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Presents

“Certificate of Need for Cardiac Care”

by

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“Certificate of NEED (CON) for Cardiac Care: Controversy over the Contributions of CON?”
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Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON

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Objectives. To test whether state Certificate of Need (CON) regulations influence procedural mortality or the provision of coronary artery bypass graft surgery (CABG) and percutaneous coronary interventions (PCI).

Data Sources. Medicare inpatient claims obtained for 1989–2002 for patients age 65+ who received CABG or PCI.

Study Design. We used differences-in-differences regression analysis to compare states that dropped CON during the sample period with states that kept the regulations. We examined procedural mortality, the number of hospitals in the state performing CABG or PCI, mean hospital volume, and statewide procedure volume for CABG and PCI.

Principal Findings. States that dropped CON experienced lower CABG mortality rates relative to states that kept CON, although the differential is not permanent. No such mortality difference is found for PCI. Dropping CON is associated with more providers statewide and lower mean hospital volume for both CABG and PCI. However, statewide procedure counts remain the same.

Conclusions. We find no evidence that CON regulations are associated with higher quality CABG or PCI. Future research should examine whether the greater number of hospitals performing revascularization after CON removal raises expenditures due to the building of more facilities, or lowers expenditures due to enhanced price competition.

Key Words. Certificate of need, CABG, PCI, panel data methods

Policy makers and providers seek to insure provision of high-quality health care while restraining cost growth. Many states pursue these two goals by enforcing Certificate of Need (CON) regulations, which require hospitals to obtain approval from a designated state agency before installing additional capacity or offering especially costly services. Federal law required that all states maintain CON for cardiac care in 1978. These regulations expired in 1986, leading many states to discontinue cardiac CON in the mid-1980s.
This study tests whether presence of cardiac CON regulations is associated with lower mortality or differences in the number of cardiac procedures performed in a state. Past studies reached conflicting conclusions on the effects of cardiac CON. A study by Vaughan-Sarrazin et al. (VS) found that the risk-adjusted odds of death for Medicare patients who received coronary artery bypass graft surgery (CABG) between 1994 and 1999 was 22 percent higher in states without CON for open heart surgery versus states with CON ($p < .001$) (Vaughan-Sarrazin et al. 2002). The authors hypothesize that CON restricts the number of health care providers, leading to higher hospital procedure volume. Higher CABG volume has been associated with lower mortality rates in previous studies (Showstack et al. 1987; Hannan et al. 1989).

In contrast, an analysis by DiSesa et al. (DS) using cardiac registry data from 2000 to 2003 found no significant difference in risk-adjusted mortality for CABG patients in states with and without CON (DiSesa et al. 2006). Another study by Ho using hospital discharge abstracts for 1989–2000 from the Nationwide Inpatient Sample collected by AHRQ HCUP found a significant association between inpatient mortality and CON status for CABG, but the magnitude of the effect was much smaller than that identified by VS (Ho 2007).

The analyses conducted by VS and DS attribute any unexplained difference in risk-adjusted mortality between states with and without CON to the impact of the regulations. However, the differential may be due to state-level factors that influence outcomes through mechanisms unrelated to CON (DiSesa et al. 2006). DS conduct subanalyses adding state random effects to the regressions, which account for some unobserved heterogeneity, but not all types. Ho reduces concerns regarding state-level heterogeneity by estimating fixed effect regressions, which allow one to measure within-hospital changes in mortality associated with each year after which cardiac CON regulations were removed in a state. However, Ho’s estimates mix mortality changes for states that dropped CON in the mid-1980s with those of states that dropped cardiac CON regulations more recently. If technology for cardiac surgery has improved over time, then the blending of mortality changes that resulted after
CON removal, but along different points of the technology continuum, may yield misleading results.

This paper compares the experience within states, before and after removal of cardiac CON regulations, yielding an estimate of the effects of CON, which is less subject to between-state heterogeneity concerns. We compare changes in patient mortality and the delivery of CABG and percutaneous coronary interventions (PCI) over time for states that dropped CON with states that maintained CON throughout the sample period. In doing so, we are better able to control for changes in patient mortality, which are contemporaneous with the removal of CON but unrelated to the regulations. By limiting the analysis to states that dropped cardiac CON most recently, we avoid concerns regarding the blending of estimates of the effects of CON regulations from different time periods. The results have important implications for regulators, who are concerned about the advantages and disadvantages of CON regulation.

**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.

For patient-level analyses, the outcome variable of interest was procedural mortality for CABG or PCI (death during the same hospitalization as revascularization, or after discharge but within 30 days of surgery; Likosky et al. 2006). For state-level analyses, the outcome variables of interest were the number of facilities, the average hospital procedure volume, and the total number of CABG or PCI procedures performed on Medicare beneficiaries in a given state and year.

The explanatory variable of interest was the removal of state CON regulations for cardiac care. Information on CON status for open-heart
surgery and PCI were obtained from a survey of state health departments conducted by the American Health Planning Agency (AHPA). The details and results of the survey have been described elsewhere (Ho et al. 2007). We grouped states according to whether they maintained cardiac CON through 2002 for either PCI or open-heart surgery, versus states that dropped CON between 1989 and 2002. Seven states dropped CON for open-heart surgery during the sample period. Of these seven, six simultaneously dropped CON for cardiac catheterization. The seventh state, Delaware, did not have CON regulations for PCI during the study period. These states were compared with the 27 states that maintained CON for open-heart surgery and the 25 states that maintained CON for PCI through 2002.

We excluded data for patients treated in states that dropped cardiac CON regulations before 1989. We only have information on these states’ experiences after CON regulations were dropped, not before, which is necessary for within-state comparisons. For this same reason, we excluded data from Maryland and Massachusetts in the analysis of PCI patients. These two states dropped CON for cardiac catheterization in 1990 (while maintaining CON for open heart surgery), so that there was relatively little data for the period before removal of CON.

The number of CABG or PCI procedures performed by the admitting hospital during the year the patient was treated was included as an explanatory variable in the patient-level regressions. We excluded patients treated in hospitals with <3 procedures a year because of miscoding concerns. The studies by VS and DS excluded procedure volume, reasoning that CON influenced patient outcomes by raising average hospital volume. This analysis reports results with and without hospital volume, so that one can test whether an association exists between CON and procedural mortality even after adjusting for volume.

Several variables were included in the patient-level regressions for risk adjustment. The demographic variables included sex, age (in 5-year categories), race (black/white/other), and income. The patient’s zip code of residence was used to identify the median household income as reported in the U.S. Census. Census data from 1990 and 2000 were used to extrapolate income for each year and zip code in the sample, which were then adjusted for inflation using the Bureau of Labor Statistics All Urban Consumer Price index. The secondary diagnosis codes were used to construct indicator variables for the 29 conditions comprising the Elixhauser comorbidity index (Elixhauser et al. 1998). Indicator variables were included for patients with a primary diagnosis of acute myocardial infarction (AMI) at admission, patients transferred from
another hospital, and patients whose admission status was urgent or emergent. For CABG patients, indicator variables were included for patients who received cardiac catheterization or PCI on the same day as the CABG procedure, or received an intra-aortic balloon pump before the day of the CABG procedure. For PCI patients, indicator variables were included for multivessel PCI and coronary stent insertion.

The Medicare data were merged with the American Hospital Association Annual Surveys, which contain additional hospital-level information. Hospitals affiliated with a medical school were defined as teaching hospitals. Hospitals located in a Metropolitan Statistical Area were categorized as urban (versus rural). Hospitals were classified as nonprofit, government, or for-profit facilities.

Following previous research, regressions explaining average hospital volume for CABG and PCI included controls for the population age 65+ per square mile and the HMO penetration rate in the hospital’s county of operation in each year, and smoking rates by state and year (Ho 2007). The state-level regressions included controls for population and market characteristics that have been associated with revascularization rates in previous studies (Ayanian and Epstein 1991; Heidenreich et al. 2002). We collected information on the percent uninsured (U.S. Census Bureau 2006), the annual share of the population enrolled in an HMO (National Center for Health Statistics 2004), and smoking rates by state and year (CDC 2006).

Statistical Analysis

Mean hospital procedure volumes and procedural mortality rates for CABG and PCI by year and whether states maintained cardiac CON or dropped the regulations during the sample period are graphed to illustrate unadjusted differences in the data by CON status. Multivariable logistic regressions are used to estimate the association between CON status and procedural mortality, average procedure volume, the number of providers in the state, and the total number of procedures in the state, adjusting for covariates. Separate regressions were estimated for CABG and PCI.

Similar to VS and DS, we measured CON using a 0,1 indicator for presence or absence of CON in the year the patient was treated. But unlike these studies, we only include data from states that dropped CON during the sample period or maintained CON through the end of the sample. In doing so, we obtain a direct comparison of trends in states that dropped cardiac CON regulations versus states that maintained CON. This specification is known as
a differences-in-differences analysis in the economics literature. The first “dif-
ference” is a before-versus-after comparison of states that dropped CON dur-
ing the sample period. The second “difference” is the contemporaneous
experience of states that maintained CON, which serves as a control group for
factors unrelated to CON that influenced outcomes in all states. Unlike VS and
DS, the regressions also include state-level fixed effects. Therefore, the coef-
ficient on the CON variable provides a within-state measurement of the as-
sociation between dropping CON and the dependent variables of interest.

To test whether the effects of dropping CON change over time, we
estimate additional regressions where we interact the CON variable with
indicator variables for whether a patient was treated in a state 1 year before
CON was dropped, the year CON was dropped, 1 year after, 2 years after, or 3
or more years after CON was dropped. Testing for an effect the year before
CON regulations are dropped serves as a consistency check. We should find
no significant association between dropping CON and outcomes the year
before the regulations are dropped. If the effects of CON are still statistically
significant at the 95 percent confidence level 3+ years after cardiac CON
regulations were dropped, we continue to add interaction variables 1 year at a
time, until we find no significant effect, or we reach the end of the sample
period.

The regressions are estimated in Stata 10.0. The procedural mortality
regressions are estimated using the glm command, which allows one to es-
timate a logistic model. The hospital and state procedure volume regressions
were estimated using the xtreg command, which estimates linear panel data
models. The regressions explaining the number of hospitals performing each
procedure were estimated with the nbreg command, which estimates negative
binomial regressions for nonnegative count data. The coefficients from the
nbreg command are transformed so that they can be interpreted as the per-
centage change in the number of facilities associated with the dropping of
CON. All of these regressions include state-level fixed effects and adjust the
standard errors to account for the clustering of patients within hospitals for
the patient-level regressions and within state for the hospital- and state-level
regressions (Wooldridge 2003). Fixed effects estimates were obtained by
including dummy variables for each state in the glm and nbreg regressions.

To improve the efficiency of the standard errors for our estimates, we
excluded indicator variables for the components of the Elixhauser comor-
bidity index that had low explanatory power for procedural mortality. Co-
morbidities with a $p$-value $> .05$ in an OLS regression of procedural mortality
on the full set of 29 comorbidities were excluded from the fixed effect esti-
mates. For both CABG and PCI, the indicators for HIV and AIDS, alcohol abuse, drug abuse, and chronic peptic ulcer disease were excluded. The indicators for blood loss anemia, complicated hypertension, hypothyroidism, lymphoma, and solid tumor without metastasis were dropped for CABG as well. The indicator for depression was dropped for PCI.

RESULTS

The sample contained data on 1,580,186 CABG and 1,730,733 PCI procedures from 1989 to 2002. Figure 1 graphs the mean procedure volume and mean procedural mortality rates for CABG and PCI for states that maintained cardiac CON regulations through 2002, and for those states that dropped the regulations during the study period. The seven states that dropped CON (DE, ND, NE, NV, OH, OR, and PA) did so within a narrow time frame, between 1995 and 1998.

