

## RESEARCH ARTICLE

# Impact of pediatric cardiac surgery regionalization on health care utilization and mortality

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**Objective:** Regionalization directs patients to high-volume hospitals for specialized care. We investigated regionalization trends and outcomes in pediatric cardiac surgery.

**Data Sources/Study Setting:** Statewide inpatient data from eleven states between 2000 and 2012.

**Study Design:** Mortality, length of stay (LOS), and cost were assessed using multivariable hierarchical regression with state and year fixed effects. Primary predictor was hospital case-volume, categorized into low-, medium-, and high-volume tertiles.

**Data Collection/Extraction Methods:** We used Risk Adjustment for Congenital Heart Surgery-1 (RACHS-1) to select pediatric cardiac surgery discharges.

**Principal Findings:** In total, 2841 (8.5 percent), 8348 (25.1 percent), and 22 099 (66.4 percent) patients underwent heart surgeries in low-, medium-, and high-volume hospitals. Mortality decreased over time, but remained higher in low- and medium-volume hospitals. High-volume hospitals had lower odds of mortality and cost than low-volume hospitals (odds ratio [OR] 0.59,  $P < 0.01$ , and relative risk [RR] 0.91,  $P < 0.01$ , respectively). LOS was longer for high- and medium-volume hospitals, compared to low-volume hospitals (high-volume: RR 1.18,  $P < 0.01$ ; medium-volume: RR 1.05,  $P < 0.01$ ).

**Conclusions:** Regionalization reduced mortality and cost, indicating fewer complications, but paradoxically increased LOS. Further research is needed to explore the full impact on health care utilization.

## KEYWORDS

case-volume, health care utilization, mortality, pediatric cardiology

## 1 | INTRODUCTION

Regionalization of medical care directs patients with specific high-risk conditions to designated hospitals with higher case-volumes.<sup>1-3</sup> The rationale is based upon evidence demonstrating lower mortality rates among hospitals providing services for the highest case-volumes of critically ill patients,<sup>4-8</sup> yet the mechanisms have been debated ever since Luft et al<sup>9</sup> published their

landmark 1979 article. Many researchers consider case-volume as a proxy for quality of care.<sup>10-14</sup> Jenkins et al<sup>15</sup> first reported the effect of case-volume on mortality among patients with congenital heart disease in 1995, supporting the hypothesis that high-volume hospitals had more favorable patient outcomes in pediatric cardiac surgeries. Since then, this volume-outcome relationship has been demonstrated repeatedly in cardiac surgeries for both adults and children.<sup>16-25</sup>

While literature has routinely demonstrated lower mortality rates in high-volume hospitals, resulting in recommendations to regionalize the specialized critical care of children, empirical evidence surrounding pediatric cardiac surgeries remains sparse, particularly with regard to temporal trends in regionalization, differences in regionalization trends across states, and impact on resource utilization. The databases used in previous studies were limited to only one or two states,<sup>15,21,25,26</sup> or only included information from a limited number of facilities<sup>19,27-30</sup> or limited number of years.<sup>15,25,29-32</sup> Among these studies, many only assessed mortality as an outcome, and thus, evidence of impact on resource utilization, such as length of stay (LOS) and cost, is limited,<sup>15,17,32</sup> though beneficial effects have been reported for other surgical procedures.<sup>33</sup>

Chang et al<sup>25</sup> was first to demonstrate the estimated number of avoidable deaths by regionalization. However, their database was limited to only one state, California, and limited to years 1995-1997. No further effort has been made to support their results.

The objectives of this study are to (a) reevaluate the volume-outcome relationship, using a larger longitudinal database including all hospital discharges in eleven states; (b) evaluate the effect of regionalization not only on in-hospital mortality, but also on health care utilization such as LOS and costs; (c) explore regionalization trends in pediatric cardiac surgery; (d) assess differences in regionalization trends across states; and (e) estimate the number of avoidable deaths and the number of transfers necessary to save one life, in order to assess the impact of regionalization.

## 2 | METHODS

### 2.1 | Data

States included in the study were Arizona, California, Florida, Massachusetts, Maryland, Michigan, North Carolina, New Jersey, New York, Pennsylvania, and Washington, which collectively represent approximately 46 percent of the U.S. population. These states were selected for the following reasons: (a) availability of statewide data for public use; (b) large populations; and (c) cost of data acquisition. Data were derived from the 2000, 2004, 2008, and 2012 Arizona, California, Florida, Massachusetts, Maryland, Michigan, North Carolina, New Jersey, New York, and Washington, State Inpatient Databases (SID), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality,<sup>34</sup> inpatient databases from the Pennsylvania Health Care Cost Containment Council (PHC4),<sup>35</sup> and inpatient databases from California's Office of Statewide Health Planning and Development (OSHPD).<sup>36</sup> SID includes all hospital discharges in a given state and year and contains individual-level characteristics, such as age, sex, race/ethnicity, insurance type, diagnostic and procedure codes, length of stay, and total charges, as well as hospital identifiers. PHC4 and OSHPD databases contain statewide patient-level information on all hospital discharges, similar to SID.

