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DO VOLUMES MATTER? Clinical, Operational, and Financial Implications

By Karen Hartman

Volume thresholds for cardiovascular programs have long been a debate in the healthcare industry. Do we need minimum procedure requirements to ensure that hospitals provide the best care? Or does it have to do more with the **quality** of procedures, rather than the **quantity** performed? Or does quantity drive quality? These are among the many questions being studied and discussed throughout the country as a shift in procedure volumes has occurred for several clinical specialties. While there are many agencies, research studies, and societies providing guidelines for hospitals and physicians, open heart surgery (OHS), percutaneous coronary intervention (PCI), and cardiac catheterization are three procedures that continue to be “at the heart” of this controversy.

Central to this ‘volume debate’ is the quality of care offered, not only at the hospital-level, but in terms of each individual physician as well. Just because a program has a low volume of procedures doesn’t mean that it is a low-quality program. At Corazon, we’ve worked with several low-volume programs with exceptional quality ratings; and conversely, we’ve seen high-volume programs with quality issues that need to be addressed and resolved.

Indeed, no hospital intends to implement a service that will have below-average outcomes, and there are sometimes good reasons to open or keep a low-volume, high-quality program. Most importantly, meeting a community need for access to care could justify a low-volume/high-quality program. Also, a hospital may have a high-quality program, if only a low-volume one, to maintain this clinical specialty and retain cardiologists in the community. Assuming that high-quality is strived for daily and at all levels of operation, other questions that must be posed include: Should minimal volume requirements determine whether the program must close? If the community is satisfied with the level of care, and the patients are given timely access to CV procedures, what is the purpose of an imposed volume threshold?

Why This Shift?

Nearly a decade ago, the average number of coronary artery bypass graft surgeries (CABG) performed per program in the United States was over 600 per year¹. Today, the average is less than half that total—approximately 290. But, with the increased safety of offering advanced cardiovascular (CV) services at

community hospitals, and the release of Certificate of Need requirements in many states, approximately 200 new OHS programs opened in the last 10 years, many in the community setting. So, as the quantity of programs increased, procedure volumes at tertiary centers were decreasing. Even with growing need for these services, the total procedures performed has been divided amongst a greater number of providers.

Practice advances have also contributed to lower procedure volumes, especially in the case of coronary artery bypass graft surgery (CABG). The rapid adoption of PCI in the late 90s and the introduction of drug eluting stents in 2003 have led to a growing impact on heart surgery volumes. There is less need for traditional, invasive surgery because overall, patients are experiencing positive outcomes with the less-invasive option of coronary angioplasty. Therefore, the total OHS case volumes for hospitals across the country have decreased. So has the volume per surgeon decreased as well?

Further advances in PCI practice have prompted the implementation of angioplasty without open heart surgery on-site in many community hospitals. Access-to-care issues and increasing confidence in cardiac procedures performed outside the tertiary or teaching hospital setting has resulted in an onslaught of programs seeking to offer these advanced services. Study results have shown that only 0.4% of patients require emergency surgery during or after the procedureⁱⁱ.

Furthermore, multiple clinical trials measuring the advantages of quickly performing PCI on an Acute Myocardial Infarction (AMI) patient, and the minimal capital outlay to perform angioplasty with off-site open heart surgery, allows many community hospitals the opportunity to now offer PCI. In fact, these programs are sweeping the nation today and angioplasty is fast becoming the standard of practice for the presenting AMI patient. And other clinical reviews, including state-sponsored trials and C-PORT (Cardiovascular Patient Outcomes Research Team) and PAMI (Primary Angioplasty for Myocardial Infarction) studies, which evaluate the benefit of PCI versus thrombolytics, may also be contributing to rising numbers of these procedures.

But as surgery volumes decline and PCI volumes increase despite increases in the number of providers, a question then arises about the number of PCIs a hospital should perform in order to ensure quality. Does

quality and/or “best practice” depend on the total volume of the hospital or of the interventional cardiologist?

Over 15 years ago, many community hospitals began to offer low-risk catheterization to their communities, working closely with a tertiary center for Cath Lab support, whether for staff training, emergency transfers, or physician coverage. These low-risk Cath Labs gave community hospitals an alternative so as to remain in the business of cardiovascular services without high-cost, high-risk OHS or interventional services. But another shift occurred. As practice advanced again, with the clinicians providing cardiac cath and PCI coupled in the same setting, diagnostic-only procedure volumes in the low-risk cath lab declined. Also contributing to this trend are the physicians and patients who choose to “bypass” certain diagnostic centers and instead travel to a facility that offers the opportunity to have both procedures in “one-setting,” as opposed to two procedures at two different hospitals. With these many influences on the services offered by community hospitals, we again must ask the question: Does quality depend on the number of cardiac cath performed by a hospital or the volume performed by each cardiologist?

Who’s Counting?