For both CABG and PCI, mean hospital volume peaks in 1996 for states that dropped cardiac CON regulations between 1995 and 1998. For both procedures, mean hospital volume in 1998 for these states falls below that for states that maintained CON; and remains lower through 2002. Previous
literature on the volume–outcome relationship for cardiac procedures would suggest that these declines in mean procedure volume would be associated with increases in patient mortality. However, states that dropped cardiac CON between 1995 and 1998 appear to have higher or equal unadjusted CABG mortality relative to states that maintained CON through 1994; but lower unadjusted CABG mortality relative to CON states in 1995 through 2002. For the most part, there appears to be no such systematic difference in mortality rates by CON status for PCI. These unadjusted data require more detailed examination in the context of regression analyses.

Table 1 presents estimates of the association between CON status and procedural mortality for CABG and PCI. Column 1 indicates that removal of CON is associated with significantly lower mortality for CABG (OR = 0.898, \( p < .001 \)). When we examine the effects of dropping CON by year in Column 2, we find no tangible association with procedural mortality in the year before dropping CON, or the year when CON was dropped. The significant association between dropping CON and mortality is in the years 1 (OR = 0.928, \( p = .03 \)), 2 (OR = 0.855, \( p = .003 \)), and 3 or more years (OR = 0.887, \( p = .003 \)) after removal of the regulations. When we add additional 1-year interaction terms, we find in Column 3 that the association between CON removal and procedural mortality for CABG patients becomes insignificant 5 or more years out (OR = 0.918, \( p = .08 \)). Although we do not report the results here, adding an additional interaction term 6 or more years beyond CON removal yields an even less precise association between dropping CON and mortality (OR = 0.915, \( p = .22 \)).

Columns 4 and 5 of Table 1 suggest no association between removal of cardiac CON regulations and procedural mortality for PCI. All of the specifications in Table 1 suggest a significant association between hospital procedure volume and procedural mortality. In each case the odds ratio lies between 0.999 and 1.0, and the \( p \)-values are well under 0.05. We re-estimated all of the regressions in Table 1 excluding hospital procedure volume, to test whether the beneficial volume effect would lead to a positive association between CON removal and procedural mortality. In each case, the coefficient estimates and \( p \)-values changed only slightly, and the conclusions regarding the effects of dropping CON remained the same.

Column 1 of Table 2 indicates the removal of CON is associated with 31 percent lower mean hospital volume for CABG (\( p = .009 \)). Column 2 suggests that the drop in procedure volume begins the year that CON is removed (−13 percent, \( p = .03 \)). The magnitude of the drop increases in each subsequent year, reaching 37 percent (\( p = .008 \)) for 3 years or more beyond the removal of
Table 1: Logistic Estimates of the Association between CON and Procedural Mortality for CABG and PCI

<table>
<thead>
<tr>
<th></th>
<th>CABG</th>
<th>PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1)</td>
<td>(2)</td>
</tr>
<tr>
<td>After CON dropped</td>
<td>0.898**</td>
<td>0.964</td>
</tr>
<tr>
<td></td>
<td>(0.848, 0.950)</td>
<td>(0.881, 1.054)</td>
</tr>
<tr>
<td>1 year before CON dropped</td>
<td>0.964</td>
<td>0.964</td>
</tr>
<tr>
<td></td>
<td>(0.881, 1.055)</td>
<td>(0.881, 1.055)</td>
</tr>
<tr>
<td>Year CON dropped</td>
<td>0.980</td>
<td>0.980</td>
</tr>
<tr>
<td></td>
<td>(0.902, 1.064)</td>
<td>(0.903, 1.064)</td>
</tr>
<tr>
<td>1 year after CON dropped</td>
<td>0.928*</td>
<td>0.928*</td>
</tr>
<tr>
<td></td>
<td>(0.869, 0.990)</td>
<td>(0.869, 0.990)</td>
</tr>
<tr>
<td>2 years after CON dropped</td>
<td>0.855**</td>
<td>0.855**</td>
</tr>
<tr>
<td></td>
<td>(0.771, 0.949)</td>
<td>(0.770, 0.950)</td>
</tr>
<tr>
<td>3+ years after CON dropped</td>
<td>0.887**</td>
<td>0.887**</td>
</tr>
<tr>
<td></td>
<td>(0.820, 0.960)</td>
<td>(0.820, 0.960)</td>
</tr>
<tr>
<td>3 years after CON dropped</td>
<td>0.864**</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.810, 0.921)</td>
<td>(0.782, 0.983)</td>
</tr>
<tr>
<td>4 years after CON dropped</td>
<td>0.877*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.782, 0.983)</td>
<td>(0.836, 1.009)</td>
</tr>
<tr>
<td>5+ years after CON dropped</td>
<td>0.918</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.836, 1.009)</td>
<td>(0.836, 1.009)</td>
</tr>
<tr>
<td>Hospital volume</td>
<td>0.9996**</td>
<td>0.9996**</td>
</tr>
<tr>
<td></td>
<td>(0.9995, 0.9997)</td>
<td>(0.9995, 0.9997)</td>
</tr>
<tr>
<td>Sample size</td>
<td>1,580,186</td>
<td>1,730,733</td>
</tr>
</tbody>
</table>

Regressions include indicator variables for each sample year, sex, age, race, transfer patient, urgent and emergent admissions, principal diagnosis of AMI, Elixhauser comorbidities, teaching hospital, urban hospital, and nonprofit or government-owned hospital, as well as income, a constant, and state-level fixed effects. CABG regressions also include indicators for same-day PCI, same-day cardiac catheterization, and use of an intra-aortic balloon pump on the day prior to CABG. PCI regressions also include indicators for multivessel PCI and coronary stent placement.

* p-value ≤ .05.
** p-value ≤ .01.

AMI, acute myocardial infarction; CABG, coronary artery bypass graft surgery; CON, certificate of need; PCI, percutaneous coronary interventions.
| Table 2: Estimates of the Association between CON and Hospital Volume for CABG and PCI |
|-----|----------------|----------------|-----|----------------|----------------|
|     | CABG            |                |     | PCI            |                |
|     | (1)            | (2)            | (3) | (4)            | (5)            | (6) |
| After CON dropped | -0.311** (−0.537, −0.085) | -0.293** (−0.486, −0.099) |
| 1 year before CON dropped | -0.041 (−0.108, 0.026) | -0.042 (−0.109, 0.024) | 0.036 | 0.035 |
| Year CON dropped | -0.132* (−0.250, −0.013) | -0.131* (−0.249, −0.014) | (−0.228, 0.134) | (−0.227, 0.134) |
| 1 year after CON dropped | -0.232** (−0.384, −0.079) | -0.229** (−0.379, −0.079) | (−0.275, −0.067) | (−0.274, −0.065) |
| 2 years after CON dropped | -0.339** (−0.550, −0.129) | -0.339** (−0.548, −0.129) | (−0.453, −0.173) | (−0.451, −0.176) |
| 3+ years after CON dropped | -0.369** (−0.635, −0.104) | -0.369** (−0.635, −0.104) | (−0.327, −0.117) | (−0.339, −0.117) |
| 3 years after CON dropped | -0.267* (−0.475, −0.059) | -0.267* (−0.475, −0.059) | (−0.460, −0.055) | (−0.460, −0.055) |
| 4 years after CON dropped | -0.041 (−0.016, 0.010) | -0.041 (−0.016, 0.010) | (−0.050, 0.019) | (−0.049, 0.019) |
| 5 years after CON dropped | -0.442* (−0.779, −0.105) | -0.442* (−0.779, −0.105) | (−0.520, −0.209) | (−0.520, −0.209) |
| 6 years after CON dropped | -0.525** (−0.773, −0.278) | -0.525** (−0.773, −0.278) | (−0.566, −0.193) | (−0.566, −0.193) |
| 7 years after CON dropped | 0.259 (−0.598, 0.081) | 0.259 (−0.598, 0.081) | (−0.026, 0.010) | (−0.026, 0.010) |
| Sample size | 7,857 | 8,233 |

Regressions include indicator variables for each sample year, the log of population per square mile in the hospital’s county, the county’s HMO penetration rate, and the state smoking rate by year, as well as a constant, and state-level fixed effects.

1Dependent variable = Natural log of hospital volume.

*p-value ≤ .05.

**p-value ≤ .01.

CABG, coronary artery bypass graft surgery; CON, certificate of need; PCI, percutaneous coronary interventions.
CON for open heart surgery. The relative decrease in volume continues out to 6 years beyond CON removal in Column 3 (−53 percent, \( p = .012 \)), although the differential becomes insignificant 7 years after CON removal, at the end of the sample period (−26 percent, \( p = .13 \)).

Columns 4 through 6 of Table 2 suggest similar findings for PCI. On average, removal of cardiac CON is associated with a 29 percent drop in mean hospital volume (\( p = .004 \)). Column 6 indicates that the effect is tangible 1 year after CON is removed (−17 percent, \( p = .002 \)), and increases in magnitude up to 6 years after removal of CON (−38 percent, \( p < .001 \)).

We find in Column 1 of Table 3 that dropping CON is associated with 15.2 percent increase in the number of hospitals performing CABG (\( p = .001 \)). More detailed analysis in Column 2 indicates that 4.7 percent (\( p = .049 \)) additional facilities are present the year that cardiac CON is dropped, and 17.3 percent (\( p = .003 \)) more hospitals are performing CABG 3 or more years out. In Column 3, we find that dropping CON is associated with 24.6 percent (\( p = .001 \)) more hospitals performing CABG up to 6 years after CON is dropped.

Columns 4 through 6 suggest similar findings for PCI. On average, removal of CON is associated with a 12.1 percent (\( p < .001 \)) increase in the number of hospitals performing PCI. Column 6 indicates that the effect is tangible 1 year after CON removal (7.7 percent, \( p = .004 \)) and increases in magnitude to 13.7 percent (\( p < .001 \)) up to 5 years after CON removal.

To conserve space, we do not report the coefficient estimates relating CON removal to the statewide number of procedures performed. However, for both CABG and PCI, we find no significant association between removal of CON and the total number of procedures performed. For example, the estimated association between CON removal and the percentage change in statewide procedures is −5.9 percent (\( p = .44 \)) for CABG and −13.8 percent (\( p = .22 \)) for PCI.

**DISCUSSION**

We find that removal of state cardiac CON regulations is associated with an increase in the number of hospitals performing CABG and PCI. The statewide number of procedures is unaffected by CON removal, so that average procedure volume per hospital for both CABG and PCI declines relative to states that maintained these regulations. These differentials between states that dropped cardiac CON regulations in the 1990s versus states that maintained
them are statistically significant as many as 5 years after removal of the regulations. Adjusting for differences in hospital volume, we find a within-state reduction in procedural mortality for CABG up to 4 years after CON regulations have been dropped.

The increase in providers after CON removal is consistent with a previous study documenting Pennsylvania’s experience with removal of CON
regulations (Robinson et al. 2001), and prior studies have associated CON with higher hospital volume for CABG and/or PCI (Vaughan-Sarrazin et al. 2002; DiSesa et al. 2006; Ho 2007). We differ from previous studies in finding that removal of CON is associated with lower CABG mortality. Previous studies relied on adjusted cross-section variation in the experience of states with and without CON regulations to measure the impact of the regulations, and are therefore more subject to confounding from unobservable heterogeneity across states. For example, if states that maintained CON tended to be those where hospitals generally had shorter anesthesia times, faster adoption of digital imaging, or greater use of anticoagulants, then cross-section analysis may attribute any mortality effects to CON, even if it is unrelated to the regulations.

In contrast, the differences-in-differences approach we utilize attributes a change in outcomes to CON only if the change is concurrent with the removal of CON regulations, and if the change in outcomes differs from that observed in states that maintained CON over the same time period. In addition, state fixed effects allow one to focus on changes within each state, so that the results are not confounded by systematic differences in unobservables, such as anesthesia times or anticoagulant use across states.

