Should Coronary Artery Bypass Grafting Be Regionalized?

Brahmajee K. Nallamothu, MD, MPH, Kim A. Eagle, MD, Victor A. Ferraris, MD, PhD, and Robert M. Sade, MD

Health Services Research & Development Center of Excellence, Ann Arbor Veterans Affairs Medical Center; Division of Cardiovascular Medicine, Department of Internal Medicine, University of Michigan Medical School; University of Michigan Cardiovascular Center, Ann Arbor, Michigan; Division of Cardiovascular and Thoracic Surgery, Linda and Jack Gill Heart Institute, University of Kentucky Chandler Medical Center, Lexington, Kentucky; Department of Surgery and the Institute of Human Values in Health Care, Medical University of South Carolina, Charleston, South Carolina

Introduction

Robert M. Sade, MD

Several studies have shown that cardiac care centers that provide a high volume of cardiac services, particularly coronary artery bypass grafting (CABG), have better outcomes than those with low volumes. Some analysts have used these data to suggest that patients in need of care for coronary artery disease would be best served if they were referred only to those centers that treat a large number of these patients. They reason that regionalizing coronary artery disease treatment will result in fewer deaths, because low volume-high mortality programs would be deleted and may have additional advantages in efficiencies of scale.

Those who oppose regionalization claim that the data justifying regionalization are seriously flawed. Reliable measurement of outcomes requires accurate risk stratification; technologies for accomplishing this are being developed and used, but are far from perfect. Moreover, although it is true that many studies show a relationship between volume and outcome, a few well-designed recent studies have not found such a relationship.

In the unregulated referral system that now exists in this country, regionalization already occurs informally; primary care physicians are more likely to refer their patients to centers with good results, and many large-volume centers achieved their dominant status by virtue of good outcomes. Formal regionalization already exists in other countries, such as Canada and Great Britain, and it exists on a small scale in this country (eg, in the VA hospital system). Many have suggested formal regionalization of CABG in the United States on grounds of achieving better outcomes and gaining efficiency, whereas others object on the grounds of inadequate supportive data. Do currently available data justify regionalization of CABG?

The cases for opposing points of view (ie, for and against regionalization) are made herein by scholars with deep and persistent interest in this question.

Pro

Brahmajee K. Nallamothu, MD, MPH, and Kim A. Eagle, MD

A quarter of a century has passed since Luft and colleagues [1] first published their seminal article on the hospital volume–outcome effect. In that study, the investigators found a strong and consistent association between higher hospital volume and lower in-hospital mortality for several high-risk procedures, including CABG, using a national administrative database of nearly 1,500 hospitals [1]. Numerous additional reports have confirmed this association across a variety of procedures, populations, and clinical settings [2–4].

Despite compelling evidence supporting the existence of a hospital volume–outcome effect, little has been done during the intervening 25 years to ensure minimum volume requirements for high-risk procedures in the United States. Traditional arguments against the regionalization of high-risk procedures to higher-volume hospitals through volume-based referral have relied on two fundamental lines of reasoning: (1) analyses supporting the hospital volume–outcome relationship are flawed, and (2) the design of the
United States health care system prohibits its practical application [5, 6].

In this article, we briefly review the evidence supporting the existence of a hospital volume–outcome effect for CABG and address common fears that are typically mentioned when regionalization is discussed. We conclude by proposing a practical strategy for initiating CABG regionalization within the current environment of the United States health care system.

Evidence Supporting the Hospital Volume–Outcome Effect

Nearly 300 studies have examined the hospital volume–outcome effect in various medical conditions and procedures with CABG being one of the more thoroughly studied procedures. Most published studies have reported statistically significant associations between hospital volume and outcomes favoring higher-volume hospitals [2, 3]. Only a small number of studies have not demonstrated a hospital volume–outcome effect in CABG [7, 8]. In general, these “null” analyses were performed in specific patient populations (eg, the Veterans Affairs health care system) or under circumstances in which hospital volume did not vary widely. In the largest study to date, Birkmeyer and colleagues [4] analyzed Medicare data in over 900,000 patients undergoing CABG and demonstrated a 20% reduction in 30-day mortality for hospitals with the highest volume (> 849 annual cases) when compared with those with the lowest volume (< 230 annual cases).