Risk Adjustment for Congenital Heart Surgery-1 (RACHS-1) classification was used to identify pediatric cardiac surgery patients.

RACHS-1 selects all patients <18 years of age with operative or procedure codes indicating surgical repair of a congenital heart defect, excluding those undergoing cardiac transplantation and transcatheter interventions and neonates  $\leq 30$  days or <2500 g with patent ductus arteriosus as an isolated cardiac defect.<sup>37</sup> The method was developed by a nationally representative panel of pediatric cardiologists and cardiac surgeons to adjust for the risk of in-hospital mortality among children undergoing surgery for congenital heart disease (CHD).<sup>37</sup> Together, RACHS-1 encapsulates 79 conditions and six levels of risk, as determined by patient age and procedure type. Further information on surgical procedures and risk categorization is described in a previous publication by Jenkins et al.<sup>37</sup>

The primary outcome of interest was in-hospital death. The secondary outcome of interest was hospitalization cost and LOS. All SID databases contain information on total charges for each hospital discharge, which reflect facility fees. Facility fees typically include service charges for patient use of hospital facilities and equipment, as well as most hospital-based personnel, but do not generally encompass professional fees. To estimate hospitalization cost, we used HCUP's Cost-to-Charge Ratio hospital-level files (CCR)<sup>38</sup> when available. For certain states and years, CCR data were unavailable through HCUP, so we used CCRs provided through Centers for Medicare & Medicaid Services (CMS) Impact File Hospital Inpatient Prospective Payment System (IPPS), which are derived from Medicare Cost Reports.<sup>39-41</sup> Total patient charges were multiplied by the appropriate CCR, then adjusted for inflation using the Consumer Price Index (CPI),<sup>42</sup> with 2010 as the base year.

The primary predictor of interest was hospital case-volume. Hospitals were stratified by annual volume of cases undergoing pediatric surgery for CHD and classified into three types: high-, medium-, and low-volume, following the methods of previous studies.<sup>25,43,44</sup> Cut-points were determined by examining the distribution of annual case-volume across all years, excluding hospitals with <10 cases per year and dividing into thirds. Hospitals with fewer than ten discharges per year were excluded from the calculation because a high percentage of hospitals (>25 percent) had only one discharge per year, which would skew the cut-point values. These hospitals were still included in all study analyses, classified as low-volume.

Age, sex, race/ethnicity (ie, white, black, Hispanic, Asian, and other), insurance type (ie, public, private, and other), and RACHS-1 classification were included as covariates.

### 2.2 | Descriptive statistics

We identified a total of 33 288 patients admitted to 180 hospitals. Hospital case-volumes were assigned as follows: (a) low-volume hospitals with 60 or fewer cases per year ( $n = 193$ ) (53.8 percent); (b) medium-volume hospitals with 61-144 cases per year ( $n = 85$ ) (23.7 percent); and (c) high-volume hospitals with over 144 cases per year ( $n = 81$ ) (22.6 percent). Due to fluctuation in annual hospital case-volume, a hospital's case-volume category could differ from year to year, resulting in the total number of case-volume assignments exceeding the total number of hospitals sampled. The

higher percentage of low-volume hospitals reflected the omission of those with fewer than ten heart surgery discharges per year when determining cutoff values. A total of 2841 (8.5 percent), 8348 (25.1 percent), and 22 099 (66.4 percent) patients underwent heart surgeries in low-, medium-, and high-volume hospitals, respectively.

Among 33 288 patients, 1211 died during hospitalization, yielding an overall in-hospital mortality rate of 3.64 percent. Mean age was 2.59 years, with the majority of patients (57.1 percent) under one year of age. Half (50.0 percent) were classified as low-risk with RACHS-1 of 1 or 2, whereas 3.73 percent were classified as high-risk with RACHS-1 of 5 or 6. The crude mortality rate was lower for high-volume hospitals

