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# Chapter 18. Localizing Care to High-Volume Centers

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## Background

The extent to which experience in caring for illness—as represented by a higher volume of cases—impacts outcomes has been well studied over the last 20 years. An extensive literature covering a broad range of conditions and procedures documents superior outcomes for hospitals and physicians with higher patient volumes.<sup>1-6</sup> Drawing on such evidence, various investigators have projected substantial reductions in mortality from regionalizing certain high-risk procedures with established volume-outcome relationships.<sup>4-6</sup>

When volume-outcomes relationships reflect a "practice makes perfect" effect, it may be reasonable to use volumes to assess quality of care. However, such relationships may also reflect "selective referral,"<sup>7-10</sup> when anecdotal knowledge of the superior quality of high volume centers exists in the community.<sup>11</sup> In such cases, direct measurements of processes or outcomes may represent more appropriate quality measures than volume alone.<sup>12,13</sup>

In an era of cost containment and a growing need for accountability for quality of care, any connection between site or physician-specific experience and patient outcomes has far reaching implications for patients, payers, and governmental agencies.<sup>14</sup> In fact, the Leapfrog Group (a consortium of major purchasers and purchasing coalitions) has made patient volume one of their criteria for quality, and has recently begun a project examining evidence-based referrals to high-volume centers (see also Chapter 55).<sup>15</sup>

The Institute of Medicine (IOM) recently sponsored a workshop to examine the evidence supporting this relationship,<sup>16</sup> part of which included a systematic review of investigations of the volume-outcome association.<sup>17</sup> This chapter summarizes the evidence supporting volume-outcomes relationships, drawing heavily on the IOM's systematic review and the workshop's findings.

## **Practice Description**

The use of information regarding volume and its proven or potential relationship with better outcomes may result in several actions. Simply providing patients with volume data may result in preferential selection of high-volume centers or providers. Patients might also be incentivized to choose high-volume centers (eg, through reduced co-payments). Alternatively, payers may elect to contract only with high-volume centers, or provide higher payments to these sites. Finally, low-volume centers (eg, a hospital failing to meet a minimum threshold of bypass operations) or providers (eg, a cardiologist failing to perform a minimum number of angioplasties) might be restricted from continuing to perform the practice, through some combination of credentialing, accreditation, or regulatory actions (see Chapter 56).

## **Opportunities for Impact**

Assuming that a feasible method could be developed to localize care to high-volume centers, a significant effect on patient safety and outcomes is likely. A recent study suggested that more than 500 deaths could be avoided annually in California alone if care for disorders with established volume-outcomes relationships were localized to more experienced centers. Extrapolating nationally, such localization would save 4000 lives.<sup>6</sup> In the case of acute myocardial infarction, transferring the care of these patients from hospitals in the lowest volume

quartile to those in the highest would save 2.3 lives per 100 patients.<sup>4</sup> The corresponding "number needed to treat" (NNT) of 50 falls within the range of many accepted therapeutic interventions.

Little information exists to assess differences in quality of care or rates of adverse events in high or low-volume sites. For example, the extent to which increasing volume leads to fewer medical errors or other direct impacts on patient safety (as opposed to specific improvement in care processes for discrete procedures, which would fall outside our definition of patient safety practices (Chapter 1)) is unknown. Ongoing prospective initiatives such as those proposed by the Leapfrog Group<sup>15</sup> may better quantify the various impacts of localizing care to high-volume centers.

#### **Study Designs**

We analyzed one large systematic review of 88 studies examining the relationship between volume and outcomes.<sup>17</sup> Using a structured MEDLINE search, this review included studies that examined health outcomes as the dependent variable with hospital and/or physician volume as an independent variable. The IOM review included medical and surgical conditions such as coronary artery bypass grafting, pediatric cardiac surgery, carotid endarterectomy, abdominal aortic aneurysm repair, cancer surgery, coronary angioplasty, acute myocardial infarction, AIDS, and multiple procedures. This chapter reviews the relationship for surgical illnesses only.

The source studies of the IOM review were entirely observational in nature. Close attention was paid to risk adjustment and statistical methods in assessment of results, and criteria for inclusion in the review selected for population or community-based samples. Thus, the level of the design is classified as Level 3A.

### **Study Outcomes**

The IOM systematic review examined health outcomes as related to hospital or physician volume. The primary outcome of interest was mortality. Other clinical outcomes were chosen based on complications specific to the surgical procedure (eg, stroke following carotid endarterectomy).

