



Published in final edited form as:

J Thorac Cardiovasc Surg. 2021 May ; 161(5): 1705–1709. doi:10.1016/j.jtcvs.2020.10.132.

Regionalization for Thoracic Surgery: Economic implications of regionalization in the U.S.

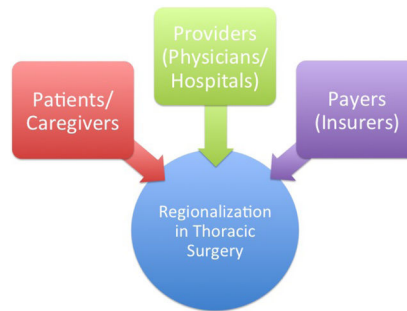
Melanie P. Subramanian, MD, MPHS¹, Zhizhou Yang, BA³, Su-Hsin Chang, PhD², Varun Puri, MD, MSCI¹

¹Washington University School of Medicine, Division of Cardiothoracic Surgery

²Washington University School of Medicine, Division of Public Health Sciences

³Washington University School of Medicine

Central Figure Abbreviated Legend: Relevant Stakeholders in Regionalization



Central Message: Volume-based referral strategies have been heavily discussed as a possible regionalization strategy for thoracic surgical procedures. However, consideration of the consequences to stakeholders and the cost-effectiveness of such policies must first take place.

Keywords

regionalization; hospital volume; cost-effectiveness

Feature Editor's Introduction - Regionalization of healthcare remains controversial and has been proposed as a way to improve outcomes in patients undergoing complex thoracic surgical procedures based on studies correlating hospital and surgeon volume to outcomes. In this month's Journal, we have an Invited Expert Opinion article written by a leading thoracic surgery health services research

Corresponding Author: Melanie Subramanian, MD, MPHS, 660 S. Euclid Avenue, Campus Box 8234, St. Louis, MO 63110, Telephone/fax: 314 393-1563/314 362-6288, m.p.subramanian@email.wustl.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Conflicts of Interest: No conflicts of interest to disclose.

group led by Dr. Varun Puri on the “Economic implications of regionalization in the U.S.” The authors provide an excellent overview of the potential benefits and consequences of volume-based regionalization of thoracic surgery care. They also describe a decision analytic model their group has developed that could be used to evaluate the cost-effectiveness of regionalization in the United States. Regionalization of care remains a complex and controversial topic of interest to thoracic surgeons, and the benefits must be carefully considered with the consequences and economic implications for key stakeholders before deciding whether regionalization can be applied more broadly in the United States.

-Jules Lin, MD

Regionalization of care has long been discussed as a possible policy solution that can improve surgical outcomes for patients undergoing complex surgical procedures. The concept of centralizing complex surgical procedures was originally discussed by Luft and colleagues' landmark study, which documented the inverse relationship between hospital volume and surgical mortality rates¹. The debate was reinvigorated by publications by Birkmeyer and colleagues, who suggested that higher hospital and surgeon volume were associated with improved in-hospital mortality for high risk surgical procedures^{2, 3}. More recently, the Leapfrog Group has advocated for the use of minimum hospital and surgeon volume standards for select surgical procedures⁴. In 2015, three high-profile hospital systems announced the “Take the Volume Pledge” initiative to regionalize the care of complex surgical procedures to higher volume hospitals and surgeons within their established healthcare network⁵. These proposals represent the modern wave of volume-based regionalization efforts intended to improve quality of surgical care.

While policies to regionalize thoracic surgical procedures have been implemented in other countries, there is no U.S. federal mandate to encourage regionalization^{6, 7}. The evidence in support of regionalization within thoracic surgery is heterogeneous, with the majority of studies focusing on implementation of volume-based thresholds. Existing studies comparing high vs. low volume facilities focused on outcomes including in-hospital mortality, complications, and length of stay. Yet, relatively little attention has been given to the potential economic implications of regionalization policies for patients and their family, providers, payers, and the entire society/nation. Understanding the implications for these stakeholders and cost-effectiveness of regionalization policies is necessary to inform a thorough discussion of the merits and feasibility of regionalization of care.

