JAMES A. BAKER III INSTITUTE FOR PUBLIC POLICY
RICE UNIVERSITY

CERTIFICATE OF NEED REGULATIONS AND THE AVAILABILITY AND USE OF CANCER RESECTIONS

BY

MARAH N. SHORT, M.A.
JAMES A. BAKER III INSTITUTE FOR PUBLIC POLICY
RICE UNIVERSITY

THOMAS A. ALOIA, M.D.
DEPARTMENT OF SURGERY, THE METHODIST HOSPITAL

AND

VIVIAN HO, PH.D.
JAMES A. BAKER III INSTITUTE FOR PUBLIC POLICY AND DEPARTMENT OF ECONOMICS, RICE UNIVERSITY
DEPARTMENT OF MEDICINE, BAYLOR COLLEGE OF MEDICINE

JULY 1, 2008

ABSTRACT

Background: Several states use Certificate of Need regulations (CON) to control the growth of acute care services, but the possible association between these restrictions and the utilization of cancer surgery has not been assessed. This study examines the association between acute care CON, the availability of cancer surgery hospitals, and utilization of six cancer operations.

Methods: Medicare data was collected for beneficiaries treated with one of six cancer resections and an associated cancer diagnosis from 1989 to 2002. Hospital, procedure, and incidence rates for each cancer diagnosis were stratified by state and year. The number of hospitals performing each operation per cancer incident, the number of procedures performed per cancer incident, and hospital volume were compared between states with and without CON, and those that discontinued CON during the sample period.

Results: The number of hospitals per cancer incident was lower in CON states versus non-CON states for colectomy (p=0.022), rectal resection (p=0.026), and pulmonary lobectomy (p=0.032). Hospital volume was significantly higher in CON states versus non-CON states for colectomy (p=0.006) and pulmonary lobectomy (p=0.043). There were no differences between states with and without CON in the number of procedures per cancer incident.

Conclusions: Although utilization of cancer procedures was similar in CON and non-CON states, those with acute care CON had fewer facilities performing oncologic resections per cancer patient. Correspondingly, average hospital procedure volume tended to be higher in CON states. These differences may have significant implications for patient outcomes and costs.

INTRODUCTION

During the past four decades, Certificate of Need regulations (CON) have been one of the government's most prominent forms of health care oversight. Policy makers first introduced CON in an attempt to control costs.[1,2] Regulators in the late 1950's were concerned that increasing availability of health insurance at that time would contribute to Roemer's law: a bed

created is a bed used.[1] Later, the Public Health Service Act (created by Public Law 96-79) and the National Health Planning and Resources Development Act of 1974 (Public Law 93-641) mandated that each state form a health planning agency to enforce CON. These acts also made the receipt of federal funding for health resources, including inpatient hospital beds, new facilities, and surgical programs contingent on state compliance.[3]

In 1983, the Federal government removed CON as a requirement for receiving federal funds for health resources. Since this time, 27 of the 50 states have chosen to retain acute care CON. In these states, CON applicants must provide evidence of need for their services in the community and demonstrate their qualifications to fulfill this need. The process applies to both the opening of new hospitals and increasing the bed size of an existing department such as acute care. The CON application process is often time consuming and costly to pursue,[4] which may limit the number of hospitals equipped to perform cancer resections. Cancer resections are an essential component of a treatment regimen; therefore, limiting the number of hospitals that perform cancer resections may create bottle necks that influence the number of cancer patients who undergo surgery as well.

Previous studies examining the impact of CON on acute care have found small decreases in acute care costs associated with CON, as well as either reduced growth or a reduction in the number of hospital beds.[2,5] However, no previous study has explored the impact that acute care CON may have on cancer care. This study was designed to determine the association between acute care CON and a set of core surgical oncology procedures (colectomy, rectal resection, pulmonary lobectomy, pneumonectomy, esophagectomy, and pancreaticoduodenectomy) by comparing their availability and utilization between states with and without acute care CON.

