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

Attendance

Subgroup Members:
Cliff Berger, MD
Madeleine Biondolillo, MD
Aaron Kugelmass, MD
Anthony Marks, MD
Laura Mauri, MD

Department of Public Health (DPH) Staff:
Nancy Murphy

Dr. Marks began the meeting at 3:20 p.m., shortly after a quorum was present. The first item on the agenda was review of the April 10, 2014 PCI Oversight Subgroup Meeting Minutes. The Minutes were unanimously approved.

Nancy Murphy began the discussion of the follow-up to the April 17 Invasive Cardiac Services Advisory Committee (ICSAC) meeting. A 'circular letter' (a memorandum) will be sent from the DPH Bureau of Health Care Safety and Quality (BHCSQ) to all acute care hospitals announcing the decision, subsequent to the recommendation of the ICSAC, that no new PCI services will be approved in Massachusetts, unless there is a change in the volume or existing PCI services that would justify the approval of a new PCI service. Dr. Biondolillo continued the discussion by announcing that another policy change would be included in the same memorandum. Despite the moratorium currently in effect that prohibits the establishment of a new cardiac catheterization service if the service would be located within a 30 minute ambulance ride of a PCI-capable hospital, a hospital that is part of an accountable care organization (ACO), either one of the five pioneer ACOs or an ACO as so designated by the Health Policy Commission, may be allowed to open a new cardiac catheterization under certain specific circumstances.

If an existing cardiac catheterization service at a hospital within the same ACO is not meeting the diagnostic minimum volume requirement in the DPH licensure regulations of 300 diagnostic procedures per year, the ACO may apply to transfer that hospital's cardiac catheterization service license to another hospital within that same ACO. The existing low volume hospital will close its cardiac catheterization service. The ACO must document how it will meet the minimum volume requirement at the new site. This policy does not allow the transfer of a cardiac catheterization service license to a hospital outside of the ACO.

Dr. Biondolillo noted that she has not yet reviewed with the Secretary of Health and Human Services the second issue voted on by the ICSAC at its April meeting, which was the refinement

to the PCI public reporting process. This issue does not require the issuance of a memorandum, but will be addressed directly with Mass-DAC.

Turning to agenda #3, Dr. Biondolillo asked the subgroup for comments on the existing diagnostic cardiac catheterization service volume minimum in the licensure regulations. Dr. Marks noted that in recent guidelines, there is no requirement or data for a volume minimum for diagnostic cath procedures. That being said, the group agreed that there is a relationship between safety and volume. Dr. Kugelmass noted that if there were any action taken around Berkshire Medical Center, he would have to recuse himself, as he had functioned as an acting cath lab director there in the past two years.

Dr. Berger raised the question of quality in labs that perform very few diagnostic caths. Dr. Mauri asked if these labs are providing value to patients, e.g., access to a lab that is closer to a patient's home. Dr. Kugelmass noted that there may be complications in a low volume lab that you will not hear about, e.g., vascular issues. In some of the low volume labs it would take years to reach the volume needed to make results of an analysis of complications data statistically significant. Dr. Marks suggested that the Department needs a minimum volume number.

Dr. Biondolillo asked the group if, in the absence of an obvious reason to change the diagnostic volume minimum, they were comfortable with a recommendation to keep the minimum at 300. The group agreed with keeping the minimum at 300 diagnostic procedures per year.

Dr. Marks began the discussion of the Primary Angioplasty Special Project Guidelines by stating that they are very out of date. The group had received draft edits to the guidelines prior to the meeting. Nancy Murphy noted that among other revisions, all language related to a special project application process has been deleted. This revision was based on the recent recommendation of the ICSAC that there is no need for additional PCI programs in Massachusetts. The revised guidelines will apply to hospitals without cardiac surgery on site that had applied to provide primary angioplasty prior to the ICSAC's April 17 recommendation. Dr. Mauri commented that the procedure should be referred to as primary percutaneous coronary intervention (PPCI), not primary angioplasty, throughout the document. The following changes were recommended to the proposed revisions (numbering refers to revised draft dated June 5, 2014, unless otherwise noted):

In section *II. Description of the PPCI Project, A. 5.*, "PPCI" was inserted before the word "protocol" to specify which protocol was referenced. The sentence now reads:

"5. adhere to the PPCI protocol including the selection of patients, …".

In section *II. A. 6*: the word "archive" was deleted after a brief discussion of the regulatory requirement for keeping records and whether there was anything that the hospitals have been archiving that is not retrievable from the medical record. The sentence was revised to read:

"6. collect and submit all data required by the Department and ensure all relevant medical record data, at the discretion of the Department, is available to the Department."

