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ORIGINAL RESEARCH

Government Regulation and Percutaneous Coronary Intervention Volume, Access and Outcomes: Insights From the Washington State Cardiac Care Outcomes Assessment Program

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BACKGROUND: It is unclear how to geographically distribute percutaneous coronary intervention (PCI) programs to optimize patient outcomes. The Washington State Certificate of Need program seeks to balance hospital volume and patient access through regulation of elective PCI.

METHODS AND RESULTS: We performed a retrospective cohort study of all non-Veterans Affairs hospitals with PCI programs in Washington State from 2009 to 2018. Hospitals were classified as having (1) full PCI services and surgical backup (*legacy* hospitals, n=17); (2) full services without surgical backup (*new certificate of need [CON]* hospitals, n=9); or (3) only nonelective PCI without surgical backup (*myocardial infarction [MI] access* hospitals, n=9). Annual median hospital-level volumes were highest at *legacy* hospitals (605, interquartile range, 466–780), followed by *new CON*, (243, interquartile range, 146–287) and *MI access*, (61, interquartile range, 23–145). Compared with *MI access* hospitals, risk-adjusted mortality for nonelective patients was lower for *legacy* (odds ratio [OR], 0.59 [95% CI, 0.48–0.72]) and *new-CON* hospitals (OR, 0.55 [95% CI, 0.45–0.65]). *Legacy* hospitals provided access within 60 minutes for 90% of the population; addition of *new CON* and *MI access* hospitals resulted in only an additional 1.5% of the population having access within 60 minutes.

CONCLUSIONS: Many PCI programs in Washington State do not meet minimum volume standards despite regulation designed to consolidate elective PCI procedures. This CON strategy has resulted in a tiered system that includes low-volume centers treating high-risk patients with poor outcomes, without significant increase in geographic access. CON policies should reevaluate the number and distribution of PCI programs.

Key Words: certificate of need ■ health policy ■ percutaneous coronary intervention ■ regulation

Over 600 000 percutaneous coronary interventions (PCI) are performed annually at >1600 centers across the United States.[1] The number of PCI centers has expanded over the past decade, out of proportion to population growth and despite declining coronary revascularization procedural volumes.[2] The rapid proliferation of PCI centers may be driven by the desire to provide timely access to primary PCI for STEMI (ST-segment–elevation myocardial infarction), and perhaps by economic incentives for hospitals in the current fee-for-service health care model.

However, there are countervailing reasons to consolidate PCI care among fewer, high-volume centers. Observational studies have demonstrated a

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CLINICAL PERSPECTIVE

What Is New?

- In this cross-sectional study including 110685 percutaneous coronary interventions (PCI) over 10 years in Washington State, most hospitals without cardiothoracic surgery backup did not meet volume targets despite government regulations designed to consolidate volume.
- PCI programs without certificate of need to perform elective PCI had poorer outcomes among patients presenting with acute coronary syndrome, compared with programs permitted to perform elective PCI.

What Are the Clinical Implications?

- Certificate of need regulations that result in low-volume PCI programs providing high acuity care may be unfavorable for patient outcomes.
- Expansion of the number of PCI programs is unlikely to improve the overall quality and access to PCI in the United States, though regulations that encourage regionalization and better match PCI services to unmet need could be more effective.

Nonstandard Abbreviations and Acronyms

COAP	cardiac care outcomes assessment program
CON	certificate of need
NCDR	National Cardiovascular Data Registry

volume-outcome relationship at the institutional and operator level.[3,4] In addition, clinical and procedural complexity of PCI procedures is increasing,[5,6] and patients may benefit from specialized care for high-risk conditions such as revascularization of chronic total occlusions.[7,8] One rational solution for these competing priorities is to consolidate elective PCI volume among high-volume centers. Currently there are 26 states that have certificate of need (CON) programs that regulate the performance of cardiac procedures, including cardiac catheterization.[9] The number of hospitals per capita performing PCI is lower in states with CON compared with states without CON.[10–12] However, studies have demonstrated mixed results regarding the impact of CON regulations on clinical outcomes for PCI and coronary artery bypass graft.[13–15]

In 2008, Washington State launched a certificate of need (CON) program that regulated hospitals' ability to perform elective PCI but allowed any hospital to perform nonelective PCIs, effectively creating 3 tiers of hospitals: (1) Full-service (elective and acute PCI) programs with cardiac surgery backup (*legacy* hospitals); (2) Full-service programs without cardiac surgery backup (*new CON* hospitals); and (3) PCI programs performing nonelective PCI only (*myocardial infarction [MI] access* hospitals). The regulation was intended to ensure annual hospital and operator volume of 300 cases and 50 cases, respectively, among programs performing elective PCI. This is a potential model for other health care systems and clinical services that seek to consolidate volume while maintaining access to care.

We analyzed the subsequent 10 years of data from the COAP (Cardiac Care Outcomes Assessment Program), a registry that captures all coronary revascularization procedures performed in nonfederal hospitals in Washington State to assess the impact of this government regulation of PCI services. We sought to determine if Washington State's strategy to regulate PCI programs was associated with: (1) achievement of minimum PCI volume standards among hospitals approved for elective PCI; and (2) similar patient outcomes among hospitals with and without elective PCI services.

METHODS

Data Source

The data that support the findings of this study are available from the corresponding author upon reasonable request. As a part of the Washington State Foundation for Health Care Quality, COAP is a physician-led initiative with universal participation from all non-Veterans Affairs sites in the state. Monthly meetings are conducted for quality improvement and sharing of best practices. The quality of the data is maintained through routine audits and data variables for the COAP registry are identical to the NCDR (National Cardiovascular Data Registry) CathPCI registry version 4.[16,17] The study was deemed exempt from institutional review board approval because the analysis was conducted by COAP for quality improvement and did not involve identified human participants.

Population and Definition

All PCI procedures performed in patients aged ≥18 years from January 1, 2009 to December 31, 2018 were included in the analysis.