### **Evidence for Effectiveness of the Practice**

Results of the systematic review are outlined in Table 18.1. The studies reviewed were of variable design and analytic sophistication, with more recent investigations generally being of higher quality. For all procedures, there was a consistent trend toward an association between improved outcomes and higher hospital or physician-specific volume.\* The evidence supporting the volume-outcomes relationship was similar when looking at hospital volume (78% of studies

<sup>\*</sup> This trend has one major exception, a study of volume-outcome relationships for 8 major surgical procedures at Veterans Affairs hospitals across the country (Khuri SF, et al. Relation of surgical volume to outcome in eight common operations: results from the VA National Surgical Quality Improvement Program. Ann Surg. 1999;230:414-429). This comprehensive national found no significant volume-outcome relationship for study any of the 8 procedures analyzed. While it is tempting to attribute these negative findings to unique aspects of the VA system, this is also one of the few studies to employ robust risk-adjustment using clinical and not administrative data. The authors of the IOM review take particular note of the superior methodologic features and negative findings of this study.

showed an association) and physician volume (74% showed an association); the former was the more frequently analyzed variable.

The impact of volume on outcomes varied across procedures and diagnoses. The effect was most marked for complex cancer surgeries (ie, esophagectomy, pancreatoduodenectomy), with numbers needed to treat (NNT) between 7 and 17. For commonly performed surgeries such as coronary artery bypass grafting, the NNT was generally larger, but still within the range of other accepted therapies. Carotid endarterectomy appeared to have a much higher NNT, but this may be because the major adverse outcome of this surgery (ie, stroke) is often an indication for surgery as well as a complication of it. This relationship cannot be discerned from administrative data, and the studies upon which the NNT is based reported mortality, a less frequent complication of carotid surgery than stroke, as a primary outcome. The few studies that collected primary data (and would have been able to determine this important difference) were generally small and of lower quality design, making their findings suspect.

The authors of the IOM systematic review conclude that the volume-outcomes relationship exists, but they raise some caveats when interpreting the literature as a whole. They first note that the literature describing the relationship in greatest detail come from a few single-State databases (63% of studies coming from New York State alone), possibly limiting the generalizability of their results. Although few studies employed rigorous risk adjustment methodologies using clinical data, the relationship between volume and outcomes was consistent in these studies. Also, they raise a note of caution in interpreting this relationship because of the possibility that publication bias (ie, studies that fail to demonstrate a volume-outcome relationship might be less likely to be submitted or accepted for publication) has affected this literature. Finally, they point out that the precise mechanism by which outcomes are improved has yet to be elucidated; no study has reported the independent effects of ancillary personnel expertise or hospital system factors on patient outcomes. For example, in interpreting the improved outcomes of high volume centers in coronary artery bypass grafting, we do not presently know what the relative contributions are of the surgeon, cardiac bypass team, cardiac anesthesiologist, and hospital resources (eg, dedicated cardiothoracic intensive care units).

#### **Potential for Harm**

In the summary accompanying the IOM workshop's proceedings, several potential pitfalls of localizing care to high volume settings were noted, as follows<sup>16</sup>:

- The focus on high volume providers may be a "distracting priority," and similar improvements in care may be achieved through more traditional local quality improvement measures.
- Hospitals with high volumes may use that data to misrepresent their experience in the absence of true outcomes data.
- High volume centers may achieve too much contractual leverage, leading to price inflation.
- Counting procedures may lead to perverse incentives to perform procedures that are not appropriate.
- Requiring high volumes will impede entry of new competitors into the marketplace.
- Narrowing the choice of providers may negatively impact patient satisfaction and override patients' preferences for care (for example, if patients are forced to travel long distances to receive care at a high volume center).

Several of these concerns have been borne out in published studies. In a study of pediatric trauma centers, Tepas et al suggested that increases in volume may strain provider resources and worsen patient outcomes.<sup>18</sup> Even assuming potential improvements in patient outcomes, diverting patients to large referral centers has important health policy implications<sup>14</sup> and may decrease patient satisfaction.<sup>19</sup>

#### **Costs and Implementation**

The major barriers to implementing a selective referral program based on hospital volume include the potential harms listed above, as well as several additional factors. These may include patients' preference for care near home, lack of resources to travel, inability to transfer unstable patients to high-volume centers, loss of access to care in areas where low-volume services are discontinued (particularly rural areas), and resistance by providers to quality measurement activities. Finally, existing high volume centers may lack the capacity to accept additional patients. When they do not, further increases in volume could lead to increased rates of adverse events due to over-stressing the system, as was noted for pediatric trauma.<sup>18</sup>

Costs of this practice are not explicitly addressed in the IOM report, but widespread implementation of selective referrals would depend on the collection of detailed and accurate data (risk adjustment, process, and outcomes data), at substantial cost. Additionally, a nationwide systematic referral model may require augmenting capability of high-volume hospitals through additional construction or other major infrastructure investments. Finally, the travel and inconvenience costs of having patients obtain care at institutions outside the local community will be borne by either the system or the patients themselves—a cost which may be compounded further by patients' and families' lost productivity.