Regionalization and the Volume-Outcome Relationship

The majority of highly publicized regionalization policies for complex procedures are reliant on volume-based referral strategies. The volume-outcome relationship is largely predicated on two assumptions¹. First, the “practice-makes-perfect” concept suggests surgeons in higher volume facilities accumulate more experience, leading to improved patient outcomes. Second, this prevailing notion suggests that over time, referral patterns are influenced by surgeon and hospital reputation, leading to facilities with good surgical outcomes generating and maintaining high surgical volumes.

The volume-outcome relationship has been used as a cornerstone of policies developed by the Leapfrog Group and the Take the Volume pledge, and has been the focus of many studies investigating the potential effectiveness of regionalization in lung cancer resection, esophagectomy, and organ transplantation. However, the use of volume as a predictor of surgical quality has been criticized on multiple fronts. The volume-outcome relationship is non-linear; yet several previous studies have failed to recognize this relationship when planning their methodology^{8, 9}. Other strategies have attempted to use dichotomous cut points or quantiles to characterize volume. However, these strategies can be flawed, as they may not always represent the true inflection point(s) where a statistically significant change occurs⁹. Some investigators have criticized the use of volume for regionalization policies citing inappropriate statistical methodology and inadequate risk adjustment in the volume-outcome evidence¹⁰.

Regardless, volume-based thresholds have been the most extensively studied when it comes to regionalization of complex surgeries. Multiple studies have utilized large administrative and clinical databases to evaluate the association between hospital and/or surgeon volume and lung resection outcomes. Wakeam et al. utilized the National Inpatient Sample (NIS, 2007–2011) to assess the relationship between hospital volume and in-hospital mortality, complications, and hospitalization cost for patients receiving elective segmentectomy, lobectomy, and pneumonectomy¹¹. They defined hospital volume by use of quartiles, and ultimately divided patients into very low volume (<21 cases/year), low volume (21–40 cases/year), high volume (40–78 cases/year), and very high volume (>78 cases/year) groups. The authors observed a statistically significant (but clinically small) decrease in in-hospital mortality across quartiles – 1.9% in low volume hospitals vs. 1.1 % in very high volume hospitals). In stratified analysis by preoperative pulmonary risk (defined as history of COPD) and age, they demonstrated a widening volume-mortality effect, ultimately suggesting that older patients with greater preoperative pulmonary risk would more likely benefit from referral to higher volume centers. Clark and colleagues came to similar conclusions in lung cancer patients who underwent an elective lobectomy or pneumonectomy, further stratified into “younger-healthier” (age 18–60 years, Elixhauser Comorbidity Index<1) and “older-sicker” cohorts (age>77 years, Elixhauser Comorbidity Index>3)¹². They utilized the Healthcare Cost and Utilization Project Florida and New York State Inpatient Databases (2007–2013) to compare outcomes based on Leapfrog Group minimum hospital (>40 annual lung resections) and surgeon (>15 annual lung resections) volume criteria. The authors found that higher hospital and surgeon volume were overall associated with decreased in-hospital mortality and complications. When examining their subgroups specifically, the authors noted two interesting findings. First, patients treated by both low-volume surgeons and low-volume hospitals had higher risk of mortality, except for patients in the “younger-healthier” group. Additionally, “older-sicker” patients treated by high-volume surgeons had the highest mortality (12%). However, being treated at a high volume hospital was protective. The authors ultimately concluded that policy should be directed by using hospital volume standards, and patients who are at advanced age or have higher preoperative risk would benefit the most from hospital minimum volume standards.

The volume-outcome relationship has been well demonstrated in esophageal cancer resection^{7, 13}. Birkmeyer et al. produced some of the earliest studies using Medicare data to

suggest that there was a volume-outcome relationship². Analyzing volume by quintiles, they demonstrated an almost 12% reduction in adjusted mortality rates between highest volume (>19 cases/year) and lowest volume hospitals (<2 cases/year). More recent analyses have echoed these findings. Using the NIS (2004–2013), Fuchs et al. found that adjusted odds of postoperative mortality were reduced by 46% when receiving an operation at high (>20 cases/year) compared to low (<6 cases/year) and intermediate (6–19 cases/year) volume centers¹⁴.

