

Association of Statewide Certificate of Need Regulations With Percutaneous Coronary Intervention Appropriateness and Outcomes

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Background—Certificate of need (CON) regulations are intended to coordinate new healthcare services, limit expansion of unnecessary new infrastructure, and limit healthcare costs. However, there is limited information about the association of CON regulations with the appropriateness and outcomes of percutaneous coronary interventions (PCI). The study sought to characterize the association between state CON regulations and PCI appropriateness.

Methods and Results—We used data from the American College of Cardiology's CathPCI Registry to analyze 1 268 554 PCIs performed at 1297 hospitals between January 2010 and December 2011. We used the Appropriate Use Criteria to classify PCI procedures as appropriate, maybe appropriate, or rarely appropriate and used Chi-square analyses to assess whether the proportions of PCIs in each Appropriate Use Criteria category varied depending on whether the procedure had been performed in a state with or without CON regulations. Analyses were repeated stratified by whether or not the procedure had been performed in the setting of an acute coronary syndrome (ACS). Among 1 268 554 PCI procedures, 674 384 (53.2%) were performed within 26 CON states. The proportion of PCIs classified as rarely appropriate in CON states was slightly lower compared with non-CON states (3.7% versus 4.0%, *P*<0.01). Absolute differences were larger among non-ACS PCI (23.1% versus 25.0% [*P*<0.01]) and were not statistically significantly different in ACS (0.62% versus 0.63% [*P*>0.05]).

Conclusions—States with CON had lower proportions of rarely appropriate PCIs, but the absolute differences were small. These findings suggest that CON regulations alone may not limit rarely appropriate PCI among patients with and without ACS. (*J Am Heart Assoc.* 2019;8:e010373. DOI: 10.1161/JAHA.118.010373.)

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ore than 600 000 percutaneous coronary interventions (PCIs) are performed in the United States each year, accounting for over \$12 billion in healthcare spending.¹ In part because of concerns about potential overuse of PCIs,

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© 2019 The Authors. Published on behalf of the American Heart Association, Inc., by Wiley. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes. the American College of Cardiology, American Heart Association, and other professional organizations released the appropriate use criteria (AUC) for coronary revascularization.^{1–3} The AUC are intended to support improved selection of patients for PCI, particularly among patients with stable coronary artery disease. Although the proportion of rarely appropriate PCI (the AUC used the term "inappropriate" previously) has improved over time, nearly 1 in 7 non-acute PCIs performed in 2014 were classified as rarely appropriate, which varied substantially across hospitals.⁴ These findings highlight the continued need to identify strategies to ensure that PCI procedures are being performed in patients in whom the benefits clearly outweigh the potential risks.

Certificate of need (CON) programs are 1 strategy to control costs, prevent overuse, and improve quality by regulating new facilities and capital equipment.^{5,6} At present, 36 states have a CON program, and 26 states have CON regulations pertaining to cardiac services involving cardiac catheterization laboratories.⁷ By regulating the supply of PCI programs, CON policies may reduce the number of excess cardiac catheterization facilities, thereby minimizing financial pressures of those facilities that may influence higher number of appropriate PCIs. Therefore,

Clinical Perspective

What Is New?

- Certificate of need (CON) programs are statewide regulations that aim to prevent overuse and improve quality.
- We assessed if states with CON regulations had significant differences in percutaneous coronary intervention appropriateness and rates of post-procedural adverse outcomes as compared with states without CON regulations.
- We found CON regulations are associated with only modest differences in the appropriateness and outcomes of percutaneous coronary intervention procedures.

What Are the Clinical Implications?