METHODS

Determination of CON Status
The American Health Planning Agency's (AHPA) annual directory of health planning, policy and regulatory agencies was reviewed to determine which states had CON for acute care during the years 1989 to 2002.[6-8] States were defined as CON states (states with acute care CON

throughout 1989 to 2002), non-CON states (acute care CON discontinued prior to 1989), and discontinued CON states (acute care CON discontinued between 1989 and 2002).

Number of Procedures and Number of Hospitals Performing Procedures

Medicare Provider Analysis and Review (MedPAR) data was obtained for beneficiaries over age 64 treated with colectomy, rectal resection, pulmonary lobectomy, pneumonectomy, esophagectomy, or pancreaticoduodenectomy for an associated cancer diagnosis between 1989 and 2002. Using previously published techniques, data was extracted from the MedPAR files based on ICD-9-CM codes.[9-14] The procedure codes were used to identify the operations of interest, and the diagnosis codes were used to filter and exclude patients who did not have an oncologic diagnosis related to the performed operation.[15,16] Patient level data was aggregated to obtain the number of hospitals performing each procedure and the number of each procedure performed by state and year. Analyses of the Medicare data were approved by the Institutional Review Board at Rice University and met the criteria for analysis of human subjects specified by the American Cancer Institute.

Incidence of Cancers

Annual incidence data for cancer of the colon excluding rectum, rectum alone, lung and bronchus, esophagus, and pancreas, stratified by state and year of diagnosis for the more recent period of 1999 through 2002 was obtained from the *Cancer in North America* (CINA) + online database.[17] Similar incidence data for 1989 to 1998 was collected from the CINA publications spanning this time interval.[18-27]

These incident counts were scaled to reflect cancer incidence for the cohort of patients over age 64. For the years 1999 through 2002, the incident counts were scaled using the ratio of cancer incidents for persons over age 64 divided by incidents for all ages, by cancer cite, as reported in the CINA+ online database (for 35 states). For the earlier years of the sample, the mean ratio was computed in the same manner using the Surveillance Epidemiology and End Results (SEER) incidence data.[28] The limited state-level data from these two sources was used to perform a two-sided t-test to identify differences in the mean ratio of persons over age 64 to all persons with cancer by site, year, and CON status. Only the lung cancer ratios had any significant difference

between CON and non-CON registries. Therefore, for all cancer sites except lung, the CINA and SEER year-specific ratios were multiplied by the state- and year-specific CINA incidence data in order to reflect the population over age 64. For lung cancer the ratios used were averaged by year and CON status to scale the incident counts.

Calculation of Critical Study Ratios

Hospital and procedure data were divided by the scaled cancer incident counts for each site, state, and year to create the standardized variables of interest: hospitals per incident and procedures per incident (measured in 100s of new cancer cases) for each procedure. In addition, the number of each procedure performed in each hospital was averaged to compute hospital volume by state, site, and year.

Independent Variables

The regression analysis controlled for market and population characteristics using population per square mile[29], and per capita income[30], in each state, as well as procedure year. Medicare specific population characteristics include the percent of black enrollees, percent age 75 or older[29], and percent enrolled in a Medicare HMO by state and year.[31] To control for patients who traveled from one state to another for treatment, the number of out-of-state patients by state and year was included as a regressor. This number was calculated by summing the number of patients with residence in a state different from the state of the treating hospital in the MedPAR data.

Analysis of Hospital Availability and Procedure Utilization Rates

After eliminating observations with missing incidence data, 535 state-year combinations remained in the sample (287 CON, 177 non-CON, 71 discontinued CON). Hospitals per incident and procedures per incident stratified by CON status for each operation were graphed. Data for the discontinued CON states was graphed separately.

Multivariate regressions were used to identify differences in the number of hospitals per incident and procedures per incident for each operation between CON and non-CON states by year. Discontinued CON states were analyzed as CON states up until the year CON was dropped (CON in force=1). They were then classified as non-CON states (CON in force=0). Preliminary

analysis showed a strong correlation between per capita income and the HMO penetration rate; therefore, per capita income was removed from the regressions. All regressions used the STATA 10 specifications for robust standard errors clustered at the state level. A p-value <0.05 was considered statistically significant.