**TABLE 1** Patient characteristics and unadjusted outcomes by hospital case-volume

	Total	Low volume <61 cases per year	Med volume 61-144 cases per year	High volume >144 cases per year	P-value
Record count	n = 33 288	n = 2841	n = 8348	n = 22 099	
Hospital count	n = 359	n = 193	n = 85	n = 81	
Outcome					
Mortality	3.64%	4.08%	4.20%	3.37%	<0.01
Length of stay (median, IQR)	7 (4~15)	6 (4~13)	6 (4~14)	7 (4~16)	<0.01
Cost (median, IQR)	\$36 343 (\$21 998 ~ \$68 530)	\$30 063 (\$17 159~ \$55 220)	\$29 831 (\$19 103~ \$55 285)	\$39 999 (\$24 260~ \$74 724)	<0.01
Patient-level characteristics					
Age (mean, SD)	2.59 (4.38)	3.28 (4.96)	2.72 (4.47)	2.45 (4.25)	<0.01
Age categories					
0 y/o	57.05%	50.62%	55.64%	58.41%	<0.01
1-5 y/o	25.34%	26.61%	25.78%	25.01%	0.03
6-10 y/o	8.14%	9.75%	8.53%	7.79%	<0.01
11-15 y/o	6.82%	8.41%	7.19%	6.48%	<0.01
>15 y/o	2.65%	4.61%	2.86%	2.31%	<0.01
Sex					
Male	54.74%	53.08%	54.48%	55.05%	0.05
Female	45.15%	46.81%	45.45%	44.82%	0.04
Race <sup>a</sup>					
White	44.96%	37.45%	42.99%	46.66%	<0.01
Black	10.49%	17.63%	13.31%	8.51%	<0.01
Hispanic	20.56%	21.40%	13.85%	22.99%	<0.01
Asian	4.17%	4.22%	3.58%	4.38%	0.05
Other	8.93%	9.61%	9.97%	8.46%	<0.01
Insurance					
Private	51.00%	41.43%	46.19%	54.05%	<0.01
Medicaid	37.59%	42.77%	41.06%	35.62%	<0.01
Other	10.84%	15.35%	12.21%	9.74%	<0.01
SES composite index (median, IQR)	0.23 (-0.24, 0.94)	0.09 (-0.32, 0.69)	0.13 (-0.27, 0.78)	0.30 (-0.20, 1.02)	<0.01
RACHS					
1	14.22%	21.79%	17.14%	12.15%	<0.01
2	35.75%	39.00%	38.21%	34.45%	<0.01
3	35.94%	30.02%	33.34%	37.69%	<0.01
4	10.36%	7.88%	9.08%	11.16%	<0.01
5+	3.73%	1.76%	2.23%	4.54%	<0.01

<sup>a</sup>Some state datasets included Hispanic as a Race variable and others included Hispanic as an Ethnicity variable, separate from Race. For states with separate Race and Ethnicity variables, the data were recoded into the following new categories: white (ie, non-Hispanic white), black (ie, non-Hispanic black), Asian (ie, non-Hispanic Asian), Other (ie, non-Hispanic Other), and Hispanic. This was done in order to standardize the datasets across states. The percentages do not add up to 100% due to missing values for the Race and Ethnicity variables.

(3.37 percent) compared to low-volume hospitals (4.08 percent). Patient characteristics differed by hospital case-volume. Patients admitted to low-volume hospitals were more likely to be younger and nonwhite, have lower risk, and be on Medicaid insurance compared to medium- and high-volume hospitals (Table 1). Table S1 provides number of patients per state by hospital case-volume.

### 2.3 | Statistical analyses

Trends in number of patients, in-hospital mortality, LOS, and cost were examined for each volume category, overall and stratified by risk. Trends in percentage of patients were then examined by case-volume and risk category, overall and stratified by state. For these analyses, RACHS-1 were collapsed into three categories, with scores of 1 and 2 defined as low, 3 and 4 defined as medium, and 5 and 6 defined as high. In order to assess temporal trends, logistic regression models were used for mortality, negative binomial regression models were used for cost, and Poisson regression models were used for LOS, with year included as a primary predictor. These models were selected for the analyses based on the distribution of each outcome.

Multilevel regression analyses with complete-case analyses were conducted using STATA (version 14.2; College Station, TX), with individuals nested within the hospital-level random effects, controlling for state and year fixed effects. Logistic regression was used to assess mortality, as it is a binary outcome. Poisson regression was used to assess LOS, as LOS is a count datum. Negative binomial regression was used to assess cost in favor of the Poisson model due to overdispersion in the data. There is no gold standard method for handling patients who died; therefore, LOS and costs were estimated for mortality cases as if patients had not died using multiple imputation<sup>45</sup> from hospital case-volume, state of residence, year, and the covariates listed above. Costs were log-transformed and imputed using linear regression. LOS values were imputed using Poisson regression. A two-sided *P*-value <0.05 was considered statistically significant.

Lastly, we estimated the expected number of deaths with three different hypothetical scenarios of regionalized care: (a) All patients were assumed to receive surgery in high-volume hospitals; (b) patients undergoing operations in low-volume hospitals were assumed to be treated in medium-volume facilities; and (c) patients undergoing operations in low-volume hospitals were assumed to be treated in high-volume facilities.

The analyses were conducted as follows. First, the probability of dying ( $\hat{Y}$ ) was calculated from the regression model above, using the original case-volume category for each hospital to which individual patients were admitted. Second, the expected number of deaths was calculated by the sum of the  $\hat{Y}$ , representing the expected number of deaths adjusted for all factors in the regression above. Third, patient case-volumes were reassigned in accordance with each hypothetical scenario, and  $\hat{Y}$  was calculated for each scenario, using the new hypothetical case-volume categories and corresponding regression coefficients from the above regression model. Fourth, expected number of deaths under each hypothetical scenario was calculated by the sum of the  $\hat{Y}$ . Fifth, the difference between expected number

of deaths under originally recorded conditions vs the hypothetical scenario of regionalized care was calculated and defined as avoidable death. Sixth, we estimated the number of patient transfers needed to avoid one death.