- Our study suggests there may be limited efficacy in CON regulations as public policies to improve percutaneous coronary intervention appropriateness and outcomes.
- Additional research is needed to evaluate whether the effectiveness of CON regulations for facilities performing invasive cardiac procedures outweigh the opportunity costs of implantation and maintenance.

one might expect that patients undergoing PCI in states with cardiac CON might have more favorable appropriateness ratings and quality as assessed by lower rates of adverse outcomes compared with patients treated in states without cardiac CON. Investigators have examined the association of CON regulations with appropriateness and outcomes, but the studies have been inconsistent and did not use contemporary updated AUC criteria.^{1,5,8–10}

To address these gaps in knowledge, we used data from the American College of Cardiology National Cardiovascular Data Registry's CathPCI Registry. Specifically, we compared the appropriateness of procedures performed for both acute and non-acute indications in states with and without cardiac CON regulations. Given known associations of patient outcome variations with PCI appropriateness,¹¹ we also investigated whether state CON status was associated with differences in adverse outcomes including peri-procedural complications and in-hospital mortality. We hypothesized that there will be modest differences in PCI appropriateness such as states without CON will have a lower proportion of rarely appropriate PCIs and lower rates of adverse outcomes compared with states without CON regulation.

Methods

Data Sources

The National Cardiovascular Data Registry's CathPCI registry is cosponsored by the American College of Cardiology and the

Society for Cardiovascular Angiography and Interventions and collects detailed information on patient and hospital characteristics, clinical presentations, treatments, and outcomes from participating hospitals in the United States.^{12,13} For this analysis, we used data from PCIs performed between January 1, 2010 and December 31, 2011 using Version 4.0 of the data collection form. This study period was chosen to correlate with availability of CON information that was validated for accuracy. The data and analytical methods will not be made available to other researchers for the purpose of replicating the results of this study.

Study Design and Population

We performed a cross-sectional analysis of all hospitals in the CathPCI registry that reported at least 20 PCI procedures during the study time period, excluding 34 low volume hospitals and resulting in a total of 1297 facilities included in the analysis. Among patients with >1 PCI performed during a hospitalization, we only considered information from the initial procedure.

CON Regulation

Information about state's CON regulation was obtained through reports published by the National Conference of State Legislation.⁷ Individual states and the District of Columbia were categorized according to whether they had cardiac catheterization CON regulations from 2010 to 2011. All information was verified using published information from individual states and from the American Health Planning Association National Directory.¹⁴ No states discontinued or initiated CON regulations pertaining to cardiac catheterization during the study period.

We further characterized states with CON regulations into 3 groups according to the stringency of the CON regulations (high, moderate, and low stringency; Table S1).⁵ Stringency categories were assigned based on data from 2001 to 2002, the most recent time period for which state CON stringency had been assessed.¹⁵ A total of 3 states met criteria for high CON stringency, 7 states met criteria for moderate CON stringency, and 16 met criteria for low CON stringency.

Appropriateness

We classified the appropriateness of PCI procedures using the 2012 AUC. The committee defined appropriateness as the following: *Coronary revascularization is appropriate when the expected benefits, in terms of survival or health outcomes (symptoms, functional status, and/or quality of life) exceed the expected negative consequences of the procedure.* In the process of creating the criteria, a 21-member expert panel

designated the appropriateness of coronary revascularization for the most common clinical scenarios encountered in clinical practice for consideration of PCI. Additional details about the methodology on the AUC has been previously described elsewhere.^{2,4} The AUC criteria classify the majority of PCIs performed in the context of whether the procedure was performed for an acute indication (ie, acute coronary syndrome [ACS] including myocardial infarction and unstable angina) or non-acute indication (ie, non-ACS). Procedures without the appropriate requisite data were considered unmappable and excluded from our analyses.

