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## ORIGINAL RESEARCH

# Impact of US state government regulation on patient access to elective surgical care

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### Abstract

**Purpose.** Rising health care costs in the United States have led to government regulation of services via a Certificate of Need (CON) law in many states. Such regulation may decrease access to elective surgical procedures. This study describes the impact of CON laws on elective surgical care.

**Methods.** This retrospective cohort trial used data from the Health Care Utilization Project, a publicly available, inpatient database. Rates of six elective procedures were compared between 21 CON states and 5 non-CON states (2004-2005). Further, facility type (non-profit versus for-profit), facility teaching status, and median charges were also compared as a function of CON status. Statistical analysis was performed by Student's t-tests ( $\alpha=0.05$ ).

**Results.** CON laws did not affect procedure rates ( $P = 0.11-0.97$ ), but lower charges were found for lumbar discectomy (\$16,819 versus \$13,493  $p=0.04$ ), acoustic neuroma resection (\$60,993 versus \$46,353,  $P<0.001$ ), and microvascular decompression (MVD) for trigeminal neuralgia (\$37,741 versus \$27,729,  $P<0.001$ ) in CON states. Various procedures exhibited a shift from for-profit to non-profit facilities including lumbar discectomy (20% versus

9%,  $P=0.01$ ), acoustic neuroma resection (5.5% versus 0.2%,  $P=0.03$ ), MVD (20% versus 3%,  $P=0.02$ ), and rotator cuff repair (23% versus 10%,  $P=0.01$ ). CON status had no effect on proportion of cases occurring at teaching facilities.

**Conclusions.** CON laws appear to maintain patient access to elective surgical care while successfully reducing hospital charges. The location of surgery may shift to non-profit centers suggesting preferential certificate distribution, though this only partly explains the decreased charges in states with CON regulation.

Access to medical resources is often decided at the societal level by institutions that are in neither the consumer nor the provider role. Establishing the appropriate level of service is important because medical care is not subject to normal economic theory and biases toward consumption of excessive service. Indeed, if providers in a specific region are too plentiful, patients may access unnecessary care and increase

charges for third party payers. Conversely, if resources are too scarce, unacceptable wait times and patient morbidity can result. Regulation of health care facilities can be achieved by delineating access, quality, and cost. One mechanism in which the latter is achieved in the United States is in the form of Certificate of Need (CON) legislation. The federal government is the largest payer of health care services in the United States,<sup>1</sup> and therefore has an interest in reducing health care costs. This concern was first expressed in the 1960s, with the institution of the Comprehensive Health Planning Act providing funds for states that actively regulated health care services. The motivation to regulate health care arises from the situation that consumers and providers of health care are usually not responsible for the cost associated with that consumption, with consequent rapid expansion and duplication of health care services and progressively higher health care costs.<sup>2</sup>

CON laws are a method of US state regulation of various health care services; medical equipment such as magnetic resonance imaging scanners, health care facilities such as nursing homes, and lastly, operating rooms.<sup>3</sup> Institutions affected by CON operating room regulation include hospitals and free-standing ambulatory centers. Under a CON law, a health care provider or facility who wishes to acquire or replace an operating room (OR) cannot do so without first obtaining express permission from the Department of Health and Human Services (DHHS) of that particular state.<sup>4</sup> The DHHS permits the expansion and construction of ORs if their need has been demonstrated. Each state with a CON law has a methodology for determining OR need, and these methodologies vary between states. Typically, the number of applications for ORs exceeds the number needed as determined by the DHHS, therefore the DHHS must then allocate the certificates. Various criteria exist for the distribution of certificates, such as geographic location, multi-versus single-specialty facility, as well as facility status such as for-profit versus non-profit.

Previous studies of CON laws have investigated its effect on health care charges. A study conducted by Conover and Sloan<sup>5</sup> concerning CON law reversal in various states concluded no effect on health care charges. Lanning and coworkers<sup>6</sup> determined that states with CON laws had higher hospital charges than states without CON laws. Currently, there is no information in the literature assessing the impact of CON laws on patient access to care or resident access to sufficient cases for surgical training.

