

A 'State of the Union': Percutaneous Coronary Intervention (PCI) without On-Site Open Heart Surgery

By Amy Newell

Over the past decade, a great deal of debate has erupted regarding the ability of hospitals to perform primary and/or elective percutaneous coronary intervention (PCI) without on-site open heart surgery. Angioplasty is considered the 'gold standard' of care for patients with acute myocardial infarction (AMI or, heart attack), but has been questioned as a stand-alone service...is on-site open heart surgery needed when performing PCI?

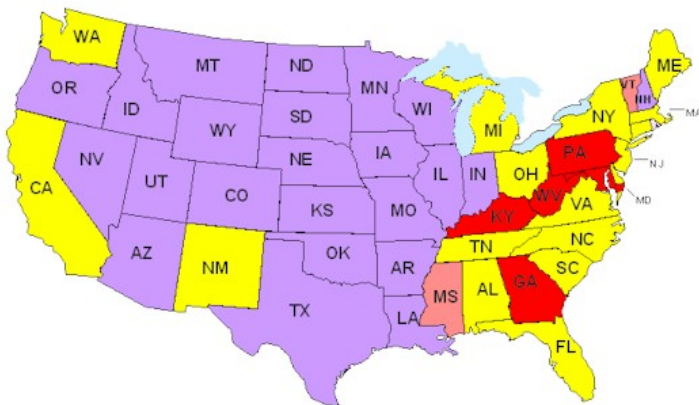
Despite the safety and efficacy of this practice at hospitals with strong quality standards in place, the ACC/AHA/SCA&I guidelines hold this practice to a Class II-B recommendation for primary PCI and a Class III for elective angioplasty. But, several clinical trials in the United States and in Europe have challenged this position; in fact, most providers offering PCI have demonstrated outcomes that are equal to or better than those at facilities with on-site open heart surgery.

Unfortunately, Corazon believes that any regulations that limit access to this life-saving therapy in various regions of the country results in differing standards of care based on patient location...An alarming scenario at best.

Who's doing what?

Based on Corazon research, the following map represents a state-by-state breakdown of **primary and elective** PCI without on-site open heart surgery across the nation:

PCI without On-Site Open Heart Surgery



The purple states, mostly located across the central plains of the U.S. as seen above, have little or no state restrictions and/or state involvement in hospitals' performance of PCI with off-site surgical support. All other states are regulated to some degree.

Where does your state fit?

As seen in the map, many states "regulate" a hospital's ability to perform PCI—either through demonstration projects, state-specific statutes, pilot projects, or clinical trial participation. Throughout this past year, Corazon has witnessed, and in many states assisted, community hospitals with petitioning and/or protesting current state regulations. As simple as that may sound, it is not...Challenging state regulations can oftentimes be an arduous task, consuming significant resources; and, depending on the state in which you reside, such disputes could take several months or years to settle.

Most states, through their departments of health, governing agencies, or health commissions list specific criteria or thresholds that a community hospital must meet—and also document—to provide PCI services with surgery off-site. In Corazon's experience, community hospitals that meet state criteria or guidelines must also adhere to the ACC/AHA/SCA&I guidelines for PCI.

Despite the limitations, growing support to allow PCI with off-site open heart surgical support is sweeping the United States due to outcomes data that clearly proves the efficacy of this process for patients with acute myocardial infarction (AMI) or heart attack. Corazon closely tracks this activity and listed below are several states that have endorsed varying levels of practice:

In January, **Florida's** Agency for Health Care Administration (AHCA) reported the formal adoption of Level I and Level II Licensure for Adult Cardiovascular Services. Level I Licensure allows community hospitals to offer "elective" and "primary" PCI services provided they meet **ALL** criteria set forth by the Agency. Level II Licensure allows those hospitals wanting to offer "full" open heart services to do so provided they meet **ALL** criteria set forth by the Agency.

In 2005, **Georgia's** Department of Community Health approved several hospitals to participate in a national clinical trial that allows community hospitals without on-site surgical back-up to provide primary and elective PCI. In recent months, the Georgia DCH has been challenged by several community hospitals not participating in the national trial that want to offer primary and elective PCI services. Currently, the DCH is reviewing "written comments" in hope of finalizing the "new" language mid to late summer of 2009. This would allow those community hospitals not participating in the national trial to offer this life saving therapy.

