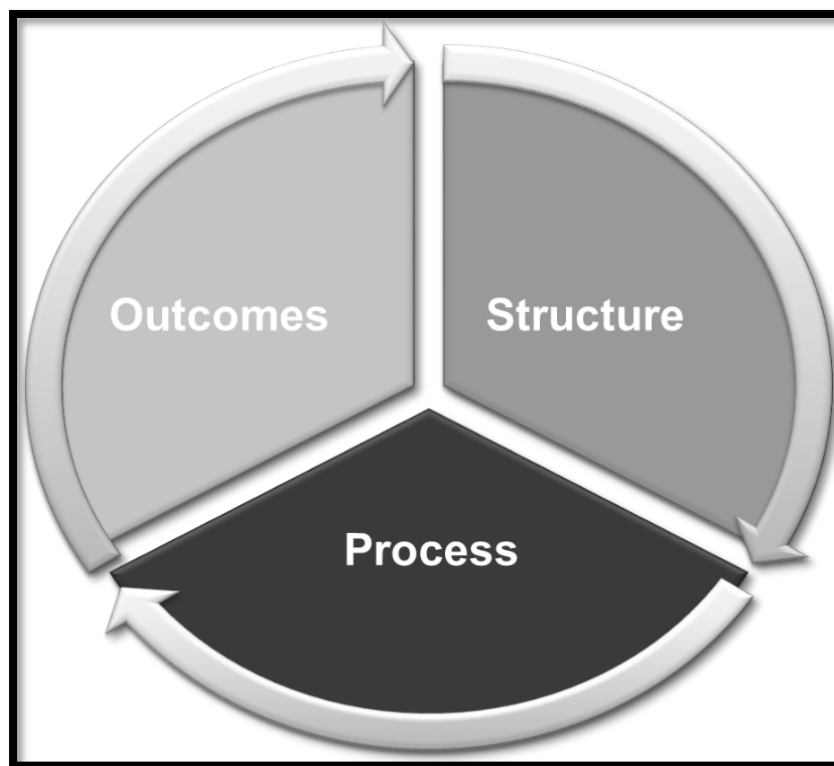


# Hospital volume as a quality-of-care metric in cardiovascular practice

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### Interest

My primary interest is in cardiovascular outcomes and quality of care based research. I have been involved with multiple domains in this field, including acute coronary syndromes, peripheral vascular disease and valvular heart disease.

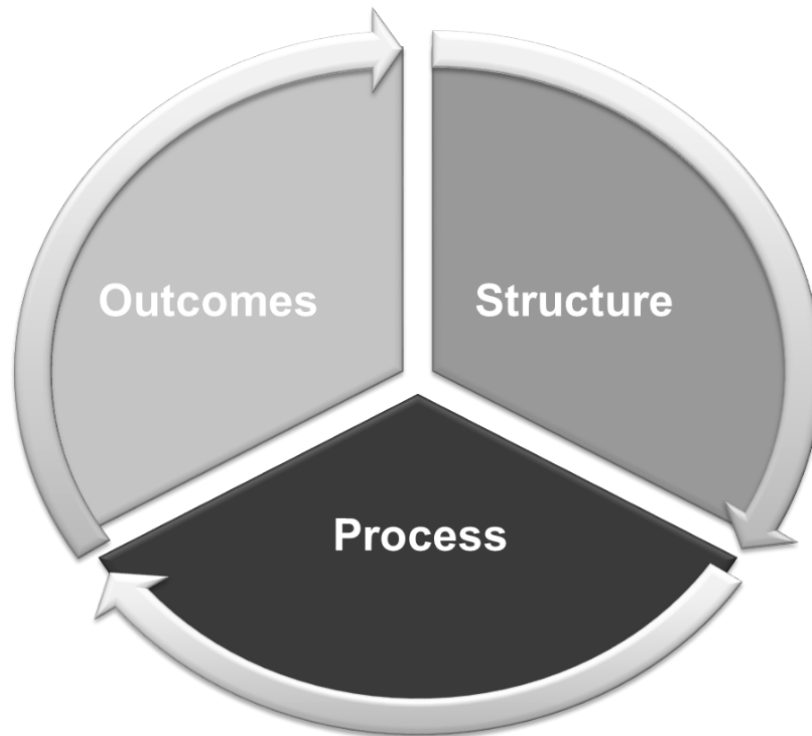
### Objectives

1. To understand the evolution of volume as a metric for quality of care in cardiovascular practice
2. To evaluate the utility of volume as a structural metric for quality of care
3. To discuss the correlation between volume and process measures and outcomes for a number of cardiovascular conditions

We have witnessed tremendous progress in cardiovascular medicine over the past half century. Innovations in science, medical therapy and technology have helped reduce cardiovascular mortality in the US nearly 400% over this period.<sup>1</sup> More recently, there has been greater emphasis on quality-of-care metrics to ensure a more uniform dispersion and delivery of these great advances.