Evidence Supporting Regionalization: Moving Beyond the Fears

Critics of regionalization strategies have raised both methodological and practical concerns regarding earlier hospital volume–outcome studies and their implications for regionalization:

- **Fear No. 1:** Most studies are outdated and use administrative data sources. The concern is that studies do not reflect recent advancements in surgical technique, anesthesia, and perioperative medical therapy, or they inadequately adjust for important confounding variables. Some have also focused exclusively on Medicare patients, a group that is generally older and at higher risk for complications.

  However, recent data from the New York Cardiac Surgery Reporting System (CSRS) and the Society for Thoracic Surgery (STS) National Cardiac Database continue to support the existence of a hospital volume–outcome effect in CABG [9, 10]. Both CABG registries are well established and include a broad spectrum of patients. The New York Cardiac Surgery Reporting System requires mandatory reporting of data and includes independent site audits. However, the STS’s National Cardiac Database contains data from all across the United States, but it relies on a voluntary reporting system.

- **Fear No. 2:** There is inconsistency of statistical analyses in earlier reports. Studies have varied broadly in their methodological modeling of the hospital volume–outcome effect (ie, volume as a continuous vs categorical variable and the inclusion of individual surgeon volume) and for their adjustment of clustering at the facility-level [11, 12]. Inconsistent low-volume thresholds for CABG across studies (varying from 100 to 500 annual cases) have made it difficult for policy makers to identify a uniform standard for regionalization strategies.

  Yet more recent analyses have largely addressed these methodological concerns. Both contemporary studies from the New York CSRS and the STS National Cardiac Database have used complex statistical techniques (ie, adjusting for surgeon volume and use of a hierarchical modeling), and they have reconfirmed significant associations between hospital volume and surgical mortality [9, 10]. The issue of inconsistent volume thresholds is discussed in greater detail as follows.

- **Fear No. 3:** Hospital volume is an imperfect proxy for quality. This concern is undeniable. There are certainly some low-volume programs that may have acceptable risk-adjusted mortality rates for CABG when compared with hospitals that have higher-volume programs. However, an unfortunate reality is that policy, like clinical decisions based on randomized clinical trials, needs to be based on aggregated or “averaged” data. As Luft [13] stated, rejecting the volume–outcome hypothesis because of outliers is like “rejecting the research on the efficacy of antibiotics because some people get better without them and some get worse even with them.”

  Furthermore, hospital volume has been correlated with quality measures such as postoperative renal failure or prolonged mechanical ventilation in addition to short-term mortality [10]. Presumably, hospitals with higher CABG volumes have better processes of care and more resources to care for these complex patients, especially after a complication. There is also research suggesting that the use of hospital volume as a criteria for regionalization may be additive to other quality measures such as risk-adjusted mortality rates [14].

  Finally, the use of risk-adjusted mortality rates to assess hospital quality in CABG (ie, the strategy most commonly suggested as an alternative to volume-based standards) may be substantially limited at very low-volume programs due to small sample sizes. Dimick and colleagues [15] have recently shown that a minimum of 219 annual cases of CABG would be required to detect an outlier mortality rate that was twice the national benchmark [15].

- **Fear No. 4:** There is insufficient data for setting a specific volume threshold. As mentioned earlier, studies have varied widely in their use of specific thresholds during statistical analyses. The Leapfrog Group’s threshold of 450 annual CABG cases has been criticized as outdated and overly strict [16]. A recent empirical evaluation of data from the University...
Health System Consortium has determined that a lower threshold of 250 annual CABG cases may better discriminate between outcomes at high-volume and low-volume hospitals [17]. The American College of Cardiology and the American Heart Association CABG guidelines recommends a minimum volume of 100 cardiac surgery cases per surgeon per program [18]. This threshold takes into account the fact that experience with other “open-heart” surgeries, such as valve replacement and individual surgeon volume powerfully modify the hospital volume–outcome relationship [19, 20]. This more conservative threshold also recognizes the fact that the greatest outcome differences occur between hospitals at the extremes of the volume spectrum.