### 2.4 | Sensitivity analyses

Three sensitivity analyses were conducted in order to assess the robustness of the results. First, we added a composite index of community-level socioeconomic indicators (SES index) based on patients' five-digit zip code, when available, or three-digit zip code, which was created from the following three socioeconomic variables, obtained from the U.S. Census Bureau<sup>46</sup>: (a) median household income; (b) median house value; and (c) percent of population on public assistance, by a principal component analysis (PCA) with varimax rotation. The composite index was created in order to avoid multicollinearity because those three socioeconomic factors are correlated with each other. This method has been used in previous publications.<sup>47-51</sup> This sensitivity analysis was conducted to assess whether the community-level SES acted as a confounder, since previous literature demonstrated that patients from lower income communities had worse outcomes.<sup>52,53</sup>

Second, all hospitals that performed fewer than 10 pediatric cardiac surgeries were excluded from the analyses to reflect the method used to define case-volume cutoff values, and mirror a previous study.<sup>25</sup>

Last, we tested the following two models: (a) a multivariate regression model including another dichotomous indicator variable to signify mortality, coded as 1 for patients who died and 0 for those who did not die; and (b) a multivariate regression model excluding patients who died during hospitalization.

## 3 | RESULTS

Table 2 shows an upward trend in the proportion of patients having surgeries at high-volume hospitals, while a downward trend was observed at medium-volume hospitals (all *P*-values were <0.01). This shift was especially apparent among low- and medium-risk patients (both *P*-values were <0.01), with no statistically significant increase in trend among high-risk patients (*P* = 0.08). Table S2 presents trends in number of hospitals by hospital case-volume. Table 3 shows trends in patient outcomes by hospital case-volume. Patient mortality decreased over time, with lowest total rates in high-volume hospitals. LOS and cost increased over time for all volume categories. Increasing trends in LOS and cost were observed in all risk categories and all volume categories (Table S3).

Trends in regionalization varied by state (Table S4). For example, compared to other states, Massachusetts was an early adopter of regionalized care, with high-volume hospitals performing 92 percent of heart surgeries in 2000 and over 96 percent of surgeries in 2012. Other states, like Arizona, did not become regionalized until later years. Regionalization in New York remained static, with a similar

**TABLE 2** Trends in hospital case-volume by patient risk category

	Total	2000	2004	2008	2012	
Patient count	n = 33 288	n = 8803	n = 8219	n = 8409	n = 7857	
Hospital count	n = 718	n = 206	n = 176	n = 174	n = 162	
	%	%	%	%	%	P-trend
Case-volume						
Low volume	8.53	8.60	9.10	8.60	7.80	0.04
Med volume	25.08	30.90	26.30	21.50	21.00	<0.01
High volume	66.39	60.50	64.50	69.90	71.20	<0.01
Case-volume × patient risk						
Low risk	49.97	52.40	50.36	48.67	48.22	<0.01
Low volume	5.15	5.50	5.39	4.97	4.70	0.21
Medium volume	13.88	17.87	14.69	11.67	10.95	<0.01
High volume	30.94	29.04	30.28	32.04	32.58	<0.01
Medium risk	46.30	44.14	45.05	46.95	49.34	<0.01
Low volume	3.24	2.96	3.59	3.40	2.99	0.15
Medium volume	10.64	12.40	10.99	9.31	9.71	<0.01
High volume	32.43	28.77	30.48	34.24	36.64	<0.01
High risk	3.73	3.45	4.59	4.38	2.43	<0.01
Low volume	0.15	0.14	0.16	0.19	0.11	0.57
Medium volume	0.56	0.67	0.67	0.56	0.32	0.02
High volume	3.02	2.65	3.76	3.63	2.00	0.08

number of patients receiving heart surgery from medium- and high-volume hospitals at the beginning of the study period compared to the end of the study period.

Results from adjusted hierarchical logistic regression (Table 4) suggest that high-volume hospitals had significantly lower odds of mortality and significantly lower costs compared to low-volume hospitals (odds ratio [OR] 0.59; 95% confidence interval [CI]: 0.46-0.76,  $P < 0.01$  for mortality, and relative risk [RR] 0.91; 95% CI: 0.86-0.96,  $P < 0.01$  for cost). High- and medium-volume hospitals had longer LOS than low-volume hospitals (RR 1.18; 95% CI: 1.15-1.21,  $P < 0.01$ , and RR 1.05; 95% CI: 1.03-1.07,  $P < 0.01$ , respectively). Results from all sensitivity analyses mirrored findings from our main analysis (Table 4 and Table S5). The results from PCA are provided in Table S6. In order to present differences between medium- and high-volume hospitals, results from regression models comparing high-volume to medium-volume hospitals are provided in Table S7. Results show lower odds of mortality (OR 0.73; 95% CI [0.61, 0.88],  $P < 0.01$ ) and longer LOS (RR 1.15; 95% CI: [1.13, 1.16],  $P < 0.01$ ) in high-volume hospitals compared to medium-volume hospitals and no significant differences in cost between medium- and high-volume hospitals (RR 0.97; 95% CI: [0.93, 1.02],  $P = 0.26$ ).