Why might the removal of cardiac CON be associated with lower mortality? Perhaps the elimination of CON oversight led hospitals to alter their casemix for CABG, avoiding surgery for lower income, high-risk patients that many CON regulators would expect to be treated; and treating additional lower risk patients instead. To test this hypothesis, we calculated the expected mortality for each CABG patient by estimating logistic regressions of mortality as a function of patient characteristics by year. We regressed predicted mortality rates derived from these regressions on the CON indicator variable, and the hospital characteristics, year indicators, and state dummy variables used in our previous regressions. We find that removal of state CON regulations is associated with a 0.1 percent ($p < .001$) increase in expected mortality rates. Given that observable patient characteristics suggest that CON removal is associated with treatment of a higher risk patient population, we conclude that it is unlikely that deregulated hospitals shifted their casemix toward unobservably lower risk patients.

It may be that removal of CON led state regulators to consider other options for oversight that improved the quality of care for CABG patients. We contacted the state health departments in all seven states that dropped CON in the 1990s to inquire about their experience with cardiac CON removal. Both Ohio and Pennsylvania introduced requirements around the time that CON regulations were dropped, that hospitals report CABG
outcome data to the state health department. Hospitals were notified that poor outcomes could trigger a detailed licensing review by the state (Maryland Health Care Commission 2000). The CON regulations in these two states contained minimal oversight of facilities once they received initial approval to open. Therefore, the new oversight measures may have led to reductions in procedural mortality. None of the five remaining states introduced new oversight regulations for CABG. Moreover, none of the seven states received additional funds to support oversight of CABG programs after CON was dropped. The lack of funding may explain why the decrease in procedural mortality for CABG patients after CON was dropped lasted for 4 years, and not longer.

The temporary drop in CABG mortality after CON removal may also represent a Hawthorne effect. Short-term improvements in productivity associated merely with observing worker performance were first identified in a series of experiments at the Hawthorne Works company from 1924 to 1932 (Landsberger 1958). It may be that hospitals temporarily devoted more attention to outcomes improvement for CABG, because they were concerned that removal of CON would lead to additional scrutiny of their performance, and perhaps new regulatory measures. This effect would be more plausible for CABG versus PCI, because mean CABG mortality rates are higher, and therefore greater cause for concern by both hospitals and regulators.

Our results differ from those reported by Ho et al. (2007), which used the same dataset we analyzed, but found that CON was successful in restraining the number of PCI procedures performed relative to non-CON states. However, the prior study did not include either state-level random or fixed effects to control for unobserved differences in the propensity to perform PCI across states. For example, if states with CON tended to have physicians who were more likely to recommend medical management of angina rather than interventional therapy, failure to include either state random or fixed effects may cause this correlation to be reflected in the coefficient on the CON indicator variable.

There are several caveats to our analysis. The MedPAR data only contains information for the Medicare population, not the population under age 65. We examined data for all hospitals with CABG and PCI patients in the AHRQ HCUP dataset from 1988 to 1999. For the 2,034 hospital/years in this dataset, the correlation between the procedure volumes for the 65+ population and the total population is 0.98. Therefore, differences across hospitals in the number of patients aged 65+ receiving either CABG or PCI are an
excellent proxy for differences in the total number of patients receiving these procedures at a given hospital.

The MedPAR database lacks information on Medicare HMO patients, who are younger, have less disability, and lower mortality rates than fee-for-service patients (Maciejewski et al. 2001). In the mortality regressions, year dummies and fixed effects were included in the regressions to account for differences in managed care penetration across states. In addition, the state regressions included managed care penetration as a control variable.

We lack information on ejection fraction, rates of left main disease, smoking, and hypercholesterolemia, which may influence the need for revascularization. No database contains information on these variables by state for our study period. Thus, we are limited in our ability to compare procedure appropriateness in CON and non-CON states. However, past research finds no association between cardiac revascularization and admission rates for AMI for Medicare patients across different parts of the United States (The Center for the Clinical Evaluative Sciences and The Center for Outcomes Research and Evaluation 1999). These findings suggest that heart disease risk factors are not the principal cause of variability in revascularization rates between CON and non-CON states.

Despite these caveats, the results have important implications for the debate regarding the benefits of regulation for cost control. Dropping CON does not appear to influence the statewide number of CABG or PCI procedures, but spreads these revascularizations over a larger number of facilities. Both CABG and PCI have significant fixed costs, and lower hospital volume has been associated with higher costs per patient for both of these procedures (Ho 2002; Ho and Petersen 2007). Therefore, cardiac CON regulations may be successful in restraining cost growth, by limiting fixed cost investments in cardiac surgery to fewer facilities. This hypothesis requires careful future study, because a previous comprehensive analysis based on both primary data collection and review of the previous literature found no evidence that CON succeeded in hospital cost containment or reducing total expenditures per capita (Conover and Sloan 1998). However, this past study found no evidence of a surge in expenditures or bed supply after CON laws were lifted, whereas we found a significant association between lifting CON and the number of hospitals offering CABG and PCI. In addition, the prior study by Conover and Sloan was based on data from 1980 to 1993, before the series of CON changes that we examined. Future research should also test whether removal of CON for CABG and PCI is associated with enhanced price competition. More providers in the market may lead hospitals to lower the price of cardiac services for private-pay patients.
Cardiac CON regulations often require that facilities providing open-heart surgery provide hematology, nephrology, radiology, and neurology services, intensive care, and 24-hour emergency care for cardiac emergencies. Even though these requirements should improve quality, we find no evidence that cardiac CON regulations lower procedural mortality rates for CABG or PCI. Nevertheless, the additional oversight introduced by Ohio and Pennsylvania after the removal of cardiac CON leaves open the possibility that some form of regulatory intervention may be beneficial for patient outcomes. As states seek to restrain cost growth while encouraging the provision of high-quality care, the benefits and costs of alternative regulatory interventions should be carefully weighed for each medical treatment.

ACKNOWLEDGMENTS

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*Disclosures:* None.

REFERENCES


SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.

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“Does certificate of need affect cardiac outcomes and costs?”
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Does certificate of need affect cardiac outcomes and costs?

Vivian Ho

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Abstract Several U.S. states enforce Certificate of Need (CON) regulations, which limit the number of hospitals performing open heart surgery or coronary angioplasty. CON regulations were intended to restrain cost growth and improve quality of care. This study compares mortality rates and costs for cardiac care in states with and without CON. CON appears to raise hospital procedure volume and lower the average cost of care. However, CON is associated with little reduction in inpatient mortality, and it may lead hospitals to operate on more patients than they would otherwise. The claimed welfare benefits of CON regulations require careful reconsideration.

Keywords Regulation · Certificate of need · Outcomes assessment · Cardiac surgery · Costs

JEL Classifications I110 Analysis of Health Care Markets · I180 Health: Government Policy, Regulation, Public Health

Introduction

Several U.S. states enforce Certificate of Need (CON) regulations for cardiac care, which limit the number of hospitals that may perform open heart surgery or coronary angioplasty. These rules were originally implemented by regulators who argued that controlled entry into markets for new technologies would restrain cost growth and improve the quality of care. Limiting the number of providers would avoid unnecessary duplication of costly, highly specialized manpower and facilities. Medical evidence
V. Ho

suggested that minimum case loads were essential to maintaining and strengthening
the skills required to perform complex cardiac procedures. Therefore, restricting
the number of facilities that patients could choose from also insured that each certi-
fied facility had enough patients to maintain their expertise in complex cardiac care.
Because provision of open heart surgery and angioplasty require a substantial fixed
cost investment, greater centralization of services through CON was also likely to
yield economies of scale.

Many potential providers without CON approval argue that these regulations are
anti-competitive. With fewer competitors performing open heart surgery and angio-
plasty in a market, certified providers can charge higher prices for their services.
Because publicly available data on charges for cardiac procedures does not accurately
reflect the prices actually paid by insurers and patients for the care they receive, this
hypothesis cannot be directly tested. However, past studies cast doubt on the argu-
ment that CON regulations restrain cost growth or improve quality in the cardiac
care market. For instance, greater competition (as opposed to regulation of entry) has
been found to lower average expenditures per patient and mortality among Medicare
patients being treated for heart attacks in the 1990’s (Kessler, & McClellan, 2000).

Other research suggests that the evidence supporting the clinical benefits of higher
procedure volume is tenuous. Analysis of longitudinal data suggests that all facilities
performing angioplasty improve over time regardless of patient volume; and within-
hospital increases in procedure volume over time provide minimal benefits in terms
of patient outcomes (Ho, 2000, 2002). However, the impact of cardiac CON regula-
tions on hospital procedure volume, patient outcomes, and costs has not been studied
systematically.

This study uses AHRQ HCUP data to compare patient outcomes and costs for
cardiac care in those states with and without cardiac CON regulations. The study first
tests whether hospitals in states with CON regulation perform higher numbers of
open heart surgeries and angioplasties relative to states without CON. The impact of
increased procedure volume associated with CON on inpatient mortality and average
costs is then assessed. Because CON regulations often include minimum volume stan-
dards (e.g. Providers must perform at least 200 open heart surgeries per year), these
rules may lead providers to perform surgery on patients that they would otherwise
have treated with medications. Therefore, the analysis also tests whether states with
CON have a greater number of individuals overall receiving these cardiac interven-
tions.

The results suggest that CON regulations increase patient volume. However, CON
regulations are associated with only small reductions in inpatient mortality for open
heart surgery patients, and they have no tangible effect on inpatient mortality for
patients undergoing angioplasty. The regulations lead to noticeable reductions in
average cost. However, CON also increases the propensity to perform cardiac sur-
gery, which may raise total expenditures for these procedures.

The results have important implications for understanding the role that regulations
can play in controlling health care costs and influencing the quality of patient care.
The CON regulations for cardiac care appear to have only a marginal impact on
patient mortality. The regulations have been more effective in reducing average costs
through economies of scale. However, increases in the propensity to perform cardiac
procedures with CON may still lead to higher expenditures for the health care system
as a whole.

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The section ‘Background’ provides information on cardiac CON regulations and previous related research. Section ‘Data and descriptive statistics’ describes the dataset to be used for analysis and provides descriptive statistics. Section ‘Model specification’ outlines the models to be estimated. The last two sections present results and conclusions, respectively.

Background

The National Health Planning and Resources Development Act of 1975 (Public Law 93641) authorized funding for state CON programs. CON programs required that certain proposed capital expenditures, changes in health facilities or services provided, or purchases of major medical equipment were subject to the review and approval of a designated state agency. If a state did not implement a CON program, then no providers in the state were eligible to receive funds under the Public Health Service Act for the development, expansion, or support of health resources in the state.

CON programs were originally adopted in part to achieve cost containment. However, a study of hospital regulation over the period 1966 to 1982 found that CON appears to increase per capita hospital expenditures in the long run (Lanning, Morrissey, & Oshfeldt, 1991). Using annual state-level data collected from the American Hospital Association and other sources, Lanning et al. found that per capita hospital expenditures were 20.6% percent higher in states with CON versus states without CON. The authors suggest that CON programs may act to protect inefficient hospitals from competition.

More recent studies have been able to analyze health care expenditures after the repeal or sunset of various state CON laws. Conover and Sloan examined annual state-level data from 1980 to 1993 to test whether lifting of CON regulations led to changes in per capita hospital spending (Conover, & Sloan, 1998). This study found no evidence of lower hospital costs per capita in states with mature CON programs; or a surge in hospital costs following removal of CON regulations. Similarly, Grabowski et al. found no evidence of increased nursing home expenditures in states which repealed CON regulations or construction moratoria (Grabowski, Ohsfeldt, & Morrissey, 2003).