- **Fear No. 5:** The hospital volume–outcome effect is small in CABG and not worth the effort. When compared with other high-risk procedures, such as operations for pancreatic or esophageal cancer, the absolute risk difference in surgical mortality between very high-volume and very low-volume hospitals for CABG is relatively small at between 1% and 2% [4]. However, the large number of CABG procedures performed each year in comparison with these other procedures makes it likely to have a broader impact in regard to avoiding deaths. Using California-specific data from 1997, Dudley and colleagues [2] estimated that 43% of the avoided deaths from regionalization of several procedures (including coronary angioplasty and high-risk vascular and cancer surgeries) would be attributable to regionalization of CABG alone. Similarly, Birkmeyer and colleagues found that regionalization of CABG using volume standards would save more lives nationally than the combined regionalization of percutaneous coronary intervention (PCI), carotid endarterectomy, abdominal aortic-aneurysm repair, and esophagectomy [21].

- **Fear No. 6:** Regionalization will limit access and be impractical for a large number of patients due to geographic location. Previous studies have suggested that physical access would not be substantially restricted if very low-volume programs were closed as most patients live within reasonable distances of high-volume hospitals [22]. In addition, existing data suggest that although a substantial number of health referral regions (ie, tertiary-care catchment areas) do not have a single high-volume hospital for CABG, the number of annual population-based rates for surgeries performed in these areas could support a high-volume hospital if smaller surgical programs were combined [23]. Despite these facts, we recognize that there will continue to be geographically-isolated communities that need to be excluded from any strategy for CABG regionalization.

- **Fear No. 7:** The quality of care and financial viability of smaller hospitals will be threatened. This is an important and valid fear. The performance of CABG at a hospital is tied to a large number of cardiovascular-related services including PCI, cardiac catheterization, and noninvasive cardiovascular services. In general these services are financially lucrative for hospitals. Indeed, in hospitals providing such care, cardiovascular-related services are often responsible for 25% to 40% of a facility’s general revenue [24]. Lost revenue from eliminating CABG and related services may reduce the hospital’s ability to provide other less lucrative but necessary care to its community. Although this fear is a compelling argument, it must be balanced against the strong evidence supporting the potential benefits of regionalization for patients undergoing major surgery such as CABG.

**Recommendations for Regionalization in the United States**

With several legitimate fears still existing, how can regionalization possibly occur? We believe that the availability of empirical data highlighting the limitations of CABG regionalization should be used to guide policy, not to eliminate any attempts toward regionalization. We support a strategy that uses volume-based standards in addition to other criteria for hospital referrals with CABG. The alternative, which would be waiting for the “ideal” study to be performed, is inadequate in our view. Accordingly, we suggest the following strategies for regionalization:

1. **Eliminate very low-volume programs at hospitals with an average annual cardiac surgery volume of less than 100.** This would include the total number of CABG procedures and other adult open-heart procedures, with exceptions made for hospitals that serve geographically-isolated communities. The evidence is too strong and consistent that hospitals with such low numbers of cases have poor outcomes when compared with higher-volume centers. In addition, other alternatives for measuring quality at these very low-volume programs like risk-adjusted mortality rates may be problematic and less reliable.

2. **For hospitals with annual cardiac surgery volumes above 100 cases, additional criteria, such as the use of risk-adjusted mortality rates, should be used to assess hospital quality.** When annual cardiac surgery volumes are between 100 to 250 annual cases, strong consideration should be made for referring high-risk patients such as the elderly (> 65 years old) or complex procedures like concomitant valve replacement to higher-volume hospitals [10, 25, 26]. Again, these recommendations should be modified for remote areas and individual surgeon volume.

3. **Initiate a nationwide, mandatory reporting system for CABG in order to collect outcomes data on quality and processes of care at individual programs.** This could be piggybacked onto the established framework of the current STS National Cardiac Database. With this we would encourage participation in regional collaborative networks tar-
getting key quality opportunities and providing a forum for continuous quality improvement strategies. The reporting system and regional networks should be co-led by local professional organizations (eg, The STS, the American Heart Association) and state health departments to ensure adequate physician and public input. Organizing these programs at state or regional levels would provide for a broad enough regulatory authority while maintaining flexibility for addressing local needs.