The mortality and morbidity benefit associated with higher volume hospitals is perhaps best demonstrated in lung transplantation. Mooney and colleagues linked Medicare administrative claims data to the Scientific Registry of Transplant Recipients (SRTR) to compare in-hospital mortality, hospital/intensive care unit length of stay, complications, 30-day readmission, and index hospitalization cost in 3,128 lung transplant recipients who underwent transplantation at low volume (<20 annual transplants), mid-volume (20–34 annual transplants), and high-volume (>34 annual transplants) centers¹⁵. Notably, after adjusting for recipient characteristics, patients who received transplantation at a low volume center had a 41% increased risk of in-hospital mortality compared to high-volume centers. Additionally, these patients were observed to have longer ICU admissions, longer hospital length of stays, and increased rates of postoperative respiratory and renal failure.

Is the Volume-Outcomes relationship Causal?

There has been controversy surrounding the use of volume-based referral strategies. Beyond criticisms of the statistical limitations on the estimated volume-outcomes relationship, some have advocated that the use of volume is overly simplistic¹⁶. More specific alternatives to volume have been proposed for thoracic cancer operations, including proportion of cases performed by a thoracic-specialty trained surgeon, presence of a dedicated cardiothoracic surgical intensive care unit, and proportion of cases performed using a minimally invasive approach^{16, 17}.

Others have suggested that overall improvements in the perioperative care of thoracic surgical patients play a more influential role in determining surgical outcomes than volume. Sheetz et al. performed a longitudinal cohort study (2005–2016) using Medicare claims data¹⁸. They observed significant decreases in mortality for esophagectomy and lung resection patients over the study time period. However, these findings were independent of hospital volume, and only 31% and 23% of hospitals met minimum Leapfrog esophagectomy and lung resection volume criteria by the end of the study period.

Other studies attempted to show that volume standards were not correlated to improved surgical outcomes. Harrison and colleagues utilized the Healthcare Cost and Utilization Project State Inpatient Database (California, Florida, and New York) to compare in-hospital mortality, major complication rates, and length-of-stay for patients whose hospitals that did and did not meet Leapfrog volume criteria for lung (>40 resections/year) and esophageal (>20 esophagectomies/year) surgery¹⁹. They performed a propensity-matched analysis of patients undergoing lobectomy/pneumonectomy and esophagectomy. Although limited by the lack of granularity associated with administrative data, the study ultimately found that there were

no differences in in-hospital mortality or complications. Interestingly, they found that 62% of lung resection patients and 82% of esophagectomy patients received care at hospitals that were “low-volume.” They concluded that the use of highly publicized volume standards was an unsophisticated and crude way to capture surgical quality, and implementation of these volume standards could potentially have widespread negative effects on a significant portion of surgical patients.

The Volume-Outcome Relationship and Cost

An important consideration to the discussion of regionalization is cost. Unfortunately, the volume-outcome-cost relationship has not been extensively studied. It is possible that regionalization of care to high volume centers can benefit from economies-of-scale. Higher volume facilities may have more robust and efficient processes of care (i.e., experienced perioperative care teams and postoperative enhanced recovery care pathways) that can drive down unit costs (costs per patient)²⁰. However, this has not been well demonstrated in the literature.

Few studies have attempted to examine hospitalization cost by surgical volume. Wakeam et al. utilized the NIS to compare elective lung resection by volume quartile. On adjusted analysis, they observed similar hospitalization costs across all four volume strata (median cost \$24,836 in very low volume hospitals vs. median cost \$26,728 in very high volume hospitals)¹¹. Kennedy *et al.* evaluated hospitalization costs by volume for patients undergoing esophagectomy²¹. They utilized the NIS (2004–2013) to categorize patients by volume quartile (< 7, 7–22, 23–87, and > 87 cases/year). They observed significant mortality reductions by increasing hospital volume (lowest quartile 8.9% vs. highest quartile 3.6%). They performed stratified analysis of costs by age and preoperative risk. Patients with higher preoperative risk accrued considerably higher costs compared to all other patients (\$92,017 vs. \$54,874). However, very high-volume hospitals had similar costs compared to low-volume facilities (\$62,758 vs. \$67,173). The authors used this similarity to suggest that higher volume facilities could effectively manage high-risk patients, and that hospital networks would not be at risk of increasing costs by selectively referring high-risk patients to higher-volume centers within their network.

