

As seen in **Hospital News**

A Cross Roads in Care Delivery: Angioplasty with Off-Site Surgical Support

Traditionally, the performance of coronary angioplasty, also referred to as percutaneous coronary intervention (PCI), has required open heart surgery services on-site; however, recent clinical trials have suggested that patients presenting with acute myocardial infarction (AMI) have better outcomes with intervention, rather than drug therapies (i.e., thrombolytic agents) alone. Furthermore, 60% of patients with AMI present to community hospitals without cardiac surgery programs. Many of these patients are transferred to tertiary centers, and may incur delays in treatment and poorer outcomes.

In order to provide more comprehensive cardiovascular services and increase access to state-of-the-art treatment, community hospitals without open heart surgery are implementing angioplasty programs. This has become an increasingly popular practice due to the substantial clinical benefits, but a controversial one as well. In light of such trends, angioplasty with off-site surgical support has received much scrutiny and attention from many cardiovascular program leaders over the past year. The result is two differing perspectives about how to offer this progressive treatment while maintaining the viability of community programs and their tertiary counterparts.

There are two basic ways of including “unsupported” PCI within the continuum of cardiac services: performing only primary angioplasty for emergency treatment of acute myocardial infarction patients, or offering emergent and elective angioplasty for stable patients with a clinical condition and symptoms suggesting revascularization.

Historically, programs have more easily received approval to provide primary angioplasty. The Atlantic Cardiovascular Patient Outcomes Research Team (Atlantic C-PORT) studied primary angioplasty vs. thrombolytic therapy as treatment for AMI and found that patients fare better with an interventional approach, even in the community setting without on-site cardiac surgery. Data continues to be collected, though participating hospitals have all shown superior patient outcomes using primary angioplasty. The results also show that the C-PORT registry hospitals (all community sites without on-site cardiac surgery) have lower mortality than their tertiary counterparts that are often nationally recognized for volumes and door-to-balloon times.

Acknowledging the magnitude of the C-PORT trial outcomes, in 2001 the American College of Cardiology and American Heart Association revised their *Guidelines for the Management of Patients with Acute Myocardial Infarction*, giving primary PCI at hospitals with off-site cardiac surgery a ‘Class IIb’ indication (usefulness/efficacy less well established by evidence/opinion), provided that certain volume and operational criteria are met. States have relied on these *Guidelines* to direct practice changes related to PCI and several have ‘opened the door’ to primary angioplasty based this revision; however, they do not provide a recommendation in favor of elective procedures in the non-surgical setting because only available data can be used. The absence of the ACC/AHA’s stamp of approval has created somewhat of a wrinkle for community hospitals seeking approval for elective angioplasty services.

Community hospitals argue that elective PCI is necessary to support primary angioplasty programs, reasoning that added volumes would increase operator and staff competency. Primary angioplasty

patients are clinically unstable and at much higher risk, so it is difficult for smaller hospitals to recruit full time interventionalists and staff needed to operate 24/7 emergent angioplasty services. The addition of elective procedures assures continuity of care due to the availability of the patient’s primary care physician, who may contribute to the acute care delivery.

The performance of angioplasty without on-site surgical support is common practice in Europe, and such programs are increasing in the United States. Results in both countries demonstrate the safety and efficacy of coronary interventions with off-site open heart surgery, but the development of these programs is not easy. Legal restrictions, market opposition, and manpower issues all make implementation a long and arduous process.

As a result, few hospitals in the nation are outfitted with the technology and equipment to perform angioplasty without on-site OHS services. The core elements of a program can vary, but must include a quality infrastructure of the following components:

- Pre-hospital triage of AMI patients
- Empowerment of emergency department physicians
- Standardized protocols and order sets
- Ongoing education and attention to competency
- Clear patient risk stratification and selection criteria
- A structured approach to measuring and assuring quality
- A formal transfer agreement with a tertiary partner

Hospitals seeking to add angioplasty to their CV service line have many options available, depending on the state in which they reside. Corazon has successfully assisted clients in multiple states in their endeavors to gain approval and then with subsequent implementation of the new program. The Corazon team and can attest to the benefits and challenges of implementing this innovative practice and work with programs to understand the clinical and business challenges associated with this cardiac program expansion.

The landscape for cardiovascular services is rapidly changing and community hospital entry in the angioplasty market is just another example of the complexities and competitiveness facing CV service providers today. Research and documentation will continue to evaluate the best way to attain win-win-win scenarios for communities, patients, and hospital tertiary affiliates.

Clearly, the broad-based adoption of angioplasty without on-site surgery has the potential to change the scope of cardiac care delivery across the country and is a trend to be followed closely.

Corazon Consulting is a national leader in specialized consulting services for CV program development from strategic business planning through clinical implementation. 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 programs. Corazon is a 2003 Ernst & Young Entrepreneur of the Year Company. Call 412-364-8200 or visit www.corazon-consulting.com