#### Comment

Changing practice patterns based on the compelling data linking volume and improved outcomes is a complex task involving patients, hospitals and communities, as well as payers and employers. Actually closing hospitals or designating specific health care centers as "magnet" sites for care of specific illnesses would require, in addition to a wholesale change in health care systems, major infusions of resources and difficult political choices. For these reasons alone, this policy decision seems unlikely. Alternatively, hospitals or medical groups may use physicianspecific outcomes information to make decisions about staffing needs (eg, hiring a lower number of surgeons to ensure that all operators have high volumes), although this too seems unlikely unless meeting volume thresholds become mandatory or are strongly incentivized.

The Leapfrog Group's efforts represent one of the first major initiatives to use empiric data to direct selective referrals using volume data. As an initiative begun and carried out within a specific employer/health care purchaser system it may be limited in its generalizability. However, prospective evaluation of the effort will yield important information regarding the costs and outcomes of such a referral system and its impact on patient satisfaction with care.

Outside of the Leapfrog effort, the widespread publication of outcomes, especially mortality data, has been proposed as a way to help consumers to make more informed health care choices. A recent systematic review of this paradigm or "strategy" suggests that its impact has been mixed.<sup>20</sup> There are no data to suggest that patients or payers will make major changes in health care purchasing decisions when provided with volume data alone. To date, press reports of particularly noteworthy errors seem to have more of an impact on patients' choices of care than information about volume or even outcomes of care.<sup>20,21</sup>

In addition to the potential use of volume data to guide health care purchasing decisions, the IOM workshop and authors of the systematic review recommend using volume as one of several quality measures to initiate local or regional quality improvement efforts. This data may motivate or inform care improvement efforts at low-volume sites (or those with worse-than-expected outcomes) through use of site visits, feedback of risk-adjusted outcomes information, and assessment of care processes. This collaborative approach to quality improvement has been used successfully in the VA National Surgical Quality Improvement Project<sup>22</sup> and in several projects in New York State.<sup>23,24</sup> However, it seems likely that as the volume-outcome relationship becomes better defined and understood, its influence on the health care choices of both patients and payers is likely to grow.

Condition	Number of Studies Reviewed	Comments
Coronary artery bypass grafting	9	<ul> <li>All studies used appropriate risk adjustment</li> <li>VOR for both physicians and hospital: 7 studies</li> <li>Absolute difference in mortality between high- and low-volume centers and surgeons was 3-10% (NNT 10-33)</li> <li>Some evidence to suggest that centers and surgeons with good outcomes experienced increasing volumes over time ("selective referrals")</li> </ul>
Carotid endarterectomy	19	<ul> <li>Only 9 studies performed adequate risk adjustment</li> <li>Most studies employed administrative data, making accurate ascertainment of postoperative stroke impossible</li> <li>VOR found for surgeon: 9 studies</li> <li>VOR found for hospital: 7 studies</li> <li>Absolute difference in mortality between high- and low-volume hospital/surgeon was 0.2-0.9% (NNT 100-500)</li> </ul>
Cancer surgery	20	<ul> <li>Risk adjustment methods variable, most are dependent on administrative data only</li> <li>VOR most marked for rare cancers/procedures such as pancreatic resection and esophageal surgery</li> <li>VOR unclear for common surgery such as colectomy and pneumonectomy</li> <li>For esophagectomy, absolute difference in mortality between high- and low-volume hospitals was 11-13.9% (NNT 7-9)</li> <li>For pancreatic resection, difference in mortality between high- and low-volume hospitals gives NNT 10-15</li> </ul>
Abdominal aortic aneurysm repair	12	<ul> <li>11 studies performed adequate risk adjustment</li> <li>VOR for hospitals and physicians noted</li> <li>Absolute reduction in mortality due to surgeon or hospital volume was 5-9% (NNT 11-20)</li> <li>"Selective referrals" noted</li> </ul>
Pediatric cardiac surgery	3	<ul> <li>All studies used appropriate risk adjustment</li> <li>VOR found for both hospital and surgeon volume</li> <li>Absolute difference in mortality due to surgeon or hospital volume</li> <li>was 3% (NNT 33)</li> <li>Possibly greater benefit for more complex/sicker patients</li> </ul>

Table 18.1. Summary of findings from IOM systematic review <sup>17</sup> of volume-outcome relationship\*

\* NNT indicates number needed to treat; VOR, volume-outcome relationship

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