4. Begin formal assessments of the appropriateness of CABG at individual programs. We believe no volume-based regionalization strategy can be properly implemented without concurrently evaluating appropriateness [27]. Without this precaution, the incentive to do inappropriate cases may be too great for providers and hospitals wishing to meet strict volume criteria. Measuring appropriateness will also cause policy makers to determine whether regionalization leads to any potential adverse effects such as the avoidance of high acuity patients. Of course appropriateness is a critical quality improvement area for CABG and PCI, and it will require additional research regardless of whether volume-based referral strategies are implemented.

We believe the last two points are critical. As regionalization is implemented in small steps, the process of collecting and refining data to modify structural changes in the strategy is needed. As procedures “mature” and transform over time, the importance of the hospital volume–outcome effect may change. Although this strategy for regionalization may not completely address all the fears previously raised, we believe that it is a fair and equitable plan that can be transitioned into the current health care system. Of course we recognize that its implementation may be very challenging. However, cardiac surgery has a unique and established history of quality-improvement initiatives due to professional leadership from The STS and the American Heart Association. This may provide an opportunity for successfully implementing this strategy for CABG that would be less daunting than what may be anticipated for other procedures.

Future Issues
Techniques for coronary revascularization are advancing rapidly in the United States. In particular, recent evidence supporting the use of PCI in acute coronary syndromes and ST-segment elevation myocardial infarction is compelling. The impact of eliminating very low-volume CABG programs on the availability of PCI in the general population will need to be evaluated. In addition, advances in medical therapy and PCI may be contributing to diminishing population-based rates for overall CABG. How regionalization will influence cardiac surgical training programs and the physician workforce, given the declining use of CABG, will need to be assessed. We also believe that continued research into why volume is so strongly associated with better outcomes is needed. If key system-level characteristics are identified, these processes of care can hopefully be disseminated across more hospitals. Finally, the impact of regionalization on cost needs to be better understood. Although the movement of a large number of patients may incur costs, regionalization may lead to greater overall operating efficiencies by decreasing lengths of stay and lowering rates of re-hospitalizations. Reimbursement strategies for CABG may also need to be restructured if higher-volume programs begin to accept a higher percentage of complex cases.

Conclusions
Evidence supporting the hospital volume–outcome effect in CABG is persuasive. Although several studies have cautioned us on the importance of cautiously interpreting the data, these studies should not be used to justify avoidance of regionalization. Instead, we should use the data to inform and direct our policy decisions to create a rational and effective system of regionalization. This is particularly important as diminishing CABG volumes may create larger numbers of very-low-volume CABG programs. For the nearly 500,000 patients undergoing CABG each year in the United States, the implications of regionalization are enormous. Given its potential benefits, we should not wait to collect data for yet another 25 years before considering its implementation.

Con
Victor A. Ferraris, MD, PhD

What is Regionalization?
Regionalization of health care resources is the selective referral of patients to regional centers. Health care payers have jumped on the concept of regionalization to attempt lowering the spiraling health care costs. There are at least two unique features of the United States health care system: (1) the ability of patients to seek medical care from whom-ever they want (ie, access), and (2) the expectation that access to health care will be readily available at a local level (ie, availability). Regionalization infringes on these two principles. To understand regionalization, it is necessary to talk about provider volume, health care costs, and quality of care. All of these concepts are wrapped up in discussions of regionalization of health care resources.
Examples of Regionalization of Health Care

There is absolutely no evidence that deliberately concentrating procedures in the hands of regional providers will actually improve outcomes. In fact, the opposite may be true. The hypothesis that regionalization based on some criteria (either provider volume or cost) results in better outcomes has not been tested in a randomized trial or in any rigorous way.

Some evidence suggests that regionalization of health care procedures does not work. Simply going to the internet to search for information on “regionalization of health care” would give one a negative view of the results of regionalization in Canada (http://www.srpc.ca/librarydocs/Regionalization_SRPC.PDF). A search of the internet using the Google search engine produces 66,900 links dealing with regionalization of health care. The 100 most relevant references deal with regionalization of resources in Canada, many describing some problem related to regionalization. In one study the impact of regionalization in the Canadian health care system did not improve surgical mortality but dramatically changed the practice patterns of surgeons [28]. It is astounding that not one of these references suggests that the main reason for considering regionalization is to provide better quality care for patients. Almost all of these 100 references suggest that there is an economical benefit to be gained from regionalization (ie, “better alignment of resources and needs” [29]). Health care payers have embraced the concept of regionalization in hopes of limiting spiraling health care costs.