For a long time, quality of care was considered to be something of a mystery: real, capable of being perceived and appreciated, but not subject to measurement. The very attempt to define and measure quality seemed to denature and belittle it. Now, we may have moved too far in the opposite direction. Those who have not experienced the intricacies of clinical practice demand measures that are easy, precise, and complete—as if a sack of potatoes was being weighed. A classic example of this is hospital and physician volume, which I will discuss as it pertains to the field of cardiology.

In Donabedian's classic paper on quality of care, he defined three domains in quality-of-care (Figure 1).<sup>2</sup>



**Figure 1:** Domains of quality-of-care

1. **Structure:** attributes of health care systems that are organized to deliver quality care
2. **Process:** describes what we do to and for patients
3. **Outcome:** describes the changes in patients' health status that may be linked to the health care process

Over time, volume became an important surrogate for structural measures. Typically, studies have assessed the correlation between hospital volume and in-hospital outcomes – primarily, in-

hospital mortality. As we think about the practice of cardiology, the inpatient delivery of care can be described in two broad areas:

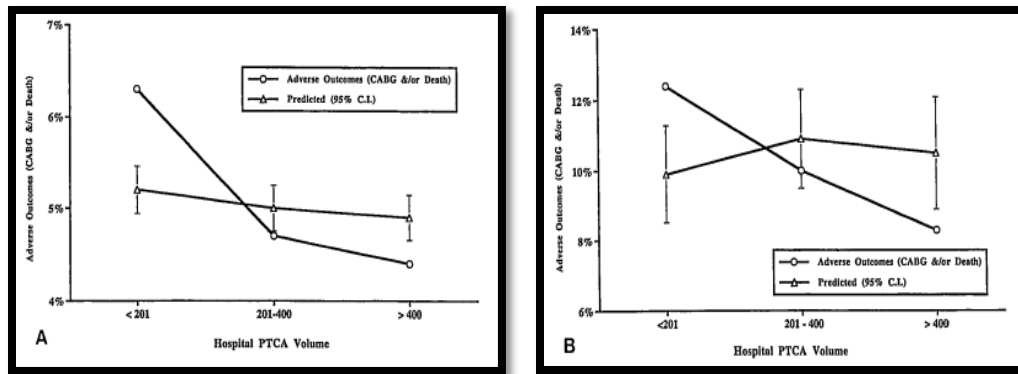
1. **Procedural** – angioplasty, cardiac surgery, pacemakers/ICDs, etc.
2. **Medical care** – routine care for patients admitted with heart failure, acute myocardial infarction, etc.

### **Relationship between cardiac procedures and hospital volume**

From the outset, it has been believed that, for procedural fields, higher volume directly equates to better care.<sup>3</sup> For example, comparing outcomes for intraabdominal surgeries such as gall bladder surgery and aortic surgery between low volume and high volume hospitals suggested better outcomes with increasing volumes. In that era, there was also a push for regionalization of care based on volume.<sup>4-6</sup>

For cardiac procedures, the first one to be assessed was coronary artery bypass graft (CABG) surgery. Showstack and colleagues assessed patients undergoing CABG in the California state inpatient database, and observed that for CABG, especially urgent CABG, hospitals with an annual volume of at least 200 had lower mortality than those with lower volumes. They estimated that if these low volume patients were transferred to high volume hospitals, 13 deaths could be averted for urgent CABG at each site annually.<sup>7</sup> In a landmark analysis of data from the Center for Medicare and Medicaid services (CMS), Birkmeyer and colleagues reported that, for most cardiac surgical procedures including CABG, AVR and MVR, there was a robust inverse relationship between hospital volume and risk-adjusted outcomes. Thus, for CABG, adjusted 30-day mortality was reduced from 5.6% to 4.5% between the lowest and highest volume quintile; for AVR, mortality was similarly reduced from 9.3% to 7.1%, and for MVR, it reduced from 15.1% to 11.6%. Although this was an association, causality was immediately inferred; the authors conclude, “In the absence of other information about the quality of surgery at the hospitals near them, Medicare patients undergoing selected cardiovascular procedures can significantly reduce their risk of operative death by selecting a high-volume hospital”.<sup>8</sup>