Outcomes Measures

We examined in-hospital procedural complications and mortality. Procedural complications included vascular complications requiring treatment, red blood cell/whole blood transfusion, major bleeding event within 72 hours, stroke, and emergency or salvage coronary artery bypass grafting. We also calculated a risk-adjusted composite end point of any adverse outcome (complication and death). Risk-adjusted outcomes were performed in a manner consistent with prior studies and adjusted for variables previously shown to be associated with risk of adverse events (Table S2).^{1,9,16}

Statistical Analysis

We compared patient and hospital characteristics of PCI procedures performed in states with and without CON regulations for cardiac catheterization using t test and x^2 analyses. Patient characteristics included information about demographics, clinical presentation, comorbid diseases, and relevant past medical history and risk factors. Hospital characteristics included geographic region, teaching status, and cardiac surgery capabilities. We compared the proportions of PCI procedures classified as appropriate, may be appropriate, and rarely appropriate in states with and without CON regulations, and further stratified analyses by whether the procedure was performed for acute and non-acute indications. We repeated analyses stratifying patients in CON states by state CON stringency. Finally, we repeated these analysis adjusting for within-facility clustering and hospital characteristics.

We also compared unadjusted PCI complications and mortality events, as described previously, in patients in states with CON and without CON status. We then used multivariate logistical regression to examine the association of CON status with the composite end point of any adverse outcome including death. Analyses were conducted using SAS version 9.3 (SAS Institute, Cary, NC). All reported *P* values are reported as 2-sided with significance at *P*<0.05. The Yale University Human Investigations Committee approved analysis of a limited National Cardiovascular Data Registry's data set for research and waived the requirement for informed consent.

Results

Patient Demographics

A total of 1 268 554 PCI procedures performed at 1297 facilities between January 2010 and December 2011 met criteria for inclusion in this study. In our analysis, 53.2% of patients were from 26 states with CON regulations, 67.5% were male, 88.0% were white, and the mean age was aged 64.7 years (Table 1). Compared with patients treated in non-CON states, patients treated in CON states were modestly more likely to be a current or recent smoker, have hypertension, diabetes mellitus, hyperlipidemia, and a history of prior myocardial infarction or PCI. Patients treated in non-CON states were more likely to have been transferred from an outside emergency department. Median and interguartile ranges (25th, 75th) of PCI volume performed in facilities in states with CON was 445 (215-824) and in states without CON, 385 (198-611). A higher proportion of PCIs performed in states with CON regulations were considered elective compared with states without CON regulations. Additional clinical demographics and clinical characteristics of patients before PCI are shown in Table 1.

Association of CON Status With PCI Appropriateness

The proportions of procedures that did not have the data elements needed to map to an AUC indication were similar in CON and non-CON states (11.7% versus 11.1%) .The proportion of PCIs classified as appropriate or maybe appropriate in states with CON regulations was higher than in states without CON (85.2% versus 84.3%, P<0.01) (Table 2) and a lower proportion of procedures were considered rarely appropriate (3.7% versus 4.0%, P<0.01) (FigureA). Absolute differences were larger in patients undergoing PCI for non-acute indications. In this group, 76.9% of procedures were classified as appropriate or maybe appropriate in states with CON compared with 75.0% in states without CON (P<0.01) (Table 2). Furthermore, in cases of non-acute PCI, 23.1% of procedures performed were classified as rarely appropriate (FigureB). Among acute PCIs, there were no statistically significant differences between states with and without CON regulations seen in the proportions of procedures considered appropriate (99.4% versus 99.4%) or rarely appropriate (0.6% versus 0.6%). Within CON states, the stringency of CON was associated with differences in PCI appropriateness, both overall and among PCIs performed for non-acute indications.

Table 1. Patient Baseline Clinical Characteristics in States With and Without CON Programs

