# Access or excess? Examining the argument for regionalized cardiac care



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***Feature Editor's Note—****The Congenital editors of the* Journal *encourage open, productive discourse on the structure of the system of care in which congenital heart surgery is provided. We therefore welcome the timely, expert opinion by Karamlou and coauthors, who offer an articulate overview on the pros and cons of regionalization of cardiac care. I suspect the authors gave careful consideration to the issues before presenting the final "sort of neutral" conclusion which they capture with Voltaire's "doubt is an uncomfortable position, but certainty is a ridiculous one." However, despite the complexity of the issues, I am confident the authors are not advocates of stifled inactivity.*

*We are a capable specialty, have overcome seemingly insurmountable challenges, and should view this challenge as yet another opportunity. Much like organ transplantation, transcatheter valve replacement, and other advanced therapies, it would seem we could define the standards of a congenital heart center—a version of "regionalization" that emphasizes a patient-first approach. Perhaps it's too alarming, too radical, too simple-minded, or maybe impossible? While Voltaire was no fan of Pascal, I believe Pascal also has words apt to our circumstance: "Set the greatest philosopher in the world on a plank really wider than he needs, but hanging over a precipice, and though reason convince him of his security, imagination will prevail. Many will scarce bear the thought without a cold sweat." The authors have provided our dimension, the size of the plank, the nature of the precipice, and sound reason. What's wrong with a little cold sweat?*

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**CENTRAL MESSAGE**

Regionalization of cardiac surgical services is supported by the volume–outcomes relationship and may represent a viable solution to optimize value-based care. We examine both sides of the argument for and against a regionalized cardiac surgery system.

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Rising health care expenditures undoubtedly galvanized early governmental efforts to devise pragmatic cost-containment mechanisms. That the volume–outcomes relationship might be exploited to reduce length of stay for surgical procedures was elucidated by Forrest and colleagues[1] in their 1970 report to the US Department of Health and Human Services. Since this initial treatise, multiple studies have evaluated the percipience of concentrating highly complex care in high-volume perceived centers of excellence.[2-7] While characterization of an idealized care delivery system for congenital cardiac surgery has been an interest of our investigative group for several years,[3,8-12] the recent article by Goldstone and colleagues[13] on outcomes of regionalized care for adults with type A aortic dissection has provided an important opportunity to explore the wisdom of extending these

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discussions to the larger population of patients receiving cardiac surgical care.

## ARGUMENT FOR REGIONALIZED CARE DELIVERY

Goldstone and colleagues used the Centers for Medicare and Medicaid Services database over a 5-year period (1999-2014) to identify 16,886 patients with type A aortic dissection. Of this initial population, 8956 patients treated at 3153 unique hospitals were ultimately included after application of the instrumental variables method to ensure more uniform treatment (and transfer) patterns. Primary outcome measures included 30-day mortality and all-cause mortality over a median follow-up of 2.4 years. One unique feature of this study vis-à-vis other papers investigating regionalization is the inclusion of survival beyond hospital discharge. The importance of this metric cannot be overemphasized; if the salutary impact of regionalized care can be extended to improvement in longer-term aggregate productivity (ie, QALYs or the like), regulatory organizations (ie, government and third-party payors) may be incentivized to consider these alternatives. The results of Goldstone and colleagues showed that 52% of patients underwent surgery at a high-volume center (defined as $\geq$105 total proximal aortic operations), and 40.3% of the patient population was transferred to another facility (either high- or low-volume) for definitive care. As anticipated, patients treated primarily at a high-volume center, and those rerouted to a high-volume hospital, had improved operative survival (relative risk reduction of 8.1%) compared with those treated at a low-volume hospital. Surgical treatment at a high-volume center also translated into a realized mid-term survival benefit. Importantly, mortality was not increased by interfacility transfer and was also insensitive to patients age <65 years. Based on these data, Goldstone and colleagues advocated for regionalization of care by rerouting patients with type A dissection to high-volume facilities.