Table S8 presents full results of the regression analysis to evaluate the association between hospital case-volume and in-hospital mortality. Using predicted values (Table 5), we estimated that there would be approximately 1052 deaths overall. This value decreased to 934 deaths, yielding 118 avoidable deaths (11.2 percent reduction), if all patients had surgeries exclusively at

high-volume hospitals. On average, for every 80 patients transferred, one life would be saved. By risk category, the number of transfers needed to avoid one death was 14 for high-risk, 51 for medium-risk, and 186 for low-risk patients. When predictions were based on estimates from the scenario whereupon all patients who had surgeries at low-volume hospitals, instead, had surgeries at medium-volume hospitals, the number of deaths decreased slightly to 1035, yielding 17 avoidable deaths (1.6 percent reduction). The number of deaths in the third scenario decreased to 1012, yielding 40 avoidable deaths (3.8 percent reduction). These numbers fluctuated during the study period.

## 4 | DISCUSSION

Using a longitudinal database representing almost half of the U.S. population, our findings substantiate that (a) in general, pediatric cardiac surgical care has undergone a trend of increasing regionalization during the last decade; (b) case-adjusted in-hospital mortality was significantly lower in high-volume compared to low-volume hospitals; and (c) study findings were mixed regarding the effect of hospital case-volume on health care utilization, as reflected in lower facility fees but longer LOS in high-volume compared to low-volume hospitals.

Salazar et al<sup>44</sup> reported that regionalized care was advancing in multiple pediatric surgical procedures, but due to the limited availability of data, cardiac care was excluded from their review. Our

**TABLE 3** Trends in patient outcomes by hospital case-volume

Case-volume	Patient count Hospital count	Total	2000	2004	2008	2012	P-trend
		n = 33 288 n = 718	n = 8803 n = 206	n = 8219 n = 176	n = 8409 n = 174	n = 7857 n = 162	
<b>Mortality</b>							
Total	n (%)	1211 (3.64%)	377 (4.28%)	302 (3.67%)	309 (3.67%)	223 (2.84%)	<0.01
Low volume	n (%)	116 (4.08%)	36 (4.76%)	34 (4.53%)	33 (4.58%)	13 (2.12%)	0.03
Med volume	n (%)	351 (4.20%)	131 (4.81%)	83 (3.83%)	74 (4.09%)	63 (3.82%)	0.13
High volume	n (%)	744 (3.37%)	210 (3.93%)	185 (3.49%)	202 (3.44%)	147 (2.63%)	<0.01
<b>Length of stay</b>							
Total	Mean (SD)	15.13 (24.39)	12.54 (19.51)	14.86 (23.00)	15.70 (24.64)	17.68 (29.61)	<0.01
	Median (IQR)	7 (4, 15)	6 (4, 13)	7 (4, 16)	7 (4, 17)	8 (4, 18)	
Low volume	Mean (SD)	15.10 (26.65)	13.05 (22.16)	15.23 (26.66)	14.39 (24.59)	18.31 (33.05)	<0.01
	Median (IQR)	6 (4, 13)	5 (3, 11)	7 (4, 15)	6 (4, 13)	6 (4, 14)	
Med volume	Mean (SD)	13.85 (22.48)	11.53 (17.24)	13.03 (21.28)	15.47 (25.28)	16.97 (27.39)	<0.01
	Median (IQR)	6 (4, 14)	6 (3, 11)	6 (4, 13)	7 (4, 15)	7 (4, 17)	
High volume	Mean (SD)	15.61 (24.76)	13.00 (20.17)	15.55 (23.08)	15.93 (24.44)	17.82 (29.85)	<0.01
	Median (IQR)	7 (4, 16)	7 (4, 14)	8 (4, 17)	8 (4, 17)	8 (4, 18)	
<b>Cost</b>							
Total	Mean (SD)	\$68 025 (\$99 135)	\$39 647 (\$49 099)	\$54 194 (\$59 454)	\$78 622 (\$116 335)	\$92 539 (\$137 086)	<0.01
	Median (IQR)	\$38 417 (\$23 533, \$72 130)	\$24 020 (\$15 315, \$43 380)	\$33 838 (\$21 639, \$62 426)	\$43 831 (\$27 443, \$81 568)	\$48 954 (\$30 170, \$96 592)	
Low volume	Mean (SD)	\$57 985 (\$93 212)	\$38 860 (\$52 691)	\$43 551 (\$60 016)	\$58 861 (\$90 970)	\$92 218 (\$143 193)	<0.01
	Median (IQR)	\$31 204 (\$18 707, \$57 063)	\$21 317 (\$13 822, \$39 351)	\$27 840 (\$17 356, \$46 940)	\$33 662 (\$20 575, \$58 425)	\$43 596 (\$26 573, \$96 893)	
Med volume	Mean (SD)	\$55 629 (\$77 295)	\$37 015 (\$45 465)	\$49 107 (\$52 498)	\$72 263 (\$111 116)	\$68 258 (\$87 391)	<0.01
	Median (IQR)	\$31 612 (\$19 801, \$59 091)	\$22 600 (\$15 160, \$38 377)	\$31 316 (\$20 544, \$55 477)	\$38 959 (\$22 763, \$73 709)	\$35 753 (\$23 285, \$73 922)	
High volume	Mean (SD)	\$74 054 (\$106 394)	\$41 275 (\$50 400)	\$58 027 (\$61 778)	\$82 929 (\$120 193)	\$97 339 (\$143 639)	<0.01
	Median (IQR)	\$42 483 (\$26 275, \$78 671)	\$25 648 (\$15 714, \$46 309)	\$36 487 (\$22 909, \$68 642)	\$47 098 (\$29 920, \$86 077)	\$52 420 (\$32 674, \$101 657)	

current study provides further evidence that regionalization of pediatric cardiac surgeries has also progressed. This regionalization was mainly attributable to trends among low- and medium-risk patients, echoing results from previous studies in other areas of surgical care.<sup>44,54</sup>