In section *II.A.7*: the words "365 days per year" were added. The sentence now reads:

"7. Provide PPCI availability at the project hospital 24 hours a day, seven days a week, 365 days per year."

In section *III. Minimum Criteria for Ongoing Participation in the Project, 1.:* deleted the last sentence about notifying DPH within one week of any change in personnel in Physician Director and Nurse and Data Coordinator positions.

In section *III. 2.,* language (taken from the MASS COMM Trial protocol) is to be inserted here to indicate that the collaboration agreement will include language that every effort shall be made to ensure arrival of a patient at the surgery on site hospital within 60 minutes of a decision to transport the patient. The following sentences were added:

"Among the issues to be addressed in the collaboration agreement is the transfer of patients in whom a procedural complication warrants surgical intervention. Transport to a hospital providing cardiac surgical support requires rapid and efficient transfer, specifically: ambulance transport must be on site or arrive on-site at the non-SOS hospital within 30 minutes of request by catheterization staff due to procedural complication. Every effort must be made to ensure arrival of the patient at the SOS hospital within 60 minutes of decision to transport the patient."

(Similar language added to Attachment A: Guidelines for the Development of a Collaboration Agreement).

In section *III.3.1.a.,* last sentence regarding rescue angioplasty to be deleted.

In section *III.3. 1.b.*, deleted "operate the cardiac catheterization service" from the beginning of the sentence. The sentence now reads:

(now c.) "provide PPCI 24 hours per day, 7 days per week, 365 days per year."

In section *III.3.1.c.,* insert "and have active ACLS certification" after the word "Cardiology". The sentence now reads:

(now d.) "have ***at least*** 2 physicians on the staff who are board certified in Interventional Cardiology, have active ACLS certification, and actively participate in the performance of PPCI procedures at the Project hospital."

The group clarified in discussion that for section *III.3. 3 (now d. 2.),* which requires physicians to maintain credentials at a hospital where he/she performs elective angioplasty procedures, that hospital does not need to be a surgery-on-site hospital, but may be a former MASS COMM community hospital.

There was a brief discussion of the retaining the staff to patient ratios in former section *III. 3. 1.f. c. and e*. It was agreed to leave them in.

In section *III. 3. 1.f.d.1.*, the requirement for monthly staff training on the intra-aortic balloon pump was deleted.

In section *III. 3. 1.f.f.*, "RN" was inserted after the word "technician" and the phrase "at a tertiary facility" was deleted from the first sentence. The second sentence remains unchanged. The first sentence of the section now reads:

"All "second operators" for PCI procedures must either be a physician or a technician, RN, NP or PA who is trained in the performance of PCI procedures through direct observation of at least 25 PCI procedures within the past two years."

After a brief discussion of the intent of section *III. 3. 1.f.g.*, which in the past required a dry run if a cardiac catheterization service did not perform a PPCI in any given month, the section was deleted because it was unclear and unnecessary.

Section *III. 3. 1.f.h.*regarding the requirement of current ACLS certification for interventionalists, nurse and technicians in the emergency department, cardiac catheterization lab and on the units caring for PPCI patients was deleted. With the previous addition to section *III.3.1.c.* that requires the interventionalists to have current ACLS certification, this section is redundant. The ACLS requirement is covered in other sections.

In Section IV. C. 4., the group agreed that language from the MASS COMM Trial protocol (similar to what was added in section *III. 2.*, above) will be added regarding the transfer of a patient in the event of an emergency to an SOS hospital. The section now reads:

"include specific provisions for the emergency and routine transfer of patients. For patients in whom a procedural complication warrants surgical intervention, transport to a hospital providing cardiac surgical support requires rapid and efficient transfer, specifically: ambulance transport must be on site or arrive on-site at the non-SOS hospital within 30 minutes of request by catheterization staff due to procedural complication. Every effort must be made to ensure arrival of the patient at the SOS hospital within 60 minutes of decision to transport the patient."

In section V. A. Clinical Protocol, 1. Clinical Selection Criteria, 1.b. 1., 'greater than 30 minute" was deleted. The section now reads:

"1. ongoing ischemic cardiac pain"

In section V.A. 1.b.2., it should read greater than or equal to 0.1 mv in both places, not just greater than; another B is needed after LBB (left bundle branch block) and the words in parenthesis following LBBB (ST-segment elevation infarction group) should be deleted. The section now reads:

"≥ 0.1 mv ST-segment elevation in 2 or more contiguous ECG leads
or
new or suspected new LBBB
or

≥0.1 mv ST-segment depression in V1 and V2 consistent with true posterior infarction"

After a discussion of the implications of including section *A.1.b.3* (about suspected electrocardiographically silent MI in the circumflex distribution), it was agreed that these cases would be NSTEMIs, that the operator will only know it's truly an MI in retrospect, and the patient should not be taken emergently to the cardiac catheterization lab. This might be an infrequent exception that would be reported under the paragraph that follows in the guidelines. Section *V. A.1.b.3*. was therefore deleted.