The CON process in Washington State regulates hospitals' ability to perform PCI for elective indications. There are 17 hospitals that were historically allowed to perform elective PCI because of the presence of onsite surgical backup. In 2008, the Washington State legislature directed the Department of Health to developed standards for the consideration of new elective

PCI programs without surgical backup. Criteria included anticipated annual hospital and operator PCI volume of >300 cases and 50 cases, respectively, within 3 years of CON designation. Nine hospitals were approved by the end of 2009. Finally, 9 hospitals did not apply or were not approved for elective PCI. However, the ability to perform PCI for urgent or emergent indications was not regulated before or since the CON legislation. Some hospitals providing acute PCI services continued to do so, and 3 hospitals started new PCI programs for nonelective PCI without review by the state. To facilitate interpretability of this analysis, we have labeled these groups of hospitals as *legacy hospitals* (n=17), *new CON hospitals* (n=9) and *MI access hospitals* (n=9). No hospital lost CON status over the study period. Hospitals included in this analysis were approved under the 300 annual cases standard, though this has subsequently been revised to only 200 cases for *new CON* applications.

Clinical Outcomes

We analyzed the temporal trend and distribution of PCI volumes at the operator and institutional level for all 3 groups of hospitals (*legacy*, *new CON*, and *MI access*). Furthermore, volume benchmarks were analyzed as the proportion of hospitals performing at least 300 cases per year and the proportion of operators performing at least 50 cases per year, per clinical society volume benchmarks. For operators, we included all PCIs performed in a given year regardless of site, potentially including PCIs performed at multiple different hospitals with different CON designations. Since site-specific operator volume may also impact clinical care and outcomes, we additionally calculated operator volume by year at each site (Figure S1). With both methods, operators were counted multiple times if they practiced at multiple sites within a given year.

The primary outcome was risk-adjusted in-hospital mortality using the NCDR in-hospital mortality model. We also assessed the incidence of procedural complications, including bleeding within 72 hours (retroperitoneal bleeding, gastrointestinal bleeding, genitourinary bleeding, or blood transfusion), vascular complications (vascular injury requiring intervention), and coronary complications (coronary artery dissection, coronary artery perforation, or emergent coronary artery bypass graft surgery). Clinical outcomes of all 3 hospital groups were compared for nonelective patients only, because *MI access* hospitals only performed cases in this subset. We defined “nonelective” as any PCI with a *PCI indication* code of “PCI for STEMI” or “PCI for high-risk non-STEMI or unstable angina.” All other PCIs were considered “elective.” For some patients, this coding conflicted with the *PCI status* coding (elective, urgent, emergent, salvage) or the *CAD presentation* coding (stable angina, unstable angina, etc). There were 190 “elective” PCIs performed at *MI access* hospitals without a diagnosis of acute coronary syndrome. These PCIs were excluded from the primary outcomes analysis, since it was unclear if they were performed inappropriately in a center without CON or were miscoded. A sensitivity analysis including these cases did not alter the overall results (Table S1). Separately, a comparison of outcomes of elective PCI cases was performed for *legacy* and *new CON* hospitals only.

Geospatial Analysis and Mapping

Geospatial analysis was conducted to determine access to care to PCI centers for all residents of Washington State. A Google Maps API key was obtained and used with R software (ggdistance package) to calculate the minimum driving distance from each nonpostal zip code centroid in Washington State to the closest PCI capable center zip code centroid. Iterative analyses were performed for minimum driving distance for: (1) *legacy* hospitals alone; (2) *legacy+new CON* hospitals; and (3) all hospitals, to determine the extent to which the presence of each group of hospitals improves access to care. Zip-code tabulated area and Washington state polygon data were obtained from US Census Bureau’s MAF/TIGER geographic database. R software was used (ggmaps package) for graphical representation of minimum driving distance from each zip code. After calculating minimum driving distance, our data were linked with the 2010 US Census Bureau population by zip code. The population weighted mean and unweighted median (interquartile range) driving distances were then calculated.

Statistical Analysis

Unadjusted outcomes were compared with Chi-square statistic. Logistic regression was performed for in-hospital death with adjustment for the NCDR-CathPCI predicted probability of death and hospital type. This risk model includes age, body mass index, cerebrovascular disease, peripheral artery disease, chronic lung disease, prior PCI, diabetes (insulin dependent versus noninsulin dependent versus no diabetes), glomerular filtration rate, renal failure (glomerular filtration rate < 30 or on dialysis), ejection fraction, cardiogenic shock, and PCI status, heart failure within 2 weeks, cardiac arrest within 24 hours, previously treated lesion within 1 month, highest-risk lesion, number of diseased vessels, and chronic total occlusion.[18] Standard errors of the regression coefficients were adjusted for site-level correlated error using the Huber White Sandwich Estimator. This model demonstrated excellent discriminatory function in our data set with a c-statistic for nonelective patients of 0.90 (95% CI, 0.90–0.91). Similarly, adjustment of the bleeding outcome was performed using logistic regression including the NCDR-CathPCI bleeding risk score[19] and hospital type. Only unadjusted outcomes were presented for vascular and coronary complications, since validated risk models are unavailable and we were unable to assess for potential confounders. SPSS version 19.0 was used to analyze COAP data and R software used for geospatial analysis and mapping.

RESULTS

Among 110 685 PCIs between 2010 and 2018, 79 417 (71.8%) were performed for a nonelective indication and 32 268 (29.2%) electively. Overall, 88 641 PCIs (80.1%) were performed at *legacy* hospitals, 17 842 (16.1%) at *new CON* hospitals, and 4202 (3.8%) at *MI access* hospitals.

The distribution of annual hospital and operator PCI volume are summarized in Figure 1. Overall annual hospital volume was highest in *legacy* hospitals with median 605 PCI/year (interquartile range [IQR], 466–780); followed by *new CON*, 243 PCI/year (IQR, 146–287); and *MI access*, 61 PCI/year (IQR, 23–145). The state-mandated volume threshold of 300/cases on average per year was achieved by 93.8% of *legacy*, 11.1% of *new CON*, and 0% of *MI access* hospitals for the full study period. Similarly, annual operator PCI volume at each hospital was highest in *legacy* hospitals with median 78 PCI/year (IQR, 44–118), followed by *new CON* with 73 PCI/year (IQR, 40–115) and *MI access* with 51 PCI/year (IQR, 20–136). The annual benchmark of at least 50 cases was satisfied by 68.8% of operators practicing in *legacy* hospitals, 67.8% of operators in *new CON* hospitals, and 51.8% in *MI access* hospitals (Figure 1B), when considering operator volume cumulatively for operators who practice at >1 hospital in the state. An alternative method of assessing operator volumes, counting only cases performed by an operator within each hospital, showed lower volumes at *new CON* and *MI access* hospitals (Figure S1).