| | Total | | CON | | No CON | |
|---|-----------|--------|---------|-------|---------|-------|
| Variable | # | % | # | % | # | % |
| n | 1 268 795 | 100.00 | 594 411 | 46.85 | 674 384 | 53.15 |
| Demographics | | | | | | |
| Age, y: Mean (SD) | 64.70 | 12.08 | 64.11 | 12.03 | 65.22 | 12.11 |
| Sex:Female | 412 546 | 32.51 | 195 517 | 32.89 | 217 029 | 32.18 |
| Race:White | 1 115 986 | 87.96 | 511 788 | 86.10 | 604 198 | 89.59 |
| Insurance:Private | 445 043 | 35.08 | 201 347 | 33.87 | 243 696 | 36.14 |
| History and risk factors | | | - | - | | |
| BMI:Mean (SD) | 29.93 | 6.18 | 30.04 | 6.22 | 29.84 | 6.15 |
| Current/recent smoker (<1 y) | 349 974 | 27.60 | 174 463 | 29.37 | 175 511 | 26.04 |
| Hypertension | 1 039 722 | 81.98 | 491 856 | 82.79 | 547 866 | 81.28 |
| Dyslipidemia | 1 011 549 | 79.81 | 477 014 | 80.34 | 534 535 | 79.35 |
| Family history of CAD | 314 490 | 24.80 | 146 894 | 24.72 | 167 596 | 24.86 |
| Prior MI | 381 457 | 30.08 | 180 856 | 30.44 | 200 601 | 29.76 |
| Prior HF | 150 985 | 11.91 | 71 195 | 11.99 | 79 790 | 11.84 |
| Prior valve surgery/procedure | 18 638 | 1.47 | 8243 | 1.39 | 10 395 | 1.54 |
| Prior PCI | 515 908 | 40.67 | 248 062 | 41.74 | 267 846 | 39.72 |
| Prior CABG | 234 904 | 18.52 | 112 476 | 18.92 | 122 428 | 18.16 |
| Currently on dialysis | 30 073 | 2.37 | 13 818 | 2.33 | 16 255 | 2.41 |
| Cerebrovascular disease | 156 442 | 12.34 | 75 572 | 12.72 | 80 870 | 12.00 |
| Peripheral artery disease | 159 268 | 12.56 | 75 005 | 12.63 | 84 263 | 12.50 |
| Chronic lung disease | 192 731 | 15.20 | 94 588 | 15.92 | 98 143 | 14.56 |
| Diabetes mellitus | 461 911 | 36.42 | 220 078 | 37.04 | 241 833 | 35.87 |
| Clinical evaluation before procedure | - | - | | | | |
| CAD presentation | | | | | | |
| No symptom, no angina | 105 985 | 8.35 | 47 399 | 7.98 | 58 586 | 8.69 |
| Symptom unlikely to be ischemic | 36 100 | 2.85 | 16 767 | 2.82 | 19 333 | 2.87 |
| Stable angina | 216 721 | 17.08 | 99 158 | 16.68 | 117 563 | 17.44 |
| Unstable angina | 472 465 | 37.24 | 228 959 | 38.53 | 243 506 | 36.11 |
| NSTEMI | 233 281 | 18.39 | 108 531 | 18.26 | 124 750 | 18.50 |
| STEMI or equivalent | 204 032 | 16.08 | 93 491 | 15.73 | 110 541 | 16.39 |
| Anginal classification w/in 2 wks | | | | | | |
| No symptoms | 160 651 | 12.70 | 72 341 | 12.21 | 88 310 | 13.12 |
| CCS I | 75 136 | 5.94 | 29 183 | 4.93 | 45 953 | 6.83 |
| CCS II | 248 589 | 19.65 | 114 698 | 19.36 | 133 381 | 19.90 |
| CCS III | 413 901 | 32.71 | 200 995 | 33.93 | 212 906 | 31.64 |
| CCS IV | 366 969 | 29.00 | 175 133 | 29.57 | 191 836 | 28.51 |
| Anti-anginal medications | 870 262 | 68.62 | 419 495 | 70.61 | 450 767 | 66.87 |
| Heart failure w/in 2 wks | 122 348 | 9.65 | 54 179 | 9.12 | 68 169 | 10.11 |
| Cardiomyopathy or LV systolic dysfunction | 127 302 | 10.04 | 57 431 | 9.66 | 69 871 | 10.36 |
| Cardiogenic shock w/in 24 h | 24 843 | 1.96 | 10 814 | 1.82 | 14 029 | 2.08 |

