Invasive Cardiac Services Advisory Committee
Percutaneous Coronary Intervention (PCI) Oversight Subgroup Meeting
December 10, 2013
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

ICSAC Member:
James Waters, MD

Madeleine Biondolillo began the meeting at 3:05 p.m. by welcoming everyone and thanking them for volunteering to participate in the important work of this committee. She added that the work around this issue is being closely monitored by the Department of Public Health Commissioner Cheryl Bartlett as well as Secretary John Polanowicz of the Executive Office of Health and Human Services.

Dr. Kugelmass disclosed for the record that he is a partner of a for profit, Limited Liability Corporation that formerly performed peer review of invasive cardiology, but no longer does so. DPH will check with the DPH legal office to see if there is anything that needs to be done other than verbal disclosure.

Dr. Biondolillo announced that she has asked Dr. Marks to chair the subgroup meetings and he has graciously accepted that role.

The members reviewed the proposed future meetings schedule for January through March 2014. Staff will find alternative dates for February and March. The March meeting may be held in Framingham.

The group reviewed slides showing statewide location and number of current cardiac catheterization services (36), sites the perform PCIs and hospitals that only perform diagnostic cardiac catheterization procedures:

- 14 hospitals perform cardiac surgery and PCI
- 12 hospitals perform only diagnostic cardiac catheterization procedures

- 10 non-surgery-on-site hospitals perform emergency PCI (former MASS COMM hospitals and Beverly Hospital)
- 9 non-surgery-on-site hospitals perform non-emergency/elective PCI (former MASS COMM hospitals).

Dr. Biondolillo mentioned that there is one application pending for participation in the primary angioplasty special project. Dr. Marks asked if he needed to recuse himself for the discussion regarding that application. It was noted that this application was submitted under existing guidelines, so actions by the subgroup will not effect that application.

Dr. Biondolillo commented that this group is to consider parameters for performing non-emergency PCI. This group of experts has been convened to assess geographic and economic parity as well as quality and access. She added that she, with Dr. Marks, would like to brief the Commissioner on the direction that this group is going sometime in January.

Dr. Rosenfield presented a draft PCI oversight proposal for discussion that included inter-facility peer review, including review for appropriateness of cases. The Massachusetts Chapter of the American College of Cardiology (MCACC) would take a leadership role. There would be a Coordinating Center. Cases would be randomly selected based on operator volume, i.e., lower volume operators would have a higher percentage of cases reviewed. There would be a standardized online review form. Reports would be sent to an Executive Committee, back to the hospitals and DPH would receive information about outliers. A plan similar to Mass-DAC's Physician Outlier Review Protocol would be developed to address outliers.

Dr. Kugelmass noted that there is a body of law surrounding peer review and perhaps the group should seek advice of outside counsel. He added that how the data are received and where the data go needs to be clarified.

Dr. Biondolillo noted that DPH has a privacy office within the Office of General Counsel and mentioned a process used in the early 2000's for review of maternal/fetal deaths.

Dr. Rosenfield added that this would involve more than the former MASS COMM hospitals.

There was a brief discussion of **t**he Blue Cross and Blue Shield of Michigan Percutaneous Coronary Interventions Collaborative (BMC2 PCI) 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. Dr. Mauri offered to contact Hitinder Gurm, MD, the Project Director. https://bmc2.org/welcome

Dr. Marks raised his concern about physicians coming out of training and performing PCI in community hospitals without oversight or interaction with a tertiary facility. He added that physician participation in any peer review process must be mandatory.

Dr. Resnic suggested that a provider requirement for performing PCI should be that they participate in peer review. He recommended that a preliminary, blinded review could be done at the convenience of the reviewer, but the information needs to be distributed in a secure fashion.

Dr. Mauri stated that review of non-fatal complications, not just mortality, is important. A random sample is needed to audit the data.

Dr. Rosenfield added that there should be review of appropriateness of the procedure.

Dr. Kugelmass raised a concern about unredacted medical records.

