EXCEPTION COMMITTEE PROCEDURE:

ELECTIVE PERCUTANEOUS CORONARY INTERVENTIONS (PCI)

The Department of Health's (Department) highest priority is to protect the health, safety and welfare of the commonwealth's citizens. This commitment includes the commonwealth citizens' need for reasonable access to cardiac diagnostic and treatment services. Within the mandate to ensure the delivery of safe, quality health care services, the Department is sensitive to the need to support development of new, evolving programs of care, while minimizing risk associated with new technology and newly trained operators and support staff.

This paper addresses the Department's policy on PCI and rationale for decisions supporting the policy position.

GENERAL OVERVIEW OF PCI

Percutaneous coronary interventions (PCI) refers to an invasive procedure that provides treatment for patients with coronary artery disease. Because PCI is less invasive and less traumatic than coronary artery bypass surgery, in many situations, this procedure is the treatment of choice to relieve symptoms related to coronary artery disease (narrowing and blockages).

In years past, when the overall PCI complication rate was 10 percent, the standard of care was to limit PCI services to only those hospitals that also had onsite cardiac surgery services. Numerous studies now demonstrate that, with improved technology and techniques, the PCI complication rate has decreased dramatically, and mortality has fallen for all PCI procedures, allowing for PCI procedures to be performed with acceptable outcomes in facilities without onsite cardiac surgery capacity. Currently, approximately 17 Pennsylvania hospitals that do not have cardiac surgery services perform elective high risk cardiac catheterization, which includes PCI.

In Pennsylvania, the Department of Health permits all hospitals with the capacity to perform PCI to do so on an emergency basis, allowing, for example, treatment for acute myocardial infarction, because the lifesaving nature of the procedure outweighs the known risk. (28 PA Code §138.17(c)) However, performing elective PCI without onsite cardiac surgery services is currently permitted only by exception in Pennsylvania hospitals that do not also offer cardiac surgery onsite.

Pa. Department of Health hospital regulations in 28 PA Code Chapter 138 address cardiac catheterization services. §138.15 states "A hospital may perform high-risk cardiac

catheterization only if it has an open heart surgical program onsite." High risk cardiac catheterization is defined to include[1]:

> diagnostic cardiac catheterization procedures that present a high risk of significant cardiac complication;
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> percutaneous transluminal coronary angioplasty (PTCA);
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> pediatric cardiac catheterization; and
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> therapeutic electrophysiology except for the implantation of routine permanent pacemakers.

The Department's regulations (28 PA Code §138.16) permit low-risk/diagnostic cardiac catheterizations[2] to be performed in a hospital that does not have an open heart surgical program onsite if the hospital has protocols for distinguishing between low- and high-risk cardiac catheterization patients and has a formal written agreement with at least one hospital that does have an onsite open heart surgical program.

The regulatory requirement that all hospitals providing cardiac catheterization services report to the Department (28 PA Code §138.20(b)) is now integrated in reports made to the Pennsylvania Healthcare Cost Containment Council (PHC4).

The Department's regulations also authorize exceptions to the regulations in certain circumstances defined by the Department.[3] Exceptions are considered if a facility meets the Department's pre-defined requirements and demonstrates that adherence to a regulation constitutes an unreasonable hardship. Hospitals granted an exception must submit specified documents to the Department and demonstrate, through evidence at the time of licensure survey, that they are meeting the terms under which the exception was originally granted.

Beginning in 2001, the Department granted four hospitals without onsite cardiac surgery capacity an exception to allow them to perform elective PCI. These hospitals were required to meet specified conditions related to physician operators, quality oversight, and reporting. In 2005, the Department added the requirement that hospitals requesting this exception also participate in a research study conducted by The Johns Hopkins University. In order to participate in the study, hospitals had to perform a minimum of 200 angioplasty

[1] See definition at 28 PA Code §138.2.
[2] Defined in 28 PA Code §138.2
[3] See, 28 PA Code §51.31- 51.34 regarding the exceptions.

procedures each year and develop a formal angioplasty development program to prepare their staff and establish protocols and policies. Pennsylvania facilities without onsite cardiac surgery are permitted by exception to offer elective PCI.