### The Volume–Outcome Paradigm

The ideas raised by this article are provocative and mirror similar perspectives in other cardiothoracic subspecialties, including congenital cardiac surgery, thoracic surgery, and other quaternary surgical disciplines.[3,8-12,14-18] Moreover, surgical case volume per se has also been studied as a primary driver for accelerated deployment of alternative innovative techniques, such as transcatheter aortic valve placement, in which surgical aortic valve replacement volume criteria of 50 cases/year were required. While we should not devolve this analysis into the simple equation that a positive volume–outcome relationship is sufficient to advocate for regionalization, it is instructive to triage the nuances by examining related data. In a seminal paper from 1995, Grumbach and colleagues[19] determined that a regionalized system for coronary artery bypass grafting (CABG) surgery in California, similar to those in New York State and Canada, would decrease mortality without reducing access. One may argue that the single-payor system in Canada may negate the validity of this parallel, but the data presented were compelling. The shape of the relationship between improved outcome and repetition in CABG was further elucidated by Banta and Bos,[20] who found that survival continued to improve even at relatively high hospital and surgeon annual case volumes: 650 and 116, respectively. Defining thresholds where curves may plateau is difficult given the dearth of very high-volume hospitals and surgeons. Whether there is an upper volume limit beyond which mortality rates may increase in high-volume centers secondary to growth outpacing resources remains an unanswered question. In our series of studies on congenital cardiac surgery programs, we could not find evidence to support a volume above which quality was negatively affected.[3,10] Data from large-volume aortic and aortic valve centers such as the Cleveland Clinic, in which morbidity and mortality continue to be exceedingly low despite yearly increases in case volume, would suggest that economies of scale expand appropriately with equally scaled programmatic commitment to quality and patient safety within a single institution.[18,21]

### Natural and Theoretical Regionalization Experiments

The potential benefits of a regionalized system of congenital cardiac care have been recognized by several countries. Consolidation of CHS in Sweden from 4 hospitals to 2 with the best survival was temporally associated with a decrease in the national mortality rate from 9.5% to 1.9%.[22] Similarly, the National Health Service of the United Kingdom proposed a reduction in the number of hospitals performing CHS from 11 to either 6 or 7 and recommended that each center perform at least 500 cases divided by 4 surgeons to maintain competency.[23] Interestingly, the centralization of care to only 2 centers in Sweden necessitated a major restructuring of pediatric cardiology and educational programs which, ironically, increased collaboration and communication among the local centers and reciprocally with the remaining 2 surgical centers.[22] Both Sweden and the UK have also leveraged regionalization to reduce variation in clinical practice, a phenomenon which is widely believed to lead to adverse clinical outcome and higher cost.[24,25] Alignment between real-world practice and consensus-based guidelines can be improved by a regionalized system of cardiac care. Whether equivalent or superior adherence to empiric best practices can be achieved

and sustained by alternative voluntary methods remains unclear.

### Defining Ideal Regionalization Models: Volume, Complexity, or Geography?

Beyond the assessment of volume-outcome relationships or the applicability of this analogy to regionalizing care, is there meaningful evidence that a regionalized system would represent an improvement over the current system?

Heart and lung transplantation is a clear example of the success of coordinated, national deployment of regionalized care. Accreditation by organizations such as the Adult Congenital Heart Association for comprehensive care centers for adult congenital heart disease is another excellent example of a rational process to regionalize high-quality care. Clustering of US hospitals performing aortic surgery, many of which are low-volume centers located near high-volume centers, was apparent in Figure 4 of the Goldstone article.[13] Data from the initial report from our group that characterized the geographic distribution of CHS centers in the United States, were nearly identical.[3] In our study, 101 of 153 existing centers (66%) were located within 25 miles of one another—a system that is inherently redundant and inefficient.[3] Further, similar to the Goldstone article[13] in which interfacility transfer patterns were often consistent among hospitals, we demonstrated that regionalization already occurs in congenital heart surgery (CHS) centers, with the majority of patients bypassing their nearest hospital and 25% traveling more than 100 miles.[3] Importantly, many patients traveling long distances do so for relatively simple, elective procedures, such as closure of ventricular septal defect, in which there is unlikely to be meaningful mortality differential among CHS centers. Our subsequent report explored whether regionalization of CHS centers would decrease in-hospital mortality without prohibitive increases in travel distance using simulations whereby patients were redistributed to successively higher-volume-quintile hospitals.[10] This idealized system was derived by modeling regionalization simulation algorithms based on case complexity or empiric volume thresholds. An unexpected finding was that redistributing all patients to high-volume centers reduced mortality by 17% (116 potential lives saved), eclipsing the minimal 1.2% mortality reduction gained by redistributing only patients in the higher-complexity categories.[10] Travel distance to the resulting 37 hospitals was modestly increased by approximately 40 miles. These data would suggest that optimum regionalization efforts should be extended to all patients with congenital heart disease regardless of complexity. Distillation of the decision algorithm for patient triage to an "all-or-none" dichotomy in lieu of an algorithm based on complexity could be beneficial, given the significant limitations of current risk stratification models.