There are numerous independent agencies and societies, such as Leapfrog and the ACC, that monitor volumes and create threshold requirements for both hospital and/or physician competency. In light of industry trends detailed above, Leapfrog recently changed their hospital OHS procedure requirement from 500 cases to 450 and is using risk-adjusted mortality instead of volumes as the primary basis for their scoring. This group continues to monitor their rationale, realizing that volume-by-surgeon may need to be monitored and reported as well. Likewise, insurance providers evaluate programs on not only volume thresholds, but on quality indicators as well, to decide on payment for CV cases or even inclusion of the hospital as an approved site to receive particular procedures.

In Corazon’s experience, hospital volume does not tell the whole story. For instance, a hospital may report 300 OHS cases per year. Even though this volume is below the Leapfrog standard of 450 cases per year, it may meet the thresholds of their state and/or payors. However, some of these organizations have five surgeons. It is simple to do the math and note that in this case, on average the surgeons are performing 60 cases. On the other hand, at

many “low volume” programs (200 OHS cases or less), there are generally only two surgeons. Simple division reveals that the “low volume” hospital’s surgeons may actually have a better opportunity to maintain their skill sets than those at the higher volume program.

Dependent upon various regulations, Certificate of Need (CON) laws can prohibit entrants into a service market, and will monitor the progress of programs currently in operation. In states with CON laws, programs that do not meet the established volume requirements can be closed. In Kentucky and Illinois for example, each cardiac program must achieve published volume thresholds by Year 3 of operation; however, to Corazon’s knowledge, no OHS programs have been ordered to close yet, even though they have not reached the volumes stated.

In Pennsylvania, hospitals are mandated to submit volume and quality data to the state for public reporting that rates each healthcare operator. Pennsylvania then uses this data to report quality indicators, such as risk-adjusted mortality, readmission rates, and lengths of stay by hospital program AND by physician operator. The findings showed that operator volume is in fact the key to outcomes, rather than program volume. Furthermore, this study revealed that outcomes did not appear to drive patient selection. A Solucient study comparing beating heart surgery vs. conventional on-pump bypass surgery also pointed to the importance of operator volume instead of program volume.ⁱⁱⁱ

Other volume-related studies have been performed in various states. The *New England Journal of Medicine* compared high- and low-volume facilities and found only a small gap in mortality rates for coronary artery bypass graft surgery (CABG). However, a greater disparity in quality outcomes was found in valve surgery cases. A New York study of 57,000 CABG cases proved that as physician volumes increased, the odds for lower mortality likewise increased. The findings suggest that surgeon volume could matter as much as or more than program volume, and if given the choice between a high-volume surgeon at a low-volume hospital or the reverse option, patients fare better in the first scenario^{iv}. These and other findings support that using standards of practice at high- or low-volume programs can greatly increase quality outcomes, regardless of the quantity of procedures performed.

In some situations, there is value to thresholds for quality assurance. For instance, Corazon typically recommends that a cardiac surgery program perform at least three open heart surgery cases per week to maintain the “engine” and keep the staff competent and ready. But, this number is only a guide. In certain scenarios, low volume will not maintain profitability of the program. All programs must measure quality outcomes and also pay attention to the volume of cases performed and the cost per case. This analysis will ensure the program is viable, high-quality, and financially-sound.

Quality and finances do indeed go ‘hand-in-hand.’ Low-volume programs could have issues with excess capacity, high costs for equipment and facility needs, and/or inefficient staffing. Thus, it is very important to give adequate attention to the cost of keeping a low-volume program open. Because indeed,

providing quality care cannot alone sustain a successful service line indefinitely.

Recommended Volumes:

- ♥ Leapfrog
 - ♥ ≥ 450 CABG cases
 - ♥ ≥ 400 PCI cases
- ♥ American College of Cardiology (ACC)
 - ♥ 75 PCIs per year, per physician
 - ♥ Minimum of 200 PCI per hospital per year with experienced operator
 - ♥ Ideal of 400 PCI per hospital per year
- ♥ Society of Thoracic Surgery (STS)
 - ♥ 150 procedures per year per physician
 - ♥ Procedures do not have to be all OHS

Also Influential to the Debate

It’s important to note the influence of tertiary centers in this controversy. Many larger hospitals, medical centers, or academic teaching hospitals wield “power” in their region. These hospitals are feeling the pressures of competition from new players in the market for procedures, which affects the bottom lines of these larger centers. This financial impact can be even stronger as profits are already shrinking from the decrease in CABG procedures and the introduction of expensive drug-eluting stents. Sharing the already decreasing case load can have an impact on profitability.

Physicians also have a significant role in this debate because of increasing malpractice costs. With only a Class-Ib recommendation from the American College of Cardiology regarding elective PCI with off-site OHS, many cardiovascular physicians are skeptical about performing these procedures. It is also a lifestyle change for these physicians, who may have to cover multiple locations, and basically go to the patient, as opposed to the patient coming to them. This situation is compounded by issues regarding the use of their time and the ongoing cardiology manpower shortage throughout the country. Beyond the 8 to 5 routine work day for cases and office visits, the interventional cardiologist needs to be available for 24/7, “round-the-clock” procedures, which leaves many hospitals paying extra for “on-call” coverage.