Analysis of Hospital Volume

Since hospital volume was not scaled by incidence data, 681[+] observations were available for analysis of hospital volume per operation (367[+] CON, 214[+] non-CON, 97[+] discontinued CON). Again, multivariate regressions were used to identify differences in hospital volume for each operation between the CON and non-CON states by year. A p-value <0.05 was considered statistically significant.

RESULTS

CON Status

Table 1 lists the acute care CON status of the 50 states for the period 1989 to 2002. There were 27 CON states, 16 non-CON states, and 7 discontinued CON states. The year when acute care CON was discontinued was listed.

Hospital Availability: CON vs. non-CON states

Figure 1 graphs the number of hospitals performing procedures on Medicare patients over age 64 per incident of cancer by CON status and procedure from 1989 to 2002. In all years, states with continuous CON had fewer hospitals performing colectomies, rectal resections, and pulmonary lobectomies than non-CON states (e.g. 4.7 vs. 7.3 per new colon cancer case; 12.2 vs. 15.0 per new rectal cancer case; and 1.4 vs. 1.7 per new lung cancer case in 2002). For pneumonectomies, esophagectomies, and pancreaticoduodenectomies, CON states had more hospitals performing operations per cancer incidence in some years, but in other years the availability of hospitals was higher in non-CON states.

Table 2 lists the multivariable regression results for the determinants of the number of hospitals per cancer incident. Across the sample period, having CON in force was associated with fewer

hospitals per cancer incidence for colectomy, rectal resection, and pulmonary lobectomy. On average, states with acute care CON had 1.3 fewer hospitals per incidence performing colectomies (p=0.022), 1.9 fewer hospitals per incidence performing rectal resections (p=0.026), and 0.2 fewer hospitals per incidence performing pulmonary lobectomies (p=0.032). There was no significant association between CON and the number of hospitals per incidence performing pneumonectomies, esophagectomies, or pancreaticoduodenectomies.

Procedure Utilization Rates: CON vs. non-CON states

Figure 2 graphs the number of procedures performed on Medicare patients over age 64 per cancer incident by CON status and procedure. For all six procedures, there was substantial overlap in the number of procedures per incident in CON and non-CON states. Trends in procedure rates for CON and non-CON states tended to follow each other closely across years, except for greater rates of esophagectomies in non-CON versus CON states in the earlier half of the sample period.

Table 3 lists the multivariable regression results for factors associated with procedures per cancer incident. Across the sample period, there was no significant association between CON status and rates of procedure use.

Hospital Availability & Procedure Utilization Rates: discontinued CON states

Figures were created to show the number of hospitals performing procedures and the number of procedures performed on Medicare beneficiaries over age 64 per incident for Massachusetts, Nebraska, Indiana and Pennsylvania. The other discontinued CON states were excluded from the graphs since they did not have data prior to and after their discontinuation date. These figures have not been included, because the analysis yielded no systematic change in hospital availability or procedure utilization for any of these states after CON was discontinued.

Hospital Volume

Results of the analyses of hospitals per incidence and procedures per incidence were used to compare hospital volume (average procedures per hospital) by CON status. Table 4 lists the multivariable regression results for factors associated with hospital volume. Analysis suggested a

positive association between CON being in force and mean procedure volume for all six operations. This association was statistically significant for colectomy (p=0.006) and pulmonary lobectomy (p=0.043). In states with acute care CON, mean hospital volume was 1.7 procedures greater for colectomies and 0.7 procedures greater for pulmonary lobectomies than for hospitals in non-CON states.