## ARGUMENT AGAINST REGIONALIZATION: REAL AND PERCEIVED OBSTACLES TO IMPLEMENTATION

### Antitrust Legislation and Regulatory Constraints

National regionalization would mean consolidation of many centers into fewer centers rather than continued expansion of a high-performing center, which may have adverse consequences for global value-based care. A successful regionalized model must be built with the potential negative consequences of consolidation in mind, including the possibility of antitrust action. While antitrust legislation is generally enforced in business markets other than health care where there is implicit horizontal versus vertical restraint, several highly publicized hospital mergers have been blocked by the Federal Trade Commission.[26] The theoretical concerns about centralized care were voiced by Paul Levy, CEO of the Beth Israel Deaconess Medical Center in his statement equating ever-expanding hospital systems with financial organizations responsible for the financial crisis in 2008: "Organizations deemed 'too big to fail' pose a risk in any industry. In health care, systems may grow so large that they technically survive, but fail in other aspects of patient care."[27] If cardiac surgery regionalization initiatives are to succeed in the goal toward optimizing the patients' longitudinal experience, we may collectively need objective, comprehensive data—or at least more than a nod toward the clichéd notion that "practice makes perfect." Nonetheless, the hard endpoint of improved survival associated with regionalization is difficult to argue against.

### Risk Assessment and the Power Equation

In congenital cardiac surgery, accurate assessment of the potential benefits, and ultimate success, of regionalization is especially challenging owing to procedural and anatomic heterogeneity, low numbers of high-complexity procedures, and relatively obtuse performance metrics. While it may be true that low-volume centers have suboptimal outcomes, expected mortality metrics are not sufficiently sensitive to measure risk differentials among the spectrum of centers. Welke and colleagues[28] elegantly demonstrated the improbability of studying this phenomenon with the current distribution of centers and mortality rates. They found that the minimum annual case volume (or power) to detect meaningful mortality differences among congenital cardiac surgery centers (N = 525) was achieved by only 1.6% (n = 4) of hospitals. For the least-complex cases, nearly 3000 cases would be required, clearly not an achievable mark. Thoracic surgical volume–outcome relationships

are similarly difficult to define because of heterogeneity and small volumes at many centers.[14,15] Finally, a link between superior surgical performance and repetition may be an absolute in the early period in which the learning curve is operational; however, this link may be much less important in the later stages, when one's skill set is established—suggesting a metric for surgeon and program experience. Stability may be a necessary adjunct to volume. Similarly, highly evolved cardiac surgery centers may treat a disproportionate number of high complexity or high-risk cases than smaller centers, obfuscating the ability to fairly compare outcomes across centers. Much better and more consistent risk adjustment data is needed, and the current American Association of Thoracic Surgery database initiative may provide some solutions. Explainable artificial intelligence, deep learning with convolutional neural networks, and other types of machine learning constructs may also contribute substantially to our comprehension and measurement of complexity, such that providers can recognize a case that should be regionalized.

## Socioeconomic Disparities: Will Regionalization Widen the Access Gap?

Regionalization may reduce access to specialized health care services, particularly among disadvantaged sociodemographic groups. Comparably worse outcomes among African Americans and those in lower income quartiles are consistently reported following both congenital and acquired cardiac surgery.[29,30] Benavidez and colleagues[31] investigated race/ethnic disparities in outcomes following congenital heart surgery using the Kids Inpatient Database 2000. In this study, in-patient mortality was significantly increased in the black population compared with white ethnicity and regional geographic differences in racial/ethnic outcomes were apparent. In the Benavidez study, socioeconomic status was not associated with increased risk of death, but as Karamlou and colleagues[29] discussed, studies of sociodemographic influence are often superficial (usually as a result of nongranular variable capture in most available datasets) and incompletely assess interactions among highly collinear or modifying factors. Building on this contention, we recently used the Pediatric Health Information Systems database to explore whether inflection points could be determined whereby race/ethnicity could be mitigated by positive modifiers, including discrete income level or more evolved programmatic/process factors on the one hand, or exacerbated by negative modifiers, including genetic abnormalities or center experience.[32] The results of these analyses may provide more informative targets for outreach efforts or education—and, perhaps more importantly, reorient policy to the largely ignored population–health disparity issue.