This study examines the impact of CON status on patient access to elective surgical care as well as surgical resident training. The results suggest that CON implementation does not affect the delivery of elective surgical care as assessed by procedure rates, reduces costs as assessed by median hospital charges, and does not sacrifice caseload performed at teaching institutions.

## Methods

Data was collected for six elective surgical procedures: lumbar discectomy, carpal tunnel release, acoustic neuroma resection, microvascular decompression for trigeminal neuralgia, tonsillectomy and adenoidectomy, and rotator cuff repair. This data was obtained online from the State Inpatient Database (SID) of the Health Care Utilization Project (HCUP), which is a collection of health care databases sponsored by the Agency for Healthcare Research and Quality (AHRQ). Thirty-nine states provide information to this dataset, with hospital participation yielding approximately 90% of all inpatient discharge from participating states. This includes clinical and non-clinical information regardless of payer, with discharges from community and specialty hospitals.<sup>7</sup> Furthermore, the database is subject to periodic quality checks that are available through the Health Care Utilization Project website, improving upon the data accuracy and completeness.<sup>8</sup>

Procedure information on the SID database is classified according to ICD-9 procedure codes which

TABLE 1. Statewide Procedure Rates by CON Status

Procedure	CON Status		P
	No	Yes	
Lumbar discectomy	51.7	51.4	0.97
Carpal tunnel release	0.55	0.46	0.49
Acoustic neuroma resection	1.02	0.96	0.29
Microvascular decompression for trigeminal neuralgia	0.52	0.60	0.76
Rotator cuff repair	7.2	5.8	0.24
Tonsillectomy and adenoidectomy	3.6	2.7	0.11

\* Procedure rates calculated per 100,000 population

were obtained online: lumbar discectomy (80.51), carpal tunnel release (04.43), acoustic neuroma resection (04.01), microvascular decompression for trigeminal neuralgia (04.41), tonsillectomy and adenoidectomy (02.83), and rotator cuff repair (83.63). Patient access was measured indirectly by analyzing procedural rates between states with and without CON regulation. Quantifying the demand for procedures by investigating wait times was not possible, as this information is not available from this database. Variables investigated in this study included procedure rate, proportion of procedures performed at different facilities (government, non-profit, and for-profit), proportion of procedures performed at teaching and non-teaching facilities, and median charges for each procedure. States were grouped by whether they had CON regulation of health care, and data was collected for 2004 and 2005. State populations for the years 2004 and 2005 were obtained from the U.S. Census Bureau. Statistical analysis involved Student's t-test of procedure rate, facility payer, facility teaching status, and hospitalization charges by state CON status at the 0.05 level of significance.

**Results**

Data was available from the SID for 21 states with CON legislation and 5 states without such regulation. Evaluation of per capita rates of all procedures revealed no statistically significant differences between states with and without CON legislation (Table 1). However, CON status did significantly impact on

TABLE 2. Median Procedure Charges by CON Status

Procedure	CON Status		P
	No	Yes	
Lumbar discectomy	\$16,819	\$13,493	0.04
Carpal tunnel release	\$15,195	\$10,150	0.08
Acoustic neuroma resection	\$60,993	\$46,353	<0.001
Microvascular decompression for trigeminal neuralgia	\$37,741	\$27,729	<0.001
Rotator cuff repair	\$14,726	\$12,422	0.10
Tonsillectomy and adenoidectomy	\$8,048	\$7,196	0.27

hospitalization charges (Table 2), with reductions in charges for lumbar discectomy ( $P=0.04$ ), acoustic neuroma resection ( $P<0.001$ ), and microvascular decompression for trigeminal neuralgia ( $P<0.001$ ). For example, median charge for the most common procedure evaluated, lumbar discectomy, was \$16,819 in states without CON regulation and \$13,493 in those with such laws. Although no differences were detected for carpal tunnel release ( $P=0.08$ ), rotator cuff repair ( $P=0.10$ ), and tonsillectomy and adenoidectomy ( $P=0.27$ ), there were trends towards reduced charges. These differences in procedural costs are illustrated in Figure 1.