Meanwhile, a substantial cost savings has been reported with high volume lung transplant centers. Mooney et al. utilized Medicare claims data to compare cost of lung transplantation admission between low (<20 cases/year), intermediate (20–34 cases/year), and high volume (> 35 cases/year) centers¹⁵. On adjusted analysis, they found that factors associated with increased cost included recipient pulmonary hypertension, preoperative use of ECMO, higher lung allocation score, and hospital volume. In fact, low volume transplant centers were associated with an 11.7% increased hospitalization cost compared to high volume centers. Accompanied by findings of decreased in-hospital mortality, reduced complication rates, and reduced hospitalization and intensive care unit length of stay, the authors concluded that higher volume transplant centers offered high quality and high *value* care.

Understanding the Stakeholder Position in Regionalization

Going forward, evaluations of cost-effectiveness will be crucial to understanding the potential feasibility of implementing a regionalization policy. Central to understanding cost-effectiveness is acknowledging that there are multiple stakeholders who stand to benefit and/or lose from volume-based referral strategies. Broadly speaking, these include payers, providers, and patients.

Payers

Payers, including public and private insurance agencies, have a vested interest in paying for facilities that can deliver high *value* care. Payers (like the Leapfrog Group) have taken the lead in advocating for volume thresholds⁴. Central to their argument is the belief that improved care processes and increased expertise will lead to delivery of quality care without excess healthcare utilization that can result from postoperative complications, prolonged length of stay, and readmissions²².

Providers

For high volume hospitals (and surgeons), volume-based referral strategies would lead to higher operative revenue. To be able to provide care for an additional influx in surgical referrals, high volume hospitals may have to make an upfront additional investment in additional infrastructure (i.e. operating rooms, surgical beds, etc.), which could result in increased costs in the short term²³. In the long term, however, high volume hospitals stand to benefit financially from volume-based referral strategies and economies-of-scale. This impact may be somewhat blunted if the lower volume facilities refer only the highest risk patients (those expected to have higher utilization due to operative morbidity) to larger volume centers.

Overall, however, lower volume hospitals (and surgeons) may have much more at stake. As previously described, a significant portion of thoracic surgical procedures takes place in facilities that do not meet recommended volume criteria¹⁸. The potential effect that regionalization based on volume-referral strategies could have on low volume hospitals could be profound. It is well recognized that most hospitals derive a substantial proportion of their revenue from operations and procedures. The financial strain of losing case volumes may lead to the closure of lower volume facilities resulting in severely reduced access to care. These effects may be profound for socioeconomically disadvantaged populations.

Patients and Their Caregivers

While patients who live close to a high volume facility may not experience many changes from a volume-based regionalization policy, those who live far away may suffer many negative consequences. First, patients and their caregivers would require long-distance travel to receive care at a high volume referral center. This could result in significant out-of-pocket costs for loss of productivity, travel, and lodging. This may not just be for the index hospitalization, but could affect postoperative and cancer surveillance visits. There are specific concerns that regionalization policies could result in barriers to care, especially for minority patients and those of lower socioeconomic status. Liu and colleagues studied

socioeconomic and racial disparities in patients receiving care at higher and lower volume hospitals²⁴. They performed a retrospective study of patients undergoing complex surgery (including lung resection) using California discharge data. They identified some alarming trends. Compared to white patients, minority patients (including Black, Asian, and Hispanic individuals) were 34–52% more likely to receive a lung resection at lower volume hospitals. Additionally, compared to Medicare patients, those who were insured by Medicaid or were uninsured were 30–50% less likely to receive lung resection at a higher volume hospital.