Sensitivity Analysis

Analysis based on data for patients over age 64 may not be representative of the entire cancer population. To address this issue we obtained data from 2002 for patients of all ages in a random sample of hospitals from 35 states collected by the Agency for Healthcare Research and Quality (AHRQ) to compare hospital numbers, procedure rates, and hospital volume by CON status.[32] In this analysis, the variable for out of state patients was excluded, since the dataset did not report patient state of residence. This analysis yielded associations between CON status and the dependent variables of interest that were similar to those found for the Medicare population. However, the associations that were significant in the MedPAR analysis were insignificant in the AHRQ analysis, because access to the AHRQ data was limited to only one year of data and information from fewer states. Within the AHRQ sample, the number of hospitals performing cancer resections on the population over age 64 represents a large percentage of the number of hospitals performing these procedures on the full population. This finding was especially true for colectomy (97.6%), rectal resection (90.1%), and pulmonary lobectomy (92.2%).

For the MedPAR analysis, several states were missing cancer incidence data in select years. To determine the presence of any bias introduced by missing incidence information, data from only those states for which information from all years was available was analyzed and compared to data from the full sample. We repeated the multivariate regression analysis of hospital availability and procedure utilization by CON status with this limited sample. Due to a smaller sample size, the difference in hospital volume between CON and non-CON states for pulmonary lobectomy and the difference in hospital availability between CON and non-CON states for colectomy and pulmonary lobectomy became insignificant in the smaller dataset. All other results obtained from the larger dataset and the reduced dataset were similar.

Incidence data for the subset of people over age 64 was not available for the full sample, and the methods used to scale cancer incidence by state to reflect incidence for those over age 64 in the Medicare population may be inaccurate. To validate the methods used, the cancer incidence data was scaled using two alternative methods. The first alternative scaled the entire sample using the SEER ratios. The second alternative utilized the CINA incidence data of people aged 65 and over, available for 35 states across the years 1999-2002, in conjunction with SEER-scaled incidence data for the years 1989-2002. The multivariate regression analyses comparing CON and non-CON hospital availability and procedure utilization were repeated using both alternative scaling methods. Again, sensitivity analysis using both alternative methods of scaling yielded similar final results. In the second alternative, the difference in hospital availability between CON and non-CON states for colectomy and rectal resection became insignificant due to a smaller sample size.

DISCUSSION

The impact of discontinuing CON on acute care hospital bed availability has been studied and debated in various settings.[2] However, the impact on major cancer surgery availability and utilization has not been specifically addressed. This analysis determined that hospital availability was higher in non-CON than CON states, yet procedure utilization was similar across all states. Correspondingly, hospital procedure volume tended to be higher in CON states than in non-CON states.

Past research has suggested that an increase in hospital volume for cancer procedures leads to a decrease in procedural mortality.[10,14,16] Colon, lung, esophagus, and pancreatic cancer resections have been shown to have lower operative mortality when performed at higher volume hospitals.[33] The same is true for rectal cancer resections, yet the impact of surgeon and hospital volume on outcomes is under continued debate.[34] Although the current study did not compare hospital cancer procedure volume to clinical outcomes, it raises the question of whether lower average hospital volumes in non-CON states could be associated with higher mortality rates compared to CON states. The differential of 1.7 colectomies between CON and non-CON states identified in this study may not be clinically significant, given that previous research has found

only small differences in mortality rates (2%) between hospitals performing fewer than 58 versus more than 165 colectomies per year.[35] Similarly, significant mortality differences have only been identified for volume differentials of <9 versus 18+ procedures for pulmonary lobectomy.[33] These volume differentials exceed the adjusted differences in volume we identified for these procedures in CON versus non-CON states. However, the association between CON, hospital volume, and patient outcomes should be directly studied in future research.

From a health care economics point of view, these data may have several implications. The lower supply of hospitals per cancer incidents in CON states versus non-CON states may enable providers in CON states to charge insurers higher reimbursement rates for cancer surgery. At the same time, higher volume CON hospitals may be able to reduce costs through economies of scale. Further study is needed to define the potential impact of acute care CON on both the medical and the financial aspects of cancer care.