Continued

Table 1. Continued

| | Total | | CON | | No CON | |
|--|---------|-------|---------|-------|---------|-------|
| Variable | # | % | # | % | # | % |
| Cardiac arrest w/in 24 h | 24 585 | 1.94 | 10 843 | 1.82 | 13 742 | 2.04 |
| Preoperative evaluation before non-cardiac surgery | 25 473 | 2.01 | 11 500 | 1.94 | 13 973 | 2.07 |
| Stress imaging studies performed | 426 392 | 33.63 | 200 516 | 33.77 | 225 876 | 33.51 |
| PCI procedure | | | | | | |
| Transfer from outside ED | 464 013 | 36.57 | 206 880 | 34.80 | 257 133 | 38.13 |
| Hospital status | | | | | | |
| Outpatient | 304 797 | 24.03 | 143 413 | 24.14 | 161 384 | 23.94 |
| Outpatient converted to inpatient | 229 880 | 18.13 | 104 494 | 17.59 | 125 386 | 18.60 |
| Inpatient | 733 510 | 57.84 | 346 173 | 58.27 | 387 337 | 57.46 |
| PCI status | | | | | | |
| Elective | 558 873 | 44.07 | 269 787 | 45.41 | 289 086 | 42.89 |
| Urgent | 481 428 | 37.96 | 221 510 | 37.28 | 259 918 | 38.56 |
| Emergency | 223 759 | 17.64 | 101 095 | 17.02 | 122 664 | 18.2 |
| Salvage | 4109 | 0.32 | 1728 | 0.29 | 2381 | 0.35 |
| Cardiogenic shock at start of PCI | 28 018 | 2.21 | 12 179 | 2.05 | 15 839 | 2.35 |

BMI indicates body mass index; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CCS, Canadian Cardiovascular Society; CON, certificate of need; ED, emergency department; HF, heart failure; LV, left ventricular; MI, myocardial infarction; NSTEMI, non-ST-segment–elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment–elevation MI.

More stringent CON regulations were associated with a higher proportion of rarely appropriate PCIs although the absolute difference was small (least stringent: 3.75% versus most stringent: 4.03%; *P*<0.01). Among PCIs performed for non-acute indications, statewide CON stringency was associated with reduced rates of rarely appropriate PCI such that states

with more stringent CON regulations were associated with lower proportions of rarely appropriate PCIs (least stringent: 22.92% versus most stringent: 20.58%; P<0.01) (Table 3).

After adjustment for hospital clustering and characteristics, CON remained significantly associated with PCI appropriateness in all cases (P<0.05) and in non-acute PCI

| Table | 2. | Appropriateness | of PCI | Procedures | Stratified | by | CON | Status |
|-------|----|-----------------|--------|------------|------------|----|-----|--------|
|-------|----|-----------------|--------|------------|------------|----|-----|--------|

| | Total | | No CON | | CON | | |
|-------------------------------|-----------|-------|---------|-------|---------|-------|----------|
| | # | % | # | % | # | % | P Value |
| All | | | | | | | |
| Appropriate use criteria | | | | | | | |
| Appropriate/Maybe appropriate | 1 074 517 | 84.70 | 568 131 | 84.26 | 506 386 | 85.21 | < 0.0001 |
| Rarely appropriate | 49 111 | 3.87 | 27 142 | 4.03 | 21 969 | 3.70 | |
| Acute indications | | | | | | | |
| Appropriate use criteria | | | | | | | |
| Appropriate/Maybe appropriate | 929 985 | 99.37 | 491 522 | 99.38 | 438 463 | 99.37 | 0.79 |
| Rarely appropriate | 5860 | 0.63 | 3087 | 0.62 | 2773 | 0.63 | |
| Non-acute indications | | | | | | | |
| Appropriate use criteria | | | | | | | |
| Appropriate/Maybe appropriate | 136 278 | 75.91 | 72 263 | 75.03 | 64 015 | 76.93 | <0.0001 |
| Rarely appropriate | 43 251 | 24.09 | 24 055 | 24.97 | 19 196 | 23.07 | |

CON indicates certificate of need.

