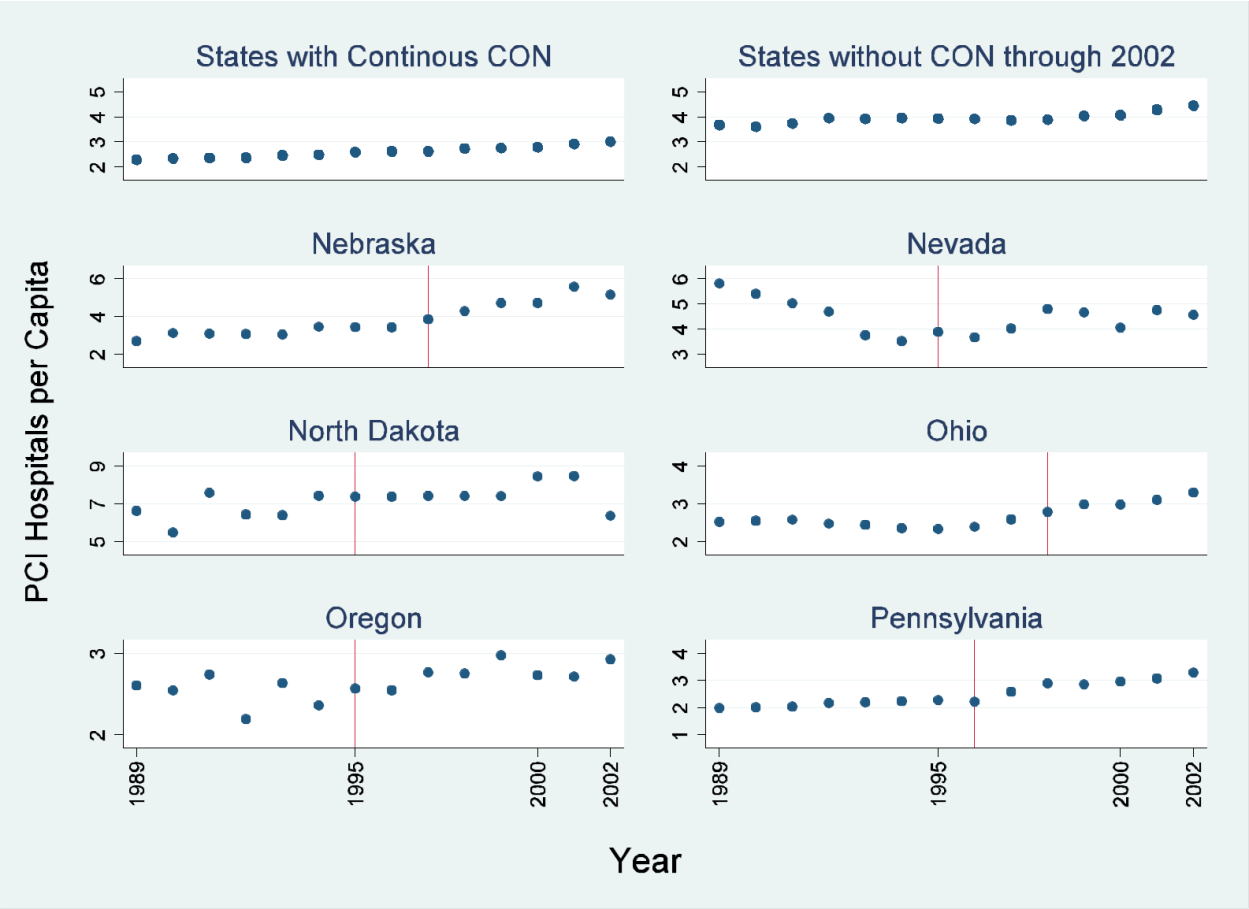
Figure II. Number of Hospitals per Capita* Performing 3 or more CABGs per year, by CON Status†



* per Capita = per 100,000 residents age 65+.

† Mean values for states with continuous CON versus states without CON from 1989 to 2002. Vertical lines indicate when states dropped CON.