All hospitals without cardiac surgery programs that have been approved to perform PCI are now required to participate in the National Cardiovascular Data Registry (NCDR) CathPCI Registry, which collects detailed clinical, process-of-care and outcomes data for patients undergoing coronary angiography and PCI in the United States. The registry contributes to improvements in quality of care by providing feedback data on a wide range of performance metrics to participating facilities. The facilities can evaluate how their performance compares with like-sized hospitals and the national aggregate. This aids programs in the development of quality improvement initiatives and helps facilities to define performance goals.

The department is using the NCDR reports to monitor outcomes in order to help prevent or minimize harm to patients, while still permitting the benefits of PCI to be available in medically underserved geographic areas.

DEFINITIONS

Notwithstanding regulatory definitions hereinabove discussed, in this paper, words and terms have the following meanings, unless the context clearly indicates otherwise:

"Cardiac catheterization" refers to the invasive, non-surgical diagnostic procedure used to study the coronary arteries and heart.

"PCI" refers to therapeutic interventions for treatment of coronary artery disease, such as stent placement or angioplasty (including percutaneous transluminal coronary angioplasty [PTCA]). Therapeutic catheterization is included in the definition of PCI.

"Elective PCI" refers to PCI procedures that are not performed in emergency circumstances.

"Primary PCI" means PCI performed in emergency circumstances.

SCIENTIFIC AND CLINICAL EVIDENCE

When coronary artery disease (CAD) is diagnosed, choice of treatment must be based on risk factors such as the patient's overall health and cardiovascular health history, nature and extent of CAD, presence of other active chronic disease such as diabetes, and the urgent or emergent need for treatment based on the patient's presenting symptoms. PCI is often the treatment of

choice over the more invasive coronary arterial bypass graft (CABG) surgery for treatment of coronary artery disease. The need for emergency CABG has dramatically decreased with advances in PCI technology, particularly coronary stents.

In order to safely offer elective PCI in hospitals without the ability to perform CABG onsite, very careful screening and selection of patients is critical. Equally important, however, are the expertise of the physician operator and the experience of the facility in which the procedure is performed. It is generally accepted that a direct relationship exists between procedural volume and outcomes. Therefore, one quality parameter that has been suggested for elective PCI is the number of procedures per year. Consequently, much of the medical literature has looked at volume as a measure of quality. While volume may be an important indicator of quality, other indicators may be as important as or even more important than volume for measurement of safety and quality. Thus, the latest ACCF/AHA/SCAI 2013 Clinical Competence Statement[4] cautions against overemphasis on specific volume recommendations, recognizing that volume is just one of many factors related to clinical outcomes. Other groups have added other quality measures to volume measures, while other international groups have avoided giving specific volume recommendations for operator or facilities altogether.

Additionally, according to the Agency for Healthcare Research and Quality (AHRQ), the volume-outcome relationship may not hold over time as providers become more experienced or as technology changes. It is unclear whether simply increasing volume at low volume hospitals would actually improve outcomes. It is possible that hospitals could increase volume simply by increasing the number of borderline or inappropriate procedures performed. In the concluding statement on the relationship of volume to operator and clinical competency in the May 2013 consensus document, the study authors confirm that there was no relationship between higher volumes and improved outcomes above a PCI volume of 200[5]. While the ACCF/AHA/SCAI recommends a minimum institutional volume of 200 PCIs per year, they recommend that those facilities that have less than 200 cases annually must have stringent systems and process protocols, close monitoring of clinical outcomes and additional strategies that promote adequate operator and staff experience. They must also be in locations where access to PCI service is limited. This posits that poor case outcomes associated with PCI volume below 200 can be mitigated by rigorous adherence to quality standards.

[4] Also known as "2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures", by ACCF/AHA/SCAI (A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physician Task Force on Clinical Competence and Training)

[5] Also known as "2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures", by ACCF/AHA/SCAI (A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physician Task Force on Clinical Competence and Training)

An external review process provides one way to determine if the quality standards that are recommended are being instituted with the necessary rigor in order to protect patient safety. External accreditation and external quality review are generally accepted strategies for hospitals to use for program quality assurance. Accreditation generally includes retrospective review of angiography films, hospital policies and procedures, and patient outcomes. External quality review will permit experts in the field to conduct an unbiased evaluation of all PCI services to accepted quality standards.