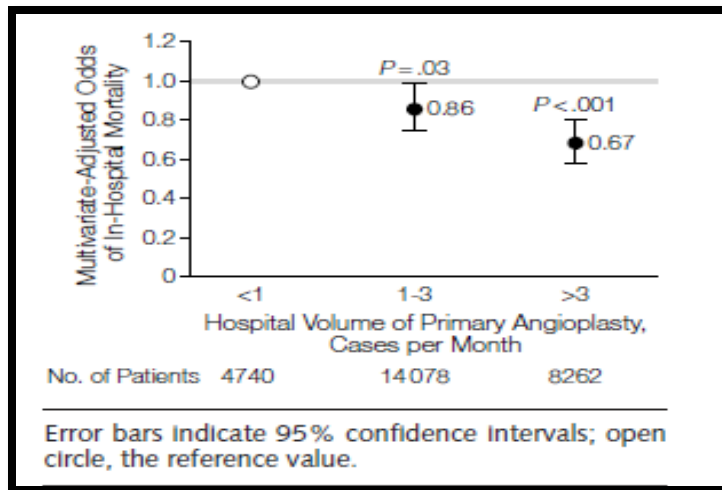
The CABG data inspired similar analyses on coronary angioplasty. Phillips and colleagues performed an analysis of the California state inpatient database among patients undergoing balloon angioplasty (PTCA) in 1989. Among 24,856 patients, PTCA at low volume hospitals ( $\leq 200$ /year) was associated with a higher than expected rate of in-hospital CABG/death compared with PTCA at hospitals performing  $> 400$ /year (**Figure 2**). Of note, the 200/year threshold was chosen based on the earlier CABG data.<sup>9</sup>



**Figure 2: PTCA volume for patients presenting without AMI (A) and with AMI (B)**

Accordingly, one of the first guidelines from the AHA/ACC for PCI stated that hospitals should perform a minimum of 200 PTCAs annually to maintain quality and deliver safe care. Subsequently, there were two other large analyses on this topic. Jollis and colleagues assessed data from 217,836 CMS beneficiaries undergoing PTCA between 1987 and 1990. Balloon PTCA performed in CMS patients performing < 100/year was associated with higher risk of CABG/-in-hospital mortality (translating to about 200-400 total PTCA/year).<sup>10</sup> Hannan and colleagues reported an optimal volume threshold of 600/year from the NY state database between 1991 and 1994.<sup>11</sup>

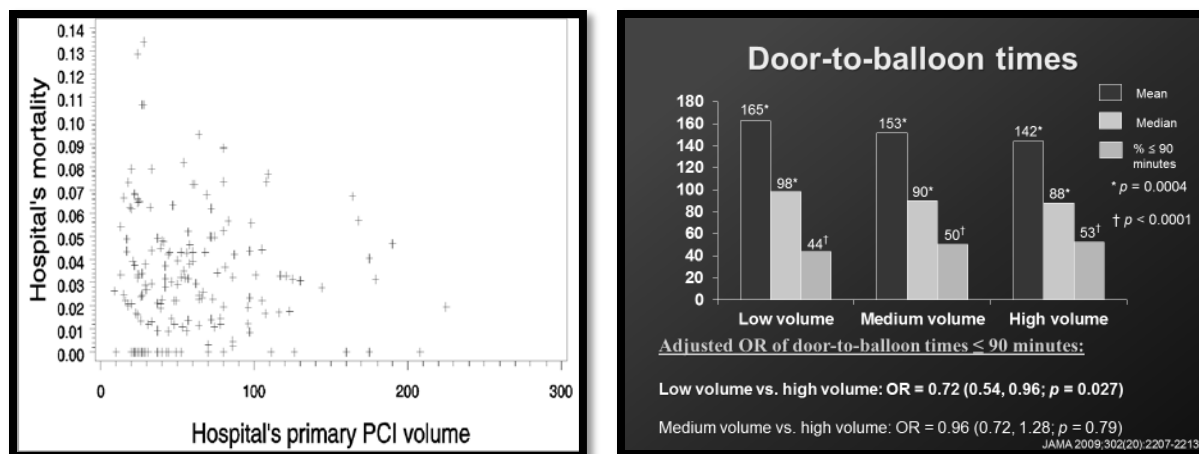
The early 1990s established the importance of primary angioplasty over fibrinolytic therapy for patients presenting with STEMI. Canto and colleagues assessed 257,602 patients with STEMI in the National Registry of Myocardial Infarction (NORMI) registry. In-hospital mortality was 28% lower among patients who underwent primary angioplasty at hospitals with the highest volume (>33/year) than among those who underwent angioplasty at hospitals with the lowest volume (< 11/year) (RR 0.72; 95% CI, 0.60 to 0.87;  $p < 0.001$ ). Interestingly, there was no significant relation between the volume of thrombolytic interventions and in-hospital mortality among patients who received thrombolytic therapy (7.0% for patients in the highest-volume hospitals vs. 6.9% for those in the lowest-volume hospitals,  $p = 0.36$ ).<sup>12</sup> Cannon et al. assessed a similar cohort of patients in the NORMI-2 data and established that a volume of 3 PCIs/ month or 36/year was associated with a threshold effect for mortality (**Figure 3**).<sup>13</sup>