The sample size of states that discontinued CON during the study period was small, limiting the power of pre and post CON discontinuation analyses. Even with a larger sample size, rapid changes in surgical oncology procedure availability and utilization following CON discontinuation would be unlikely to be observed given the time it takes to add hospital acute care capacity. Though no generalization may be made about acute hospital changes related to CON discontinuation, the fact that there were no significant differences found for Pennsylvania and Indiana before versus after they discontinued CON is consistent with a previous analysis of CON discontinuation that found "no surge in acquisition of facilities or in costs" when CON were removed.[2]

Given the focus on cancer-related procedures, the study methods were uniquely designed to capture these data. Cancer incidence data was used to adjust the analyses of differences in the need for cancer surgery across states and years. Information on population by state and year was more readily available, but would not have accounted for the possibility that cancer incidence may have varied across states according to risk factors such as the age distribution of the local population, smoking rates, dietary behavior, and general health status.

There are several caveats to the study. This study reveals no firm conclusion about the association between acute care CON regulations and mortality rates, although we hypothesize an association, based on past research of the volume-outcome association for cancer operations. Though we conclude that CON states have higher hospital volume than non-CON states, we are also unable to infer the appropriateness of the procedures performed in CON versus non-CON states.

The data set does not include information regarding timeliness of the procedures from diagnosis to surgery or cancer stage at presentation. The spectrum of cancer stages is unlikely to be correlated with state CON status. Although stage at presentation affects outcomes, it is less likely to influence findings regarding the number of hospitals performing cancer surgery and the number of procedures performed in the state.

The finding that hospital availability is lower in CON states than non-CON states suggests that CON regulations are indeed binding. Given that mean hospital procedure volume is higher in CON states, the fixed costs associated with hospital care are divided among more patients per hospital, leading to lower average costs per procedure in CON states. By limiting facilities, CON may be a successful form of cost control by reducing the average cancer procedure-related cost per patient.

In summary, this analysis identified the significant differences in hospital availability and procedure utilization for six index cancer operations between CON and non-CON states. Further research should investigate the association of acute care CON with determinants of cancer procedure access, hospital costs, and patient mortality rates. This information could be valuable to state policy makers who must weigh the advantages and disadvantages of CON regulation.