Table 3 reveals that CON regulation leads to a reduction in procedures in for-profit institutions with a resultant shift to non-profit institutions. This was significant for lumbar discectomy ( $P=0.01$ ), acoustic neuroma resection ( $P=0.03$ ), microvascular decompression for trigeminal neuralgia ( $P=0.02$ ), and rotator cuff repair ( $P=0.01$ ). For example, in states without CON regulation, 20% of lumbar discectomies were

TABLE 3. Proportion of Procedures Performed in For-Profit Facilities by CON Status

Procedure	CON Status		P
	No	Yes	
Lumbar discectomy	20%	9%	0.01
Carpal tunnel release	3%	1.5%	0.61
Acoustic neuroma resection	5.5%	0.2%	0.03
Microvascular decompression for trigeminal neuralgia	20%	3%	0.02
Rotator cuff repair	23%	10%	0.01
Tonsillectomy and adenoidectomy	2%	6%	0.53

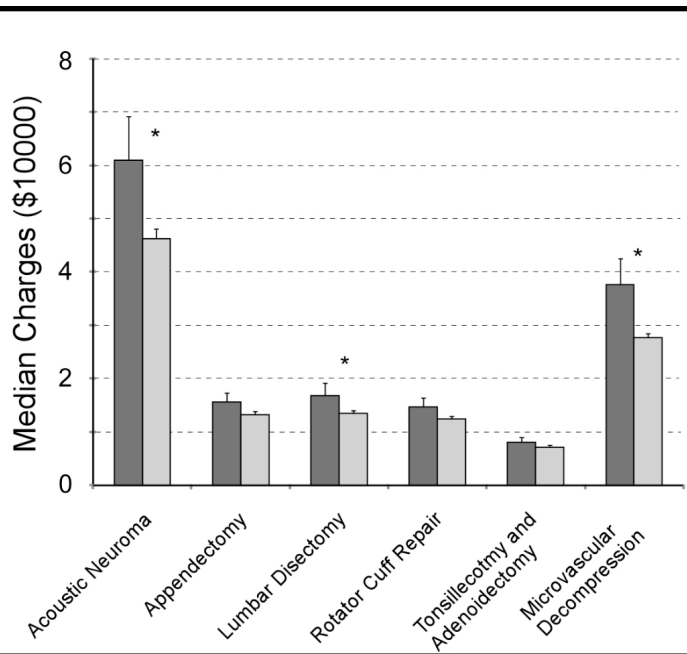


FIGURE 1. Median hospitalization charges for six separate surgical procedures in states without (dark grey) and with (light grey) certificate of need regulation of operating rooms. Data are presented as mean  $\pm$  standard error, and a significant reduction in charges were noted for acoustic neuroma resection, lumbar discectomy, and microvascular decompression for trigeminal neuralgia. Significance at the  $\alpha = 0.05$  level is denoted by '\*'.

performed in for-profit centers whereas this figure was 9% for states with regulation. No difference was observed for either carpal tunnel release or tonsillectomy and adenoidectomy. Furthermore, no differences in the proportion of cases performed in teaching facilities were found between states with and without CON regulation (Table 4).

**Discussion**

Regulation of ORs via CON regulation did not affect the overall rate of procedures performed, but did lead to a reduction of procedures in for-profit centres and an increase in procedures performed in non-profit centers. There was also a reduction in hospital charges associated with CON status that was significant for three of the six procedures analyzed. The proportion of procedures performed in teaching centers did not

differ between states with and without CON legislation.

The result that CON status does not impact on rates of various procedures suggests that this legislation does not impact negatively on patient access to elective surgical care. It has been speculated that health care functioning in a free market system would lead to supply limited access to health care, however this study does not support that hypothesis for the specific delivery of elective surgical care.<sup>3</sup> Further, our investigation revealed decreased hospital charges for procedures performed in states with CON regulation. These decreased charges are not correlated with the proportion of procedures performed in non-profit centers,  $r^2$  ranges from 0.011 to 0.15 for all six procedures investigated in this study. Consequently, our findings are in contrast to previous work revealing no correlation between CON status and hospital costs,<sup>9</sup> though that investigation analyzed hospital admissions in non-profit centers whereas our study focused on surgical procedures in various types of facilities. A cross-sectional analysis performed by Conover and Sloan showed that for states with mature CON legislation, there was a slight decrease in acute care spending, but no overall reduction in total spending.<sup>5</sup> This investigation examined spending on surgical and medical admissions as well as long-term care facilities.