**Figure 3:** Primary angioplasty volume and in-hospital mortality: NRMI-2

These volume thresholds then became part of the guidelines; the 1998 ACC PCI competence statement recommended at least 200, but preferably 400 angioplasties annually;<sup>14</sup> and the 2004 ACC/AHA STEMI guidelines recommended that primary angioplasty be performed by a laboratory that performs > 200 PCIs/year, of which at least 36 are primary angioplasties.<sup>15</sup> Once bare-metal stents were commonly used for PCI, the volume-outcomes hypothesis was revisited by Epstein and colleagues. They found that patients undergoing PCI at sites performing < 200 PCIs had higher mortality than hospitals performing > 1,000; the relationship with other volume thresholds (< 400) was not significant.<sup>16</sup>

Kumbhani and colleagues assessed 29,513 patients undergoing primary PCI during the DES era in the AHA's Get With the Guidelines registry. Although unadjusted in-hospital mortality was higher in low volume hospitals (< 36/year) compared with high volume hospitals ( $\geq 70$ /year), after hierarchical risk adjustment, there was no relationship between in-hospital mortality and volume for low (OR= 1.22; 95% CI 0.78 - 1.91, p=0.38) and moderate (OR = 1.14, 95% CI 0.78 - 1.66, p=0.49) volume hospitals, compared with high volume hospitals. This was true even when total PCI volumes (not just primary PCI) volumes were considered. Interestingly, process measures such as likelihood of achieving a door-to-balloon time of < 90 minutes and use of evidence-based medications at discharge were lower in low volume hospitals compared with high-volume hospitals (**Figure 4**). This suggested that high-volume hospitals had superior systems of care in place compared with lower volume hospitals.<sup>17</sup>



**Figure 4: PPCI volume and in-hospital mortality (left) and D2B times (right): AHA GWTG**

In contrast, Kontos and colleagues assessed patients undergoing PPCI for STEMI between 2006 and 2009 in the ACC's NCDR registry (also in the DES era). They reported that hospitals performing  $\leq 36$  PPCIs/year had worse in-hospital mortality compared with intermediate and high volume ( $> 60$  PPCI/year) hospitals (adjusted OR 1.2, 95% CI 1.08 – 1.33,  $p=0.61$ ). Process measures such as DTB times were consistently higher in higher volume hospitals.