Kentucky recently evaluated outcomes from their primary PCI pilot project and is expected to review and possibly revise its current regulations. Currently, Kentucky does not allow "elective" PCI unless a facility is either an open heart provider, or holds a CON to offer open heart services.

In May 2007, The **Maryland** Health Care Commission approved a tentative plan to allow hospitals that do not offer open heart surgery services the right to perform elective angioplasties, provided the hospitals meet criteria established by the Commission. A limited number of hospitals based on volume and region will be able to provide elective PCI services under the auspice of a national clinical trial, according to the new regulatory language.

New Hampshire allows primary PCI as long as there is a "formal" tertiary agreement in place with a facility that provides open heart services. Elective PCI is permitted as long as there is 24/7 coverage for Primary or emergent PCI, and this must be demonstrated within the first 12 months of program commencement.

New York State implemented a demonstration project allowing 10 facilities to perform primary PCI. These facilities have been permitted to offer "elective" PCI through a continuation of the demonstration project. New York has begun to evaluate the "elective" programs and have begun a new review of current state regulations relative to PCI services. New York State expects to release any changes to these regulations within the coming year.

Pennsylvania has approved 10 programs as part of a demonstration project to allow both primary and elective PCI at facilities without on-site open heart capabilities. There has been much debate as to whether the PA facilities will provide interventional services as part of clinical trial participation. In early 2008, Pennsylvania's Department of Health required that facilities outside of the demonstration project wanting to offer PCI services first apply and be accepted into a national clinical trial. Once those facilities have met all of the necessary requirements outlined by the trial, and have been accepted into the study, these facilities must make application with the State of Pennsylvania and be approved before starting PCI services.

West Virginia published new regulations in August 2008 that structure PCI into three tiers of service. Programs must be able to demonstrate a minimum diagnostic catheterization volume threshold; after one year of diagnostic cardiac catheterizations a hospital can apply to offer primary PCI services. Hospitals must offer primary PCI for a minimum of two years before they can apply to offer elective PCI and must meet a minimum volume threshold. Overall, for a hospital that is considering elective PCI but is not currently performing diagnostic cath, this process can take as long as four years in some cases. Corazon recommends those hospital seeking to expand services take a methodical approach and assess their current situation.

Corazon strongly recommends, as does the leadership in most states listed above, that **all** hospitals offering PCI submit clinical data to the ACC/NCDR PCI registry for quality assurance and benchmarking. It is critical to the success of PCI within community hospitals that every effort is made to ensure that each PCI program possesses exemplary quality outcomes.

One key issue critical to the success of a PCI program within a community hospital is the need for a formal written plan and transfer agreement with a hospital that provides open heart surgery, often referred to as the tertiary partner. As simple as it sounds, Corazon has found this agreement to be one of the most difficult challenges a community hospital will face. In fact,

often times the tertiary hospital will give an adversarial response in fear of losing market share or revenue, not clearly understanding what this relationship could mean. Instead, they merely ask, "what's in it for me"? Corazon believes that given solid and open communication, each hospital can garner growth through services not offered at the other facility. This could allow for a win-win scenario.

It is vital that communication between both parties remain clear and open, looking at **all** services offered within each facility, so each can recognize and understand how to best achieve a win-win scenario. A tertiary agreement can mean many things for both: a halo of other services within either facility, a new "branding" opportunity, better quality oversight processes, and more robust staff education. Corazon believes through careful planning and understanding, both parties can, in fact, promote sustainability for both programs.

As regulations change and/or are challenged by many community hospitals across the United States, Corazon recommends hospitals be fully prepared: understand the regulatory landscape in your state and region, know what your options are should your rules change, and have a strong strategic plan in place for your cardiac program. Such a plan will strategically position your organization for the future within the context of PCI regulations. Hospitals that have invested time and money are those most likely to succeed in their endeavor, reaping not only the financial benefit, but also one of quality and excellence by becoming the community provider of choice.



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