Baseline clinical and procedural variables for patients presenting with ACS are summarized in Table 1. Patients treated with PCI at *legacy* hospitals had a higher prevalence of medical comorbidities including previous MI (29%), heart failure (14%), diabetes (34%), and hypertension (76%). Patients treated at *MI access* hospitals had higher prevalence of high acuity clinical presentations including STEMI (38%), cardiogenic shock (6.7%), and cardiac arrest (7.5%). Comparison of clinical and procedural variables assessed among all patients (ACS and elective) are demonstrated in the Table S2. Among elective patients with PCI, procedural complexity was higher in the *legacy* compared with the *new CON* hospitals, including higher rates of left main intervention (1.8% versus 0.7%), bypass graft intervention (4.9% versus 3.4%), and chronic total occlusion intervention (11.4% versus 3.2%) (Table S3).

Clinical outcomes were analyzed separately among patients presenting with ACS and for elective PCI. For ACS indications, crude mortality was lower in the *legacy* hospitals (2.7%) and *new CON* hospitals (2.7%) compared with the *MI access* hospitals (5.1%) (Table 2). Risk-adjusted mortality was also lower in the *legacy* (OR, 0.59 [95% CI, 0.48–0.72]) and *new CON* (OR, 0.55 [95% CI, 0.45–0.65]) compared with the *MI access* hospitals. Unadjusted rates of bleeding, vascular complications, and coronary complications are reported in Table 2. Risk adjusted bleeding was similar at *legacy* (OR, 1.05 [95% CI, 0.86–1.27]) and lower at *new CON* hospitals (OR, 0.55 [95% CI, 0.43–0.69]) compared with *MI access* hospitals. Among patients with elective PCI, crude in-hospital mortality rates were higher in *legacy* (0.6%) compared with *new CON* hospitals (0.2%), with the small number of events precluding risk adjustment (Table 3).

Geospatial analysis was performed to determine access to care for PCI centers in Washington state. The *new CON* and the *MI access* hospitals were geographically clustered around existing *legacy* hospitals (Figure 2). *New CON* hospitals are located at a median of 24.7 minutes (IQR, 20.3–30.9) and a median of 15.0 miles (IQR, 12.4–21.7) from *legacy* hospitals. *MI access* hospitals are located at a median of 19.8 minutes (IQR, 14.4–24.8) and a median of 13.0 miles (IQR, 12.9–14.0) from *legacy* hospitals. Iterative analyses were performed to assess timely access to a PCI capable center, defined as a driving time <60 minutes. Including only *legacy* hospitals, geospatial analysis demonstrated that 90.0% of the Washington State population lives within 60 minutes of a PCI-capable center. The inclusion of *new CON* (n=9) and *MI access* (n=9) hospitals resulted in only an additional 1.5% of the state population having access within 60 minutes.

DISCUSSION

Our study examines a unique 3-tiered system of PCI programs in Washington State. The CON regulation was intended to control the expansion of elective PCI services, thereby rationally consolidating patients at higher-volume centers in areas of geographic need. Nonelective PCI was not regulated, potentially maintaining urgent access to PCI through smaller, more geographically dispersed hospitals. If effective, this system could serve as a model for other states or health care systems that wish to redistribute PCI volume to better meet the needs of their population. However, our analysis revealed significant limitations of this approach. First, the CON regulation failed to consistently ensure volume benchmarks among hospitals