In section *V.A.1. (formerly c.) 2*, regarding door to balloon time, the " ±30" (minutes) was deleted after "90". "(D2B)" was inserted after the word "ED arrival" and the remainder to the section was deleted. The section now reads:

"can have a PPCI procedure performed ("balloon inflation") within 90 minutes of ED arrival ("D2B")."

The group agreed with the paragraph that had been inserted after section *V.A.1. (formerly c.) 2* (regarding D2B) in this version of the guidelines. The paragraph requires reporting to DPH in writing within 24 hours of any PCI performed on a patient who did not strictly meet the inclusion criteria, the reasons for proceeding with the case, any complications, and information regarding any transfers to a tertiary facility.

To begin the discussion on clinical exclusion criteria, Dr. Mauri asked are there 'late presenters' who should be excluded? She added that true late presenters should not go to the cath lab immediately. As a result of the discussion, *Section V.A. Clinical Protocol, 2. Clinical exclusion criteria, a.,* which was deleted in the revised version sent to the subgroup prior to this meeting, was added back and revised further to read:

"a. The patient has experienced >12 hours of ongoing pain ("late presenter" or completed MI)."

The exclusion criterion (previously 'a.') related to a patient with severe peripheral vascular disease with inability of operator to obtain vascular access was deleted.

Section V.A.3. regarding patients in cardiogenic shock was deleted.

Section V.A.6.a., the last remaining criterion under which "primary angioplasty should not be performed" (severe triple vessel disease best treated initially with CABG), was deleted.

The group did not want to address treating a non-culprit lesion at the same time as treating a culprit lesion in these guidelines.

Section *V. C. Notification of Ambulance Service* was discussed. There was consensus that faxing an ambulance company each time a PPCI was to be performed and having the crew on site on standby during the procedure was a waste of resources. Dr. Berger asked who pays for this. Dr. Biondolillo responded that she will check with the Office of Emergency Medical Services. Pending additional changes, the current language was deleted. Language from the

MASS COMM Trial protocol ensuring ambulance response within 30 minutes will be added. The language will now read:
"Section V. C. Ambulance service availability
Ambulance transport must be on site or arrive on-site at the non-SOS hospital within 30 minutes of request by catheterization staff due to procedural complication. Every effort must be made to ensure arrival of the patient at the SOS hospital within 60 minutes of decision to transport the patient."

In Section *V. E. Notification of the Department*, sections *1.a.1.-2.* were deleted. The group indicated that the language in *V.E.1.a.* ("death within 24 hours of the cardiac catheterization procedure or hospital discharge.") was sufficient and that the additional detail in sections 1. and 2. that defined cardiac and non-cardiac death was unnecessary.

There was a discussion of a situation where the patient is transferred to another hospital. Who is responsible for reporting the death? Ms. Murphy responded that currently the hospitals submit monthly reports (included in the guidelines as Attachment C) to BHCSQ that indicate each PPCI patient's outcome. The outcomes include "8: death in project hospital during index hospitalization; 9: transferred to tertiary hospital" and "10: death in tertiary hospital". Dr. Biondolillo noted that beginning in the fall, hospitals will report 30-day outcomes to Mass-DAC.

The group addressed agenda item #5, DPH data collection. From 1998 through 2012, DPH collected hospital and physician volume data for diagnostic and therapeutic cardiac catheterization and electrophysiology procedures. Dr. Biondolillo asked the group if they thought the continued collection of this data was useful. In the interest of non-duplication, it was agreed that DPH does not need to collect PCI volume data because it is collected by Mass-DAC. The group recommended that DPH continue to collect diagnostic cardiac catheterization procedure volume and diagnostic and therapeutic electrophysiology procedure volume.

The group discussed the plan for meetings for the next few months. The next PCI subgroup meeting will take place on July 15 at the time previously scheduled for an ICSAC meeting. The group will complete review and revision of the PPCI Guidelines and discuss the peer review proposal. The next ICSAC meeting will be held on September 4.

In advance of the discussion of peer review, Dr. Mauri will speak with Dr. Rosenfield about contacting Dr. Hitinder Gurm, Project Director for BMC2, the PCI Collaborative that pays hospitals for data collection and increased rates to cover it. The program does not include audit or chart review. Data are collected for all sites and they are compared publicly.

The meeting adjourned at 5:02 p.m.