Our data must be interpreted with caution as the database did not include patient wait times, and there-

TABLE 4. Proportion of Procedures Performed in Teaching Facilities by CON Status

Procedure	CON Status		P
	No	Yes	
Lumbar discectomy	43%	55%	0.07
Carpal tunnel release	41%	21%	0.21
Acoustic neuroma resection	86%	91%	0.72
Microvascular decompression for trigeminal neuralgia	81%	68%	0.15
Rotator cuff repair	22%	33%	0.13
Tonsillectomy and adenoidectomy	64%	58%	0.51

fore no information exists about how long patients have sustained symptoms prior to arriving at surgical intervention. Long-term outcomes are also not described, precluding analysis of the impact of regional variation in quality of care. An underlying assumption of this analysis was that all patients were treated in the state in which they reside, and the national population was homogeneous for the disease being studied. Both of these may not be valid, with Weinstein and coworkers demonstrating geographic variation in major surgery for degenerative diseases of the hip, knee, and spine.<sup>10</sup> Nevertheless, this study demonstrates equivalent rates at which procedures were performed in states with and without regulation of surgical care. Previous studies examining this outcome have focused on hospital investment in inpatient beds and surgical suites<sup>11,12</sup> and concluded that CON laws negatively impacted access. However, those studies did not specifically examine procedure rates, so the results presented herein may be more relevant.

Hospital charges were affected by CON status, with trends for decreasing charges in states with CON status, statistically significant at the 0.05 level for half the procedures. This data suggests that the implementation of CON regulation satisfies its objective in reducing health care expenditures. Previous investigations<sup>5,6</sup> have shown either no change in costs, or an increase in costs, associated with CON laws but these studies did not focus specifically on elective surgical procedures. There may also be other factors affecting hospital charges such as regional and hospital variation in costs. Research done by Fisher and coworkers<sup>13</sup> shows marked regional variability in Medicare spending in the United States, which is attributed to a propensity for inpatient-based, specialty oriented care.

Although overall access to care was unaffected by CON status, it did alter where the procedures were performed. Regulation of ORs was associated with a shift of procedures into non-profit institutions. This may reflect a preference for the state to award certificates to non-profit health care facilities. This preference might be attributed to the fact that elective surgi-

cal procedures generate revenues that can be used to fund other necessary, but expensive, health care services such as emergency rooms, intensive care units, and burn units. The emergency room is unique in that it is the primary source of health care for uninsured individuals, and hospitals often absorb the costs associated with this delivery of care. Campbell and Fournier<sup>14</sup> were able to show that this cross-subsidization of services is an implicit goal of CON regulation. Therefore, this outcome suggests that CON regulation may also be used to preserve health care services to indigent populations.

Each of the procedures evaluated was performed with similar ratios in teaching facilities independent of CON regulation. This result indicates that CON regulation does not negatively affect resident access to sufficient caseload for surgical training. This is an important result because regulation of surgical procedures might be expected to limit resident exposure by shifting procedures to more time-efficient hospital settings. It has previously been shown that care in teaching institutions is associated with greater 30-day morbidity, owing to the greater proportion of high-risk and complex procedures,<sup>15</sup> though the procedures evaluated in this study were routine cases to which residents should be exposed during training. Another method to assess quality of resident training is self-reported number of cases, however this information is not available from this database and would best be obtained from a survey or training program case logs.

Future directions for this work include analysis of wait times and the introduction of ambulatory data. Such data is not available from the SID and is beyond the scope of this analysis, but may serve to answer some of the questions that could not be addressed above. The technique described herein is best applied for common procedures where small number bias does not skew or excessively weight the results.

## Conclusion

This study has yielded important results regarding the impact of health care regulation on patient access to surgical. The goals of CON legislation include limiting unnecessary growth of health care services and containing health care costs. Key findings include that patients do not sustain decreased access to surgical intervention, but that the location at which this care is delivered shifts from for-profit to non-profit organizations. Further, a point of relevance to resident education is that there is no shift away from teaching centers. From this analysis, the CON system has achieved the objectives of decreasing costs while ensuring patient access to necessary care and maintaining sufficient volume for resident training.

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