These studies provide no support for the argument that CON laws are helpful in restraining expenditure growth. CON laws may in fact increase market power, enabling high volume providers to raise the prices they charge for procedures. CON laws have been found to deter entry and allowed hospitals to raise prices 4.0–4.9% (Noether, 1988). However, none of these studies have examined the impact of CON regulations on expenditures for a particular treatment class, such as cardiac surgery. It is particularly interesting to study the impact of CON for cardiac surgery, because these patients represent an extremely high proportion of total inpatient care for large hospitals; and caring for them can be extremely profitable. In addition, with the exception of Grabowski et al., these studies do not analyze the impact of CON laws on both the total quantity of services provided and average costs per patient. Although CON may be successful in helping unit costs to decline (through economies of scale), an offsetting increase in the total number of procedures performed may be cause for concern, if the marginal benefit of these procedures is low. Although this study does not directly address the issue of the marginal benefit of increased access to cardiac
surgery, it does attempt to measure the potential for changes in the total population receiving intervention as a result of CON legislation.

In 1978, the Federal government issued the National Guidelines for Health Planning, which included standards on the minimum numbers of open heart procedures and cardiac catheterizations that should be performed annually in cardiac care facilities. The guidelines stated that there should be a minimum of 200 open heart procedures performed annually, within three years after initiation, in any institution in which open heart surgery is performed in adults. This recommendation was made in order to maintain quality of patient care and make most efficient use of resources. In addition, the guidelines stated, "In order to prevent duplication of costly resources which are not fully utilized, the opening of new units should be contingent upon existing units operating, and continuing to operate, at a level of at least 350 procedures per year."

Open-heart surgery is performed while the bloodstream is diverted through a heart-lung bypass machine. The overwhelming majority of these operations are coronary artery bypass graft (CABG) procedures. Standards were set for cardiac catheterization as well: “There should be a minimum of 300 cardiac catheterizations, of which at least 200 should be intracardiac or coronary artery catheterizations, performed annually in any adult cardiac catheterization unit within three years after initiation.” This standard effectively regulates percutaneous transluminal coronary angioplasty (PTCA), because a cardiac catheterization laboratory is required to perform angioplasty. State CON review criteria were expected to reflect these national standards.

The Federal law supporting CON expired in 1986, leading many states to discontinue their CON programs. Currently, 35 states and the District of Columbia fund and administer a CON program. Of these, 28 continue to explicitly regulate cardiovascular services. A 2000 Maryland Health Care Commission survey found that no state reported studying the effect of its repeal (Maryland Health Care Commission, 2000). Even for those CON states without explicit requirements for cardiac services, the general presence of CON regulations (e.g. restrictions on bed supply) may limit the number of hospitals in the market, which could lead to higher volumes for CABG and PTCA among existing providers. However, this hypothesis has not yet been examined in the literature.

Meanwhile, applications to establish new cardiac programs in states which maintain CON regulations are attracting growing attention in the press (Hensley, 1997; Pallarito, 1998; Wysocki, 2002). Increased competition in the health care market along with the high profitability of performing cardiac surgery imply great financial returns to those facilities which are able to gain certification or prevent the entry of new competitors in a local market. For example, Coliseum Health System’s application to perform high-end cardiac care in Macon, Georgia has been denied, granted or appealed 7 times since 1999, in part due to legal actions by Macon’s existing provider of these services, Medical Center of Central Georgia (Wysocki, 2002).

A recent study published examined the short-term impact of the termination of cardiac surgery CON laws in Pennsylvania in 1996 (Robinson et al., 2001). In the 3 years prior to the termination of CON in Pennsylvania (1994–1996), the number of open-heart surgery programs rose from 43 to 44. In contrast, in the 3 years following CON termination, the number of programs increased from 44 to 55. The study found no significant change in the inpatient mortality rate for CABG. The impact of CON termination on mortality for PTCA was not reported. The authors speculate that the sharing of surgeons between open-heart surgery programs established before and
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after CON termination may have helped to prevent an increase in inpatient mortality with the opening of 11 new cardiac programs.

In contrast, a more in-depth analysis of Medicare data found a substantial association between cardiac CON laws and reduced mortality for patients undergoing CABG. Vaughan-Sarrazin et. al. used Medicare Provider and Analysis Review (MedPAR) Part A data from 1994 through 1999 from all 50 states to examine the impact of CON laws on delivery of care for CABG patients (Vaughan-Sarrazin et al., 2002). The analysis found that hospital volume in the 26 states with continuous CON was 84% higher than in the 18 states with no CON (191 cases per year vs. 104 cases per year). The study also reports the remarkable finding that risk-adjusted in-hospital mortality was 22% higher for patients in states with no CON regulation versus states which maintained CON.

The authors acknowledge an important limitation in their analysis; any associations between CON regulation and study outcomes may represent confounding due to other factors which may differ according to CON status. That is, the 22% mortality differential between CON and no-CON states may in fact be due to other factors which are correlated with the extent of regulation in a state (e.g. level of managed care penetration, local physician practice styles, etc.). In contrast, this study will employ fixed effects in all regression analyses to control for unobserved hospital and state characteristics. Although the Vaughan-Sarrazin et al. analysis is based on data from all 50 states, the Medicare dataset lacks information on patients under age 65, as well as those enrolled in Medicare managed care. Therefore, the differences in hospital volume and mortality identified in this study may be upward biased due the higher rate of managed care penetration in states without CON regulation in their sample. (Ho, 2003). Although this study lacks data from all states, the sample includes patients of all ages, regardless of insurance type. It is important to test whether these notable differences in volume and outcomes for CABG persist with these differences in both the sample and method of analysis.

Data and descriptive statistics

This study uses data from the AHRQ HCUP Nationwide Inpatient Sample (NIS) database to compare hospital procedure volumes and costs for PTCA and CABG in states with and without cardiac CON laws. The NIS data is analyzed for the years 1988 to 2000. Ideally, one would conduct an analysis of changes in procedure volume and costs in states before and after repeal of CON legislation; using states that never repealed CON as a control group. Unfortunately, all of the states in the HCUP sample except one discontinued their cardiac CON program prior to 1988. Therefore, analyses in this study will focus on examining differences in hospital procedure volume or costs, as a function of the number of years since CON legislation was repealed in a given state.

The HCUP NIS data is a stratified random sample of community hospitals in the United States. The dataset contains a 20% sample of acute care hospitals in each of five strata (geographic region, ownership, location, teaching status, and bedsize). The first release of the NIS for the years 1988 to 1992 contained information from 11 U.S. states, and the 2000 release contains information on over 1,000 hospitals in 28 states. Although the sampling strategy for the NIS re-sampled many hospitals over several
years, very few facilities are included for all 13 years. On average there are four years of data for each hospital in this study.

The NIS contains patient-level clinical and resource use information included in a typical discharge abstract. All discharge abstracts from each sample hospital are included, so that one can obtain accurate counts of PTCA and CABG volume for each facility. All patients with a procedure code for CABG (ICD-9-CM 36.1x) or PTCA (ICD-9-CM 36.01, 36.02, or 36.05) were included in the sample for this study.

Information on CON status for each state was drawn from the 2000 Maryland Health Care Commission survey. The survey lists the 28 states which maintained a cardiac CON program through the year 2000 (18 are in the NIS sample), as well as the 8 states which never implemented a CON program (2 are in the NIS sample). The survey also lists the 15 states which repealed their cardiac CON legislation and the year in which the repeal occurred (7 are in the NIS sample). See the Appendix A for a summary of CON programs as reported by the Maryland survey.

Figure 1 graphs mean PTCA and CABG volume by year for hospitals in states with and without cardiac CON. Note that in both cases that procedure volumes in CON and non-CON states were remarkably similar in the years just following repeal of the Federal CON legislation. However, procedure volume begins to diverge between CON and non-CON states in 1992, and mean hospital volumes in CON states remain higher through 2000. These data are consistent with the hypothesis that CON restricts entry, allowing CON hospitals to grow larger on average. One may be concerned that this observed difference is attributable to the increasing number of states and hospitals added to the NIS sample over time. The graph was repeated including only hospitals in states that were in the NIS for all years from 1988 to 1992. The pattern in the graph remains almost the same.1

Figure 1 excludes data from Pennsylvania, which repealed its cardiac CON legislation in 1996. Procedure volumes by year are reported for Pennsylvania in Fig. 2. Note the dramatic decline in average procedure volume for both PTCA and CABG after 1996.2 These changes in average volume are consistent with a previous study which noted that the average number of open-heart surgery programs in Pennsylvania increased from 44 to 55 between 1997 and 1999 (Robinson et al., 2001). Figure 3 presents graphs of the average costs per patient in hospitals performing PTCA and CABG. Costs for each patient were derived by multiplying the reported charge for each patient by a hospital-specific cost-to-charge ratio obtained from Medicare Cost Reports.3 These costs were then deflated by the All-Urban Consumers CPI to reflect 2000 dollars. Past studies of disease-specific costs have also relied on aggregate hospital cost-to-charge ratios rather than department-level data (Meltzer, Chung, & Basu, 2002, Cutler, & Huckman, 2003). As one of these studies notes, analysis of a specific treatment with large fixed costs such as CABG and PTCA yields a more homogeneous sample of hospitals, which is likely to mitigate any bias created by the use of

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1 Results are available from the author upon request.

2 An unusually large rise in PTCA and CABG volume occurs just prior to CON repeal in Pennsylvania in 1996, as well as a relatively large drop in average costs for CABG. Hospitals with CON may have aimed to boost their cardiac procedure numbers in anticipation of repeal, in an attempt to deter potential entrants. Volume growth has been identified as a method of strategic entry deterrence in previous research (Dafny, 2005).

3 The hospital cost-to-charge ratio was calculated excluding outpatient service cost centers, as well as inpatient service cost centers that were not likely to be used by cardiac care patients (e.g. nursery, delivery room, and labor room costs).
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Sample: All states in NIS dataset, except PA.
CON: CT, FL, GA, HI, IA, IL, KY, MA, MD, ME, MO, NC, NJ, NY, SC, TN, VA, WA
no CON: AZ, CA, CO, KS, OR, UT, TX, WI

Fig. 1  Mean hospital procedure volume by year for states with and without CON
hospital-level data. Further, costs computed using aggregate hospital cost-to-charge ratios have been found to be generally within 10% of costs obtained from department-level cost data (Dranove, 1995).

Note that average costs tend to be lower in hospitals in states with CON, particularly for CABG procedures. If there are economies of scale in performing PTCA and CABG, then higher procedure volumes in CON states may lead to lower costs of care.
per patient. Figure 4 presents average costs for hospitals in Pennsylvania. The graph for PTCA suggests a sharp increase in PTCA costs after the repeal of CON legislation, although the effect is not lasting. Average costs for CABG also rise somewhat after the repeal of CON legislation; although again the effect does not appear to persist.

**Model specification**

The previous figures do not control for differences in patient populations across states which may explain differences in procedure volume for PTCA and CABG. The following regression specification is estimated to identify the effect of CON legislation and other factors on hospital PTCA procedure volume:

$$\log(\text{PTCA})_{ht} = f(\text{yrsnoCON}_{ht}, Z_{ht}, \text{Year}_t, \theta_h)$$  (1)

where $\log(\text{PTCA})_{ht}$ is the natural log of the number of the of PTCA procedures performed by hospital $h$ in year $t$. The explanatory variable yrsnoCON$_{ht}$ is the number of years since state CON legislation has been repealed for hospital $h$ in year $t$. This variable is set equal to 0 for hospitals which maintained cardiac CON legislation through 2000. For Oregon and Wisconsin, which never imposed cardiac CON legislation, the year of repeal was coded as 1987, when the general Federal CON program was dismantled.