Dr. Mauri asked if the point is to review operators or sites. Dr. Biondolillo responded that the Bureau of Health Care Safety and Quality oversees the facilities and the Board of Registration in Medicine, which is within DPH, oversees the physicians. Dr. Biondolillo recommended that we should start with sites. She added that most of the time, problems are a result of a systems issue.

Dr. Mauri asked what are the minimum requirements that we need to audit. She noted that the MASS COMM Trial reviewed ten percent of angiograms. Dr. Resnic commented that we should build off of current surveillance and add a second phase of narrowly defined review.

Dr. Kugelmass asked what are we trying to measure and what are we trying to prevent. He added that you could randomly audit angiograms for appropriateness.

Dr. Rosenfield asked how far we would drilldown.

Dr. Biondolillo responded that the group should continue to think about "post MASS COMM" PCI and how to ensure that good quality care is provided.

Dr. Kugelmass suggested that the oversight can be built in stages. Angiographic review could be done by a core lab, which would be less expensive than paying an individual physician to review. Dr. Rosenfield commented that passing off the review to a core lab is not ownership anymore. Dr. Mauri added that it depends on what you are looking at the angiogram for.

Dr. Biondolillo commented that we need to develop something realistic in terms of implementation, noting that the privacy issue is a huge concern. She added that we are trying to develop a proxy for good quality care in a system that can be applied universally. We also want to build good will in the community.

Dr. Rosenfield noted that a core lab could de-identify angiograms and combine that with a cathPCI report form to distribute in peer review fashion.

Dr. Marks stated that the focus in the past has been on identifying problems, if they exist, but what is missing is the education piece.

Dr. Kugelmass asked what constitutes a problem and what happens when there is a problem? where does it go?

Dr. Biondolillo suggested that one or two members redo the straw man proposal for the next meeting.

Dr. Rosenfield asked if there were buy-in to interfacility. The group agreed there is.

Then discussion then turned to the agenda item regarding refining public reporting. Dr. Resnic presented information related to risk aversion in response to public reporting for PCI. He presented information on mortality trends, including the decline by 21% of in-hospital mortality in Massachusetts from 2003-2010. He presented similar data from New York, where there was a 29% reduction in in-hospital mortality between 1998-2004. He provided additional NY data that showed a 43% reduction during that same period in the PCI treatment of cardiogenic shock. In Massachusetts, between 2003 and 2005 there was a decline in revascularization in patients in cardiogenic shock (43% shock PCI; 37% shock CABG). He presented information from several trials and studies regarding selective utilization and asked if there modifications to public reporting that could mitigate the risk of risk-averse behavior by physicians.

Dr. Mauri noted that public reporting has resulted in lower rates of treatment.

Dr. Resnic proposed the following for consideration:

1. exclude from public reporting, but continue to collect and adjudicate, extremely high risk patients, including:
    a. out of hospital cardiac arrest with impaired neurologic status on presentation
    b. cardiogenic shock on presentation
    c. exceptional risk patients (currently excluded)
    d. compassionate use patients
    e. prohibitive surgical risk patients (Heart Team decision).

    (Dr. Resnic noted that "a" through "d" are already adjudicated almost 100%)

2. mandate a preliminary clinical quality review of any outlier institution to be published in the PCI Quality Report (before the report is published)

3. monitor the rates of treatment of very high risk cases by institution (billing data as denominator).

Dr. Biondolillo asked, with the possibility that an institutional PCI outlier could be identified by Mass-DAC in early 2014, could the group develop a strategy. Perhaps a

time-limited pilot project would be useful and develop a peer review process rather the the process that has been used in the past (i.e., review by the American Medical Foundation).

Dr. Kugelmass supported confirmation by a review before the information goes public.

Dr. Biondolillo recommended that for the next meeting Drs.Rosenfield and Kugelmass work with Dr. Marks to revise the straw man proposal for consideration to use as the Department considers outliers. The proposal should be developed with input from Sharon-Lise Normand at Mass-DAC and should address the risk aversion issues presented by Dr. Resnic. The proposal will be discussed and further refined at the next meeting.

The meeting adjourned at 5:15 p.m.