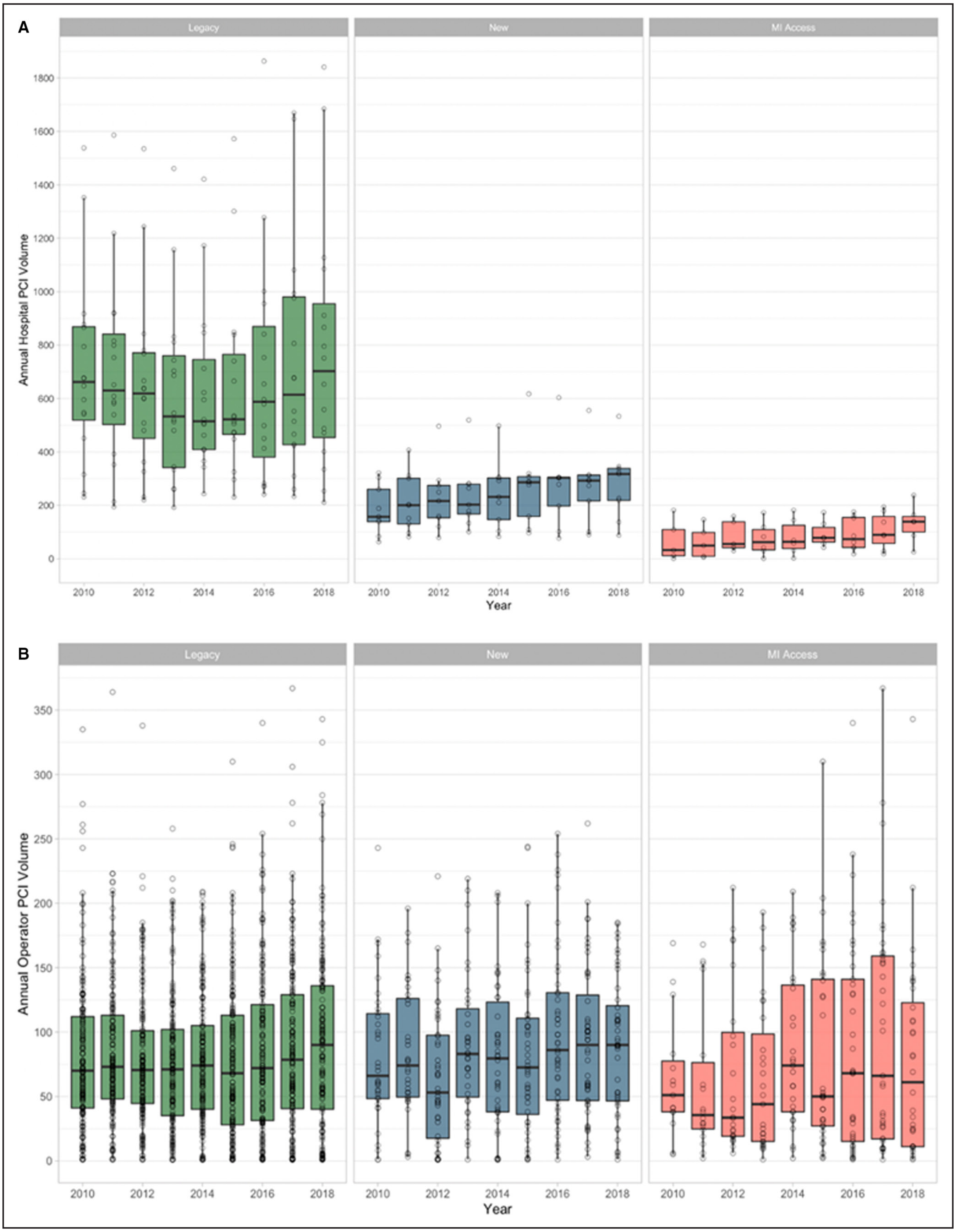

Figure 1. Annual hospital (A) and operator (B) percutaneous coronary intervention volume by certificate of need status. Each circle represents an individual hospital or operator. PCI indicates percutaneous coronary intervention; New, new certificate of need hospitals; *Legacy*, *legacy* certificate of need hospitals; *MI Access*, myocardial infarction access hospitals. Operators practicing at multiple sites with different certificate of need status were assigned to each group with their full cumulative annual case volume.

Table 1. Baseline Characteristics and Demographics of Patients Presenting for Nonelective PCI

Characteristic	*Legacy* (n=60866)	*New CON* (n=14539)	*MI Access* (n=4012)
Demographic variables			
Age, y (mean, SD)	66±12	64±12	65±13
Men	42971 (71%)	10526 (72%)	2859 (71%)
Insurance status*			
Private	38153 (63%)	7757 (54%)	1739 (47%)
Medicare	30909 (51%)	6048 (42%)	1620 (44%)
Medicaid	6871 (11%)	1156 (8%)	491 (13%)
Other	5395 (9%)	919 (6%)	401 (11%)
Uninsured	3322 (5%)	772 (5%)	265 (7%)
Prior MI	17567 (29%)	3557 (24%)	1045 (26%)
Prior PCI	21087 (35%)	4315 (30%)	1076 (27%)
Prior CABG	9566 (16%)	1365 (9%)	360 (9%)
History of HF	7387 (12%)	1253 (9%)	389 (10%)
Prior cerebrovascular disease	7736 (13%)	1276 (9%)	375 (9%)
Diabetes	20505 (34%)	4419 (30%)	1284 (32%)
On dialysis	1393 (2.3%)	265 (1.8%)	92 (2.3%)
Chronic lung disease	8169 (13%)	1485 (10%)	501 (12%)
Peripheral artery disease	6512 (11%)	996 (7%)	335 (8%)
Hypertension	46395 (76%)	10538 (72%)	2880 (72%)
Dyslipidemia	45372 (74%)	9619 (66%)	2598 (65%)
Predicted risk of mortality	0.016±0.062	0.015±0.059	0.024±0.074
Clinical presentation			
CAD presentation**			
Stable angina	629 (1%)	186 (1%)	24 (1%)
Unstable angina	22592 (37%)	4743 (33%)	985 (25%)
Non-STEMI	21565 (35%)	4898 (34%)	1436 (36%)
STEMI	15731 (26%)	4584 (32%)	1524 (38%)
No symptoms	243 (<1%)	78 (1%)	15 (<1%)
Non-ischemic	103 (<1%)	48 (<1%)	25 (1%)
Missing	3 (0%)	2 (0%)	3 (0%)
HF within 2 wk	6640 (11%)	1232 (8%)	380 (10%)
Cardiogenic shock within 24 h	2408 (4.0%)	497 (3.4%)	270 (6.7%)
Cardiac arrest within 24 h	2276 (3.7%)	752 (5.2%)	299 (7.5%)
Procedure priority**			
Elective	10336 (17%)	2179 (15%)	122 (3%)
Urgent	32527 (53%)	6890 (47%)	2029 (51%)
Emergent	17426 (29%)	5314 (36%)	1808 (45%)
Salvage	565 (1%)	149 (1%)	50 (1%)
Procedural characteristics			
Multivessel disease (2 or more), %	8289 (15%)	1701 (14%)	452 (13%)
Number of treated lesions (device deployed)			
1	43793 (72%)	11067 (76%)	2960 (74%)
2	12207 (20%)	2645 (18%)	814 (20%)
3+	3415 (6%)	585 (4%)	156 (4%)
Highest-risk lesion segment			
Proximal LAD	5865 (9.6%)	1315 (9.0%)	561 (14.0%)
LM	979 (1.6%)	74(0.5%)	44 (1.1%)

(*Continued*)

Table 1. Continued

Characteristic	*Legacy* (n=60 866)	*New CON* (n=14 539)	*MI Access* (n=4012)
Lesion in graft, %	3371 (5.5%)	500 (3.4%)	130 (3.2%)
Bifurcation lesion, %	8416 (14%)	2598 (20%)	826 (21%)
CTO, %	2441 (4.0%)	341 (2.3%)	142 (3.5%)
IABP	1912 (3.1%)	311 (2.1%)	171 (4.3%)
Referral to cardiac rehab among eligible patients, %	29 050 (53%)	6089 (44%)	1796 (50%)
Door to balloon time for STEMI, min (mean, SD)	75±51 (n=13 386)	72±42 (n=4275)	81±58 (n=1413)
Radial access	14 510 (24%)	4016 (28%)	934 (23%)
Fluoroscopy time, min (mean, SD)	17±14	16±11	21±38
Contrast volume, mL (mean, SD)	181±80	184±77	194±81

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; CON certificate of need; CTO, chronic total occlusion; HF, heart failure; IABP, intra-aortic balloon pump; LAD, left anterior descending; LM, left main; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment–elevation myocardial infarction; and UA, unstable angina.

*Columns do not total to 100% because many patients had >1 payer. "Other" includes patients with military, non-United States, and Indian Health Service insurance.

**This cohort of "non-elective" patients was defined by the "PCI Indication" of PCI for STEMI, non–ST-segment–elevation myocardial infarction, or unstable angina. For some patients this conflicted with the coded data for "CAD presentation" and "procedural priority."

and operators providing elective PCI services. Next, *MI access* hospitals without elective PCI programs had markedly lower volumes, higher-risk patients, and worse outcomes compared with PCI programs with full elective and acute services. Finally, the presence of *MI access* hospitals had little impact on patient access. These findings have important implications as hospitals and health systems consider restructuring care delivery models for PCI.