ACKNOWLEDGEMENTS

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Figure 1: Hospitals per 100 Incidents[a], by CON Status[b] and Procedure
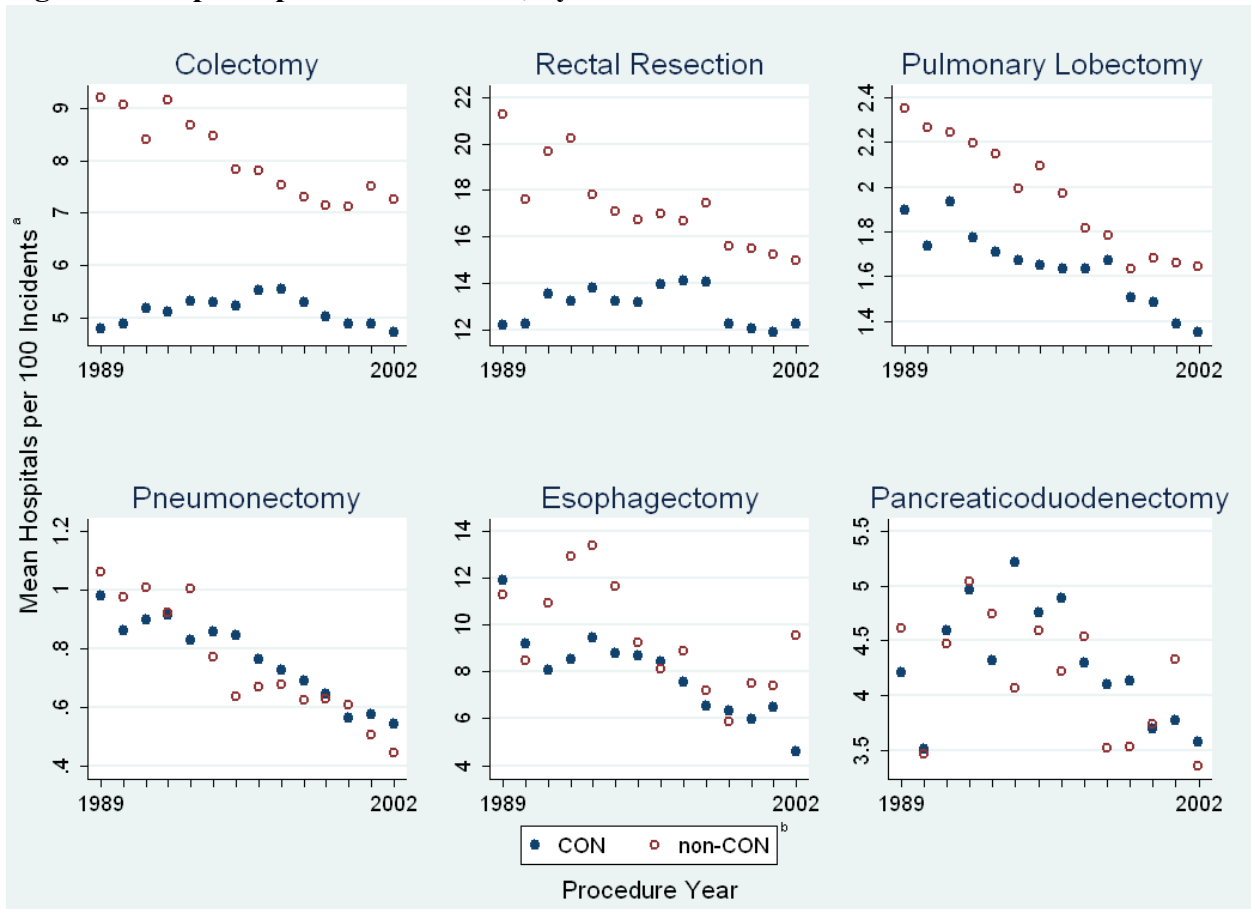
[a] The graphs indicate the number of hospitals performing procedures on Medicare beneficiaries, per 100 incidents of cancer.
[b] Mean values are reported for states with continuous CON versus states without CON from 1989 to 2002.