In the interim, proponents of the perspective outlined above correctly point out that if centralization of care widens access disparities among vulnerable groups, then adverse outcomes and costs of care will increase, undermining any gains regionalization may provide in the value-based equation. We have framed this conflict as "access versus excess" to underscore the competing components of the regionalization equation. Efforts to provide solutions to this dilemma have been articulated by the World Health Organization in concert with specific Asian and African countries. These groups have advocated for health care delivery models optimized by geospatial analysis[33,34] that can be scaled to future population growth.

## Caveats and Complicating Factors: Regionalization of Personnel or Hospitals?

As if the argument were not already sufficiently complex, another issue that requires attention is what exactly would be consolidated? Would regionalization of hospitals address the multiple components of the cardiac surgical ecosystem so as to exploit this relationship for positive gain? Would regionalization of physical structures (ie, hospitals) be required, or would regionalization of personnel or select resources be sufficient to achieve the same endpoint? Unfortunately, there is sparse data in the cardiac surgery literature to dissect this question further.[3,10,35-38] To be sure, theoretical rationale for a regionalized system are supported directly by the "practice makes perfect" model, and indirectly through the "selective referral" mechanism, in which centers with superior outcomes attract more patients. The relevance of either explanation varies with the complexity of specific diagnoses and procedures and with the contribution margin of the surgeon compared to the center environment. Calibration of the relative weight of these factors vis-à-vis patient outcome, was elucidated by Karamlou and colleagues[8] in their examination of in-hospital mortality following the arterial switch operation, a highly technical operation in which survival is aligned with surgeon volume, with minimal attenuation by center factors. The results of this study contrasted with those from Hornik and colleagues,[36] in which in-hospital mortality for the Norwood operation were more aligned with center volume with little attenuation by surgeon volume. While the Norwood operation is a complex sequence, the perioperative care rendered by the comprehensive capabilities of the center, dominate the survival equation. Similar ideas regarding the complexities of perioperative care, including prehospital factors, were raised by Goldstone and colleagues[13] in their analysis of aortic dissection outcomes and these associations may vary on a condition to condition basis. This dichotomy is instructive to the regionalization argument because it demonstrates that a better definition of "complexity" may

be required to arbitrate selective referral if a centralized system is based on perceived case difficulty. Refinement from an aggregate procedural-based categorization to a diagnosis-based system, as is currently underway by the Society of Thoracic Surgeons Congenital Heart Surgery Database Taskforce, will be helpful in this regard.

A final thought regarding the collective understanding of these important relationship is that future efforts to concentrate patients in selected hospitals should be sensitive to the possibilities that unmeasured, but nonetheless important, physician and hospital factors influence outcomes, and that existing referral patterns may already reflect such factors. In other words, the de facto regionalization (whether driven by patients, providers, or third-party payors) that exists in the current cardiac care landscape may be an adaptive response. Other factors that are more difficult to assess directly may also drive referral patterns to specific hospitals despite lower-quality care, including aggressive marketing of ''new'' cardiac surgical (eg, robotics) or interventional procedures (eg, MitraClip, expanded-indication transcatheter valves), or by offering access to limited clinical trials (eg, stem-cell therapies for hypoplastic left heart syndrome). The real-time assessment and public reporting of outcomes should serve to check these confounding influences on volume and quality.

## Alternatives to a Regionalized System

**Collaborative models.** What are plausible alternatives to optimize cardiac care delivery besides a regionalized system? One promising model was leveraged successfully by the 8 centers within the Northern New England Cardiovascular Study Group.[38] This seminal initiative used prospective data collection coupled with collaborative learning to drive quality improvement. Importantly, survival following CABG improved among all centers regardless of whether implementation of best practices occurred, suggesting that simply participation in a quality collaborative was sufficient to drive positive change. The Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative used similar collaborative learning methods to increase the use of internal mammary artery grafts among 31 hospitals from 91.9% to 95.8% overall, with a more pronounced increase among the 7 low-IMA utilizing centers, ranging from 82.0% to 92.7%.[39] Extension of similar coordinated efforts based on transparency and shared experience have been successful in reducing adverse outcomes and costs in congenital cardiac care and others,[40,41] although the sustainability of these largely voluntary efforts may be low.

