

## **External Peer Review Requirements for PCI Programs**

### **Discussion Guide for the MHCC Cardiac Services Advisory Committee**

#### **Introduction**

Through these discussions, the Commission will obtain advice on how to evaluate the attributes and adequacy of external peer review of PCI services conducted by Maryland hospitals as part of MHCC's regulatory oversight of PCI services. This evaluation will occur in the context of reviews of on-going program performance. Staff recognizes that consensus may not be possible on every issue and members may need additional time to consider some ideas proposed. We currently expect that the first external review undertaken by hospitals, which would cover the period from approximately August 2014 to February 2015, will not be evaluated beyond those criteria already included in the Cardiac Surgery and PCI Services chapter of the State Health Plan. However, staff hopes to develop regulations prior to the following cycle for external review, by August 2015. This would likely mean seeking Commission approval of proposed regulations in April 2015, which would then likely be posted for public comment in late May.

A preliminary staff proposal for external review follows, which can serve as a starting point for discussion. Some specific discussion questions are also noted.

#### **Procedure for Reviews**

COMAR 10.24.07D(5) and C(4) describe the requirements for external review. These requirements provide that the review will include a review of angiographic images, medical test results, and patients' medical records. Reviews will be conducted by reviewers who meet all standards established by the Commission to ensure consistent rigor among reviewers. External review, under COMAR 10.24.17.09, is defined as "independent review by clinical experts who are not affiliated with the hospital or health care system associated with the cases being reviewed. In addition, a hospital may not have its physicians perform external review in exchange for physicians at another Maryland hospital performing its external review unless such reviews are done through a Commission-approved blinded system that involves four or more hospitals." Although the requirements in the regulations eliminate some opportunities for reviewers' biases, MHCC staff has concluded that additional safeguards are needed to assure that the reviews are truly independent.

MHCC staff proposes the blinding of hospital and physician names to eliminate possible bias based on this information. For a small company, this may pose a challenge because the company will get paid by a hospital, and a hospital will need to sign a contract. The contracting and payment process would need to be handled by someone uninvolved in the review of PCI

cases who would not reveal the information to the reviewers. MHCC staff notes that this approach does not allow a hospital in Maryland to exchange records with another hospital outside the state in exchange for reviewing its records because the identity of the hospital would be known.

#### Discussion Questions

1. Do you agree that blinding the hospital and physician name is essential? Do all or most hospitals have the ability to remove this information themselves?
2. Are other safeguards needed to assure that reviews are truly independent and not subject to the potential bias that an individual reviewer may have with respect to a particular hospital, system, or practitioner?

#### **Approval of Organizations to Conduct External Review in Maryland**

Staff does not have a specific proposal for handling approval of organizations that may conduct external review of PCI cases for Maryland programs and is not specifically endorsing that MHCC undertake such a process. However, Staff thinks this issue should be discussed.

#### Discussion Questions

1. Should there be required standards/attributes for organizations that want to conduct external review of PCI cases in Maryland, or should the Commission rely only on standards for how to conduct such reviews and on standards for the qualifications of individual reviewers?
2. If there should be standards for organizations that want to conduct external review of PCI cases in Maryland, should some or all of the following be addressed: training of reviewers; standards of professional conduct; experience performing external review (measured by case volume); and standards for maintaining confidential information?
3. If an organization is certified or approved to conduct reviews, how often should the organization be re-certified or approved?
4. Should this issue be considered in the future, after seeing how well the process works without approval of reviewing organizations?

#### **Reviewer Qualifications**

Staff proposes that only board-certified interventionalists who have practiced within the past five years may conduct the required external review of hospital PCI cases.

#### Discussion Questions

1. Do you agree with this recommendation?

2. Should review of some clinical information by a nurse, in terms of testing and documentation, be allowed as long as the angiographic images and the conduct of the procedure itself are reviewed by an interventionalist?
3. Is there any training that could or should be mandated for all reviewers?

### **Elements to Be Evaluated by the Reviewer**

The following pages contain lists of questions that MHCC staff believes need to be answered by a reviewer during the review of a primary PCI case, an elective PCI case, or in either type of case. The questions are grouped together by type of case or topic. Basic discussion questions follow most subsections.

#### ***Primary PCI Cases***

Staff notes that the first four questions below are designed to make sure that the patient selection criteria in COMAR 10.24.17.06A(6) are covered by the reviewer. Questions 6 and 7 refer to circumstances that are identified in the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention as inappropriate indications for PCI in STEMI patients, resulting in either harm or no benefit to such patients.