A vector of control variables $Z_{ht}$ is hypothesized to capture differences in demand for cardiac procedures across hospitals. These include the natural log of the population age 65 plus per square mile and the HMO penetration rate in hospital $h$’s county of operation in year $t$. State-level annual data on smoking rates, per capita income, and the percent of the population uninsured were also included in preliminary regressions. However, per capita income and uninsurance rates are excluded from the reported estimates, because they had poor explanatory power and did not influence the other regression estimates. See Appendix B for a list of summary statistics for these data and data sources.

Hospital-level counts of the number of heart attack patients and the number of patients admitted with chest pain were also available. However, preliminary regressions indicated substantial multicollinearity between these two variables and the population per square mile. Therefore, only the population per square mile is included in the regressions.

The regression includes a vector of year dummies and a vector of hospital-specific fixed effects. Thus, the coefficient on yrsnoCON can be interpreted as the...
Average Cost per PTCA by CON status

Average Cost per CABG by CON status

Sample: All states in NIS dataset, except PA.
CON: CT, FL, GA, HI, IA, IL, KY, MA, MD, ME, MO, NC, NJ, NY, SC, TN, VA, WA
no CON: AZ, CA, CO, KS, OR, UT, TX, WI

Fig. 3 Average cost per procedure by year for states with and without CON
within-hospital increase in PTCA volume associated with each additional year past repeal of state CON legislation. A similar regression is estimated to determine the association between the number of years since CON repeal and hospital CABG volume. As explained previously, only Pennsylvania switched its cardiac CON status during the sample period. Therefore, the sample size is insufficient to estimate hospital-specific fixed effects regressions with only a dummy variable for CON as the explanatory variable of interest.
Specifying a linear relationship between the number of years since CON repeal and hospital volume procedure volume seems reasonable, given that Fig. 1 suggests a gradual divergence in both PTCA and CABG volume between CON and non-CON states in the 1990s. The figures are consistent with the hypothesis that limited entry in CON states enabled hospitals to markedly increase procedure volume year after year, while volume in non-CON states grew more slowly or remained constant.7

I also test whether changes in hospital procedure volume attributable to CON legislation have a noticeable impact on inpatient mortality for PTCA and CABG. Given that higher procedure volume is associated with better patient outcomes, it is hypothesized that an increase in hospital procedure volume associated with CON will be associated with lower inpatient mortality. To test this hypothesis, I estimate regressions of the following form:

$$(\text{RAMR}_{PTCA})_{ht} = f((\text{PTCA Volume})_{ht}, \text{Year}_t, \theta_h)$$

where $$(\text{RAMR}_{PTCA})_{ht}$$ is the risk-adjusted inpatient mortality rate for patients undergoing PTCA in hospital h in year t, and $$(\text{PTCA Volume})_{ht}$$ represents the number of PTCA procedures performed by hospital h in year t. The remaining variables on the right-hand side of this equation have definitions identical to those provided for Eq. (1).

The data are aggregated to the hospital-year level for estimation of the mortality regressions in order to obtain results which are interpretable for policy purposes. Estimation of the relationship between hospital volume and mortality at the patient level would require a logit specification. However, one cannot compute partial effects from a hospital fixed-effects logit equation, because the distribution of the unobserved hospital heterogeneity component is unknown (Wooldridge, 2002). Aggregation to the hospital level yields the mortality rate as the dependent variable, so that fixed effects estimates are readily interpretable.

An RAMR is calculated as the hospital’s observed mortality rate for a given procedure in a given year, divided by its expected mortality rate, all multiplied by the entire sample’s average mortality rate in that year. This figure provides an estimate of what the hospital’s inpatient mortality rate would have been if it had served a mix of patients identical to the entire sample’s mix.

The hospital’s expected inpatient mortality in a given year is calculated using the coefficient estimates of a logistic regression of inpatient mortality on patient-specific characteristics. Thus, a separate logistic regression is estimated for each year in the sample, where the unit of observation is a patient in that year and the dependent variable equals 0 if the patient was discharged alive and equals 1 if the patient died in hospital. Separate logistic regressions are also estimated for PTCA and CABG patients. The patient characteristics included in the logistic regression are: age (dummy variables for ages 65 to 69, 70 to 74, 75 to 79, 80 to 85, and 85+ versus those under age 65), as well as indicator variables for female, black, emergency admission, transfer from another hospital, primary diagnosis of acute myocardial infarction (AMI, commonly known as a heart attack). Indicator variables are also included for the individual comorbidities that comprise the Charlson comorbidity index (Romano, Roos, & Jollis, 1993), which are: prior AMI, peripheral vascular disease, dementia, chronic obstructive pulmonary disease, rheumatologic disease, liver disease (mild), liver disease (moderate/severe),

7 The data for Pennsylvania in Fig. 2 also appears consistent with this hypothesis. After repeal of CON in 1996, average procedure volume for both PTCA and CABG fell dramatically, then remained relatively constant, similar to non-CON states in Fig. 1.
diabetes (mild/moderate), diabetes with complications, kidney disease, cancer, and metastatic solid tumor. For the regressions for PTCA patients, indicator variables for stent insertion and performance of multiple-vessel PTCA were also included.

As with prior studies, I hypothesize that the coefficient on procedure volume will be negative. That is, higher procedure volume will be associated with lower inpatient mortality. Specification tests are run to determine whether the relationship between hospital volume and risk-adjusted mortality is best represented with the log of volume or polynomials of hospital volume.\textsuperscript{8} The specification with the best fit is reported in the tables.

Regressions with average hospital costs per patient for both PTCA and CABG are also estimated. The same patient characteristics which are used to construct risk-adjusted mortality rates are included as explanatory variables in the cost regressions for PTCA and CABG patients. Patient-specific factors such as age, gender, presence of comorbidities, and urgency of the procedure are all likely to affect costs.

The presence of minimum procedure volume standards in cardiac CON legislation may lead hospitals to perform more cardiac procedures than they otherwise would have. To test this hypothesis, one needs accurate measures of statewide procedure volume for both PTCA and CABG. One could then determine whether states that maintain CON rules experienced higher growth in procedure volume versus those states that repealed the rules. Unfortunately, the HCUP NIS does not contain information on all hospitals in any state, so that this dataset cannot be used to obtain accurate statewide procedure volume estimates. However, the AHRQ maintains an interactive tool on its website which allows one to determine the total number of PTCA and CABG procedures performed by all hospitals in select states that participated in the NIS for the years 1997 to 2002. I supplemented this information with PTCA and CABG counts based on comprehensive hospital discharge abstract covering the years 1988 to 1996 for California, Florida, New Jersey, and New York, as well as data from 1990 to 2001 for Colorado and Pennsylvania.\textsuperscript{9} The resulting sample contains 145 state-year observations.

Regressions are then estimated to identify the impact of number of years beyond repeal of CON legislation on procedure volume at the state level. These regressions include year dummies, the log of population age 65 plus per square mile, the HMO penetration rate, the smoking rate, per capita income, and the percent uninsured at the state level. State-level estimates of the number of heart attack patients and the number of patients admitted with chest pain each year were also available. However, similar to the hospital-level analyses, preliminary regressions indicated substantial multicollinearity between these two variables and the population per square mile. Therefore, only the population per square mile is included in the regressions.

The state-level results are first reported including state fixed effects, then with first-differencing. Correlation of the error term with the explanatory variables in any

\textsuperscript{8} The standard errors for volume in logs and polynomials are compared in regressions including both volume specifications. In addition, predicted mortality based on log volume is added as a regressor in a mortality regression with polynomials of procedure volume to determine whether it yields any additional explanatory power. Likewise, predicted mortality based on polynomials of volume is added as a regressor in a mortality regression with volume expressed in logs to evaluate its explanatory power.

\textsuperscript{9} Obtaining comprehensive discharge abstract data from individual states is time consuming and costly. I chose to collect data from four large states, which represent 27% of the population in the United States. Because so few states in the NIS discontinued their cardiac CON programs, I also purchased the state-level data which was available for this time period from Colorado and Pennsylvania.
time period (current, past, or future) leads to inconsistent estimates (Wooldridge, 2002). Therefore, for each specification, a Wald test was performed to test for strict exogeneity of the explanatory variables with respect to the error term.

The fixed effect estimates of the determinants of annual procedure volume and costs are estimated using the areg command in Stata 8.0. This approach allows for the estimation of fixed effects, as well as heteroskedasticity-robust standard errors which also account for the correlation of the error terms across time within hospitals. Regressions estimated at the hospital level incorporate hospital-level fixed effects; and regressions at the state level incorporate state-level fixed effects.

In cases where the dependent variable is risk-adjusted mortality, the regressions are first estimated by OLS with standard errors robust to clustering within hospitals, but no hospital-specific fixed effects. These estimates provide a standard of comparison to volume-outcome effects for CABG and PTCA which are commonly reported in the medical literature. The effects of procedure volume on mortality with hospital-specific random effects, then fixed effects are also reported. Although the risk-adjusted mortality rates control for observable differences in casemix across hospitals, the discharge data may not fully capture more detailed clinical characteristics of patients that may be correlated with hospital volume and risk of death. Regression estimates based on fixed effects will provide consistent estimates of the effect of procedure volume on mortality, whether or not unobservable differences in patient casemix are correlated with volume. However, random effects estimates will yield smaller standard errors if unobserved heterogeneity across hospitals is uncorrelated with hospital volume. Therefore, Hausman tests are performed to determine whether the random effects or fixed effects specification is more appropriate when examining the impact of hospital volume on mortality for both PTCA and CABG.

Past studies suggest that hospital procedure volume may be an endogenous regressor. The association between high procedure volume and favorable patient outcomes may be driven in part by selective referral. For complex procedures, doctors may refer their patients to facilities that they perceive to provide higher quality care. If hospital volume is endogenous in regressions analyzing the determinants of inpatient mortality, then an alternative estimation strategy is to estimate a two-stage instrumental variables equation. The number of years since CON repeal is a likely candidate for an instrument that predicts procedure volume, but is unlikely correlated with unobserved differences in mortality across hospitals. The population per square mile in a hospital's county and the number of patients admitted with a heart attack are also hypothesized to influence the demand for cardiac care and therefore serve as instruments. If in fact hospital procedure volume is not an endogenous regressor in the mortality regressions, then this approach will yield inefficient estimates. Hausman specification tests were conducted to test for the endogeneity of procedure volume. In each case, one could not reject the null hypothesis that the preferred random or fixed effects estimates treating volume as exogenous were consistent and efficient. Therefore, only these estimates are reported in this study.

**Results**

Table 1 contains regression estimates for the determinants of hospital PTCA and CABG procedure volume. In general, later years are associated with increases in procedure volume for both PTCA and CABG. County population age 65 plus per
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Table 1  Regression estimates, determinants of hospital procedure volume

<table>
<thead>
<tr>
<th></th>
<th>ln(PTCA volume)</th>
<th>ln(CABG volume)</th>
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<td>Coefficient</td>
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<td>-.022*</td>
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<td>HMO penetration rate</td>
<td>-.036</td>
<td>-.109</td>
</tr>
<tr>
<td>State smoking rate</td>
<td>1.176</td>
<td>-.507</td>
</tr>
<tr>
<td>1989</td>
<td>.075 (1.39)</td>
<td>.017 (1.29)</td>
</tr>
<tr>
<td>1990</td>
<td>.297*** (4.15)</td>
<td>.096 (1.44)</td>
</tr>
<tr>
<td>1991</td>
<td>.407*** (5.13)</td>
<td>.139 (1.95)</td>
</tr>
<tr>
<td>1992</td>
<td>.540*** (6.21)</td>
<td>.163** (2.00)</td>
</tr>
<tr>
<td>1993</td>
<td>.626*** (6.63)</td>
<td>.189** (2.19)</td>
</tr>
<tr>
<td>1994</td>
<td>.727*** (7.60)</td>
<td>.253*** (2.79)</td>
</tr>
<tr>
<td>1995</td>
<td>.849*** (7.89)</td>
<td>.302*** (3.06)</td>
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<td>1996</td>
<td>.882*** (7.85)</td>
<td>.385*** (3.67)</td>
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<tr>
<td>1997</td>
<td>.993*** (8.52)</td>
<td>.390*** (3.57)</td>
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<tr>
<td>1998</td>
<td>1.092*** (9.05)</td>
<td>.381*** (3.32)</td>
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<tr>
<td>1999</td>
<td>1.155*** (9.64)</td>
<td>.332*** (2.85)</td>
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<td>.381*** (3.05)</td>
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<td>.102 (.05)</td>
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<tr>
<td>Obs.</td>
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<td>2195</td>
</tr>
<tr>
<td># hospitals</td>
<td>561</td>
<td>497</td>
</tr>
</tbody>
</table>

a Regressions include hospital-specific fixed effects. All standard errors are estimated with robust standard errors, which account for clustering of patients within hospitals.

