

**Invasive Cardiac Services Advisory Committee
Percutaneous Coronary Intervention (PCI) Oversight Subgroup Meeting
April 10, 2014
3-5 p.m.
Minutes**

Attendance

Subgroup Members:

Cliff Berger, MD
Madeleine Biondolillo, MD
Aaron Kugelmass, MD
Anthony Marks, MD
Laura Mauri, MD
Frederic Resnic, MD
Kenneth Rosenfield, MD

Department of Public Health (DPH) Staff:

Nancy Murphy

Madeleine Biondolillo began the meeting at 3:20 p.m., once a quorum was present. The first item on the agenda was review of the March 3, 2014 PCI Oversight Subgroup Meeting Minutes. The Minutes were unanimously approved.

The group then addressed the draft Non-Emergency Angioplasty Guidelines and Recommendation, with Dr. Marks leading the discussion of the items in “Section IV. Proposal”.

- Item 1: There was a brief discussion of revising the language regarding the mechanism for monitoring for safety and quality, but no changes were recommended. There will be a separate discussion of the proposed peer review process.
- Item 2: Addressing a note regarding existing primary angioplasty programs, the group recommended that the requirement of providing primary angioplasty 24 hours per day seven days a week for 365 days a year be specifically added to the proposal as number 2.
- Item 3: There was a brief discussion of the 60 minute time frame (“emergency CABG must be available to be provided within 60 minutes”), but no change was recommended.
- Item 6: The group agreed that hospitals need to ensure that their interventionalists are board certified in interventional cardiology. There was discussion of addressing a situation when certification expires. The group decided not to get into that level of detail in this document.
- Item 8: The last sentence was deleted (“Each hospital must send a representative”).
- Item 9: The item specific to the peer review process was deleted. This will be discussed separately.
- Item 11 (misnumbered in the draft; it should have been item 10) is now Item 9: The group recommended adding the following as the last sentence: “Operators should refer to contemporary national guidelines.”

- New Item 10: “DPH, as advised by the ICSAC, reserves the right to establish additional quality oversight mechanisms”. This language will be reviewed by the DPH legal office.

The group reviewed Tables V and VI from the *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention without on-site Surgical Backup*. The members determined that nothing in these tables (regarding case selection and patient and lesion characteristics that might be unsuitable for nonemergency procedures at facilities without on-site cardiac surgery) conflicts with the inclusion/exclusion criteria that were issued by DPH for the former MASS COMM non-surgery-on-site hospitals in July 2013.

The group reviewed two maps that were drafted to try to show availability of cardiac catheterization and PCI-capable facilities relative to the burden of ischemic heart disease. The group did not think these maps accurately captured the necessary information. Because it is based on hospital discharge data counts based on ICD-9 codes for ischemic heart disease, it did not identify unique patients. In addition, ‘ischemic heart disease’ was too broad a category. They suggested instead that what was needed was a map of the number of individual patients with a primary discharge diagnosis by zip code of acute myocardial infarction (AMI) and another for ST-Elevation Myocardial Infarction (STEMI). They suggested that STEMIs would probably be about 15% of the AMIs. Dr. Rosenfield noted that the “driver” of a new service should be STEMI.

Dr. Kugelmass stated that in the west, the rates would be high but the absolute numbers would be small. Dr. Rosenfield added that we are ignoring facilities across state lines. Dr. Kugelmass agreed, noting that he treats STEMIs from New Hampshire and Vermont. Dr. Biondillo acknowledged that DPH is aware of the limitation and commented that with its mapping the Department is not able to reflect out of state availability of services.

For the recommendation regarding additional PCI programs, the group wanted to confirm the statement that “it is currently estimated that more than 95% of the population of Massachusetts lives within a 30-minute ambulance ride of a PCI-capable hospital”. There was a brief discussion of separate recommendations for emergency and non-emergency angioplasty, but it was determined that that would be dependent on the distance calculation. DPH will check that estimate and revise the recommendation’s language accordingly.

The group recommended reordering the paragraphs in Section A. General Considerations: #3 becoming #1, #1 becoming #2 (and within #2 putting “c”, regarding safety, first), and #2 becoming #3. Dr. Rosenfield also recommended that the recent SCAI/AHA/ACC Consensus Document should be referenced in what will now be #1, along with the existing reference to the 2013 clinical competence statement.