Regionalization of trauma care is an important component of most statewide trauma systems. On the surface it may seem that regionalization of trauma resources would focus care in high-volume hospitals and result in a drop in mortality. Many other factors undoubtedly influence improved outcome from major trauma, including better treatment algorithms (Advanced Cardiac Life Support protocols), improved response times, and focused training of physicians. A review of the National Trauma Databank in the United States found no positive relationship between outcome and treatment of severe trauma in high-volume centers [30].

Another example of regionalization of resources is the localization of cardiac care in regionalized centers in the Department of Veterans Affairs (VA) health care system. Petersen and co-authors found underuse of indicated angiography in patients with acute myocardial infarction in the VA system [31]. This rate of underuse was greater than that of similar non-VA Medicare patients. These authors suggested reassessment of regionalization policies and better understanding of the implications of the process.

Malpractice costs may be increased by regionalization. A publication by Morris and colleagues [32] suggests that medical indemnity costs from malpractice are actually increased by regionalization of health care. Many actionable adverse events occur at the interface between hospitals.

Regionalization Based on Provider Volume

Almost by default, the concept of regionalization springs from multiple investigations that find better outcomes from high-volume providers (both hospitals and surgeons). Among health care planners it is almost axiomatic that high-volume providers will have better outcomes (http://www.nap.edu/books/N1000322/html). Health care payers are quick to embrace this concept. A logical implication of this volume–outcome relationship is that concentration of procedures in the hands of high-volume providers will improve outcomes and save patient lives. The process of encouraged or even enforced referral to regional providers who perform high volumes of selected procedures is the closest thing approximating regionalization in the current United States health care environment.

Provider (either hospital or physician) volume is a structural variable. Structural variables are those that reflect the setting or system in which care is delivered. Structural variables are different than process variables that describe the care that patients actually receive. The disadvantages of using structural variables as indicators of quality include: (1) inability to evaluate outcomes by randomized trials, (2) other confounding variables are more important in determining outcomes, and (3) structural variables are not readily actionable (eg, a small hospital cannot readily increase its volume). The advantages of using structural variables include: (1) expediency, which is easily measured, (2) structural variables are inexpensive to measure, and (3) association exists between hospital volume and outcomes in most reports [23]. It is easy to see why health care payers chose structural variables as surrogates of quality, because simply put, it is easier.

More than 88 studies examined the relationship between provider volume and outcome (http://books.nap.edu/html/volume_outcome/summary.pdf). A higher-volume, better outcome association was observed in three fourths of the studies. At least 10 of these large studies addressed the notion that hospitals performing small numbers of CABG operations have higher operative mortality. Interestingly, in the three studies done more recently (since 1996) there was no clear relationship between outcome and volume [7, 25, 33]. In two separate studies done on some of the same patients in the New York state cardiac surgery database, completely opposite results were obtained [25, 33, 34]. The Institute of Medicine summarized the relationship between high-volume and better outcome (http://www.nap.edu/catalog/10005.html) and concluded that “volume per se does not lead to better outcome”. It is a proxy measure for other factors that affect care [35]. The dilemma is that some low-volume providers have excellent outcomes, whereas some high-volume providers have poor outcomes.