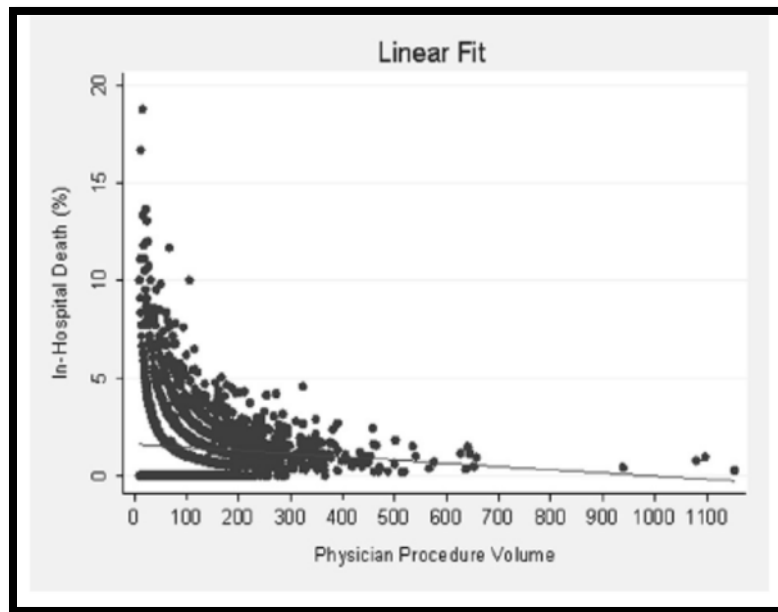
Another key component of this volume-outcomes construct is operator volume. In a CMS analysis, high-volume operators at medium-volume hospitals did as well as low and medium volume operators at high-volume institutions (Figure 5).<sup>18</sup> This was found to be true for PPCI as well in the NY state database.

Hospital Medicare PCI Volume per Year	Physician Medicare PCI Volume per Year		
	<30	30-60	>60
<80	6.13	6.05	5.96
80-160	6.06	5.71	5.17
>160	5.06	4.88	4.59

\*All rates are percentages. CABG indicates coronary artery bypass graft; PCI, percutaneous coronary intervention. P trend across table,  $<.05$ . Adjusted for age, sex, race, acute myocardial infarction as primary diagnosis, comorbidity score, urgency of admission, and multivessel PCI.

**Figure 5: CABG/30-day mortality by physician and hospital volume**

In fact, in a NCDR analysis of a few million PCIs, the operator volume-outcomes relationship was more robust, with operators > 75 doing better than those with lower volumes with an absolute mortality difference of 0.3%. This relationship gets even muddier when years of experience was introduced into the mix. Thus, a low volume operator with experience of 5-10 years appeared to do as well as a high-volume operator with less experience.



**Figure 6:** Physician volume for PCI and in-hospital mortality

The above findings prompted the most recent iteration of the ACC/AHA/SCAI competence statements for PCI. They state that, “In the current era, volume–outcome relationships are not as robust as those that were shown when balloon angioplasty was the only treatment modality. An institutional volume threshold <200 PCIs/annually appears to be consistently associated with worse outcomes, but above this level, there was no relationship between even higher annual volumes and improved outcomes. It is the opinion of our writing committee that the public, policymakers, and payers should not overemphasize specific volume recommendations recognizing that this is just 1 of many factors that may be related to clinical outcomes. Volume is not a surrogate for quality and should not be substituted for risk-adjusted outcomes and other measures of quality.”<sup>19</sup>