* statistical significance at the 10% level
** statistical significance at the 5% level
*** statistical significance at the 1% level

square mile increases volume for these procedures, although the coefficients on other factors hypothesized to influence demand (HMO penetration and the smoking rate) are imprecisely estimated.

The coefficient on yrsnoCON is negative and precisely estimated in both the PTCA and CABG regressions, although the coefficient on yrsnoCON has a p-value of only 0.07 in explaining hospital CABG volume. The average value of yrsnoCON for the states in the sample which repealed CON legislation is equal to 14 years in 2000. The coefficient estimate on yrsnoCON in the PTCA regression is equal to −0.033. This estimate implies that on average, PTCA volume for hospitals in states which repealed cardiac CON legislation was 37% lower than it would otherwise have been by the year 2000 if CON rules had been maintained (using the formula $\%\Delta y = 100\cdot(\exp(\hat{\beta}(\Delta x)) - 1)$ (Wooldridge, 2000). Similarly, the estimates for the CABG regression suggest that average hospital CABG volumes were 27% lower by 2000 than they otherwise would have been.

Table 2 contains regression estimates of the relation between procedure volume and hospital risk-adjusted mortality for both PTCA and CABG procedures. Due to space constraints, the first-stage patient-level estimates of inpatient mortality regressed on patient characteristics are excluded from the tables. The estimates are similar to those reported in Table 1.
those reported in previously published studies. Older patients have higher mortality rates. Black patients, urgent/emergency admissions, and those with severe comorbidities are also more likely to die in hospital.

The first three columns of Table 2 report the association between the annual number of PTCA procedures performed by a hospital and its risk-adjusted mortality. The OLS and random effects estimates suggest that higher hospital procedure volume is associated with lower mortality rates for PTCA patients. However, the coefficient on volume is imprecisely estimated when hospital-specific fixed effects are included. A Hausman test rejects the null hypothesis that the random effects estimates are consistent. This test result suggests that unobserved differences in patient casemix across hospitals are correlated with both procedure volume and mortality. This might be the case if, for example, hospitals that perform higher numbers of PTCA procedures also attract greater numbers of patients with unstable angina or lower ejection fractions. These factors have been demonstrated in previous clinical studies to be risk factors for increased inpatient mortality among PTCA patients (Hannan et al., 1997, Ho, 2002, Kimmel et al., 1995). Therefore, although CON appears to lead to a sizeable increase in average hospital PTCA volume, there is no evidence that beneficial reduction in inpatient mortality accompanies this volume change.

The last 3 columns of Table 2 present regression estimates of the impact of hospital procedure volume on risk-adjusted mortality rates for CABG patients. Again, the regression estimates including hospital-specific effects yield an imprecise estimate for the log(volume) coefficient. However, in this case, a Hausman test indicates that one cannot reject the null hypothesis that the random effects estimates are consistent and efficient ($\chi^2(13) = 16.1, P = 0.24$). The volume coefficient in the random effects risk-adjusted mortality regression for CABG is equal to $-0.004$, indicating a negative and precisely estimated association between increased CABG procedure volume and inpatient mortality. It is notable that the magnitude of the volume coefficient in the random effects regression is two-thirds the size of the volume effect obtained from estimating pooled OLS. Therefore, previous clinical studies based on OLS estimates may have overestimated the benefits of increased volume in reducing inpatient mortality.

To examine the magnitude of this effect in the context of CON legislation, one can substitute Eqs 1–2. The RAMR associated with an increase in the number of years past repeal of CON then becomes the coefficient on yrsnoCON in Eq. 1 multiplied by the coefficient on log(CABG Volume)$_ht$ in Eq. 2, multiplied by yrsnoCON. One finds that for an average hospital in a state 14 years beyond repeal of CON rules, inpatient mortality rates for CABG are .1 percentage points higher than they otherwise would have been. In the year 2000, 29,194 patients in the NIS sample underwent CABG in states which had repealed CON rules. In these states, the average risk-adjusted mortality rate was 3.9% in 2000. These estimates suggest that retaining CON would have led to 29 fewer inpatient deaths overall in that year.

One can apply a similar exercise to the PTCA results to assess whether the imprecise coefficient estimates relate to the absence of a tangible effect of volume on mortality, or instead an insufficient sample size. The lower bound of the 95% confidence interval for PTCA volume in the fixed effects regression in Table 2 is $-0.0038$. Let this value represent the largest potential effect that hospital volume could reasonably have in reducing mortality for PTCA patients. One then infers that 14 years after CON repeal, the mortality rate for PTCA patients would be .2 percentage points lower if CON had instead been retained. In 2000 there were 51,539 PTCA patients in...
Table 2  Regression estimates, determinants of risk-adjusted mortality rates

<table>
<thead>
<tr>
<th></th>
<th>PTCA</th>
<th>CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OLS</td>
<td>Random effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>log(Volume)_{hit}</td>
<td>−.0037*** (−2.54)</td>
<td>−.004*** (−2.38)</td>
</tr>
<tr>
<td>1989</td>
<td>−.0001 (−.07)</td>
<td>.0004 (2.6)</td>
</tr>
<tr>
<td>1990</td>
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<td>.001 (4.1)</td>
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<tr>
<td>1991</td>
<td>.002 (95)</td>
<td>.002 (1.22)</td>
</tr>
<tr>
<td>1992</td>
<td>.005 (1.41)</td>
<td>.005 (1.62)</td>
</tr>
<tr>
<td>1993</td>
<td>.003* (1.73)</td>
<td>.004** (2.23)</td>
</tr>
<tr>
<td>1994</td>
<td>.005** (2.35)</td>
<td>.006*** (2.93)</td>
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<td>1995</td>
<td>.007*** (3.25)</td>
<td>.008*** (3.63)</td>
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<td>1996</td>
<td>.006** (2.77)</td>
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<td>1997</td>
<td>.005*** (2.53)</td>
<td>.005** (2.83)</td>
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<td>1998</td>
<td>.004* (1.92)</td>
<td>.004** (2.08)</td>
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<td>.007* (1.66)</td>
<td>.007* (1.75)</td>
</tr>
<tr>
<td>2000</td>
<td>.002 (1.13)</td>
<td>.003 (1.33)</td>
</tr>
<tr>
<td>Constant</td>
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<td>.035*** (4.30)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Obs.</td>
<td>2367</td>
</tr>
<tr>
<td># Hospitals</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* statistical significance at 10% level
** statistical significance at 5% level
*** statistical significance at 1% level

Does certificate of need affect cardiac outcomes and costs?
non-CON states in the NIS sample, and their risk-adjusted mortality rate was 1.6%. Therefore, even at the 95% confidence limit, the estimates suggest that retaining CON would lead to 103 fewer deaths, a relatively small amount.

Table 3 contains regression estimates of the relation between repeal of CON legislation and mean hospital costs. The estimates indicate that increasing PTCA volume is associated with lower average costs per patient. This result is consistent with the hypothesis of substantial economies of scale in the performance of these procedures. Specification tests indicated that polynomials of hospital volume to the third power (rather than log volume) provided the best fit in explaining the cost of performing CABG. The estimates indicate that within-hospital increases in CABG volume are associated with declining average costs up to an increase of 852 procedures. The mean one-year increase in hospital CABG volume is 15 procedures, and the largest one-year increase is 490 surgeries. In addition, the largest within-hospital increase in CABG volume over the entire time period is 834 procedures. Therefore, the estimates are consistent with economies of scale in performing CABG over the range of procedure volumes observed in the sample.

Applying the same exercise described above, the volume estimate in the PTCA cost regression suggests that on average, hospitals in states that repealed cardiac CON legislation had mean patient costs in 2000 which were 3.0% higher than they otherwise would have been. Among states in the sample without CON legislation in 2000, mean CABG volume equalled 300 procedures. The results in Table 1 suggest that average procedure volume for CABG is 27% lower than it would have been in 2000 if these states had maintained CON rules; implying that average CON volume would have equaled 411 procedures per year with CON. The cost estimates in Table 3 suggest that a within-hospital increase in CABG volume of 111 procedures (from 300 to 411) is associated with a 6.7% decrease in average costs. Given the large number of patients undergoing these procedures, these estimates suggest that by lowering average hospital procedure volume, repeal of CON legislation potentially has a noticeable impact on overall expenditures.

Regressions were also estimated with state-level volumes for PTCA and CABG as the dependent variables. The results are reported in Table 4. For the fixed effect estimates, a test of strict exogeneity for the number of years since CON repeal and the population per square mile involves performing a Wald test on one-year leads of these variables when added to the reported specifications. For the first-difference regressions, a Wald test of the significance of number of years since CON repeal and the population per square mile in levels when added to the reported specification is used to test for strict exogeneity.

For the state PTCA volume regressions, one cannot reject the hypothesis of strict exogeneity of the explanatory variables ($F(6, 20) = 0.81$), and therefore the fixed effects estimates are the most efficient. Each year beyond CON repeal appears to lower the number of PTCA procedures performed in the state by 3.8%. For the CABG regressions, one rejects the null hypothesis of strict exogeneity in the fixed effects estimates. However, one does not reject the hypothesis of strict exogeneity of the explanatory variables in the first-difference regression. The results suggest that each year beyond CON repeal reduces statewide CABG surgeries by 1.6%.

For both PTCA and CABG, the repeal of CON appears to be associated with a decrease in the total number of procedures performed statewide. The estimates suggest that 14 years after repeal of cardiac CON laws, statewide procedure volumes
Does certificate of need affect cardiac outcomes and costs?