Observations on CABG volume and outcome prompted some authorities to suggest regionalization to refer non-emergent CABG patients to large volume centers [1, 22, 36]. A role for “selective regionalization” was
advocated by Nallamothu and co-authors [25], because they found that low-risk patients did equally well in high-volume or low-volume hospitals. They suggested regional referral for elective high-risk patients to high-volume institutions. A study by Glance and co-authors [37] found opposite results. They found that low-risk patients benefit the most from CABG done at high-volume centers. There is by no means a consensus about how regionalization should be done. Should high-risk or low-risk patients be selectively referred to regional centers? What constitutes high volume? Is the timing of referral important? The answers to these and other questions about regionalization are unknown. Should we assume that the best indicator of provider outcome is hospital volume? There is no good answer. In the United States, the Leapfrog Group (Washington, DC) and other consortiums of health care payers are concerned about the spiraling increase in health care costs, and ultimately the cost that corporations must pay to provide health care to their employees. By default, and because there is no other good measure of outcome that is readily understood by corporate executives and beneficiaries, these consortiums chose provider volume as the most easily understood surrogate for quality. These same consortiums assume, without much justification that high quality will translate into lower costs. Menke and Wray [39] suggest that most empirical estimates of the cost implications of regionalization suffer from methodological shortcomings. He outlines the various factors that must be taken into account before an accurate assessment of cost benefit from regionalization can be assessed. The remarkable thing is that no one has done this assessment, yet regionalization is viewed as cost beneficial. Regionalization is just as likely to result in increased costs as it is to result in decreased health care costs.

What Regionalization is Not
In the current health care climate, it is important to understand what regionalization does not imply. What regionalization is not is the concentration of patients with a particular medical illness, such as diabetes or hypertension, in centers that only treat high volumes of these medical illnesses. Why are medical illnesses excluded from talks about regionalization? Procedures such as CABG, esophagectomy, and aortic aneurysm repair are big-ticket items and cost far more than giving a shot of insulin to a diabetic. Furthermore, very little data is available on quality of care for common medical illnesses. For example, it is far simpler to track operative mortality for CABG than it is to track adequacy of glucose control of diabetic patients. Health care payers have specifically targeted big-ticket items such as CABG at the expense of less, well-studied, but perhaps more prevalent common medical illnesses.

Make no mistake that regionalization of health care resources is about money and the potential for saving health care dollars. Proponents of regionalization advocate, quite rightly, that there is nothing wrong with using cost savings as a driver for regionalization, yet no clear cut cost savings has ever been observed from any form of regionalization.

Unintended Consequences of Regionalization
Regionalization of health care resources is an untested concept that may have the opposite effects to those anticipated. Crawford and co-workers [40] pointed out that a policy of regionalized referrals for CABG may have several adverse effects on health care, including increased cost, decreased patient satisfaction, and reduced availability of surgical services in remote or rural locations. Hannan and colleagues [34] reported the possible consequences of using the New York State risk-adjusted CABG mortality to direct referrals. He noted that one third of high volume surgeons (ie, those performing at least 150 procedures per year) had higher than average costs.
risk-adjusted mortality rates. In the setting of regionalization, a large number of patients would be cared for by providers with high risk-adjusted mortality rates. Because approximately one third of low-volume providers had higher than average risk-adjusted mortality rates, enforced referrals of CABG patients to high-volume providers may actually increase operative mortality, which is an undesirable consequence of regionalization.

Advocates of regionalization point to the potential number of lives saved by artificially forcing referrals to high-volume providers [2]. They attempt to intervene and influence the natural market forces that are expected to result in patients migrating to the best places regardless of the volume of cases done. The very clear impression is that patients should have their CABG done by high-volume providers [41]. In the past, market forces shifted patients to places where they get good outcomes regardless of the volume of the provider. After all, high-volume providers were once low-volume providers and only achieved their high-volume status by providing excellent care and obtaining high-quality outcomes. The philosophy implied by advocates of regionalization would artificially alter market forces without really knowing the consequences of these actions.

Several authors speculated on the consequences of directed referral of patients [2, 42–44]. There are likely to be adverse effects on the health care systems from these directed referrals. Emphasis on volume will push some hospitals to increase their volume without much regard for improving quality. Clinical processes may be disrupted in high-volume hospitals from increased referrals. This will almost certainly limit competition and increase health care costs while lowering quality [45, 46]. Low-volume hospitals would lose specialists while suffering economic risk [2, 44]. Directed patient referrals would deny choice to local patients near low-volume centers. These same patients would suffer increased transportation costs and in some cases be denied timely care because of transportation and referral delays [47, 48]. Should we embrace regionalization without knowing the consequences?