Federal CON regulations emerged in the 1970s with an intent to rationally allocate specialized health care resources to high-volume institutions to improve quality of care and restrain health care expenditure. In 1986, the federal legislation was revoked and the decision to maintain CON regulations were left to individual states.[14] Older studies described lower mortality for patients treated in states with CON programs,[11,20] a difference that was attributed to higher-volume hospitals performing coronary revascularization procedures. More contemporary studies, however, have demonstrated similar outcomes for PCI and coronary artery bypass graft in states with or without CON.[13,14,21] These findings have brought to question whether CON policy is inherently ineffective or if states have failed to adequately enforce policy measures.

In our study, only *legacy* hospitals (with cardiac surgery programs) consistently maintained PCI volumes greater than 300 per year. Most *new CON* hospitals (without cardiothoracic surgery programs) failed to meet this target, despite committing to this minimum volume to obtain CON certification. Furthermore, a large proportion of operators at all 3 types of hospitals failed to achieve the currently recommended volume of 50 PCI cases/year. Previous studies have established an inverse relationship between operator or hospital volume and in-hospital mortality.[3,4,22] Our findings parallel national trends, with increasing number of PCI programs despite stable or declining case volumes.

Table 2. Outcomes of Patients Receiving Nonelective PCI at *Legacy*, *New CON*, and *MI Access* Hospitals

Characteristic	*Legacy* (n=60 866)	*New CON* (n=14 539)	*MI Access* (n=4012)	*Legacy* vs *MI Access* (OR, 95% CI)	*New CON* vs *MI Access* (OR, 95% CI)
Unadjusted in-hospital death	1655 (2.7%)	398 (2.7%)	205 (5.1%)	0.52 (0.30–0.89)	0.52 (0.31–0.89)
Adjusted in-hospital death				0.58 (0.37–0.92)	0.54 (0.35–0.84)
Unadjusted bleeding*	1558 (2.6%)	208 (1.4%)	125 (3.1%)	0.82 (0.59–1.13)	0.45 (0.30–0.67)
Adjusted bleeding				1.04 (0.69,1.58)	0.55 (0.34,0.87)
Unadjusted vascular complication**	1041 (1.7%)	207 (1.4%)	84 (2.1%)	0.81 (0.52,1.27)	0.68 (0.39,1.17)
Unadjusted coronary complication***	1092 (1.8%)	207 (1.4%)	78 (1.9%)	0.92 (0.57–1.49)	0.73 (0.44–1.21)

CON indicates certificate of need; MI, myocardial infarction; and OR, odds ratio.

*Bleeding within 72 hours, retroperitoneal bleeding, gastrointestinal bleeding, genitourinary bleeding, or red blood cell/whole blood transfusion.

**Vascular injury requiring intervention.

***Dissection, perforation, or emergent coronary artery bypass graft surgery.

Table 3. Unadjusted Outcomes of Patients Receiving Elective PCI at *Legacy* and *New CON* hospitals

Characteristic	*Legacy* (n=27 775)	*New CON* (n=3303)	OR, 95% CI
Death at discharge	159 (0.6%)	7 (0.2%)	2.71 (1.21–6.09)
Bleeding*	309 (1.1%)	16 (0.5%)	2.31 (0.98–5.43)
Vascular complication**	343 (1.2%)	40 (1.2%)	1.02 (0.49–2.14)
Coronary complication***	579 (2.1%)	49 (1.5%)	1.41 (0.83–2.42)

CON indicates certificate of need; and OR, odds ratio.
*Bleeding within 72 hours, retroperitoneal bleeding, gastrointestinal bleeding, genitourinary bleeding, or red blood cell/whole blood transfusion.
**Vascular injury requiring intervention.
***Dissection, perforation, or emergent coronary artery bypass graft surgery.

Nationally, PCI capable centers increased by 21.2% from 2003 to 2011, during which time the US population only increased by 8.3%.[2] The new CMS rule allowing PCI in ambulatory surgical centers will likely only further this trend towards a greater number of low-volume programs.[23]

However, there is evidence that PCI without on-site surgical backup can be safe and effective.[24,25] In our cohort, the outcomes of patients treated at the *New CON* hospitals (without surgical backup) were as good as the higher-volume *legacy* hospitals. Complications were modestly lower at *new CON* hospitals, though among a lower-risk patient population. In addition, our analysis uniquely identifies a separate subset of hospitals without surgical backup that have poor outcomes. These *MI access* hospitals have low volume and care for a high-risk population that often presents with STEMI or cardiogenic shock. It is possible that the absence of routine, elective cases in these hospitals leads to challenges such as lack of dedicated staff for the catheterization laboratory and limited resources. In addition, operators in these hospitals commonly work at multiple sites, and may therefore be less familiar with staff and facilities compared with operators based at a single hospital.

These challenges at small *MI access* programs could be offset by reductions in ischemic time for patients with STEMI, if they provided improved coverage of the population of Washington State. The *MI access* hospitals cared for modestly greater proportions of patients with Medicaid or no health insurance, potentially providing a critical access role for underserved populations. However, our findings suggest that the inclusion of 18 hospitals without on-site surgical backup had minimal effect on increasing the proportion of the population with timely access to a PCI-capable hospital. Hospitals without surgical backup were often clustered around existing high-volume *legacy* hospitals. These results mirror geospatial analyses at the national level demonstrating minimal improvement in