POLICY DISCUSSION

In developing its policy position, the Department conducted an extensive review of national research findings and outcome study data, PHC4 PCI data, and outcome data the Department collected in August 2012. The Department also reviewed current national PCI guidelines and practice standards. In addition, the Department reviewed the regulatory approaches to PCI taken by other state governments.

The Department has also considered the merits of external audit as a quality improvement tool and external national certification as a quality assurance measure.

Data from several voluntary databases confirm that doing PCI in hospitals without onsite cardiac surgery is a national trend that is increasing. The NCDR indicate that on-site cardiac surgery was not available in 83 percent of facilities performing fewer than 200 PCIs annually.[6] A 2009 study analyzing the NCDR CathPCI Registry data confirmed the safety of PCI without onsite cardiac surgery available, provided that rigorous clinical, operator, and institutional criteria are in place and are monitored to assure high quality outcomes.[7] Another study, called the Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study (C-PORT-E), concluded that patients who have non-emergency angioplasty to open blocked heart vessels have no significantly greater risk of death or complications when they have the procedure at hospitals without cardiac surgery backup.[8]

[6] J Am Coll Cardiol. 2012 Nov 13;60(20):2017-31 and Epub 2012 Oct 17. "A Contemporary View of Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention in the United States: A Report from the CathPCI Registry of the National Cardiovascular Data Registry, 2010 through June 2011" Dehmer GJ, Weaver D, Roe MT, Milford-Beland S, Fitzgerald S, Hermann A, Messenger J, Moussa I, Garratt K, Rumsfeld J, Brindis RG.

[7] J Am Coll Cardiol. 2009 Jun 30;54(1):16-24. "News from the NCDR: Percutaneous Coronary Interventions in Facilities without Cardiac Surgery Onsite: A report from the National Cardiovascular Data Registry (NCDR)" Kutcher MA, Klein LW, Ou FS, Wharton TP, Dehmer GJ, Singh M, Anderson VA, Rumsfeld JS, Weintraub WS, Shaw RE, Sacrinty MT, Woodward A, Peterson ED, Brindis RG.

[8] N Engl J Med. 2012 May 10; 366(19):1792-1802. "Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery" Aversano T, Lemmon CC, Li L.

The C-PORT-E was a multistate trial that studied patients treated with PCI in hospitals with low volume and without cardiac surgery, comparing them to those patients treated at hospitals with onsite cardiac surgery. This study included many of the hospitals that perform PCI without onsite cardiac surgery in Pennsylvania and followed the development of these programs from the beginning of the PCI programs.[9] The median number of procedures for all patients in this study was 150 procedures. It was found that patients treated in hospitals without onsite cardiac surgery had no greater risk of mortality and comparable risks of major adverse cardiac and cerebral complications when compared to those who were treated at hospitals with onsite cardiac surgery. This study showed that, under certain conditions, it was possible for a low volume hospital to perform PCI with results similar to those in hospitals with onsite surgery.

Multiple studies have identified patient variables that affect PCI outcomes, regardless of whether or not it is performed where cardiac surgery is available onsite. Changes in technology and clinical practice as well as care needs of the population will continue to affect the state of the art and standards of practice for PCI.

In developing the requirements for this exception, the department has taken into consideration the ACCF/AHA/SCAI 2011 guidelines as updated in 2013:[10]

- "Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished.
- Elective PCI might be considered in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.
- Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without hemodynamic support capability for transfer."

ACCF/AHA/SCAI guidelines also make recommendations about PCI volume and experience for physician operators and facilities. The Department's authority for regulating health care facilities does not include regulation of individual practitioners practicing in those facilities. However, the Department does set standards that hold facilities accountable for establishing criteria for granting medical staff privileges and for internal quality assurance monitoring.

[9] Agreements between the Department of Health and the Pennsylvania hospitals performing elective PCI services without cardiac surgery units contained a provision that stated: "When the final report of the C-PORT E trial is issued, the Department will review the report and determine if future guidance for the provision of elective PCI procedures is necessary." This policy statement provides that guidance.

[10] ACCF/AHA/SCAI 2013 Clinical Competence Statement, pp. 16

The ACCF/AHA/SCAI guidelines advise careful consideration of elective/urgent PCI performed by low-volume operators at low volume centers, regardless of onsite cardiac surgery.