One novel finding of this study is the increasing polarization in hospital volume, with fewer patients receiving care at medium-volume hospitals as regionalization progresses over time. Michigan represents this phenomenon on a small scale. In 2000, 86.6 percent of patients had surgeries at high-volume hospitals, with this percentage gradually increasing over time. In 2008, more than 93 percent of patients had surgeries at

high-volume hospitals, with the remaining patients having surgeries at low-volume hospitals. The number of hospitals providing pediatric cardiac surgery decreased 21 percent between 2000 and 2012, with medium-volume hospitals decreasing at the highest rate (36 percent) as care became more regionalized. In fact, there were 28 medium-volume hospitals in 2000. Of them, five (17.9 percent) became high-volume and six (21.4 percent) became low-volume in 2012. As the distribution of hospitals providing pediatric cardiac surgery becomes more concentrated, medium-volume hospitals will likely continue to diminish as case-volumes diverge toward low or high volume, based on current trends.



**TABLE 4** Results from multilevel regression models evaluating the association between patient outcomes and hospital case-volume

	Results from main analysis <sup>a</sup>			Results from sensitivity analysis, controlling for SES <sup>a,e</sup>			Results from sensitivity analysis, removing cases where hospital case-volume is <10		
	OR <sup>b</sup>	95% CI <sup>c</sup>	P-value	OR <sup>b</sup>	95% CI <sup>c</sup>	P-value	OR <sup>b</sup>	95% CI <sup>c</sup>	P-value
<b>In-hospital mortality</b>	Patients: n = 29 493 Hospitals: n = 164			Patients: n = 20 402 Hospitals: n = 129			Patients: n = 29 352 Hospitals: n = 94		
Low-volume hospitals	Reference			Reference			Reference		
Med-volume hospitals	0.84	0.65, 1.08	0.18	0.84	0.63, 1.14	0.27	0.86	0.66, 1.12	0.25
High-volume hospitals	0.59	0.46, 0.76	<0.01	0.59	0.44, 0.80	<0.01	0.61	0.47, 0.79	<0.01
<b>Length of Stay</b>	Patients: n = 29 493 Hospitals: n = 164			Patients: n = 20 401 Hospitals: n = 129			Patients: n = 29 350 Hospitals: n = 94		
Low-volume hospitals	Reference			Reference			Reference		
Med-volume hospitals	1.05	1.03, 1.07	<0.01	1.02	0.99, 1.04	0.14	1.07	1.05, 1.09	<0.01
High-volume hospitals	1.18	1.15, 1.21	<0.01	1.17	1.14, 1.21	<0.01	1.21	1.18, 1.25	<0.01
<b>Hospital Cost</b>	Patients: n = 23 854 Hospitals: n = 140			Patients: n = 15 629 Hospitals: n = 92			Patients: n = 21 384 Hospitals: n = 73		
Low-volume hospitals	Reference			Reference			Reference		
Med-volume hospitals	0.96	0.92, 1.01	0.14	0.95	0.90, 1.00	0.06	0.98	0.93, 1.03	0.48
High-volume hospitals	0.91	0.86, 0.96	<0.01	0.91	0.85, 0.98	<0.01	0.93	0.88, 0.99	0.03

<sup>a</sup>Models were adjusted by age, sex, race, insurance type, and RACHS-1 category, with year and state fixed effects and state random effect.

<sup>b</sup>Odds ratio.

<sup>c</sup>Confidence interval.

<sup>d</sup>Relative risk.

<sup>e</sup>Socioeconomic status (SES) was computed based on patient zip code, available only for a limited number of states and years (n = 23 469).

For cohorts in this study, the reduction in mortality was larger when transferring all patients in low- and medium-volume hospitals to high-volume hospitals than all patients in low-volume hospitals to medium-volume hospitals. Furthermore, fewer transfers were needed to avoid one death when transferring patients from low-volume hospitals to high-volume hospitals compared to medium-volume hospitals. Chang et al<sup>25</sup> also demonstrated a small effect on avoidable death when transferring all patients in low-volume hospitals to medium-volume hospitals. In terms of outcome improvement, benefits of medium-volume hospitals for pediatric cardiac surgical care were not apparent, and consequently, could lead to a divergence as these hospitals become low- or high-volume.

Study findings were mixed regarding the effect of hospital case-volume on health care utilization, that is, longer LOS and lower cost in high-volume hospitals compared to low-volume hospitals. Some might contend that the longer LOS in high-volume hospitals could be a result of more complications among patients at high-volume hospitals than at low-volume hospitals. However, with more complications, patients at high-volume hospitals would be expected to receive more testing or treatment, resulting in higher hospitalization costs. Yet our study reflects lower costs in high-volume hospitals.