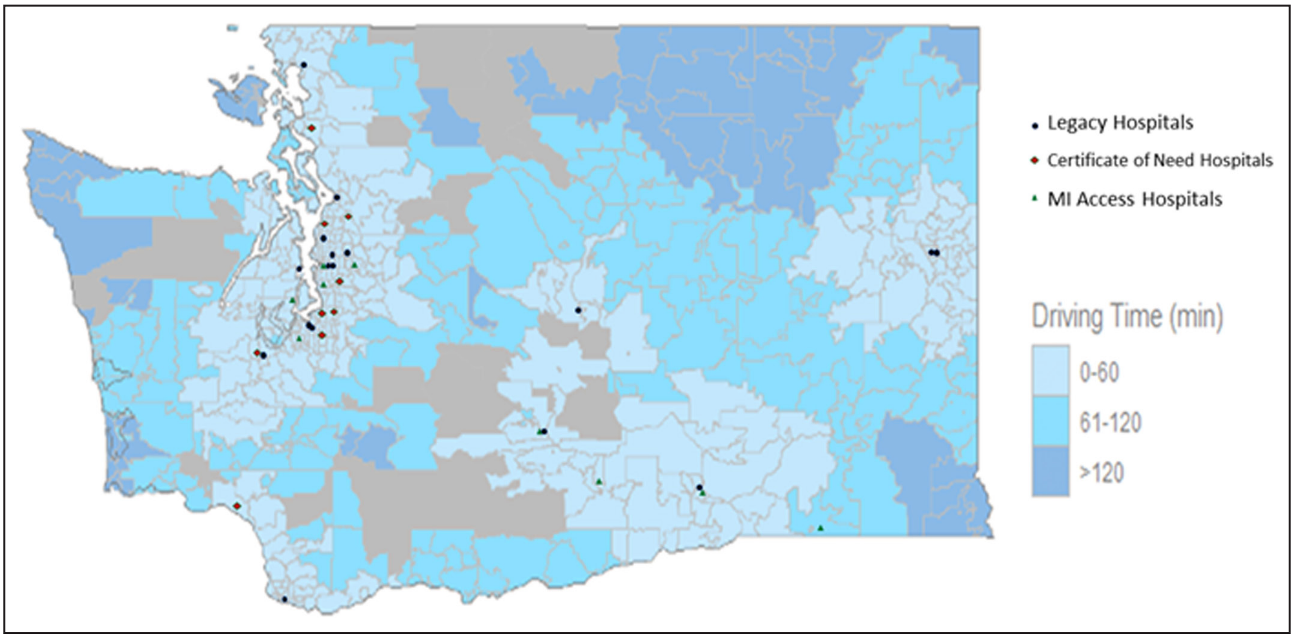

Figure 2. Geospatial mapping for driving time to nearest percutaneous coronary intervention capable center. Drive time is calculated to the nearest *legacy* hospital (full-service percutaneous coronary intervention program with surgical backup). MI indicates myocardial infarction. Gray shaded areas represent zip code tabulated areas for which driving distance could not be calculated, primarily because of national and state parks and forests.

access to care despite large growth in PCI capable centers.[2,26] It is possible that CON regulations could be used more effectively to distribute PCI programs for improved access. Alternatively, other strategies to expand revascularization access for STEMI patients may be more cost effective. Regional consortia for pre-hospital triage using a hub-and-spoke model have been associated with significant reductions in ischemic time,[27] and high acuity patients could be preferentially transferred to high-volume hospitals. Use of thrombolytics, followed by transfer to a high-volume PCI center, may be preferred for patients with STEMI in some rural areas.[28] Supporting these regional hospital collaborations could be a more effective use of government intervention.

Our results have important implications for current and future CON regulations and for the rational allocation of invasive procedures overall. First, patients are unlikely to benefit from procedural programs with both low volume and high acuity. Worse outcomes at *MI access* hospitals raise important concerns that increasing numbers of PCI programs may not translate to improved clinical outcomes for rural patients. Our data argue for consolidation of PCI programs, contrary to the current trend towards expansion. Second, CON programs may not achieve their goals if volume targets are not re-evaluated and enforced. Health systems with more centralized organization have achieved markedly greater consolidation and higher volumes, including the Canadian province of British Columbia which has only 5 PCI programs despite a population and geography similar to Washington State. Finally, it appears to be safe to perform PCI at moderate volume PCI hospitals without surgical backup that treat both elective and nonelective patients. We could not assess whether this model is financially advantageous for individual hospitals or the US health care system overall, or implications for patient convenience and satisfaction.

Several limitations with our study must be acknowledged. First, we cannot causally attribute all characteristics of Washington State PCI programs to the CON legislation, though the existence of programs that perform only nonelective PCI would be unlikely without external regulation. Secondly, in-hospital mortality was the primary comparison between groups, which may be a poor marker of PCI quality.[29,30] Risk adjustment was performed with the NCDR CathPCI mortality risk score, which may not capture all important differences in case mix in the 3 types of hospitals. This could disadvantage the *MI access* hospitals if their patients are higher risk in unmeasured variables such as poor socioeconomic status, or *legacy* hospitals if they are receiving a disproportionate number of high-risk transfers from other centers. However, the CathPCI risk score has been shown to perform well along the full spectrum of risk, and in fact hospitals with the highest estimated risk may benefit from the adjustment model.[31] Third, vascular and coronary complication rates were not adjusted, and differences may be driven by imbalances in clinical presentation. Fourth, individual address or zip code data were not available for all patients, so the geospatial analysis was conducted from zip code centroids which may not accurately reflect access to care, particularly from regions with larger zip codes areas or those where driving may not be the fastest mode of transportation. Data in this registry before 2009 are limited, and therefore a direct comparison of case volumes and outcomes before and after CON legislation cannot be performed. Finally, this study is from a single state and our results may not be generalizable to other regions.

CONCLUSIONS

Many PCI programs in Washington State do not meet minimum volume standards despite regulation designed to consolidate elective PCI procedures. Additionally, the lack of regulation of PCI for acute indications has yielded a tiered system that includes many low-volume centers treating high-risk patients with poor outcomes. Expansion of the number of PCI programs is unlikely to improve the overall quality and access to PCI in the United States, though regulations that encourage regionalization and better match PCI services to unmet need could be more effective.

ARTICLE INFORMATION

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Supplemental Material

Table S1–S3
Figure S1

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SUPPLEMENTAL MATERIAL

Table S1: Outcomes of patients presenting for non-elective indications, with all patients treated at MI access hospitals assumed to have an acute presentation. This sensitivity analysis assumes that cases at MI Access hospitals coded as “elective” (n = 190) are miscoded and are in fact acute coronary syndrome presentations.