Figure 2: Procedures per 100 Incidents[a], By CON Status[b] and Procedure
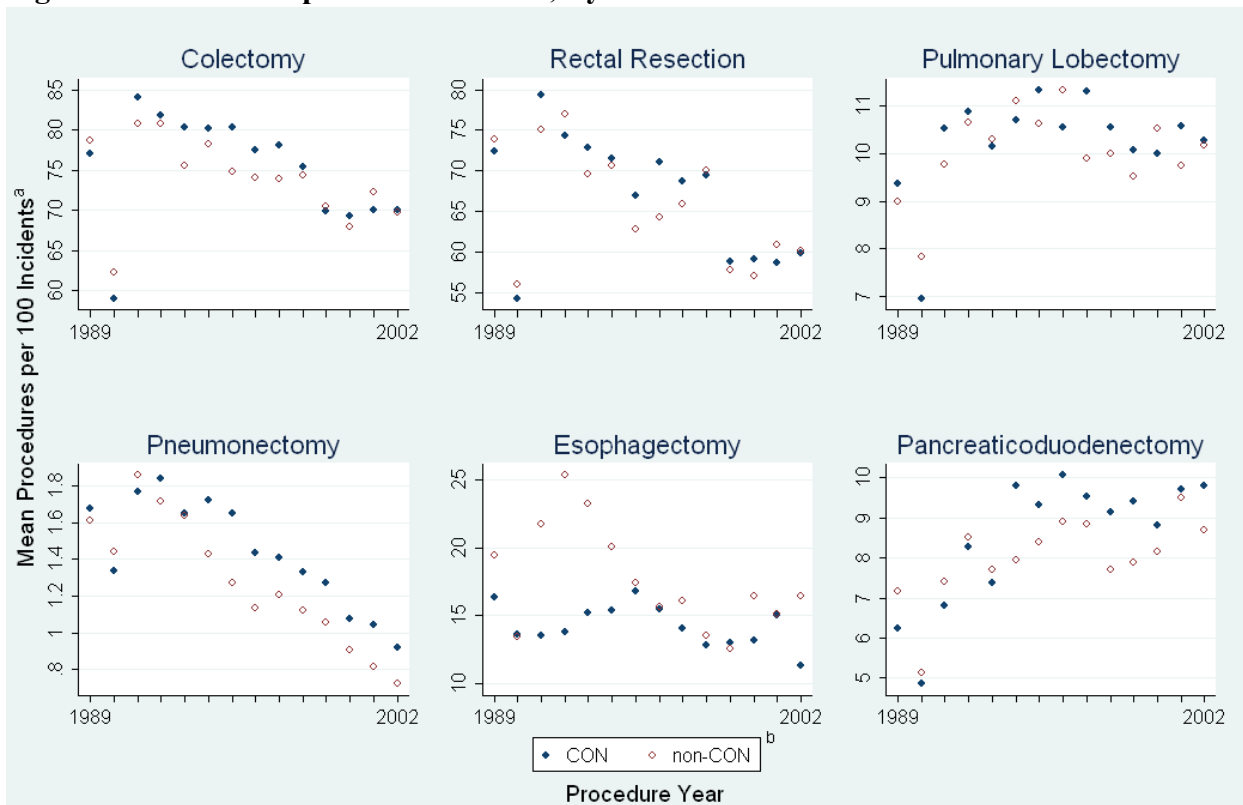
[a] The graphs indicate the number of procedures on Medicare beneficiaries, per 100 incidents of cancer.

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

Table 1: Acute Care CON Status during Sample Period 1989-2002

Continuous CON States		Discontinued CON States		Non-CON States	
Alabama[c]	New Hampshire	Indiana[c]	(1996)	Arizona	(1985)
Alaska[c]	New Jersey	Massachusetts	(1997)	Arkansas[c]	(1987)
Connecticut	New York[c]	Nebraska	(1997)	California	(1987)
Delaware	North Carolina[c]	North Dakota[c]	(1995)	Colorado	(1987)
Florida	Rhode Island	Ohio[c]	(1995)	Idaho	(1983)
Georgia[c]	South Carolina[c]	Oregon[c]	(1995)	Kansas[b]	(1985)
Hawaii[c]	Tennessee[c]	Pennsylvania	(1996)	Louisiana[d]	
Illinois	Vermont[b]			Minnesota	(1985)
Iowa	Virginia[c]			Montana	(1985)
Kentucky[c]	Washington[c]			New Mexico	(1983)
Maine[c]	West Virginia[c]			Oklahoma[c]	(1985)
Maryland[c]				South Dakota[c]	(1988)
Michigan[c]				Texas[c]	(1985)
Mississippi[c]				Utah	(1984)
Missouri[c]				Wisconsin	(1987)
Nevada				Wyoming	(1989)

[a] Years acute care CON were removed are in parenthesis.
[b] Not used in either dataset
[c] Not used in reduced dataset
[d] Never had CON

Table 2: Regression Estimates of the Effect of CON on Hospitals per 100 Incidents