Resio et al. performed a survey to identify motivators and barriers to receiving care at safer but more distant hospitals for complex cancer surgery²⁵. The authors presented survey respondents with a hypothetical option to travel >1 hour to a hospital specialized in complex cancer surgery. The authors identified that respondents with lower income and non-white race exhibited greater resistance to travel, with the most commonly cited barrier being financial (costs/insurance). For possible lung transplantation recipients, the additional impact on travel burden could be substantial. Depending on region, travel distances for lung transplant patients have been shown to range from 143 ±189 miles (California/Southwest region) to 325±420 miles (Pacific Northwest region)²⁶. Further regionalization of care could make patient travel distances and expenditures much greater.

Additionally, some studies have suggested that patients' themselves may not inherently prioritize receiving care at higher volume hospitals. Schwartz and colleagues conducted a telephone survey of 510 Medicare patients who underwent complex surgery (including 128 patients who underwent lung resection)²⁷. They attempted to identify leading factors that weighed into their selection of a surgeon or hospital. Interestingly, hospital and surgeon reputations (determined mainly by the referring physician) were the most commonly cited factor in patient decision making. Less than half (48%) of surveyed patients identified hospital volume as a key factor in the selection process.

The Need for Cost-Effectiveness Evaluations

Cost-effectiveness evaluations will be a crucial part of the discussion on regionalization as they can help physicians, payers, patients, and policy-makers understand the potential consequences of implementation in terms of patient outcomes and resource utilization. In cost-effectiveness evaluations, the denominator becomes important. Whether it is assessing mortality risk, overall survival, or quality-adjusted life years, cost-effectiveness can allow investigators to select the outcome that is most meaningful and study the outcome relative to costs. Additionally, investigators can hypothetically vary model inputs representing a potential policy change and evaluate the impact of this change on cost, outcome, and/or cost relative to outcome.

The debate surrounding regionalization of care for thoracic surgical procedures is complex. While volume-based referral strategies have been proposed, they have not received widespread national adoption. A more complete discussion that includes a consideration of the cost-effectiveness of volume thresholds in addition to surgeon outcomes and hospital-based quality metrics and their effects on relevant stakeholders will be necessary to assess the feasibility and appropriateness of regionalization in thoracic surgery.

Sources of Funding:

1 I01 HX002475-01A2 (Puri)

References

1. Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized? The empirical relation between surgical volume and mortality. *N Engl J Med.* 1979;301:1364–1369. [PubMed: 503167]
2. Birkmeyer JD, Siewers AE, Finlayson EV, et al. Hospital volume and surgical mortality in the United States. *N Engl J Med.* 2002;346:1128–1137. [PubMed: 11948273]
3. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. *N Engl J Med.* 2003;349:2117–2127. [PubMed: 14645640]
4. Group TL. *Surgical Volume.* Vol 2018.
5. Urbach DR. Pledging to Eliminate Low-Volume Surgery. *N Engl J Med.* 2015;373:1388–1390. [PubMed: 26444728]
6. Bendzsak AM, Baxter NN, Darling GE, Austin PC, Urbach DR. Regionalization and Outcomes of Lung Cancer Surgery in Ontario, Canada. *J Clin Oncol.* 2017;35:2772–2780. [PubMed: 28682689]
7. Clark JM, Boffa DJ, Meguid RA, Brown LM, Cooke DT. Regionalization of esophagectomy: where are we now? *J Thorac Dis.* 2019;11:S1633–S1642. [PubMed: 31489231]
8. Kozower BD, Stukenborg GJ, Lau CL, Jones DR. Measuring the quality of surgical outcomes in general thoracic surgery: should surgical volume be used to direct patient referrals? *Ann Thorac Surg.* 2008;86:1405–1408. [PubMed: 19049722]
9. Kozower BD, Stukenborg GJ. Volume-Outcome Relationships in Thoracic Surgery. *Thorac Surg Clin.* 2017;27:251–256. [PubMed: 28647071]
10. LaPar DJ, Kron IL, Jones DR, Stukenborg GJ, Kozower BD. Hospital procedure volume should not be used as a measure of surgical quality. *Ann Surg.* 2012;256:606–615. [PubMed: 22964735]
11. Wakeam E, Hyder JA, Lipsitz SR, Darling GE, Finlayson SR. Outcomes and Costs for Major Lung Resection in the United States: Which Patients Benefit Most From High-Volume Referral? *Ann Thorac Surg.* 2015;100:939–946. [PubMed: 26116480]
12. Clark JM, Cooke DT, Chin DL, Utter GH, Brown LM, Nuño M. Does one size fit all? An evaluation of the 2018 Leapfrog Group minimal hospital and surgeon volume thresholds for lung surgery. *J Thorac Cardiovasc Surg.* 2019.
13. Brusselsaers N, Mattsson F, Lagergren J. Hospital and surgeon volume in relation to long-term survival after oesophagectomy: systematic review and meta-analysis. *Gut.* 2014;63:1393–1400. [PubMed: 24270368]
14. Fuchs HF, Harnsberger CR, Broderick RC, et al. Mortality after esophagectomy is heavily impacted by center volume: retrospective analysis of the Nationwide Inpatient Sample. *Surg Endosc.* 2017;31:2491–2497. [PubMed: 27660245]
15. Mooney JJ, Weill D, Boyd JH, Nicolls MR, Bhattacharya J, Dhillon GS. Effect of Transplant Center Volume on Cost and Readmissions in Medicare Lung Transplant Recipients. *Ann Am Thorac Soc.* 2016;13:1034–1041. [PubMed: 27064753]
16. Lumpkin S, Stitzenberg K. Regionalization and Its Alternatives. *Surg Oncol Clin N Am.* 2018;27:685–704. [PubMed: 30213413]
17. Ely S, Alabaster A, Ashiku SK, Patel A, Velotta JB. Regionalization of thoracic surgery improves short-term cancer esophagectomy outcomes. *J Thorac Dis.* 2019;11:1867–1878. [PubMed: 31285879]
18. Sheetz KH, Chhabra KR, Smith ME, Dimick JB, Nathan H. Association of Discretionary Hospital Volume Standards for High-risk Cancer Surgery With Patient Outcomes and Access, 2005–2016. *JAMA Surg.* 2019.
19. Harrison S, Tangel V, Wu X, et al. Are minimum volume standards appropriate for lung and esophageal surgery? *J Thorac Cardiovasc Surg.* 2018;155:2683–2694.e2681. [PubMed: 29370917]
20. Birkmeyer JD. Should we regionalize major surgery? Potential benefits and policy considerations. *J Am Coll Surg.* 2000;190:341–349. [PubMed: 10703862]

21. Kennedy GT, Ukert BD, Predina JD, et al. Implications of Hospital Volume on Costs Following Esophagectomy in the United States. *J Gastrointest Surg.* 2018;22:1845–1851. [PubMed: 30066065]
22. Birkmeyer JD, Vinlayson EVA, Birkmeyer CM. Volume Standards for High-Risk Surgical Procedures: Potential Benefits of the Leapfrog Initiative. *Surgery.* 2001;130:7.
23. Birkmeyer JD, Skinner JS, Wennberg DE. Will volume-based referral strategies reduce costs or just save lives? *Health Aff (Millwood).* 2002;21:234–241. [PubMed: 12224888]
24. Liu JH, Zingmond DS, McGory ML, et al. Disparities in the utilization of high-volume hospitals for complex surgery. *JAMA.* 2006;296:1973–1980. [PubMed: 17062860]
25. Resio BJ, Chiu AS, Hoag JR, et al. Motivators, Barriers, and Facilitators to Traveling to the Safest Hospitals in the United States for Complex Cancer Surgery. *JAMA Netw Open.* 2018;1:e184595. [PubMed: 30646367]
26. Magruder JT, Shah AS, Crawford TC, et al. Simulated Regionalization of Heart and Lung Transplantation in the United States. *Am J Transplant.* 2017;17:485–495. [PubMed: 27618731]
27. Schwartz LM, Woloshin S, Birkmeyer JD. How do elderly patients decide where to go for major surgery? Telephone interview survey. *BMJ.* 2005;331:821. [PubMed: 16192286]