Characteristic	Legacy (n=60,866)	New CON (n=14,539)	MI Access (n=4202)	Legacy vs. MI Access (OR, 95%CI)	New CON vs MI Access (OR, 95%CI)
Unadjusted In-hospital death	1655 (2.7%)	398 (2.7%)	209 (5.0%)	0.56 (0.49-0.64)	0.64 (0.57-0.72)
Adjusted in-hospital death				0.56 (0.47-0.67)	0.61 (0.50-0.75)
Unadjusted Bleeding*	1558 (2.6%)	208 (1.4%)	130 (3.1%)	0.83 (0.70-0.99)	0.58 (0.50-0.66)
Adjusted bleeding				1.04 (0.86-1.26)	0.55 (0.43-0.69)
Unadjusted Vascular complication**	1041 (1.7%)	207 (1.4%)	91 (2.2%)	0.80 (0.66-0.98)	0.73 (0.61-0.87)
Unadjusted Coronary complication***	1092 (1.8%)	207 (1.4%)	84 (2.0%)	0.90 (0.73-1.11)	0.77 (0.64-0.93)

CON, certificate of need; MI, myocardial infarction; OR, odds ratio; CI, confidence interval

*Bleeding within 72 hours, retroperitoneal bleeding, gastrointestinal bleeding, genitourinary bleeding, or red blood cell/whole blood transfusion
**Vascular injury requiring intervention
***Dissection, perforation or emergent coronary artery bypass graft surgery

Table S2: Baseline characteristics and demographics of all patients receiving PCI at *Legacy*, *New CON*, and *MI Access* hospitals, inclusive of elective and non-elective presentations.

Characteristic	Legacy (n=88,641)	New CON (n=17,842)	MI Access (n=4,202)
Demographic Variables			
Age (mean, SD)	66±12 (n=88,641)	64±12 (n=17,839)	65±13 (n=4,199)
Men	63,569 (72%)	12,960 (73%)	3,007 (72%)
Insurance Status*			
Private	57,517 (65%)	9,518 (54%)	1,784 (46%)
Medicare	47,186 (53%)	7,760 (44%)	1,679 (43%)
Medicaid	9,294 (11%)	1,389 (8%)	500 (13%)
Other	7,275 (8%)	1,025 (6%)	471 (12%)
Uninsured	3,777 (4%)	834 (5%)	266 (7%)
Prior MI	27,207 (31%)	4,562 (26%)	1,095 (26%)
Prior PCI	34,594 (39%)	5,765 (32%)	1,142 (27%)
Prior CABG	15,602 (18%)	1,800 (10%)	391 (9%)
History of HF	12,121 (14%)	1,674 (9%)	423 (10%)
Prior cerebrovascular disease	11,733 (13%)	1,607 (9%)	393 (9%)
Diabetes	30,878 (35%)	5,574 (31%)	1,366 (32%)
On dialysis	2104 (2.4%)	321 (1.8%)	99 (2.4%)
Chronic lung disease	11,930 (14%)	1,873 (10%)	527 (12%)
Peripheral artery disease	10,292 (12%)	1296 (7%)	359 (8%)
Hypertension	69,247 (78%)	13,216 (74%)	3,038 (72%)
Dyslipidemia	69,246 (78%)	12,245 (69%)	2,738 (65%)
Predicted risk of mortality	0.012±0.053	0.013±0.054	0.024±0.075
Clinical Presentation			
CAD Presentation			
Stable angina	15,267 (17%)	2098 (12%)	85 (2%)
Unstable angina	29,709 (33%)	5304 (30%)	1024 (24%)
Non-STEMI	22,114 (25%)	4976 (28%)	1456 (35%)
STEMI	15,738 (18%)	4595 (26%)	1529 (36%)
No symptoms	4388 (5%)	610 (3%)	57 (1%)
Non-ischemic	1397 (2%)	229 (1%)	45 (1%)
Missing	28 (0%)	30 (0%)	6 (0%)
HF within 2 weeks	10,064 (11%)	1606 (9%)	412 (10%)
Cardiogenic shock within 24 hours	2526 (2.8%)	506 (2.8%)	273 (6.5%)
Cardiac Arrest within 24 hours	2382 (2.7%)	778 (4.4%)	306 (7.3%)
Procedure priority			
Elective	34,278 (39%)	5033 (28%)	200 (5%)
Urgent	36,158 (41%)	7274 (41%)	2132 (51%)
Emergent	17,557 (20%)	5343 (30%)	1814 (43%)
Salvage	601 (1%)	153 (1%)	53 (1%)

Procedural Characteristics			
Multivessel disease (2 or more) (%)	12,317 (16%)	2043 (14%)	477 (13%)
Number of treated lesions (device deployed)			
1	62,503 (70%)	13,434 (75%)	3103 (74%)
2	18,551 (21%)	3335 (19%)	848 (20%)
3+	5248 (6%)	734 (4%)	161 (4%)
Highest-risk lesion segment			
Proximal LAD	8293 (9.4%)	1532 (8.6%)	581 (13.8%)
LM	1470 (1.7%)	96 (0.5%)	47 (1.1%)
Lesion in graft (%)	5611 (6.5%)	447 (2.5%)	150 (3.6%)
Bifurcation lesion (%)	12,546 (14%)	3807 (21%)	855 (20%)
CTO (%)	5611 (6.3%)	447 (2.5%)	150 (3.6%)
IABP	2073 (2.3%)	323 (1.8%)	177 (4.2%)
Referral to cardiac rehab among eligible patients (%)	41,539 (51%)	7066 (41%)	1852 (49%)
Door to balloon time for STEMI (minutes) (mean, SD)	75±51 (n=88,641)	72±42 (n=4275)	81±58 (n=1413)
Radial access	21,325 (24%)	5478 (31%)	996 (24%)
Fluoroscopy time (min) (mean, SD)	18±29	16±11	21±37
Contrast volume (mL) (mean, SD)	182±82	183±79	194±81

CON, certificate of need; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; HF, heart failure; CAD, coronary artery disease; STEMI, ST elevation myocardial infarction; UA, unstable angina; LAD, left anterior descending; LM, left main; CTO, chronic total occlusion

*Columns do not total to 100% because many patients had more than one payer. “Other” includes patients with military, non-United States, and Indian Health Service insurance.

Table S3: Baseline characteristics and demographics of patients presenting for elective PCI.