(*P*<0.05). There again was no association between CON and PCI appropriateness in acute causes (*P*=0.94). Within CON states, CON stringency was no longer associated with PCI appropriateness in all cases (*P*=0.95), acute causes (*P*=0.69), and non-acute cases (*P*=0.78).

Association of CON Status With PCI Outcomes

Statewide CON regulations were inconsistently associated with unadjusted peri- and post-procedural complication rates. States with CON regulations had significantly higher bleeding events (1.74% versus 1.59%, P<0.01) and a lower proportion of post-PCI patients requiring emergency or salvage coronary artery bypass grafting (0.27% versus 0.30%, P<0.01) (Table 4). The proportions of patients experiencing vascular



Figure. A, Percentages of rarely appropriate PCIs of all patients by certificate of need status. Horizontal box plot with each dot representing a facility. Dots are stretched vertically to figuratively show a distribution. **B**, Percentages of rarely appropriate PCIs of non-acute coronary syndrome patients by certificate of need status. Horizontal box plot with each dot representing a facility. Dots are stretched vertically to figuratively show a distribution. PCI indicates percutaneous coronary intervention.

complications, stroke, or requiring a blood transfusion were similar in CON and non-CON states. (Table 4). States with CON regulations had lower crude in-hospital mortality rates compared with states without CON (1.3% versus 1.5%). In our multivariate analysis, CON status was associated with a modest increase in the composite end point of any adverse outcome (odds ratio: 1.11 [1.01–1.21]).

Discussion

In this cross-sectional analyses of data from the CathPCI registry, we found that state CON status was associated with a small but statistically significantly lower proportion of PCIs classified as rarely appropriate compared with non-CON states. Similarly, when we stratified our results by statewide CON stringency, our findings did not vary significantly according to the stringency of CON regulations. Our study also demonstrated that state CON status was associated with a higher risk of selected adverse events. Taken together, our findings suggest that CON regulations may have a limited potential to prevent overuse of invasive cardiac procedures and improve outcomes for these patients.

This analysis builds upon a prior study that examined the relationship between state cardiac CON regulations and procedural appropriateness solely in patients with acute myocardial infarction.⁸ Our analysis extends this prior work by replicating the work in ACS patients using contemporary AUC criteria and being the first to characterize the association between CON and appropriateness in PCI patients with stable ischemic coronary disease. This finding is important, as a higher proportion of PCI procedures performed on non-ACS patients are considered rarely appropriate than in ACS patients, and our present study highlights that the modest association of CON with PCI appropriateness is largely driven by the proportion of PCI done for non-acute indications. Furthermore, our study is the first to study the association between CON status and PCI appropriateness using contemporary AUC criteria. As such, the proportion of PCIs within each appropriateness category in our study sample differs from previous analyses. Despite this discrepancy, our results are consistent with prior literature in that the absolute differences in procedural appropriateness between CON and non-CON states are small.

We found that CON status was inconsistently associated with individual PCI complications and mortality rates. However, when we considered all adverse outcomes as a composite, patients treated in CON states were at increased risk of adverse outcomes compared with patients treated in non-CON states, and this risk appeared driven by increased risk of bleeding. Our findings are consistent with previous studies that suggest an equivocal association between CON