Table 3  Regression estimates of determinants of log(average costs per procedure)

<table>
<thead>
<tr>
<th></th>
<th>PTCA</th>
<th></th>
<th></th>
<th>CABG</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coefficient</td>
<td>t-Statistic</td>
<td>Coefficient</td>
<td>t-Statistic</td>
<td>Coefficient</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------</td>
<td>----------------</td>
<td>--------------------</td>
<td>---------------------------</td>
<td>---------------------------</td>
</tr>
</tbody>
</table>
| Log(volume)   | -.070***                | (-2.78)       |                    | -.001***                | (-2.85)       |                    | 5.54e-07*        | (2.43)       |                    | -1.44e-10***       | (-2.11)       |                    | -.030*          | (1.76)       |                    | .016           | (.94)       |                    | .055***         | (3.11)       |                    | .011           | (.59)       |                    | .015           | (-.69)       |                    | .063***         | (-2.65)       |                    | .137***         | (-5.02)       |                    | .192***         | (-7.91)       |                    | .227***         | (-9.34)       |                    | .218***         | (-8.41)       |                    | .228***         | (-9.07)       |                    | .222***         | (-7.79)       |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |            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    |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            |                    |                |            | right
Table 4  Regression estimates, determinants of statewide procedure volume

<table>
<thead>
<tr>
<th></th>
<th>ln(PTCA Volume)</th>
<th>ln(CABG Volume)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fixed effects</td>
<td>1 -Difference</td>
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<tr>
<td>yrsnoCON</td>
<td>−.038*** (−3.82)</td>
<td>−.022 (−1.69)</td>
</tr>
<tr>
<td>log(pop65+/sqmile)</td>
<td>.376 (.54)</td>
<td>.307 (.48)</td>
</tr>
<tr>
<td>HMO penetration</td>
<td>−.307 (−.99)</td>
<td>.027 (.15)</td>
</tr>
<tr>
<td>Smoking rate</td>
<td>1.228 (1.47)</td>
<td>.828*** (2.38)</td>
</tr>
<tr>
<td>Per capita income</td>
<td>3.0e−05 (1.40)</td>
<td>1.71e−05 (1.89)</td>
</tr>
<tr>
<td>Rate uninsured</td>
<td>−.293 (−.32)</td>
<td>−.094 (−.43)</td>
</tr>
<tr>
<td>1989</td>
<td>.108*** (2.43)</td>
<td>.009* (.27)</td>
</tr>
<tr>
<td>1990</td>
<td>.294*** (3.86)</td>
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</tr>
<tr>
<td>1991</td>
<td>.414*** (4.61)</td>
<td>.010 (.30)</td>
</tr>
<tr>
<td>1992</td>
<td>.532*** (4.38)</td>
<td>−.003 (−.09)</td>
</tr>
<tr>
<td>1993</td>
<td>.610*** (4.35)</td>
<td>−.042* (−1.42)</td>
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<td>1994</td>
<td>.721*** (4.98)</td>
<td>−.008 (−.36)</td>
</tr>
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<td>1995</td>
<td>.841*** (5.10)</td>
<td>−.003 (−.12)</td>
</tr>
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<td>1996</td>
<td>.918*** (4.61)</td>
<td>−.044 (−1.40)</td>
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<td>1997</td>
<td>.972*** (4.20)</td>
<td>−.081** (−2.69)</td>
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<td>1998</td>
<td>1.043*** (3.94)</td>
<td>−.043 (−1.57)</td>
</tr>
<tr>
<td>1999</td>
<td>1.058*** (3.83)</td>
<td>−.094*** (−2.72)</td>
</tr>
<tr>
<td>2000</td>
<td>1.090*** (3.49)</td>
<td>.063** (−2.52)</td>
</tr>
<tr>
<td>2001</td>
<td>1.163*** (3.55)</td>
<td>−.031 (−.90)</td>
</tr>
<tr>
<td>2002</td>
<td>1.210*** (3.54)</td>
<td>−.052** (−2.06)</td>
</tr>
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<td>Constant</td>
<td>6.446 (3.01)</td>
<td>.118*** (3.86)</td>
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<td>= 2.75***</td>
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<td>125</td>
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<td># states</td>
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<td>21</td>
</tr>
</tbody>
</table>

* Statistical significance at 10%
** Statistical significance at 5% level
*** Statistical significance at 1% level

Between 1989 and 2001, California’s PTCA volume increased from 22,924 to 49,613 procedures per year, or 116%. Colorado’s PTCA volume rose from 1,996 to 6,046 procedures per year between 1990 and 2001, or 203%. In contrast, Florida, New Jersey and New York are represented in all of these sample years and maintained CON regulations. In these states, the average PTCA procedure volume rose from 8,353 to 34,522 procedures per year between 1989 and 2001, or an increase of 313%. Analysis of data from a wider range of states would be helpful in confirming this finding.

However, it is also interesting to note that between 1996 (when Pennsylvania eliminated its CON rules) and 2001, total PTCA procedure volume in Pennsylvania rose 23%. During this time period, statewide PTCA volume rose an even higher average of 57% for Florida, New Jersey, and New York. Between 1990 (the first year for which Pennsylvania data is available) and 1995, rates of growth for PTCA were more similar for Pennsylvania versus these 3 states that retained CON; 74% versus 90%, respectively. These data are also consistent with the hypothesis that CON rules lead to higher statewide performance of PTCA.

12 The AHRQ HCUP website only reports statewide data by procedure volume from 1997 onwards.
The reported specifications of the association between years since CON repeal and procedure volume at the hospital and state level are linear, suggesting that repeal of CON has a persistent effect on procedure growth rate through time. To test this assumption, the number of years since CON repeal for all states that repealed CON was divided into tertiles, then quartiles. The tertiles/quartiles were used to estimate splines to determine whether the relationship between years since CON repeal and PTCA/CABG volume weakened for the years that were furthest from the repeal (i.e. closest to the present).

I tested the hypothesis that the slope of the relationship between volume and years since CON repeal was constant by testing whether the coefficients on the 2 highest tertiles or 3 highest quartiles were jointly equal to 0. The results are reported in Appendix C. In 7 of the 8 cases, one cannot reject the hypothesis that the relationship between years since CON repeal and procedure volume is constant. For state-level PTCA volume, however, the results suggest that the effect of CON repeal weakens at the third quartile, or 12 years after repeal. CON repeal still is associated with lower statewide PTCA volume after 12 years, although the effect is only about one quarter of its magnitude in the first 6 years.

I also estimated the hospital-level and state-level PTCA and CABG volume regressions adding a quadratic of number of years since CON repeal, then a quadratic and cubed term. In each case the higher order terms were imprecisely estimated, and the standard error for the coefficient on the linear term increased in magnitude. For example, for the quadratic of number of years since CON repeal, the P-values ranged from .189 to .790.

Finally, I re-estimated the hospital and state-level volume regressions using data only through 1995, to examine whether a relatively long follow-up period could be introducing unrelated time series variation. The coefficient on the number of years since CON repeal was \(-0.026(P = .21)\) and \(-0.014(P = .003)\) in the hospital-level PTCA and CABG regressions, and \(-0.037(p = .007)\) and \(-0.030(P = .08)\) in the state-level PTCA and CABG regressions. One would expect some drop in precision due to the smaller sample size. However, in each case the direction of the effect remains unchanged, and the precision of the estimates remains relatively high.

**Conclusions**

The reported estimates suggest that substantial declines in average hospital PTCA and CABG procedure volume have resulted in states which repealed cardiac CON legislation. Although not explicitly tested in this paper, these declines are likely due to the larger number of new providers entering those states which do not impose minimum volume standards for these procedures through CON laws. Reductions in average hospital volume associated with the absence of CON have a detrimental impact on mortality rates for CABG patients, although the magnitude of the estimated impact is relatively small. For the 29,294 patients who received CABG surgery in states that had repealed CON in 2000, the results suggest that 29 fewer inpatient deaths could have been avoided with CON rules. In addition, the results yield no evidence that the volume effects associated with CON rules led to reduced mortality for patients undergoing PTCA.

Nevertheless, repeal of CON legislation is associated with substantially higher costs per patient. The increase in volume associated with CON regulations is predicted to
reduce average costs by 3.0% for PTCA patients and 6.7% for CABG patients. These results might lead one to favor CON legislation, because it appears to reduce costs and either saves some lives, or leaves mortality rates unchanged.

However, the presence of minimum volume standards may lead hospitals in CON states to increase the number of procedures performed relative to states without CON. The predicted increases in the total number of procedures performed (41% for PTCA and 18% for CABG in the year 2000) are large enough to offset any potential savings resulting from lower average costs per patient treated as a result of CON regulation. These results are consistent with past research which has found CON regulations do not restrain expenditure growth.

Nevertheless, the estimates of statewide growth in PTCA procedures resulting from CON seem extraordinarily large. I am in the process of surveying states to obtain data on minimum volume thresholds for open heart surgery and cardiac catheterization. Preliminary investigation indicates that minimum volume thresholds vary across states, but little change in thresholds occurs across years within states. In future research, I aim to combine this information with data from more states to revisit the issue of CON and statewide procedure volume.

This study does not attempt to measure the potential impact of CON rules on the substitution of PTCA for CABG procedures, which has increased in the U.S. over time (Cutler, & Huckman, 2003). However, the overwhelming majority of states with cardiac CON rules restrict entry for both CABG and PTCA. Therefore, rates of substitution between these 2 procedures may not vary by CON status. This issue is an interesting question for future research.

In the meantime, policy makers must carefully weigh the costs and benefits of CON regulation. Policy makers implemented CON with the dual goals of restraining cost growth and achieving high quality care. The centralization of care which is associated with CON may lead to slightly lower mortality rates for CABG and lower unit costs due to economies of scale. However, these regulations may also inadvertently increase the total number of procedures performed. Future studies with more detailed clinical data should attempt to measure the marginal benefit of increased rates of cardiac surgery in states which have maintained CON legislation. The potential impact of differences in rates of surgery resulting from CON on long term mortality has important consequences for evaluating the welfare benefits of these regulations.

**Acknowledgements** This research was supported by grant number R01 HL073825-01A1 from the National Heart, Lung and Blood Institute. I am grateful to Hufeng Yunn for helpful research assistance and to Richard Boylan, Leemore Dafny, Andrew Epstein, Ciarin Phibbs, 2 anonymous referees, participants at the 4th IHEA World Congress, the Department of Health Administration and Policy at the Medical University of South Carolina, and the Departments of Economics at Rice University and Texas A&M for helpful comments.

**Appendix A**

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13 States in the AHRQ NIS dataset are italicized

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Does certificate of need affect cardiac outcomes and costs?

<table>
<thead>
<tr>
<th>Table 5</th>
<th>Status of CON regulation of cardiovascular services by state</th>
</tr>
</thead>
<tbody>
<tr>
<td>CON Program</td>
<td>No CON program (15)</td>
</tr>
<tr>
<td>Cardiac covered (28)</td>
<td>Cardiac not covered (8)</td>
</tr>
<tr>
<td>Alabama</td>
<td></td>
</tr>
<tr>
<td>Alaska</td>
<td></td>
</tr>
<tr>
<td>Connecticut</td>
<td></td>
</tr>
<tr>
<td>Delaware</td>
<td></td>
</tr>
<tr>
<td>District of Columbia</td>
<td></td>
</tr>
<tr>
<td>Florida</td>
<td></td>
</tr>
<tr>
<td>Georgia</td>
<td></td>
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<tr>
<td>Hawaii</td>
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<tr>
<td>Illinois</td>
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<td>Iowa</td>
<td></td>
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<tr>
<td>Kentucky</td>
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<tr>
<td>Maine</td>
<td></td>
</tr>
<tr>
<td>Maryland</td>
<td></td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Arizona (1985)</td>
</tr>
<tr>
<td>Michigan</td>
<td>California (1987)</td>
</tr>
<tr>
<td>Mississippi</td>
<td>Colorado (1987)</td>
</tr>
<tr>
<td>Missouri</td>
<td>Idaho (1983)</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>Indiana (1998)</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Kansas (1985)</td>
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<tr>
<td>New York</td>
<td>Louisiana</td>
</tr>
<tr>
<td>North Carolina</td>
<td></td>
</tr>
<tr>
<td>Rhode Island</td>
<td>Arkansas (1995)</td>
</tr>
<tr>
<td>South Carolina</td>
<td>New Mexico (1983)</td>
</tr>
<tr>
<td>Tennessee</td>
<td>North Dakota (1995)</td>
</tr>
<tr>
<td>Vermont</td>
<td></td>
</tr>
<tr>
<td>Virginia</td>
<td>Nevada (1996)</td>
</tr>
<tr>
<td>Washington</td>
<td>Oklahoma (1985)</td>
</tr>
<tr>
<td>West Virginia</td>
<td>Utah (1995)</td>
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Appendix B

