**Invasive Cardiac Services Advisory Committee**
**Percutaneous Coronary Intervention (PCI) Oversight Subgroup Meeting**
**July 15, 2014**
**3-5 p.m.**
**Minutes**

**Attendance**
**Subgroup Members:**
Cliff Berger, MD
Madeleine Biondolillo, MD
Aaron Kugelmass, MD
Anthony Marks, MD
Frederic Resnic, MD
Kenneth Rosenfield, MD

**Department of Public Health (DPH) Staff:**
Nancy Murphy

The meeting began at 3:10 with agenda item number 2, Further Follow-up to the April 17 ICSAC meeting. Nancy Murphy distributed the Department's Bureau of Health Care Safety and Quality's "Circular Letter: DHCQ 14-6-617" regarding policy updates for cardiac catheterization services. This letter had been sent to all acute care hospitals earlier in the day. The letter addressed cardiac catheterization volume minimums, an amendment to the moratorium on new cardiac catheterization services that is applicable to Accountable Care Organizations (ACOs), and the new policy regarding percutaneous coronary intervention (PCI) services. The group spent a few minutes reviewing the document. Dr. Marks asked for clarification about when the Department would revise the cardiac catheterization service regulations PCI operator volume minimum from 75 to 50. A response was provided later in the meeting by Dr. Biondolillo.

Dr. Marks then addressed the Minutes of the June 5, 2014 meeting. He asked if there was any update on the issue of refinement of the PCI public reporting process that had been voted on by the ICSAC at the April 17 meeting (noted on the bottom of page 1-2 of the June 5 PCI Subgroup Meeting Minutes). There was also a question about to which year the refinement would apply. The Department will discuss it with Mass-DAC. The Minutes were unanimously approved.

(Dr. Biondolillo arrived at 3:17)

The group reviewed for Dr. Biondolillo the issues that had been raised regarding moving forward the refinements to public reporting and changing the PCI operator volume in the regulations.

(Dr. Rosenfield arrived at 3:25)

The group raised questions about 30-day outcome reporting and mentioned previous discussions between the Mass. Hospital Association and the MA Chapter of the American College of Cardiology about a possible subscription for Mass-DAC to the national death index data. Dr. Biondolillo stated that hospitals are not reporting the 30-day outcomes this year; Mass-DAC is

providing 30-day outcomes *for Massachusetts residents only* through linkages with other datasets.

Dr. Rosenfield asked, in relation to the 'no new PCI service' policy, whether closing a cardiac surgical service would result in a PCI service at that site being considered a 'new PCI' service. The answer was no.

Dr. Rosenfield asked, with approximately 15% of interventionalists performing fewer than 50 PCIs, how will the Department manage that? After a brief discussion of enforcement of the regulations, Dr. Resnic suggested that the Department should communicate expectations to the cardiac catheterization service directors, e.g., expect adherence to regulations, under the following guidance.

Dr. Biondolillo stated that she would ultimately like to remove the volume numbers from the regulations and point toward guidance that would lend itself to uniform quality. She added that under Chapter 224, PCI is one of the domains that will be addressed in a state health plan. She would like to ask the ICSAC for recommendations for categories that should be addressed in the plan. This would include:

What defines quality and safety?
What should be reported?
Who looks at the data?

Dr. Marks asked if the volume requirements will be enforced. Dr. Biondolillo said they would be. Dr. Marks asked what the Department would do if the minimum is not met.

Dr. Kugelmass asked if the group/Department should rise to a higher level and look at regional planning.

Dr. Resnic suggested the Department needs to provide guidance and articulate a pathway to enforcement with caveats, e.g., what if a physician is out for a month? He added that the Department also does not want to encourage cases that should not be done.

The group then moved to the continuing revision of the Primary PCI Guidelines. Dr. Marks reviewed the clinical exclusion criteria that were discussed at the last meeting. The group affirmed that the only remaining exclusion is 'late presenters', e.g., a patient who has experienced more than 12 hours of ongoing pain.

The group then discussed revisions to E. Notification of the Department (p.13 of "tracked changes" version 2 of Guidelines). They recommended deleting the various 24-hour and seven day reporting requirements, moving to monthly reporting only. The revised language is:
"1. Hospitals participating in the PPCI project must report the following events to the Department within 30 days:"

On page 14, Section b. Cerebrovascular accident, was deleted.