In Section B. Specific Recommendations, Dr. Kugelmass recommended revising the end of #2.a. Instead of “from the proposed area”, it should say “from the proposed facility and a facility that currently provides this service.”

The group then reviewed the next agenda item, which was Revisions to Public Reporting – Expansion of Exceptional Risk. Dr. Resnic summarized the proposal. Clinical outcomes data

would continue to be collected, adjudicated, analyzed and interpreted as it currently is. But the cases for all patients presenting with the following diagnoses should be adjudicated and, if verified, excluded from the analysis for the public report (but included in the internal comprehensive report):

- a. All patients with *out of hospital cardiac arrest (OHCA) with impaired neurologic status* on presentation to emergency department.
- b. All patients presenting with *Cardiogenic shock (CGS)* at the start of the procedure.
- c. All patients satisfying *Compassionate Use (CU)* criteria, as previously defined by Mass-DAC, including patients with coma on presentation, very high risk STEMI patients, and patients with extensive CPR prior to PCI (overlaps with OHCA cases above).
- d. All patients satisfying *Exceptional Risk (ER)* criteria - as previously defined by Mass-DAC policy.

Dr. Resnic added that the number of OHCA patients may be low, but could contribute to up to 80% of mortality for an institution. He suggested that the review could be conducted both ways, with these patients included and then excluded, to see the impact of excluding them from the analysis.

The proposal also includes a recommendation that, prior to the release of a PCI public report, any negative outlier be reviewed by (as revised by the subgroup in italics) an *external, independent programmatic peer review organization*, e.g., American Medical Foundation (AMF) or *Accreditation for Cardiovascular Excellence (ACE)*, and that the context of their findings regarding the presence or absence of an underlying clinical quality issue be included in the public report. During the discussion, the group agreed that language justifying the recommendation should be removed from the actual recommendation, and included as background.

A third recommendation regarding the prospective monitoring of rates of treatment for patients presenting with cardiac arrest and cardiogenic shock over time as an indicator of access to care was deleted by the group.

(Dr. Berger had to leave the meeting during the discussion of the Agenda Item 4, but prior to leaving noted his support for the recommendation.)

Dr. Resnic agreed to revise the document incorporating the changes recommended by the subgroup members and provide it in a format similar to that that will be provided for the angioplasty guidelines, i.e., separate documents for the Background and Recommendations.

There was a brief discussion of what would be presented at the April 17 Invasive Cardiac Services Advisory Committee meeting. Dr. Biondolillo noted that the peer review document and the primary angioplasty guidelines would be presented to the ICSAC after other PCI subgroup meetings. She reminded the group that the driving force was looking at the evidence and the recommendation is based on national standards and guidelines. Dr. Biondolillo will chair the

ICSAC meeting but will look to the subgroup members for comments on the issues addressed by the subgroup. She suggested that Dr. Marks could provide a summary of the work of the group. At the ICSAC meeting, there will also be a presentation on the Conflict of Interest Law, which the PCI subgroup has also heard.

Regarding the peer review proposal, Dr. Rosenfield commented that a pilot program may best be done through ACE, which does credentialing of catheterization labs as well as peer review. There is a cost associated with credentialing (approximately \$25,000 for three years, and less for subsequent credentialing). He has been considering a proposal where ACE would orchestrate Massachusetts' peer review. ACE would set up the process and logistics, i.e., collect the angiograms, de-identify them, and then Mass. Chapter of the ACC would provide the reviewers from Massachusetts interventionalists.

Dr. Resnic commented that a peer review process, with enough participation, could be a standard for a better way to assess quality. A pilot would be important to show it could be done. It is what the professional societies want to be doing. Dr. Mauri asked what scale is meaningful?

Dr. Rosenfield noted that low potential benefit/low risk patients are never reviewed.

Dr. Biondolillo added that the peer review process could be used to assess whether DPH is using the correct inclusion/exclusion criteria for the former MASS COMM hospitals.

Dr. Kugelmass commented that it is not just mortality that should be reviewed. There are other issues such which wire is used, the lesion, etc.

Dr. Rosenfield noted that part of the 'buy-in' by the MASS COMM hospitals is that the peer review plan would be a statewide initiative that included the tertiary hospitals as well as the community hospitals.

Dr. Biondolillo clarified that the draft peer review document and the primary angioplasty guidelines would not be distributed to the ICSAC members at the April 17 meeting.

The meeting adjourned at 5:20 p.m.