| | Total | | Less | | Moderate | | Most | | |
|-------------------------------|---------|--------|---------|---------|----------|-------|--------|-------|---------|
| | # | % | # | % | # | % | # | % | P Value |
| All | - | - | - | - | | | - | - | |
| n | 594 306 | 100.00 | 347 271 | 58.43 | 201 388 | 33.89 | 45 647 | 7.68 | |
| Appropriate/Maybe appropriate | 506 386 | 85.21 | 297 324 | 85.62 | 170 340 | 84.58 | 38 722 | 84.83 | <0.0001 |
| Rarely appropriate | 21 969 | 3.70 | 13 027 | 3.75 | 7102 | 3.53 | 1840 | 4.03 |] |
| Acute indications | - | - | - | - | - | | - | - | |
| n | 441 236 | 100.00 | 258 283 | 58.54 | 150 464 | 34.10 | 32 489 | 7.36 | |
| Appropriate/Maybe appropriate | 438 463 | 99.37 | 256 677 | 149 551 | 145 690 | 99.39 | 32 235 | 99.22 | 0.79 |
| Rarely appropriate | 2773 | 0.63 | 1606 | 0.62 | 913 | 0.61 | 254 | 0.78 |] |
| Non-acute indications | | - | - | - | - | | - | - | |
| n | 83 211 | 100.00 | 49 831 | 59.89 | 25 672 | 30.85 | 7708 | 9.26 | |
| Appropriate/Maybe appropriate | 64 015 | 76.93 | 38 410 | 77.08 | 19 483 | 75.89 | 6122 | 79.42 | 0.14 |
| Rarely appropriate | 19 196 | 23.07 | 11 421 | 22.92 | 6189 | 24.11 | 1586 | 20.58 |] |

Table 3. Appropriateness of PCI Procedures as Stratified by CON Stringency

CON indicates certificate of need; PCI, percutaneous coronary intervention.

regulations and mortality after coronary bypass surgery or cardiac catheterization.^{6,8,17–19} Taken together, these findings raise questions about the effectiveness of CON in improving patient outcomes following PCI. From a policy perspective, the maintenance of CON regulations is not without opportunity cost and should be continued only if there is evidence of improvements in healthcare delivery. Our findings emphasize the importance of regularly analyzing and examining the effectiveness of public policies to ensure they remain relevant and effective.

This study has several limitations that may warrant consideration. First, our cross-sectional analyses study design cannot discern a cause-and-effect relationship between CON status and PCI appropriateness or PCI outcomes. Second, any associations noted in the study may reflect other aspects of healthcare delivery not captured in our analyses and are independent of CON status. Examples of these factors include regional physician practice variation, institutional and hospital policies, and managed care penetration. Statewide mandated public reporting represents another policy that may affect PCI appropriateness in our study. However, the large majority of states with public reporting are also states with CON regulations and therefore, we do not expect significant differences in our results to be attributable to public reporting. Third, there is substantial heterogeneity of the cardiac CON regulations across states. Legal statutes and processes for CON regulations vary by state, and it is challenging to quantify the potential impact of a state's regulations on cardiac services. Although we attempted to address this limitation by applying CON stringency to our analyses, the most recent categorization of CON stringency was completed over a decade ago and did

| Table | 4 | Proportion | of PCI | Procedures | With | Complications | hv | CON | Status |
|-------|-----------|------------|--------|--------------|--------|---------------|----|------|--------|
| able | . | roportion | | 1 I UCEUUIES | VVILII | Complications | Dy | 0011 | Status |

| Variable | Total | Total | | No CON States | | CON States | |
|---|--------|-------|--------|---------------|--------|------------|---------|
| Procedural Complications | # | % | # | % | # | % | P Value |
| Vascular complications requiring treatment | 5554 | 0.44% | 2904 | 0.43 | 2650 | 0.45 | 0.19 |
| RBC/Whole blood transfusion | 33 243 | 2.62 | 17 637 | 2.62 | 15 606 | 2.63 | 0.71 |
| Bleeding event w/in 72 h | 21 075 | 1.66 | 10 725 | 1.59 | 10 350 | 1.74 | <0.01 |
| Stroke | 2787 | 0.22 | 1496 | 0.22 | 1291 | 0.22 | 0.57 |
| Post-PCI patients requiring emergency or salvage CABG | 3662 | 0.29% | 2050 | 0.30 | 1612 | 0.27 | <0.01 |
| In-hospital mortality | 17 958 | 1.42 | 9994 | 1.48 | 7964 | 1.34 | <0.01 |
| Any adverse events | 84 279 | 6.64 | 44 806 | 6.64 | 39 473 | 6.64 | 0.87 |