Section c was revised by deleting the words 'or hospital discharge' at the end of the first sentence. The beginning of the section now reads:

"c. Emergency CABG within 24 hours of procedure." The definition of 'emergency' remains.

Section 2, regarding events to be reported within 7 days, was deleted.

On page 15, sections 2. a-b were deleted. Primary PCI patient data is available through the patient's medical record. The beginning of section 2 and c now become section 2. In the new section 2, 'email' was replaced with 'provide', 'report' was made plural, 'Attachment C' was revised to "Attachment B", and 'to the attention of the Hospital Manager' was revised to 'through its electronic reporting system'. Hospitals currently submit a monthly excel spreadsheet to the Hospital Manager, but the intent is to building this reporting into what is now the Health Care Facility Reporting System or "HCFRS". The section now reads:

"2. All hospitals participating in the Project will provide monthly reports (See Attachment B) to the Department's Bureau of Health Care Safety and Quality's Complaint Unit through its electronic reporting system."

In section G. Quality Assurance (QA) 1.a., the group recommended deleting 'administrators' from the required membership of the Joint QA Committee. In section b. regarding meeting frequency, "twice a year" was replaced with "annually". The group noted that cross-fertilization should be encouraged by way of the cath conference. Section e. was revised to require that a report of each meeting (Minutes) is prepared and maintained so that it is easily retrievable when requested by the Department, rather than requiring that every report routinely be submitted to the Department.

Section G.2. was revised to require only interventional cardiologists to attend a minimum of one Joint QA meeting per year. Previous language required all staff, including nurses and technicians, as well as representatives of the ED and CCU staffs, to attend at least one Joint QA meeting per year.

Section H. Clinical Research was deleted.

Section VI. Operation of the Project, section 1 regarding data collection and submission to Mass-DAC, ACC/NCDR and the Department was deleted as it was redundant to Section V. F. Data Collection.

A new section A was added to refer to the peer review process that is being developed by the group.

Section VII. General Provisions, section B, regarding the regular convening of the special project hospitals, was deleted.

Attachment A, Guidelines for development of a collaboration agreement with a surgery-on-site hospital, was revised as follows:

- The last sentence in the next to last bullet on page 22 ("Each 'trainee' will be paired with tertiary hospital staff person of the same discipline.") was deleted. The last bullet on page 22 (crossing onto page 23) regarding training for second operators was deleted.

- On page 23, the language under bullet 5 (plan for joint development of a QA program) was revised to reflect changes previously discussed in Section V.G. Quality Assurance of the main document, i.e., deleting administrators from the required participants and revising the minimum frequency of meetings to one per year.

Attachment B was deleted. Reporting requirements were revised and included in Section V. F. Data Collection.

Attachment C, the monthly volume report currently submitted to DPH, is now Attachment B. The form was revised to reflect the earlier discussion of reporting requirements. The following items were deleted from the current reporting form:

- Time at ER door
- Time at cath lab door
- TIMI flow on initial angiogram
- Initials of MD performing diagnostic angiogram
- Time of Balloon Inflation
- TIMI flow after angioplasty
- Indicate if patient had 'rescue angioplasty' performed.

The following volume/outcome information will be reported monthly:

- Patient #
- Date
- Initials of MD Performing PPCI
- Indicate if patient in cardiogenic shock
- Patient Outcome (2 outcomes to be reported):
    - death in the project hospital during the index hospitalization or within 24 hours of discharge; and
    - emergency CABG within 24 hours of PCI procedure. The existing definition of 'emergency' remains unchanged.
- Total number of primary PCIs performed during the reporting period
- Median Door to Balloon Time
- Percent of total emergency PCIs with D2B over 90 minutes

Nothing was inserted to replace the former Attachment F (AMI Case Report Forms/Definitions).

Due to the time, it was decided that another meeting will be held to discuss the proposed peer review process. The next subgroup meeting will immediately follow the September 4 ICSAC meeting. Dr. Rosenfield distributed a draft peer review document for review. Comments should be sent to DPH.

The meeting adjourned at 5:10 p.m.