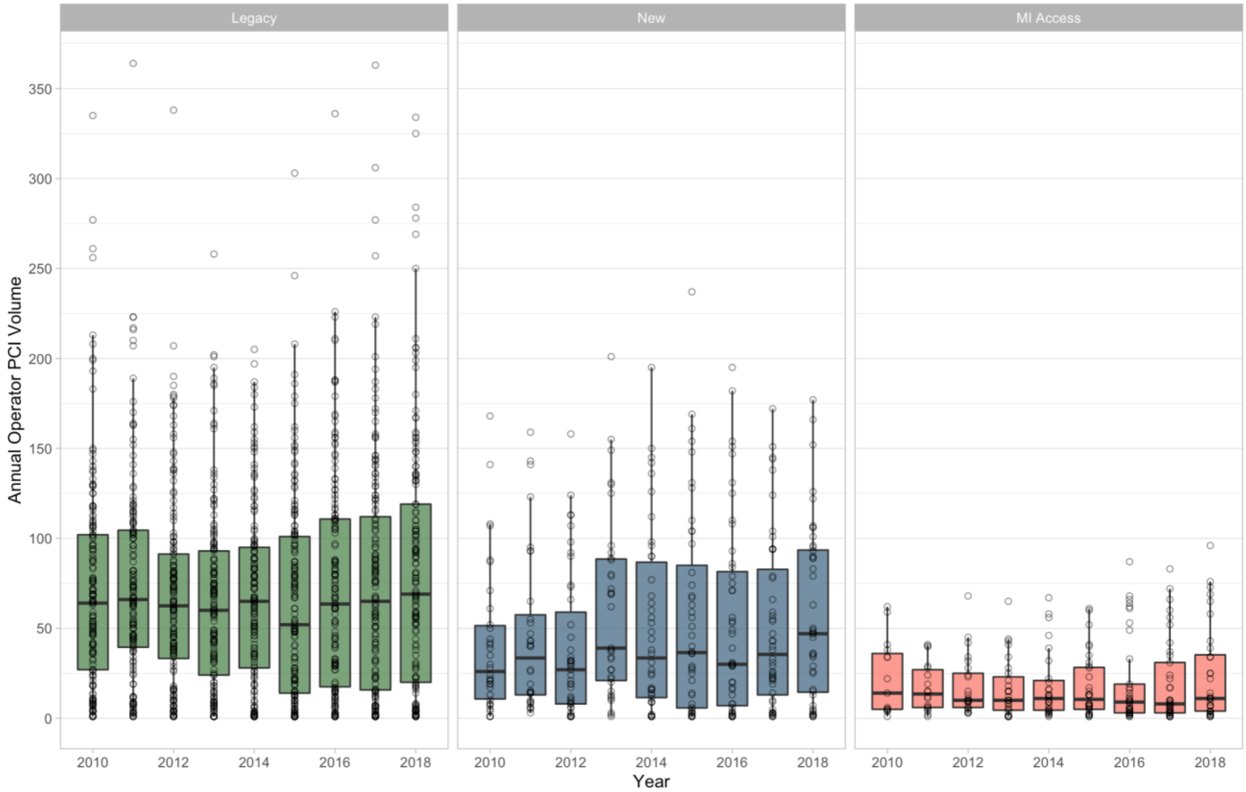
Characteristic	Legacy (n=27,775)	New CON (n=3,303)
Age	67±11	67±11
Men	20,598 (74%)	2,434 (74%)
Prior MI	9,640 (35%)	1,005 (30%)
Prior PCI	13,507 (49%)	1,450 (44%)
Prior CABG	6,036 (22%)	435 (13%)
History of HF	4,734 (17%)	421 (13%)
Prior cerebrovascular disease	3997 (14%)	331 (10%)
Diabetes	10,373 (37%)	1,155 (35%)
On dialysis	711 (2.6%)	56 (1.7%)
Chronic lung disease	3,761 (14%)	388 (12%)
Peripheral artery disease	3,780 (14%)	300 (9%)
Hypertension	22,852 (82%)	2,678 (81%)
Dyslipidemia	23,874 (86%)	2,626 (80%)
Predicted risk of mortality	0.004±0.026	0.003±0.023
CAD Presentation*		
Stable angina	14,638 (53%)	1,912 (58%)
Unstable angina	7,117 (26%)	561 (17%)
Non-STEMI	549 (2%)	78 (2%)
STEMI	7 (0%)	11 (< 1%)
No symptoms	4,145 (15%)	532 (16%)
Non-ischemic	1,294 (5%)	181 (6%)
Missing	25 (0%)	28 (1%)
HF within 2 weeks	3,416 (12%)	373 (11%)
Cardiogenic shock within 24 hours	118 (0.4%)	9 (0.3%)
Cardiac Arrest within 24 hours	106 (0.4%)	26 (0.8%)
Procedure priority*		
Elective	23,942 (86%)	2,854 (86%)
Urgent	3,631 (13%)	384 (12%)
Emergent	131 (< 1%)	29 (1%)
Salvage	36 (< 1%)	4 (< 1%)
Multivessel disease (2 or more) (%)	4,028 (16%)	342 (13%)
Number of treated lesions (device deployed)		
1	18,710 (67%)	2,367 (72%)
2	6,344 (23%)	690 (21%)
3+	1,833 (7%)	150 (5%)

Highest-risk lesion segment		
Proximal LAD	2,428 (8.7%)	217 (6.6%)
LM	491 (1.8%)	22 (0.7%)
Lesion in graft (%)	1,351 (4.9%)	112 (3.4%)
Bifurcation lesion (%)	4,130 (15%)	849 (26%)
CTO (%)	3,170 (11.4%)	106 (3.2%)
Stress or imaging test (for stable PCI)	1,148 (13%)	131 (9%)
IABP	161 (0.6%)	12 (0.4%)
Referral to cardiac rehab among eligible patients (%)	12,489 (47%)	977 (30%)
Radial access	6,815 (24%)	1,460 (44%)
Fluoroscopy time (min)	21±46	17±12
Contrast volume (mL)	183±87	181±89

CON, certificate of need; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; HF, heart failure; CAD, coronary artery disease; STEMI, ST elevation myocardial infarction; UA, unstable angina; LAD, left anterior descending; LM, left main; CTO, chronic total occlusion

**This cohort of “elective” patients was defined by the “PCI Indication” as described in the Methods section. For some patients this conflicted with the coded data for “CAD presentation” and “procedural priority.”

Figure S1: Annual operator PCI volume by Certificate of Need status, without aggregating operator volume across hospitals.



Each circle represents an individual operator. For operators practicing at multiple hospitals, volume is presented only for cases performed at each specific hospital, not cumulatively. PCI = percutaneous coronary intervention, New = new certificate of need hospitals, Legacy = legacy certificate of need hospitals, Non = non certificate of need hospitals.