1. Was the patient appropriate for emergency PCI, as defined in the Guidelines for the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) for the Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions?
2. If the patient does not fit the ACCF/AHA guidelines for primary PCI, was the patient in cardiogenic shock? Is there documentation that the physician appropriately concluded that the patient would be harmed if transferred to another institution?
3. Did the patient receive thrombolytic therapy because PCI services were initially unavailable, which subsequently failed?
4. Did the patient experience a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment?
5. If the patient had a door-to-balloon time of greater than 90 minutes, was the delay due to factors outside the physician's or hospital's control?

6. If the delay in door-to-balloon time was greater than 90 minutes and the interventionalist or hospital could have taken actions to reduce the delay substantially, then include recommendations for improvement or further investigation.
7. Was primary PCI performed on a non-infarct related artery during the STEMI PCI procedure?
8. Was primary PCI performed greater than 24 hours after STEMI in a hemodynamically stable asymptomatic patient without evidence of severe ischemia?

### Discussion Questions

1. Do you agree that the proposed list of questions is appropriate?
2. Should reviewers be specifically asked to evaluate whether coronary artery bypass graft surgery should have been performed instead or should have at least been considered, with documentation of consultation with a cardiac surgeon provided?
3. Should any questions be deleted or modified?
4. Should any questions be added?
5. Is it appropriate to reference in the regulations that cardiogenic shock is defined to be consistent with the National Cardiovascular Data Registry for CathPCI definition, as defined at the time of the intervention? This definition is as follows:

*Cardiogenic shock is defined as a sustained (>30 minutes) episode of systolic blood pressure <90 mm HG, and/or cardiac index <2.2 L/min/m<sup>2</sup> determined to be secondary to cardiac dysfunction, and /or the requirement for parenteral inotropic or vasopressor agents or mechanical support (e.g., Intra aortic balloon pump (IABP), extracorporeal circulation, ventricular assist devices) to maintain blood pressure and cardiac index above those specified levels.*

### ***Elective PCI Cases***

1. Was the patient appropriate for elective PCI, based on the Guidelines of the ACCF/AHA or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions? (see Appendix)
2. Was the patient appropriate for elective PCI only at a hospital with cardiac surgery on-site? Patients at high procedural risk are not suitable for elective PCI at hospitals without

cardiac surgery on-site, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.

3. If the patient was not suitable or may not have been suitable for elective PCI at a hospital without cardiac surgery on-site because of the high procedural risk, was the physician's decision to proceed with elective PCI justified? Is there documentation to support the physician's decision?
4. If a lesion is 70% or less, then was FFR, IVUS, or a positive stress test used to confirm whether PCI is appropriate? Alternatively, was there documentation that supported the conclusion that these tests would be contraindicated?

### Discussion Questions

1. Should Question 1 above be broken down into several questions to ensure consistent review of compliance with this standard? For example, should reviewers be specifically asked to evaluate whether coronary artery bypass graft surgery should have been performed instead of elective PCI or, at the very least, should that surgical alternative have been considered, with documentation of consultation with a cardiac surgeon provided?
2. For Question 4 above, should any other tests or conditions be added to this list? Should a percentage other than 70 percent be used? Do all programs have access to FFR and IVUS?
3. Do you agree that the proposed list of questions is appropriate?
4. Should any questions be deleted or modified?
5. Should any questions be added?

### ***Either Type of PCI Case (Emergency or Elective)***

#### ***Pre-Procedure***

1. Was the patient's medical history and clinical presentation adequately documented?
2. Was operative consent signed or, if not, is there documentation of the reason consent was not obtained?
3. Was there a diagnostic cardiac catheterization procedure performed prior to intervention?

4. Was it determined whether the patient can and would be likely to take dual-antiplatelet therapy on an ongoing basis?
5. Was the patient's renal function documented?
6. Was the contrast dose documented?
7. Was the radiation dose documented?

#### Discussion Questions

1. Do you agree that the proposed list of questions is appropriate?
2. Should any questions be deleted?
3. Should any questions be added or modified? For example, is it important to specifically list details of the patient's medical history that need to be documented, such as prior procedures and other diseases (cerebrovascular, peripheral artery disease, diabetes, etc.)?

#### ***PCI Procedure***

1. Was there any error in the interventionalist's medical judgment? If yes, explain.
2. Was there any error in the interventionalist's skill or technique? If yes, explain.
3. Was there any error in the interventionalist's management of the patient?
4. Were there any adverse patient outcomes? If a patient died, could the death have been prevented?
5. Does documentation by the physician adequately support the course of treatment?