CABG indicates coronary artery bypass grafting; CON, certificate of need; PCI, percutaneous coronary intervention; RBC, red blood cell.

not pertain specifically to CON regulations for invasive cardiac procedures. Fourth, our study sample only included patients undergoing PCI and may not be representative of patients undergoing other invasive procedures or diagnostic testing. Our findings of a lack of association between CON status with procedural appropriateness and outcomes also should not be generalized to other facets of CON such as reducing total healthcare expenditure or duplication of services. Additionally, we appreciate that the AUC may not be perfect in capturing true appropriateness. Nevertheless, studies have identified hospital performance on AUC criteria as a clinically important outcome, and the imperfections of AUC criteria presumably would apply equally to both CON and non-CON states. Finally, a major intent of CON programs is to reduce costs and our analyses could not assess this important outcome.

Conclusion

CON regulations are associated with small differences in PCI appropriateness and a modest, increased risk of adverse events following PCI procedures. These findings raise questions on the effectiveness of statewide CON regulations in improving the use of PCI and the short-term outcomes of PCI procedures. This information is relevant to any efforts to reevaluate the potential effectiveness of CON regulations for invasive cardiac procedures.

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Disclosures

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SUPPLEMENTAL MATERIAL

| States without certificate of need | States with ce | ites with certificate of need for cardiac cathertizations | | | | | | |
|------------------------------------|----------------|---|-----------------|--|--|--|--|--|
| | Low stringency | Moderate stringency | High stringency | | | | | |
| Arizona | Alabama | Georgia | Connecticut | | | | | |
| Arkansas | Alaska | Maine | Maryland | | | | | |
| California | Delaware | Michigan | New Jersey | | | | | |
| Colorado | Hawaii | North Carolina | | | | | | |
| Florida | Illinois | South Carolina | | | | | | |
| Idaho | lowa | Rhode Island | | | | | | |
| Indiana | Kentucky | West Virginia | | | | | | |
| Kansas | Mississipi | | | | | | | |
| Louisiana | Missouri | | | | | | | |
| Massachusetts | New Hampshire | | | | | | | |
| Minnesota | New York | | | | | | | |
| Montana | Tennessee | | | | | | | |
| Nebraska | Vermont | | | | | | | |
| Nevada | Virginia | | | | | | | |
| New Mexico | Washington | | | | | | | |
| North Dakota | Washington, DC | | | | | | | |
| Ohio | | | | | | | | |
| Oklahoma | | | | | | | | |
| Oregon | | | | | | | | |
| Pennsylvania | | | | | | | | |
| South Dakota | | | | | | | | |
| Texas | | | | | | | | |
| Utah | | | | | | | | |

| Wisconsin | | |
|-----------|--|--|
| Wyoming | | |

Table S2. Variables adjusted for in multivariate analysis for adverse events.

| Age |
|--|
| STEMI patients |
| BMI |
| Diabetes (insulin and non-insulin) |
| EF |
| Prior PCI |
| History of cerebrovascular disease |
| History of chronic lung disease |
| History of peripheral artery disease |
| Glomerular filtration rate (GFR) |
| Renal failure, GFR <30, or dialysis |
| Sustained cardiogenic shock |
| Transient cardiogenic shock |
| Emergeny PCI without shock/salvage |
| Urgent PCI without shock/salvage |
| NYHA class within past two weeks |
| Cardiac arrest within 24 hours |
| In-stent thrombosis |
| Highest risk lesion (proximal LAD or left main vs other) |
| Number of diseased vessels |
| Chronic total occlusion |