As PCI continues to be an evolving area of practice, the Department has determined that the best way to insure that departmental policy keeps up with the rapid changes in PCI practice is to create mandatory oversight requirements in addition to certain documentary obligations as part of any exception that may be granted. This will permit the Department to monitor facility compliance with the requirements outlined in this document, as well as to continuously review data from all hospitals performing PCI. The Department's focus will be on patient outcomes as a measure of quality care rather than procedure volume as a proxy measure for quality.

EXCEPTION REQUIREMENTS

28 Pa. Code §138.15 High Risk Cardiac Catheterization

Recommendations

The Department will permit hospitals that currently offer elective PCI without cardiac surgery onsite to continue doing so provided that the Department's requirements below are met.

A hospital without cardiac surgery onsite that desires to establish a new elective PCI service must apply for an exception. This hospital must meet the additional requirements below before this new service is offered.

PCI services may not be limited to elective PCI. A full range of PCI services must be available.

Minimum requirements for elective PCI (primary and elective) in hospitals without cardiac surgery service onsite

1. All elective PCI Services

a) Patient selection criteria and risk stratification, consistent with all current standards identified as Class I recommendations by the ACCF, AHA, STS and AATS; [11]
b) Standards for training and competency evaluation of physician operators and all professional and technical staff;
c) Hospital requirements for credentialing of participating cardiologists/ operators/interventionalists, including PCI case volume (elective and primary);

[11] These recommendations and standards can be found in 2011 ACCF/AHA/SCAI Guidelines for PCI and associated update documents such as ACCF/SCAI/AATS/HFSA/SCCT 2012 "Appropriate Use Criteria for Coronary Revascularization Focused Update" and ACCF/AHA/SCAI 2013 "Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures". However, as these guidelines are regularly updated, standards will change to be consistent with the latest updated documents.

d) Twenty-four hour/7day availability of the PCI service, including qualified professional and technical staff at the PCI hospital and cardiac surgery services available at a transfer hospital;
e) Agreement with a nearby hospital with cardiac surgery service to provide consultation and treatment as well as rapid transport of patients and the provision of hemodynamic support capability;
f) Participation in the ACC-NCDR CathPCI Registry and authorization for the Department to access the facility's registry data;
g) Quality assurance procedures that include policies for tracking and monitoring operator and patient outcomes, including complication rates;
h) Review of risk-adjusted PCI outcomes of the facility, comparison to regional and national benchmark data and incorporation of results for the improvement of quality of care; and
i) At least every five years, accreditation by Department-approved accreditation agency with standards at least equal to those of the Accreditation for Cardiovascular Excellence.

2.**Low volume elective PCI Services (existing services, less than 200 annual procedures combining primary and elective).**

a) As a modification to item 1(i) above: Annual accreditation by Department-approved accreditation agency with standards at least equal to those of the Accreditation for Cardiovascular Excellence

3.**New elective PCI Services**

In addition to the items in #1 above:

a) An agreement with a Department-approved accreditation agency and submission of an exception request to begin the accreditation process, which, once approved, will be a probationary exception to allow the accreditation process to begin;

b) Program development and implementation plan including timeline and business plan for reaching and maintaining volume of at least 200 procedures annually;

c) Accreditation by Department-approved accreditation agency with standards at least equal to those of the Accreditation for Cardiovascular Excellence prior to offering services; and

d) Occupancy inspection by the Department, prior to offering services, pursuant to 28 PA Code §51.3.

Documentation to be provided to the Department by the facility as part of the exception application:

Policies and procedures outlining patient selection criteria and risk stratification, consistent with all standards identified as Class I recommendations by the ACCF, AHA, STS and AATS;

Medical staff privileges and qualifications for performing PCI, including operator volume and outcomes;

Standards for training and competency evaluation of physician operators and all professional and technical staff;

Policies and procedures to assure 24hour/7day availability of PCI service, including qualified professional and technical staff at the PCI hospital and cardiac surgery services at the transfer hospital;

Periodic ACC-NCDR CathPCI Registry reports as requested by the Department and ongoing departmental access to ACC-NCDR CathPCI Registry data.

Policies and procedures for regular internal review of the hospital's statistics and outcome data;

Agreement with a nearby hospital with cardiac surgery service to provide consultation and treatment, as well as rapid transport of patients and the provision of hemodynamic support capability;

Transport policies and hemodynamic support procedures; and

Copy of most current approved accreditation report, no more than six months old.