#### Discussion Questions

1. What is the appropriate time frame for evaluating adverse patient outcomes? Should the reviewer specifically indicate whether an adverse outcome was minor, major, or catastrophic?
2. Should specific adverse outcomes be described as ones to include in the review, such as I-Contrast reaction?
3. Do you agree that the proposed list of questions is appropriate?

4. Should any questions be deleted or modified?
5. Should any questions be added?

### ***Angiographic Image review***

1. Is the angiographic description of the coronary vascular anatomy accurate?
2. Is the description of the lesion accurate?
3. Based on the angiographic image review and other medical tests and ACC/AHA/SCAI Guidance for PCI, was the lesion appropriate to treat with PCI? If it is uncertain whether the lesion was appropriate to treat with PCI, briefly explain why.

### **Discussion Questions**

1. Do you agree that the proposed list of questions is appropriate?
2. Should any questions be deleted or modified?
3. Should any questions be added?

### ***Post-Procedure***

1. Were post-procedure orders completed?
2. Were complications reported accurately? Was there a failure to report complications?

### **Discussion Questions**

1. Should the reviewer evaluate whether the procedure was successful? If yes, how should success be defined? Is stenosis diameter reduction to less than 20 percent of an artery a reasonable standard?
2. Do you agree that the proposed list of questions is appropriate?
3. Should any questions be deleted or modified?
4. Should any questions be added?

## ***Recommendations of Reviewer***

MHCC staff proposes that for any areas where an error was identified or where the appropriateness of the physician's actions is questionable, the reviewer should note what corrective or additional investigation, if any should be taken by the hospital.

### Discussion Questions

1. Should specific categories for describing the judgment of a physician be defined, such as "appropriate," "questionable," and "inappropriate?" For PCI procedures specifically, other wording used by some hospitals and proposed in recent ACC guidance is "appropriate," "may be appropriate," and "rarely appropriate."
2. Do you agree with MHCC staff's proposed approach to reviewer recommendations?

## **Reporting to MHCC of External Review Results**

### Discussion Questions

1. How should this be handled?
2. Should MHCC get the reviewer's report from the hospital or from the organization associated with the reviewer directly?
3. What is a reasonable time frame for completing the external review of cases? Should MHCC expect a report within three months of the end of the six-month period from which cases are selected for review?

## **Disputes Regarding the Conclusions of the External Review**

### Discussion Questions

1. How likely is it that a practitioner or hospital might strongly disagree with some of the conclusions of an external review? Do regulations need to address this? What can be done to minimize this possibility?
2. Should a second reviewer be engaged to review cases where deficiencies are identified and recommendations for improvement are noted, as a way to assure that negative findings from an external review are validated?



## Appendix: Excerpts from Guidelines Referenced in MHCC Regulations

**Table 7. SCAI Expert Consensus Document Requirements for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery**

Avoid intervention in patients with

- >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired
- Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography
- Lesions in other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms)
- Lesions with TIMI flow grade 3 that are not amenable to stenting in patients with left main or 3-vessel disease that will require coronary bypass surgery
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention

Transfer emergently for coronary bypass surgery patients with

- High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support
- Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer

IABP indicates intra-aortic balloon pump; LV, left ventricular; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis In Myocardial Infarction. Adapted with permission from Dehmer et al. (352).

**Table 8. SCAI Expert Consensus Document Requirements for Patient and Lesion Selection and Backup Strategy for Nonemergency PCI by Experienced Operators at Hospitals Without On-Site Cardiac Surgery**

Patient risk: expected clinical risk in case of occlusion caused by procedure

High patient risk: Patients with any of the following:

- Decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders
- LVEF <25%
- Left main stenosis (≥50% diameter) or 3-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries)
- Single-target lesion that jeopardizes >50% of remaining viable myocardium

Lesion risk: probability that procedure will cause acute vessel occlusion

Increased lesion risk: lesions in open vessels with any of the following characteristics:

- Diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments
- More than moderate calcification of a stenosis or proximal segment
- Location in an extremely angulated segment (>90°)
- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- Substantial thrombus in the vessel or at the lesion site
- Any other feature that may, in the operator's judgment, impede successful stent deployment

Aggressive measures to open CTOs are also discouraged because of an increased risk of perforation.

Strategy for surgical backup based on lesion and patient risk:

- High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.
- High-risk patients with non-high-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.
- Non-high-risk patients with high-risk lesions require no additional precautions.
- Non-high-risk patients with non-high-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.

CTO indicates chronic total occlusion; CVA, cerebrovascular accident; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions. Adapted with permission from Dehmer et al. (352).