This discrepancy may be partly attributed to differences in travel distance, as high-volume hospitals typically serve patients from a larger geographic radius compared to low-volume hospitals, and therefore, longer travel distances can be expected.<sup>55,56</sup> Lorch's group<sup>57</sup> demonstrated that patients with longer travel time were more likely to have a longer LOS. One possible explanation is that access to care is better for patients who live closer to hospitals than those who live farther away. Therefore, patients with shorter travel times may be able to return home earlier because follow-up care is more accessible than for patients with longer travel times. Lower cost and longer LOS at high-volume hospitals may indicate that patients from more distant regions stay longer in hospitals for additional observation, incurring longer LOS with minimal care costs, as opposed to patients suffering more complications and incurring higher costs. Economies of scale may also contribute to the differences in cost, with high-volume hospitals operating equipment more often at lower fixed costs. Assessing economy of scale as it relates to hospital equipment charges is beyond our study scope, but should be included as a topic for future research. Further investigation is needed to clarify the factors contributing to this paradox, given that a longer LOS would more plausibly result in greater consumption of health care resources.

**TABLE 5** Mortality predictions under three hypothetical scenarios of regionalized care

	Total	2000	2004	2008	2012
Expected number of death (A) (mortality rate)	1052 (3.57)	319 (4.16)	262 (3.66)	262 (3.61)	209 (2.82)
The first scenario: patients from low- and medium-volume hospitals → high-volume hospitals					
Expected death (B)					
Transfer everyone to high volume	934 (3.17)	277 (3.62)	235 (3.28)	235 (3.25)	187 (2.52)
Transfer only high risk to high volume	1037 (3.52)	312 (4.07)	260 (3.63)	258 (3.56)	207 (2.79)
Transfer only med risk to high volume	974 (3.30)	291 (3.79)	245 (3.42)	245 (3.38)	193 (2.61)
Transfer only low risk to high volume	1023 (3.47)	307 (4.00)	256 (3.58)	256 (3.53)	204 (2.75)
Avoidable death (C=A-B)					
Transfer everyone to high volume	118	42	27	27	22
Transfer only high risk to high volume	15	7	2	4	2
Transfer only med risk to high volume	78	28	17	17	16
Transfer only low risk to high volume	29	12	6	6	5
Number of patients transferred to avoid one death (C/{number of patients needed to be transferred})					
All the patients	80	69	85	81	96
High-risk patients	14	9	25	17	15
Moderate-risk patients	51	40	55	54	61
Low-risk patients	186	138	233	203	228
The second scenario: patients from low-volume hospitals → medium-volume hospitals					
Expected death (B)					
Transfer everyone in low volume to med volume	1035 (3.51)	312 (4.07)	259 (3.62)	258 (3.56)	206 (2.78)
Transfer only high risk in low volume to med volume	1049 (3.56)	316 (4.12)	263 (3.67)	262 (3.61)	208 (2.81)
Transfer only med risk in low volume to med volume	1041 (3.53)	314 (4.09)	261 (3.64)	260 (3.58)	207 (2.79)
Transfer only low risk in low to med volume	1046 (3.55)	315 (4.10)	262 (3.67)	261 (3.60)	208 (2.81)
Avoidable death (C=A-B)					
Transfer everyone in low volume to med volume	17	7	3	4	3
Transfer only high risk in low volume to med volume	3	3	-1	0	1
Transfer only med risk in low volume to med volume	11	5	1	2	2
Transfer only low risk in low to med volume	6	4	0	1	1

(continued)



TABLE 5 (Continued)

	Total	2000	2004	2008	2012
Number of patients transferred to avoid one death (C/{number of patients needed to be transferred})					
All the patients	150	98	227	159	185
High-risk patients	16	4	-12	n/a	9
Moderate-risk patients	87	47	262	126	106
Low-risk patients	258	110	n/a	367	334
The third scenario: patients from low-volume hospitals → high-volume hospitals					
Expected death (B)					
Transfer everyone in low volume to high volume	1012 (3.43)	305 (3.98)	253 (3.53)	252 (3.48)	201 (2.72)
Transfer only high risk in low volume to high volume	1046 (3.55)	315 (4.11)	262 (3.66)	261 (3.60)	208 (2.80)
Transfer only med risk in low volume to high volume	1026 (3.48)	310 (4.03)	256 (3.58)	256 (3.53)	204 (2.75)
Transfer only low risk in low to high volume	1040 (3.53)	313 (4.08)	260 (3.64)	260 (3.58)	207 (2.79)
Avoidable death (C=A-B)					
Transfer everyone in low volume to high volume	40	14	9	10	8
Transfer only high risk in low volume to high volume	6	4	0	1	1
Transfer only med risk in low volume to high volume	26	9	6	6	5
Transfer only low risk in low to high volume	12	6	2	2	2
Number of patients transferred to avoid one death (C/{number of patients needed to be transferred})					
All the patients	63	51	72	65	73
High-risk patients	8	3	n/a	13	8
Moderate-risk patients	37	25	46	41	42
Low-risk patients	132	77	257	163	151