Are There Alternatives to Regionalization?
The Leapfrog Group (http://www.leapfroggroup.org/) is a consortium of health care purchasers formed “to initiate breakthrough improvements in the safety, quality, and affordability of health care for Americans” (http://www.leapfroggroup.org/about-us). The Leapfrog Group practices “evidence-based hospital referral.” Based largely on an estimate of patient lives saved by referral to high-volume providers [2], the Leapfrog Group recommended payment premiums to hospitals that performed more than 500 CABG procedures per year. Because of concerns about rural health care, the Leapfrog Group’s standards only apply to urban settings. In 2003, the Leapfrog Group revised the minimal standards for CABG to be considered for payment premiums to 450 CABG procedures per year. For the first time they included a measure of risk-adjusted mortality. Birkmeyer and Dimick [14] reviewed the potential effects of applying these new Leapfrog Group standards to a typical CABG population. They found that standards comprised of process of care or direct outcome measures would be more effective than those based on volume alone in improving outcomes for CABG [14]. For CABG and PCI standards based on risk-adjusted mortality rates would save at least five times more lives than those based on volume criteria alone. Importantly, process of care variables and preoperative risk factors are far more important predictors of outcome than volume. It seems that health care payers are embracing quality to limit costs rather than regionalization, which is not such a bad idea.

Corporations and health care payers embrace provider volume as an indicator of outcome because of expediency. Hospital or physician volume is an inexpensive and easily measured structural variable that is readily understood by the consumer and the payer. A good portion of health care outcomes research during the last 10 to 20 years focused on identifying patient risk and process of care variables that predict outcome. There are literally dozens of systems available to stratify patients according to risk of mortality for CABG [49–51]. Most of these systems have been validated using large numbers of patients. As painful as it may be, hospitals and physicians can be compared using the various risk stratification methods. There is little doubt that a comparison among providers using risk stratification methods is better than using volume to judge quality. Using quality indicators like The STS database risk-adjustment scheme can improve quality of care by low-volume providers [52]. A multifaceted, physician-led, low-intensity quality improvement effort has been shown to improve the adoption of care processes into a guideline driven practice, especially in low-volume hospitals without regionalization.

Quality improvement projects, either in-house or in collaboration with high-volume providers, would improve outcomes to a level at which directed referrals away from low-volume providers would not be necessary. Sollano and co-workers [33] reanalyzed the CABG mortality from the New York State database between 1990 and 1995. They found that the previously observed volume–outcome relationship disappeared after the implementation of a statewide quality improvement program. Similar implications were obtained from a study of volume and outcome in lung cancer resections [46], and in CABG procedures in the Canadian health care system [53]. Clinical guidelines, quality improvement projects, provider education, and collaborative interactions between high-volume and low-volume providers are just a few interventions that do not involve regionalization but are likely to improve quality for low-volume providers.

Should we as health care professionals and scientists give in to the expediency of measuring provider volume and embracing regionalization when we know that there are better measures of outcome and better ways to improve quality? The answer seems obvious. We should use the best methods available to compare providers and monitor outcomes. It is our professional
duty to do what is right. The problem is that we as a profession have not embraced provider comparisons of this type. We are viewed by payers as obstructionists who are unwilling to talk about outcomes in a transparent way. Until and unless physicians step forward to carefully inspect outcomes, structural variables such as provider volume will be shoved down our throats as indicators of quality. The unproven concept of regionalization may become a nonissue when providers address outcomes using risk adjustment and process of care variables in an open transparent way aimed at self improvement and enhancing high-quality care. Do currently available data justify regionalization of care for CABG? They do not. Is there a better alternative? There is almost certainly a better alternative. It remains for us as a profession to lead and not to follow, to embrace transparent risk-adjusted outcome analysis proactively, and to work interactively with payers to reach a common goal of high-quality care. Regionalization is not the first place to start.

Concluding Remarks

Robert M. Sade, MD

A fundamental ethical principle is central to this discussion: the paramount obligation of physicians is to serve the medical interests of their patients [54]. Flowing from this principle is the imperative to make the health care of patients as safe as possible. Would regionalization of CABG move us toward or away from that goal? The preceding discussions suggest that the available data do not provide an unambiguous answer.