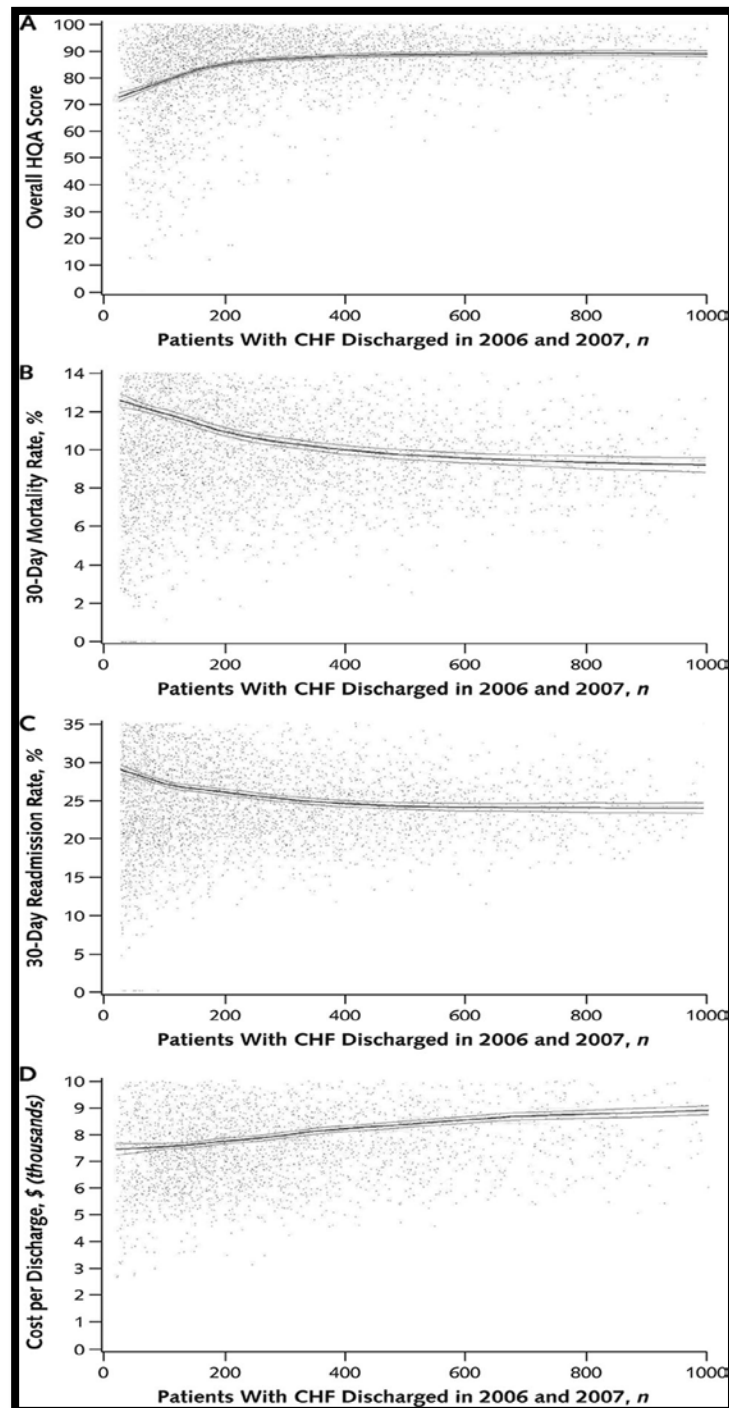
### **Relationship between cardiac medical care delivery and hospital volume**

Heart failure is one of the most common causes of cardiovascular admissions in the US. Despite pharmacologic and technical advances in the diagnosis and management of CHF, outcomes remain suboptimal: 1 in 10 patients dies in the first 30 days after hospitalization for CHF, and of those who survive, 1 in 4 is readmitted. The volume-outcomes relationship for CHF

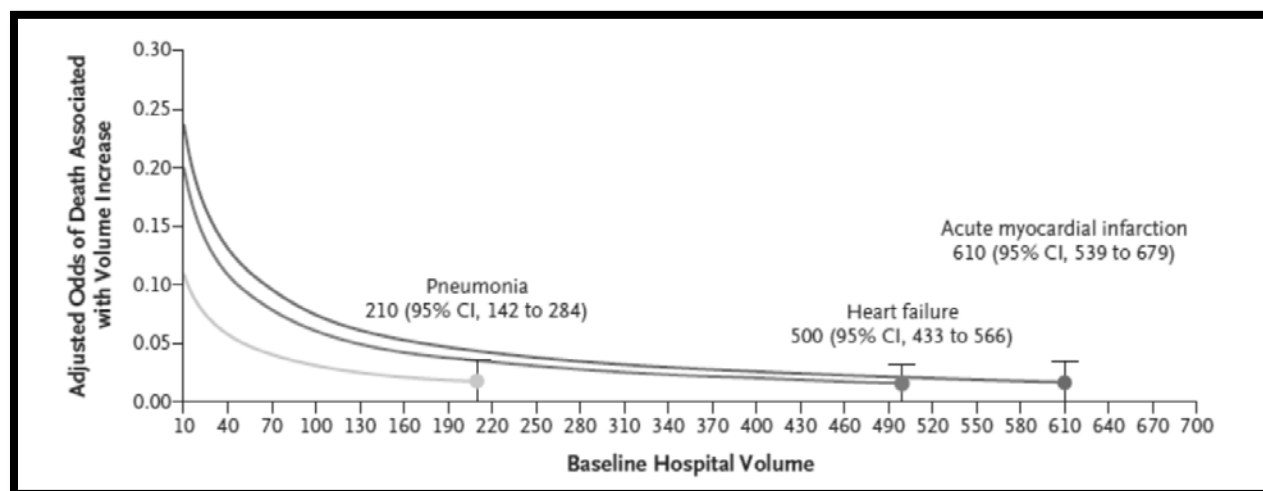


is unclear. Joynt and colleagues used National Medicare claims data between 2006 and 2007, and found that hospitals in the low-volume group had lower performance on the process measures ( $\leq 200$  discharges/year) than did medium-volume (201-400/year) or high-volume ( $>400$ /year) hospitals. Low volume centers had higher risk-adjusted mortality, but not readmission at 30 days, but were associated with lower cost compared with high volume hospitals.<sup>20</sup>