Regulators must also be considered in the discussion. Today, state authorities across the country are being forced to become “clinicians” in order to understand the need for advanced CV services in the communities. Meanwhile, tertiary centers that oppose community expansions are working with the state in hopes that they can gain support on their “side” to prohibit community hospital entrants. With so many conflicting agendas, these authorities are in a “catch-22,” and need to be focused on the patient, rather than the competing agendas of any involved parties.

The Real Issue

As we’ve seen, there are many hurdles for programs to overcome in a given market, among them, quality, volumes, profits, and politics. But, the question must be asked: is the debate about volumes or outcomes? What *should* it be about? While these pressures (and maybe others) can affect different programs in different ways and can have

varying levels of influence in a market, the welfare of the patients should be the ultimate determination as to whether or not a program stays in operation. While the issue could be decided by a third party, such as the state, the burden remains on the CV program (whether community or tertiary) to sustain a quality program, regardless of volumes.

We’ve addressed the issue of programs already in operation, but what about those seeking to expand their CV service offerings? Community hospitals must demonstrate a rationale for expanding, especially if the program may not meet the suggested or required volume thresholds.

On the other hand, a tertiary hospital may need to present a viable case to oppose a community hospital expansion, citing further decreases in volume, dangers to physician competency as volumes erode, and/or a damaging impact on revenues.

What Can You Do?

In either situation, a full review of industry dynamics is necessary, especially considering that competition will get more intense as additional programs enter a market. You must evaluate where the growth potential is and why. Are volumes increasing or decreasing? Why? What technologies and practice advances will affect your program in the years to come? How can the answers to these questions strengthen your case?

The first step is understanding your place in your market. It is necessary to define your Cardiac Service Area (CSA), the area from which you historically capture cardiac patients. An analysis synthesizing the market data by case type, utilization rates, and competition, and, trending these indicators over several years is key. By analyzing the results, you’ll be able to assess “what went right or what went wrong” over this time period. For example, if volumes within your service area are on the rise, but declining within your organization, you must investigate why a change in your market share has occurred and evaluate strategies to recapture lost cases. This process can also help define the potential market for outreach opportunities, ways to increase patient satisfaction, and the feasibility of adding new or expanded existing services.

But, this external data is of no use without an internal assessment. You must know your own stats on quality, operational, and financial indicators. Using established industry benchmarks is important, and submitting data to be benchmarked is a valuable practice as well. Several databases exist to submit CV data for ranking, such as the American College of Cardiology and Society of Thoracic Surgery registries. Compiling and submitting data to these organizations will direct internal focus to these important measures, and can reveal where your program excels, and where there is room for improvement. Such knowledge can allow your organization to benchmark internally (year to year, case to case, or physician to physician), track performance compared to other peer participants, and identify targets for improvement, marketing opportunities, or processes that can be transferred to another hospital specialty area.

You can also submit data to state and regional forums or health system partners or affiliates, or you can purchase data from

Solucient or independent companies, such as Corazon, that have conducted detailed studies on certain program areas.

In order to maintain quality (and profitability), whether a high- or low-volume program, organizational focus should be directed to achieve the most efficient processes by applying 'best practice' clinical standards. "Pay for Performance" opportunities can also assist with quality improvement initiatives, and should be evaluated as a catalyst for change, if necessary.

People are important to a cardiovascular program's success. The staff complement of any specialty area must always be evaluated for baseline and advanced competencies. Involved physician leaders will contribute a great deal to ensuring quality outcomes, regardless of procedure volumes. In fact, physician practice directly impacts quality outcomes based on the procedures they perform. Along with a CV Quality Committee, physicians and staff should work together to apply evidenced-based medicine and ensure that standardized processes are followed. Outcomes by physician, by case, or by patient selection criteria are then measured and given due attention. Such continual monitoring can optimize quality and drive operational change to assure excellent outcomes.

Coders are also important to the quality-assurance process. In accordance with the practicing physicians, they should always be up-to-date on the latest procedures, technology, and processes. While physicians always need to be at their highest level of performance, including clinical practice and appropriate documentation of patient conditions, likewise, the coders need to make sure the hospital is getting paid properly for the procedures done. Incorrect coding can lead to lost costs and incorrect or inaccurate reports of quality, or the lack of. Without precise coding and documentation of procedures, quality ratings, rankings, and outcomes can be skewed.

And finally, the facility component is another consideration that can lead to efficiencies, quality, and consequently, profitability. "State-of-the-art" equipment and facility design go a long way to contribute to optimal performance.

A Resolution?

So the question remains...Should volumes be indicative of program success – or outcomes? We believe a blend of both can produce the best results. In an industry like cardiovascular, where competition is ever on the rise, and technology and practice advances emerge continually, quality and quantity must be given due attention in light of efficiencies, profitability, patient satisfaction, and the overall health of the community. Ensuring a "hand-in-hand" cooperation of quality and costs, and/or outcomes and volumes, will create the best path for success.

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Corazon combines business planning, market and financial analysis, feasibility studies, clinical operations, Heart Hospital design, best practice benchmarking, and staff education for newly established or existing cardiovascular programs.

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