	Colectomy	Rectal Resection	Pulmonary Lobectomy	Pneumonectomy	Esophagectomy	Pancreaticoduodenectomy
CON in force	-1.298**	-1.879**	-0.217**	0.017	-0.285	0.139
	(0.022)	(0.026)	(0.032)	(0.725)	(0.683)	(0.544)
Population/ square mile	-0.005***	-0.009***	-1.82e-4	-1.03e-4	-0.004***	-4.12e-4
	(0.000)	(0.000)	(0.148)	(0.169)	(0.000)	(0.518)
# out-of-state patients	-0.009***	-0.050***	-0.003***	-0.002	0.038	-0.006
	(0.001)	(0.000)	(0.009)	(0.592)	(0.350)	(0.704)
Medicare HMO penetration	-10.432***	-17.964***	-0.767*	-0.372	-2.891	-0.541
	(0.000)	(0.000)	(0.084)	(0.202)	(0.350)	(0.623)
% black	-0.066*	-0.026	-0.010	-1.94e-4	-0.133***	0.014
	(0.088)	(0.592)	(0.210)	(0.948)	(0.006)	(0.339)
% age 75+	0.154	0.509***	0.019	0.036***	0.167	0.014
	(0.144)	(0.000)	(0.361)	(0.002)	(0.295)	(0.735)
Observations			535			

* Statistically significant at 10% level; ** statistically significant at 5% level; *** statistically significant at 1% level.
[a] Dummy indicators for procedure year were also included in the above regressions.
[b] P-values are in parenthesis.

Table 3: Regression Estimates of the Effect of CON on Procedures per 100 Incidents

	Colectomy	Rectal Resection	Pulmonary Lobectomy	Pneumonectomy	Esophagectomy	Pancreaticoduodenectomy
CON in force	-0.270	-0.592	0.297	0.116	1.274	0.262
	(0.887)	(0.797)	(0.634)	(0.318)	(0.410)	(0.702)
Population/ square mile	-0.005*	-0.003	-0.001	-2.54e-4	-0.009***	3.00e-4
	(0.057)	(0.297)	(0.425)	(0.219)	(0.000)	(0.850)
# out-of-state patients	0.022	0.109**	0.039**	0.040***	0.996***	0.290***
	(0.122)	(0.016)	(0.014)	(0.000)	(0.000)	(0.000)
Medicare HMO penetration	-68.225***	-61.557***	-6.164**	-1.625**	-9.566	-4.217
	(0.000)	(0.000)	(0.028)	(0.020)	(0.142)	(0.230)
% black	-0.040	-0.063	-0.028	-0.002	-0.303***	0.007
	(0.793)	(0.787)	(0.491)	(0.748)	(0.002)	(0.867)
% age 75+	1.360***	1.267	0.288**	0.088***	0.378	0.028
	(0.009)	(0.142)	(0.028)	(0.002)	(0.203)	(0.778)
Observations				535		

* Statistically significant at 10% level; ** statistically significant at 5% level; *** statistically significant at 1% level.
[a] Dummy indicators for procedure year were also included in the above regressions.
[b] P-values are in parenthesis.

Table 4: Regression Estimates of the Effect of CON on Hospital Volume

	Colectomy	Rectal Resection	Pulmonary Lobectomy	Pneumonectomy	Esophagectomy	Pancreaticoduodenectomy
CON in force	1.727***	0.286	0.714**	0.093	0.228*	0.012
	(0.006)	(0.136)	(0.043)	(0.209)	(0.060)	(0.911)
Population/ square mile	0.016***	0.004***	2.29e-4	-2.81e-5	4.73e-5	3.87e-4*
	(0.000)	(0.000)	(0.802)	(0.844)	(0.891)	(0.053)
# out-of-state patients	0.021***	0.021***	0.036***	0.059***	0.097***	0.086***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Medicare HMO penetration	3.010	-0.021	-1.672	-1.292***	-0.715	-1.135*
	(0.521)	(0.989)	(0.424)	(0.001)	(0.291)	(0.082)
% black	0.005	-0.015	0.011	-0.001	-0.010	-0.007
	(0.927)	(0.448)	(0.716)	(0.868)	(0.226)	(0.264)
% age 75+	-0.153	-0.060	0.063	0.023	-0.006	-0.012
	(0.529)	(0.470)	(0.542)	(0.131)	(0.801)	(0.545)
Observations	700	700	700	682	683	690

* Statistically significant at 10% level; ** statistically significant at 5% level; *** statistically significant at 1% level.
[a] Dummy indicators for procedure year were also included in the above regressions.
[b] P-values are in parenthesis.