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Percutaneous Coronary Intervention without On-site Open Heart Surgery: A “State of the Union” for 2013

By Amy Newell

Hard to believe that it’s been a little over three years since our article, A ‘State of the Union’: Percutaneous Coronary Intervention (PCI) Without on-site Open Heart Surgery, appeared in Cath Lab Digest in May of 2009. Fortunately, much has improved across the country relative to access to life-saving PCI, and in fact, regulatory changes are still occurring across the country in response to the recent 2011 ACCF/AHA/SCAI PCI guideline update....even now as this update is published!

In November 2011, the ACCF/AHA/SCAI published the latest guidelines for Percutaneous Coronary Intervention, and with these guidelines came an elevation of the classification (from a Class III to a IIb indication) and level-of-evidence supporting elective PCI being performed in a hospital with open heart surgery off-site (PCI with SOS). The societies have based their latest guidelines on the success and preliminary outcomes from the most recent national CPORT-E trial, and have considered other national studies such as the MAYO Clinic meta-analysis.

Corazon has found that, in response to the 2011 published guidelines, many individual state regulating bodies have begun to revise, or are in discussions to consider revisions to their current PCI regulations. This is not to say the process for offering PCI with SOS will be any less difficult for hospitals in those states, but perhaps having the medical professional societies as a champion to drive change within a particular region will no doubt provide the necessary support to impact change and ultimately save the lives of patients with acute MI. Also, the promotion of elective PCI with SOS within the latest guidelines can ultimately act support the provision of more timely access to care to those patients requiring coronary ischemic management.

Our experience across the United States continues to suggest a change of perception and acceptance of PCI with SOS. Many of our clients interested in offering this service will first ask: is it feasible and/or reasonable to consider such an expansion? In addition to making the business case, several critical program components must be taken into consideration such as: physician commitment and expertise, staff training and competencies, emergency medical support, the ability to offer 24/7/365 access to the service for the AMI patient population, and the creation of a formal tertiary relationship with an open heart provider, just to name a few.

When truly considering these questions, many hospital administrators fully recognize the obstacles they may face, whether they are challenges from the State Health Department, opposition from cardiac full-continuum of care (inclusive of Open Heart Surgery) competitors, or even the lack of aforementioned critical program components. However, dedication to the goal of increasing immediate access to best-practice care delivery for heart attack victims could serve as the motivation necessary to move forward with an official evaluation of program feasibility, followed by a strategic plan for the expansion.

Despite the limitations, growing support to allow elective PCI with off-site open heart surgical support is sweeping the United States due to outcomes data that clearly proves elective PCI is just as safe at the community provider with SOS compared to tertiary centers that provide on-site open heart surgery. Of course for the AMI patient population, we cannot underestimate the evidence of Primary PCI being first choice of treatment, and superior to thrombolytic therapy. Corazon closely tracks the state activity of PCI with SOS. Listed below are several states that have endorsed varying levels of practice and in some cases have begun to take the necessary, although daunting, steps to affect change within their State. Let’s again look across the country, and more specifically at the east coast, recognizing that PCI continues to remain a HOT bed of activity.

Figure 1 - This Map illustrates the current state of the union regarding PCI without on-site open heart surgery as of 1/10/2012 utilizing Corazon’s experience.

For several years, New Jersey has permitted hospitals without on-site open heart surgery to offer primary PCI, though only 12 hospitals have been granted permission to offer elective PCI with SOS under the auspice of CPORT-E trial participation. Recently, several New Jersey hospitals have developed a consortium to engage the New Jersey Department of Health to create revisions that will allow hospitals without on-site open heart surgery to provide elective PCI without having to participate in a national registry, and without limiting the “number” of elective PCI providers. Although New Jersey has taken on this daunting task, it may take several months, or...
Pennsylvania is a Non-Certificate of Need (CON) state, which allows those hospitals wanting to expand into additional and often more advanced cardiovascular services such as, open heart surgery, without a formal CON application that usually demonstrates services based on particular need. As is common in many Non-CON states, Pennsylvania does have prohibitory Department of Health (DOH) Codes limiting PCI with SOS. In 2001, the Commonwealth of Pennsylvania was approached by many community providers asking to offer PCI at their facilities with SOS. After many meetings with officials at the Commonwealth DOH and the engagement of legal support, ten (10) programs were permitted to initiate PCI as part of a demonstration project to offer both emergent and elective PCI. There were specific criteria that each selected facility was required to meet, and specific quality metrics that were collected and reported to the Commonwealth as part of an independent settlement agreement specific to each organization. In essence, the Commonwealth was granting ‘exceptions’ to the Codes and no two agreements were the same.