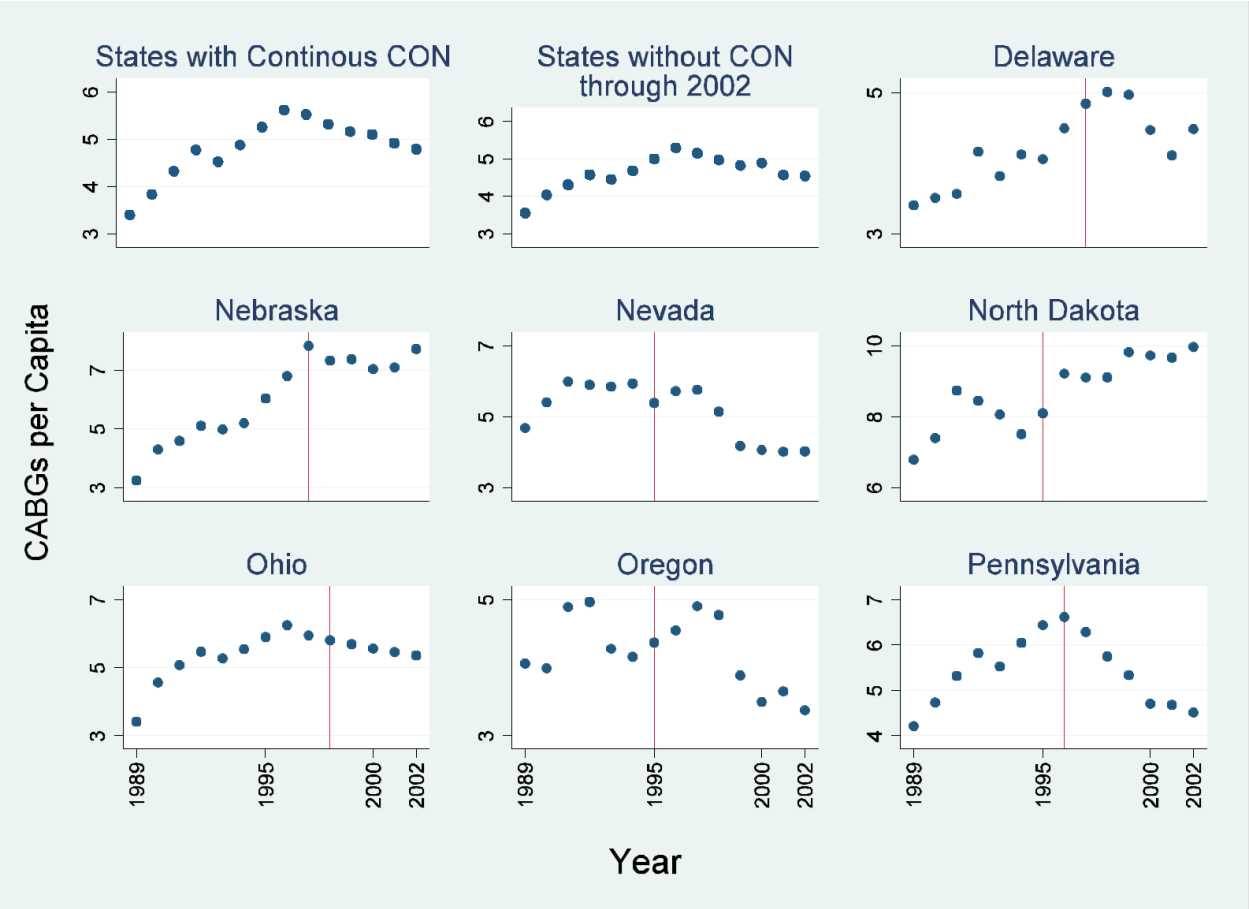
Figure III. Number of Hospitals per Capita* Performing 3 or more PCIs per year, by CON Status†



* per Capita = per 100,000 residents age 65+.

† Mean values for states with continuous CON versus states without CON from 1989 to 2002. Vertical lines indicate when states dropped CON.