Another novel finding of this study is that LOS and cost increased over time for all volume categories. Some might suggest that increasing trends in health care utilization may be caused by an increase in higher risk patients. This study revealed a significant decrease in low- and high-risk patients, in contrast to a significant increase in medium-risk patients over time (Table 2). Further detailed analyses demonstrated an increasing trend for LOS and cost for all risk categories and all volume categories (Table S3). Thus, our findings cannot be explained by changes in patient risk. Another possible explanation is that increasing health care utilization is due to a broader nationwide increase in health care cost, in which costs have risen faster than inflation and Medicare increases, with some hospitals charging rates 10 times that of Medicare.<sup>58</sup> However, this still does not explain the increasing trend in LOS. Other studies on pediatric cardiac surgeries have reported a similar increase in LOS over time, especially among higher risk patients.<sup>59,60</sup> This increase could be partially attributed to the decreasing trend in in-hospital mortality, as patients who would have died in surgery are now surviving and may require more postoperative care.

This study has the following limitations. First, this is an observational study, utilizing large administrative databases. Potential confounding may arise from unmeasured factors, including individual or hospital characteristics. For individual-level factors, such as patient comorbidities, the higher frequency of older patients and lower RACHS-1 score observed in the lower volume hospitals suggest that these procedures are more likely elective and for lower risk conditions, on average, compared to those performed at higher volume hospitals. This would lead to an underestimation of relative risk at lower volume hospitals, and in a way, would support the robustness of our conclusion. However, lower SES, higher percentage of nonwhite population, and higher percentage of nonprivate insurance type observed among lower volume hospital patients suggest an increased chance of social vulnerability in the group,<sup>61-63</sup> possibly arising from patient selection at the performing hospitals, which, if not sufficiently adjusted for by the variables included in our models (including community-level SES index and insurance type), may lead to overestimation of our reported outcome. On the other hand, for hospital-level factors, possible differences between high-volume hospitals and low-volume hospitals may come from differences in hospital resources, such as presence of pediatric anesthesiology departments or specialized intensive care teams, which were not adjusted for due to lack of information. The relative risk of death and differences in cost and LOS observed in the current study may therefore be a combined effect of factors associated with high-volume hospitals, and not purely the difference associated with case-volume. It is important to note that while the estimates for high- vs low-volume hospitals in our model may be biased considering the causal relationship between volume and outcome, the impact of the bias on the simulation analysis will be minimal. The volume would work as a proxy for other related hospital-level characteristics in this prediction model.

Second, all mortality estimates are based on in-hospital mortality. Long-term mortality outcomes such as 1-year mortality were not assessed. Further research using linked inpatient-death records is needed to more comprehensively explore the full effect of regionalization on long-term health outcomes.

Third, there is potential for miscoding in the administrative databases. The true incidence of miscoding is unknown. However, non-differential misclassification is likely to have diluted the associations found in our study.

Fourth, this study only included patients assigned to RACHS-1, which excludes some patients with cardiac-related procedures such as ligations for patent ductus arteriosus (PDA).

Fifth, patient zip-code information was not available for all states and years. Therefore, we did not include the SES composite index as a covariate in our main analysis regression models. However, estimates from our sensitivity analysis controlling for SES mirrored those in our main analysis, suggesting minimal impact on the model.

Sixth, information on hospital characteristics is not provided in SID. Due to this limitation, we were unable to identify whether the hospital to which each patient was admitted was a children's hospital, though many children's hospitals are likely to be categorized as high-volume hospitals.

Seventh, the current paper is unable to provide information on the specific forces driving regionalization. In general, regionalization is driven by the desire to increase geographic reach of services, quality of care, and economy of scale. However, the decision to regionalize care is likely to involve financial, operational, strategic, cultural, and political influences, among other factors, which is beyond the scope of our study. Our study presented trends in regionalization by state and demonstrated geographic differences in the regionalization of pediatric cardiac care. We believe that these findings will encourage future studies on the mechanisms driving regionalization. For example, investigating the differences among states may help to elucidate the forces driving regionalization in different regions and systems.

Last, results were derived from a convenient sample of eleven states, which were selected based on cost and data availability. Therefore, results may not be generalizable to the rest of the United States.

## 5 | CONCLUSION

During the 2000-2012 period, a trend toward regionalization in pediatric cardiac surgical care was noted, with low- and medium-risk patients accounting for a greater part of the shift. Hospital case-volumes diverged in the process, as fewer patients received pediatric cardiac surgery at medium-volume hospitals. High case-volume was associated with better health outcomes; however, more research is needed to establish the full impact of hospital case-volume on health care utilization.

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This study utilized 2000, 2004, 2008, and 2012 discharge data from Arizona, California, Florida, Massachusetts, Maryland, Michigan, North Carolina, New Jersey, New York, and Washington, State Inpatient Databases (SID), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality.<sup>64</sup>

This study also utilized data from the California Office of Statewide Health and Planning Department (OSHPD) and the Pennsylvania Health Care Cost Containment Council (PHC4).

The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of health care, and increasing access to health care for all citizens. While PHC4 has provided data for this study, PHC4 specifically disclaims responsibility for any analyses, interpretations, or conclusions.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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