It has been almost 12 years since these programs began offering PCI services and thousands of successful outcomes have been recorded, and so one must ask “has the burden been met.” In 2008, the Commonwealth was once again challenged by additional providers wanting to offer elective PCI with SOS, and the Commonwealth responded by permitting those facilities to commence services. However, in this particular subgroup, the facilities would agree to participate in the CPORT-E study, and do so at their own expense. Recently, approximately six (6) of these providers have initiated discussions with the Department of Health to develop a standard for those currently offering PCI, both PCI with Surgery on-site and off-site, as well for those hospitals considering expanding Acute MI services to include elective PCI. The Pennsylvania DOH does recognize the recent changes published by the professional societies, and the DOH will be working over the next several months with those hospitals to assure that standard care practices and quality review processes are developed and must be maintained moving forward.

South Carolina has also recognized the revised 2011 ACCF/AHA/SCAI PCI guidelines and is proposing the adoption of those guidelines into their existing State Health Plan, and in fact, is presenting the proposed changes to the States Health Plan November 2013. Alabama has also proposed written changes encompassing the same 2011 guidelines, and have extrapolated physician and quality criteria directly from the guidelines that must be met in order to provide this life-saving service. The state has recently reported that the new language, which is now posted for public comment, is available for review and comment through January 2013. The Maryland Healthcare Commission continues to debate whether or not to lift certain geographic restrictions as well address the recent PCI guidelines that would allow other community based providers without SOS to expand their services beyond primary or emergent PCI.

Over this past year, the State of Kentucky has drafted criteria and is awaiting a decision by the state that will formally recognize and adopt these criteria into their current State Health Plan. A decision is anticipated by end of 2012. We continue to recognize those states, such as Georgia and Florida, which have risen above bureaucracy and stalemate politics, have allowed community-based hospitals to expand CV services beyond diagnostic services only. In fact, in these states even emergent PCI with expansion elective PCI with SOS services are being developed in many communities. In Georgia, Corazon continues to act as a “third party verifier”, and at the request of the hospital, our team will provide an annual quality review to ensure those PCI providers continue to meet necessary program requirements, and in many cases excel in quality outcomes. Our team often receives information about the number of times that lives have been saved due to those programs offering life-saving PCI service.

As one examines the geographical boundaries distant from the east coast, it is easily recognized that most states in the center of the country have little-to-no restrictions governing PCI at a facility without on-site open heart surgery; and this has not changed. However, there are exceptions to this rule.

In 2009, the State of California, a NON CON state, addressed elective PCI with SOS by allowing up to six (6) hospitals who met defined state requirements to participate in a “Pilot” project. Those facilities wanting to offer elective PCI must meet the CDPH – California Department of Public Health written requirements/criteria. In addition, a hospital must submit an application to be considered and selected to participate within the Pilot Program. The CDPH will look at all aspects of the “Pilot” programs from costs, safety, and quality outcomes. In addition, the department (at their discretion) has indicated that it may charge the Pilot facilities a fee for oversight should it be deemed necessary from a funding standpoint. The California “Pilot” program end date is scheduled for January 2014, at which time the CDPH will evaluate and determine the future of PCI in the State of California. The Department will submit a written report 90 days after the completion of the Pilot Program, and then decide whether or not additional programs wanting to offer PCI with SOS will be permitted.

Although changes continue to occur across the United States regarding PCI without open heart surgery off-site, you cannot understate the value of developing a solid plan for any program expansion. Careful planning, continued market surveillance coupled with a savvy administration and collaboration among physicians, clinicians, and future partners is no doubt “mission critical” for a successful program expansion. Corazon again recommends any program looking to expand cardiovascular services to offering PCI to submit to the ACC-NCDR CathPCI Registry®. Not only does participation in the Registry provide an organization benchmarking opportunities, but it will continue to drive national recognition and quality excellence among other providers. In many of the states detailed above, often existing, or proposed criteria includes the mandatory participation in the ACC-NCDR National Registry.

So as many community based providers consider an expansion to PCI, and given all of the recent literature supporting the safety and efficacy, we should perhaps no longer debate whether the burden has been met, but rather move forward considering the positive impact of these changes on programs across the country, especially in terms of improved access to life-saving care for patients who need it most.
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