**Satellite models of care.** Another alternative to regionalization, which is an increasingly common model for cardiac care, consists of 1 or more small hospitals affiliated with a large hospital: the satellite, or spoke-and-hub, model.[10,42,43] In this schema, low-complexity operations are done at the small hospital(s), while high complexity operations are referred to the large hospital. One perceived benefit of this arrangement is that while some patients must travel to the large hospital for care, many are able to be treated close to home, reducing the burden on their families.

Resource and personnel use also may be decreased in this model by eliminating redundancy among affiliated centers; for example, the Hospital for Sick Children in Toronto works closely with the Children's Hospital of Eastern Ontario to provide CHS for patients across Ontario. In this paradigm, a single chief is responsible for overall delivery of care across both sites. Through weekly teleconferenced meetings, patients are triaged according to their level of perceived complexity to maximize the number of low-complexity patients who undergo cardiac surgery close to home (with no perceived difference in outcomes). Patients with high complexity are treated at the larger center. Although this arrangement was operationalized within a Canadian single-payor system, the decisions to triage patients from one institution to another was based solely on the clinician's preference, and there was little influence due to financial pressure on individual patient decisions. In the US system, financial interests might conflict with the concept of triaging high-complexity cases from the smaller satellite program to the high-volume central program. Therefore, careful calibration of financial incentives is likely to be required in the US system to achieve the excellent working relationship achieved in the Canadian model. Indeed, financial pressure and local interests contribute to the observation that expanded complexity at the smaller hospital tends to increase over time.[10,42]

Current public reporting initiatives that do not allow for combined reporting among affiliated centers without formal joint venture arrangements, coupled with increased attention to hospital volumes and case complexity adjustment at each center, also diminish the attraction of these satellite care delivery systems. Unless evolved methods to monitor quality at participating sites exist, quality of care may decrease over time. Other mechanisms to extend specialty care both regionally and nationally include virtual consultation and telemedicine. Clearly these are not feasible for complex surgical or interventional treatment, but they could be leveraged to improve surveillance and continuity of care for patients who live in remote areas. Educational paradigms using virtual interfaces are promising avenues to optimize care and mitigate the threat of reduced access.

Finally, restructuring or quality-directed initiatives could be led by hospitals, including the provision of only those cardiac surgery cases in which a minimum volume standard is met.[44] However, the current remuneration system and local pride are barriers to these (especially self-imposed) constraints. The Center for Medicare and Medicaid Services and private insurers could alter reimbursements to favor hospitals meeting selected criteria. Yet, the

administration of Medicaid at the state level limits the potential for national policy initiatives. Legislative efforts could mandate regionalization by requiring hospitals to meet volume or other performance criteria. While opposition exists to adopt a single-payor health care system in the United States, nationalization of pediatric care as a formative step may be more palatable since children's health care accounts for less than 10% of total health care expenditures, and 50% of pediatric inpatient costs are already covered by Medicaid.[45,46]

## CONCLUSIONS

Ultimately, the argument for regionalized care across the spectrum of cardiothoracic surgery is colored by the lens through which that argument is contextualized. The majority of published data would support efforts to reduce inefficiencies in the current system by increasing regionalization of care, but financial and social implications of such a system make implementing it improbable. Antitrust and regulatory, legal, and financial aspects of hospital reorganization are powerful forces that can easily trump efforts to regionalize around quality. Even payor attempts at narrow networks may be driven more by cost or geography than by quality. What may be stated as the cautious foray into the excess versus access debate is the following: The practicality and feasibility of a fully regionalized system for cardiothoracic care in the United States is unclear at present. It is likely that a thoughtful organization of a cardiac surgery service for specific conditions and subspecialties would involve some component of centralized care at centers with demonstrated superior outcomes, coupled with collaborative learning or affiliate models to extend outreach to geographically remote areas, or regions with a high prevalence of socioeconomic disparities that could limit access. In this contentious argument, Voltaire's words are ever prescient, "Doubt is an uncomfortable condition, but certainty is a ridiculous one."[47] Any questions?

### Conflict of Interest Statement

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