Figure IV. Number of CABG procedures per Capita[*], by CON Status[†]

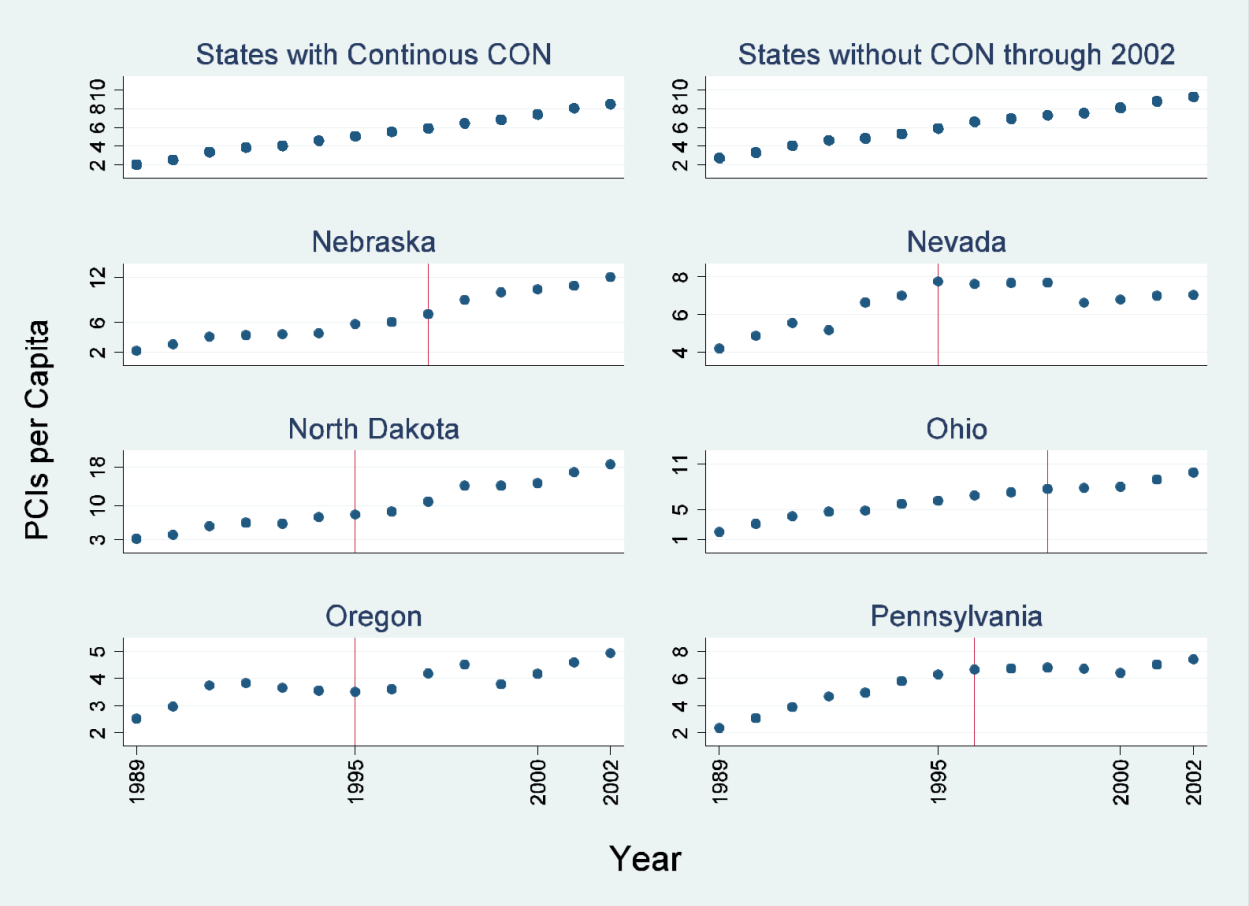


[*] per Capita = per 100,000 residents age 65+.

[†] Mean values for states with continuous CON versus states without CON from 1989 to 2002.

Vertical lines indicate when states dropped CON.

Figure V. Number of PCI procedures per Capita*, by CON Status†



* per Capita = per 100,000 residents age 65+.

† Mean values for states with continuous CON versus states without CON from 1989 to 2002. Vertical lines indicate when states dropped CON.