<table>
<thead>
<tr>
<th>Table 6</th>
<th>Summary statistics</th>
</tr>
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<tbody>
<tr>
<td>Variable</td>
<td>Obs</td>
</tr>
<tr>
<td>Year</td>
<td>2389</td>
</tr>
<tr>
<td>Hospital PTCA Volume</td>
<td>2367</td>
</tr>
<tr>
<td>Hospital CABG Volume</td>
<td>2195</td>
</tr>
<tr>
<td>yrsnoCON</td>
<td>2389</td>
</tr>
<tr>
<td>County Pop 65+/sq mile</td>
<td>2187</td>
</tr>
<tr>
<td>County HMO pen. rate</td>
<td>2389</td>
</tr>
<tr>
<td>State smoking rate</td>
<td>2389</td>
</tr>
<tr>
<td>State per capita income</td>
<td>2389</td>
</tr>
<tr>
<td>State percent uninsured</td>
<td>2389</td>
</tr>
<tr>
<td>RAMR (PTCA)</td>
<td>2367</td>
</tr>
<tr>
<td>RAMR (CABG)</td>
<td>2195</td>
</tr>
<tr>
<td>Cost per Patient (PTCA)</td>
<td>930,327</td>
</tr>
<tr>
<td>Cost per Patient (CABG)</td>
<td>744,156</td>
</tr>
</tbody>
</table>

Population figures were obtained from the U.S. census bureau. HMO penetration rates were obtained from Douglas Wholey at the University of Minnesota. Smoking rates were obtained from the Center for Disease Control’s Behavioral Risk Factor Surveillance System. State per capita income was obtained from the Bureau of Economic Analysis. The percent uninsured was obtained from the March Current Population Surveys.
### Appendix C

#### Table 7
Alternative specifications of the association between years since con repeal and procedure volume

<table>
<thead>
<tr>
<th></th>
<th>Hospital procedure volume</th>
<th></th>
<th>statewide procedure volume</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ln(PTCA volume)</td>
<td>ln(CABG volume)</td>
<td>ln(PTCA volume)</td>
<td>ln(CABG volume)</td>
</tr>
<tr>
<td>yrsnoCON</td>
<td>-0.023 (−0.65)</td>
<td>-0.012 (−0.48)</td>
<td>-0.063*** (−3.06)</td>
<td>-0.020* (−1.84)</td>
</tr>
<tr>
<td>yrsnoCON²</td>
<td>-0.001 (−0.27)</td>
<td>-0.001 (−0.41)</td>
<td>0.001 (1.36)</td>
<td>0.0003 (0.61)</td>
</tr>
<tr>
<td>yrsnoCON</td>
<td>0.044 (0.65)</td>
<td>-0.037 (−0.79)</td>
<td>-0.037 (−1.34)</td>
<td>-0.003 (−0.22)</td>
</tr>
<tr>
<td>yrsnoCON²</td>
<td>-0.011 (−1.06)</td>
<td>0.003 (0.47)</td>
<td>-0.002 (−0.65)</td>
<td>-0.002 (−1.22)</td>
</tr>
<tr>
<td>yrsnoCON³</td>
<td>0.0004 (0.96)</td>
<td>-0.0002 (−0.54)</td>
<td>0.0001 (1.16)</td>
<td>0.0001 (1.33)</td>
</tr>
<tr>
<td>Tertile 1ᵇ</td>
<td>-0.021 (−0.87)</td>
<td>-0.028 (−1.58)</td>
<td>-0.046*** (−3.98)</td>
<td>-0.020** (−2.75)</td>
</tr>
<tr>
<td>Tertile 2</td>
<td>-0.022 (−0.65)</td>
<td>0.019 (0.77)</td>
<td>0.006 (0.31)</td>
<td>0.004 (0.40)</td>
</tr>
<tr>
<td>Tertile 3</td>
<td>0.024 (0.42)</td>
<td>-0.039 (−1.10)</td>
<td>0.042 (1.47)</td>
<td>0.010 (0.58)</td>
</tr>
<tr>
<td>F—testᵈ</td>
<td><strong>F = 0.22</strong> P = 0.806</td>
<td><strong>F = 0.65</strong> P = 0.524</td>
<td><strong>F = 1.51</strong> P = 0.245</td>
<td><strong>F = 0.35</strong> P = 0.711</td>
</tr>
<tr>
<td>Quartile 1ᶜ</td>
<td>-0.014 (−0.47)</td>
<td>-0.017 (−0.82)</td>
<td>-0.045*** (−3.33)</td>
<td>-0.018** (−2.33)</td>
</tr>
<tr>
<td>Quartile 2</td>
<td>-0.023 (−0.43)</td>
<td>-0.023 (−0.71)</td>
<td>-0.003 (−0.12)</td>
<td>-0.004 (−0.34)</td>
</tr>
<tr>
<td>Quartile 3</td>
<td>-0.004 (−0.08)</td>
<td>0.043 (1.42)</td>
<td>0.032** (2.81)</td>
<td>0.017 (1.31)</td>
</tr>
<tr>
<td>Quartile 4</td>
<td>0.022 (0.25)</td>
<td>-0.077 (−1.53)</td>
<td>0.022 (0.86)</td>
<td>-0.002 (−0.11)</td>
</tr>
<tr>
<td>F—testᵈ</td>
<td><strong>F = 0.17</strong> P = 0.915</td>
<td><strong>F = 1.02</strong> P = 0.382</td>
<td><strong>F = 4.55</strong> P = 0.014</td>
<td><strong>F = 0.66</strong> P = 0.588</td>
</tr>
</tbody>
</table>

* statistical significance at 10% level
** Statistical significance at 5% level
*** Statistical significance at 1% level

ᵃ All alternative specifications of yrsnoCON include the same set of explanatory variables reported in Tables 1 and 4
ᵇ Tertile cutoffs are 8 and 14 years without CON for hospital procedure volume and 6 and 11 years without CON for statewide procedure volume
ᶜ Quartile cutoffs are 7, 12, and 15 years without CON for hospital procedure volume and 5, 8, and 12 years without CON for statewide procedure volume
ᵈ F-test for the joint significance of the coefficients on the 2 highest tertiles or 3 highest quartiles
Does certificate of need affect cardiac outcomes and costs?

References


“Cardiac Certificate of Need regulations and the availability and use of revascularization services”
American Heart Journal Volume 154, Number 4
Cardiac Certificate of Need regulations and the availability and use of revascularization services

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Houston, TX; New York and Bronx, NY; Ann Arbor, MI; and New Haven, CT

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 ≥65 years old 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 to 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% fewer PCIs per 1000 elderly (P = .01), equivalent to 322,526 fewer PCIs for 1989 to 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

Certificate of Need restricts the number of cardiac facilities, but its effect on utilization rates may vary by procedure. (Am Heart J 2007;154:767-75.)

Policy makers, health care providers, and payers are debating whether our health care system requires more competition or more regulation.1,2 The United States 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 health care oversight and intervention over the past 4 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 1980s.3 Although 27 states maintained CON for open-heart surgery through 2002, preservation of these regulations has been hotly debated in some states.4

Certificate of Need was first introduced in an attempt to control costs.3,5 Regulators in the late 1950s 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, 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 2 states. We also distinguish between CABG and PCI when examining the association between CON and procedure use. Coronary artery bypass graft is a major procedure that has substantial risk of morbidity and mortality, whereas 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 1980s. We then examine states that discontinued CON in the mid 1990s. 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 health care sector.

**Methods**

**Data**

We obtained data for Medicare beneficiaries ≥65 years old 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 MedPAR files, and data for 1989 and 1990 came from comparable inpatient files collected by Center for Medicare and Medicaid Services. Percutaneous coronary intervention (including stents) was defined based on ICD-9-CM codes 36.0, 36.01, 36.02, or 36.05 and CABG based on ICD-9-CM codes 36.1× 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 ≥65 years old who received either CABG or PCI and the number of hospitals performing each of these procedures by state. We excluded hospitals with <3 procedures a year because of miscoding concerns. Sensitivity analyses using a cutoff of ≥5 procedures yielded virtually identical results.

We standardized our results for differences in population size across states with US Census information on the population aged ≥65 years for each state and year between 1989 and 2002. We controlled for other population and market characteristics that have been associated with revascularization rates in previous studies. We included the percent uninsured, per capita personal income, the annual share of the population enrolled in a health maintenance organization, and smoking and obesity rates by state and year. We identified states reporting risk-adjusted mortality rates for CABG and/or PCI by searching Web sites 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 has been analyzed in previous cardiac CON studies. 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 before 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 of each procedure per 100,000 residents ≥65 years old. We also computed the number of Medicare beneficiaries receiving each procedure per 1000 residents ≥65 years old 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 1000 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 SEs. 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 1 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. Before 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 2 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 vs 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 3 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 vs 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 4 shows that rates of CABG procedures among Medicare beneficiaries per 1000 elderly were similar for continuous CON and non-CON states throughout the sample period. The rate of CABG per 1000 elderly in CON versus non-CON states in 1989 was 3.4 versus 3.6 (\( P = .6 \)). Coronary artery bypass graft 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 \((P = .8)\).

Figure 5 compares rates of PCI procedures among Medicare beneficiaries per 1000 residents \(\geq 65\) years old 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, \(P = .01\)). 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 vs 9.3, \(P = .3\)).

The results in column 1 of Table 1 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% fewer Medicare patients per 1000 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 2 through 5 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 before 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.

Coronary artery bypass graft utilization differed across states that dropped CON for open-heart surgery during the sample period, although 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 drop-offs 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% fewer PCIs per 1000 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. 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 2 states at most. 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 CAGBs performed after it lifted CON in 1996. However, we find that the Pennsylvania case study does not generalize to all states that discontinued CON in the 1990s and that the experience of states that discontinued CON in the last decade differs from those states that maintained CON for this entire period.

Our findings are also consistent with a recent study that found greater revascularization rates for patients with acute myocardial infarction (AMI) in non-CON versus CON states and indirect evidence of fewer facilities performing revascularization in CON states. 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 2 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, but the magnitude of difference by CON status may not have been sufficient to create a gradient in

![Figure 3](image-url)
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 1990s, 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 7 states with discontinued CON dropped cardiac CON in the mid 1990s, 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 7 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 (\( P = .15 \)).

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 toward 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 health care costs. Our analysis of CON regulations suggests that these effects may vary across cardiac procedures. Certificate of Need 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, 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.

### References


### Table I. Regression estimates of determinants of hospitals per capita and procedures per capita for CABG and PCI

<table>
<thead>
<tr>
<th>Coef (CI)</th>
<th>Coef (CI)</th>
<th>Coef (CI)</th>
<th>Coef (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals per capita</td>
<td>ln (CABGs per capita)</td>
<td>Hospitals per capita</td>
<td>ln (PCIs per Capita)</td>
</tr>
<tr>
<td>CON in force</td>
<td>-1.194 (-1.762 to -0.626)</td>
<td>-0.025 (-0.152 to 0.101)</td>
<td>-1.313 (-1.976 to -0.650)</td>
</tr>
<tr>
<td>Report card</td>
<td>-0.072 (-0.182 to 0.035)</td>
<td>-0.016 (-0.030 to -0.002)</td>
<td>-0.029 (-0.059 to 0.001)</td>
</tr>
<tr>
<td>Uninsured (%)</td>
<td>0.015 (-0.050 to 0.079)</td>
<td>-0.004 (-0.010 to 0.003)</td>
<td>0.004 (-0.066 to 0.074)</td>
</tr>
<tr>
<td>HMO penetration rate</td>
<td>-0.028 (-0.057 to 0.002)</td>
<td>0.037 (0.014 to 0.061)</td>
<td>0.105 (-0.025 to 0.236)</td>
</tr>
<tr>
<td>Obesity rate</td>
<td>0.118 (-0.004 to 0.239)</td>
<td>1.116 (0.703 to 1.529)</td>
<td>2.852 (0.691 to 5.013)</td>
</tr>
<tr>
<td>Constant</td>
<td>2.307 (0.298 to 4.315)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Regressions include indicator variables for each sample year. Coef, Coefficient; ln, natural log.