To understand how the principle of fidelity to the patient’s interests can guide our thinking about this question, let us assume much clearer data than we have now. The assumptions, for the sake of discussion, are that programs and surgeons performing a high volume of CABG procedures have significantly lower mortality rates than low-volume programs and low-volume surgeons. Assume further that patients are indifferent to how far they must travel for their cardiac care, and that family physicians referring the patients have no preferences for where the surgery is done or who will do it. The case then seems to be closed: regionalizing CABG so that all patients needing the procedure are referred to high-volume, low-mortality programs will best serve our patients.

But is the case really closed? Perhaps not, for there is a hidden assumption in this scenario, namely, that the universe of CABG programs and surgeons and their respective capabilities to provide safe operations is immutable. This assumption is false. High-volume programs can become complacent and lose their competitive edge; high-volume surgeons grow old, their skills diminish, and their knowledge may become outdated. Low-volume programs want to thrive, so they strive for efficiency and patient-friendliness; low-volume surgeons strive for better results and other means of increasing referrals. Thus, high volume may become low, and low volume may become high.

Studies of volume–outcome relationships provide a snapshot, yet health care, like every other human activity, is dynamic. The slow ebb and flow in which large programs shrink and small programs grow is driven by quality, cost, accessibility, and many other factors. Even if there were a causal relationship between high volume and low mortality, we have no way of knowing in advance which large programs have peaked and are moving down the mortality rate scale, and which small programs are dynamically moving up the scale. Health care accounts for about 15% of the United States gross domestic product, and it is as dynamic and competitive as any other economic sector, comprising a broad range of participants, from national corporations to individual physicians. To paraphrase Tip O’Neil, all health care is local [55], and at the local level, competition is based to a great extent on quality of care, which includes subjective factors (such as patient satisfaction) and objective information (such as mortality rates). These rates are known at least roughly by referring physicians, whether or not the actual data are published. So it may be that in the long run, the interests of patients will be best served by allowing physicians and patients to decide, thousands of times every day, where the patient’s cardiac care will be provided and by whom. Such freedom of choice may be the surest way to foster excellent care for the largest number of patients for the long term.

We know of no studies that examine the flux of CABG volume in surgical programs and practices over time. Therefore, even if the assumptions in the “closed case” previously described were true, there still would be no useful data with which to compare the benefits and harms of regionalizing CABG with those of freedom of choice in the CABG market. The short term would favor the lower mortality rates of regionalization, but the price would be freezing the dynamism of the current unregulated market for CABG. The long term may well favor the current dynamic system, as low-volume, low-mortality programs grow bigger and become the new high-volume, low-mortality programs.

For physicians, the ethical dilemma in the debate on regionalization, it appears, turns on the question of how to best serve the interests of patients (i.e., with a static referral system based on today’s snapshot of CABG results or with a dynamic system that more easily allows future change?). Unfortunately, we cannot weigh the
evidence for and against the alternatives, because reliable data do not exist. Volume itself does not lead to good outcomes, as both discussants have agreed; it is a proxy measure for other factors that affect care [35]. Progress is currently being made in developing accurate predictors of surgical outcomes and in using them for risk stratification. Examples of such programs include the Society of Thoracic Surgeons’ National Database [56] and the National Surgical Quality Improvement Program developed by the Veteran’s Administration in the early 1990s and later adopted by the American College of Surgeons [57]. Despite such advances, available technologies for the accurate measurement of quality of care remain far from perfect and are in need of considerable refinement.

However, even if volume were an adequate measure of quality, the assumptions of the “closed case” scenario previously described may or may not be accurate; the question of the accuracy of the data was the focus of our discussants, many patients would rather stay close to home, and family physicians have referral preferences based, in part, on quality of care.

Like most robust debates, this one has left us with more questions than answers. If an immediate decision is urgently needed, we must choose between the alternatives on the basis of philosophical beliefs about how the best outcomes are likely to be achieved (ie, from a centralized, orderly command-and-control system or from an untidy free market system). If we judge that the situation is not urgent, then we can wait for reliable and valid data generated by measures of quality of care more accurate and specific than volume to guide a well-grounded decision.

Dr Nallamothu is supported as a clinical scholar under a K-23 grant from the National Institutes of Health (NIH Grant No. RR017607-01).

References