**Figure 7:** Hospital CHF volume and process measures, outcomes and costs of care



Similarly, Ross and colleagues assessed about 1.3 million patients admitted for CHF using CMS claims data between 2004 and 2006. They found a modest relationship between hospital volume and 30-day mortality for CHF admissions. Above 500 annual admissions, but only 148 for teaching hospitals, this relationship was no longer significant. The curve also flattened significantly around 100 admissions/year.<sup>21</sup>



**Figure 7:** Predicted effect of an increase of 100 patients in annual hospital volume on all-cause mortality at 30 days and volume threshold

Kumbhani and colleagues assessed 60,507 patients admitted with CHF in the AHA's GWTG registry. A CMS-linked analysis was performed. On sequential multivariate modeling, compared with high volume hospitals, patients presenting to low volume hospitals (OR=0.50, 95% CI 0.36-0.71;  $p<0.0001$ ) but not medium volume hospitals (OR = 1.05;  $p=0.77$ ) were less likely to provide defect-free care for all CHF measures. In addition, ICD counselling/placement/prescription was lower in low (OR=0.52, 95% CI 0.35 – 0.77,  $p=0.001$ ) and medium (OR = 0.73, 95% CI 0.53 – 1.00,  $p=0.05$ ) volume hospitals. No differences were observed based on volume for in-hospital or 30-day mortality and readmissions, with modest differences in 6-month mortality and readmissions based on volume (table). Thus, the analysis of a large contemporary prospective national registry of HF patients indicated that hospital volume as a structural metric correlates with process measures, but marginally with outcomes up to 6 months of follow-up. Future quality improvement endeavors in HF should therefore focus on understanding systems of care delivery at high-volume hospitals, rather than on hospital volume itself (*data presented, not published yet*).

Table: Multivariable adjusted‡ logistic and Cox regression models demonstrating associations between annual hospital HF volume and outcomes						
Outcome of interest	Low-volume vs. high-volume OR (95% CI)*	p-value	Medium-volume vs. high-volume OR (95% CI)*	p-value	Volume as a continuous variable† OR (95% CI)*	p-value
Mortality						
In-hospital	1.04 (0.77 – 1.41)	0.80	0.92 (0.74 – 1.15)	0.46	1.01 (0.94 – 1.09)	0.74
30-day‡	1.09 (0.95 – 1.25)	0.23	1.06 (0.97 – 1.16)	0.21	1.00 (0.98-1.02)	0.93
6-month‡	1.03 (0.95 – 1.11)	0.46	1.06 (1.01 – 1.11)	0.02	0.99 (0.98 – 1.00)	0.02
Readmission						
30-day‡	1.02 (0.95 – 1.10)	0.55	1.01 (0.97 – 1.06)	0.64	0.99 (0.98 – 1.00)	0.10
6-month‡	1.01 (0.96 – 1.06)	0.77	1.03 (1.00 – 1.06)	0.05	0.99 (0.99 – 1.00)	0.05

\* Hazard ratios (HR) and corresponding 95% CI for 30-day and 6-month models

† For every 50 admissions/year increase

‡ Adjusted variables: Demographics: Age, gender, race; Medical history: Anemia, ischemic history, CVA/TIA, diabetes, hyperlipidemia, hypertension, COPD or asthma, PVD, renal insufficiency, smoking; Other patient characteristics: Systolic BP at admission, heart rate, sodium at admission, BUN at admission, EF group; Hospital characteristics: Region, hospital type (teaching/non-teaching)

‡ Among patients discharged alive; additionally adjusted for compliance with defect-free HF measures during index hospitalization

**Bottom line**

Hospital volume is a simple but flawed metric for quality of care for procedures and medical admissions in cardiovascular practice. Rather than focus on hospital volume, future quality improvement endeavors should focus on understanding systems of care delivery at high-volume hospitals. These should then be replicated and disseminated for improving quality of care. Reliance on volume as a metric remains a deeply ingrained among policy makers and third-party payers and there is an urgent need for advocacy against this mindset.

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