Invasive Cardiac Services Advisory Committee (ICSAC)
October 25, 2013
2-4 p.m.
Minutes

Members Present:
Madeleine Biondolillo, MD, Chairperson
Clifford Berger, MD
Ralph Morton Bolman, MD
Julie Bonenfant, RN
Daniel Fisher, MD
Jean-Pierre Geagea, MD
Anuj Goel
Aaron Kugelmass, MD
Anthony Marks, MD
Laura Mauri, MD
Sharon McKenna, RN
Karen Nelson
Frederic Resnic, MD
Kenneth Rosenfield, MD

Designee Present:
Ann Lovett, RN (for Sharon-Lise Normand, PhD)

Members Absent:
Alice Jacobs, MD
Sharon-Lise Normand, PhD
James Waters, MD

DPH Staff Present:
Carol Balulescu, Office of General Counsel
Nancy Murphy, Bureau of Health Care Safety and Quality
Kara Murray, Bureau of Health Care Safety and Quality

Others Present:
Jacqueline Dall, MGH Institute of Health Professions
John DiGiorgio, Beth Israel Deaconess Medical Center
Margaret Ekholm, Jordan Hospital
Shoshana Farber, MGH Institute of Health Professions
Andrew Levine, Attorney for Jordan Hospital

Madeleine Biondolillo, MD, Chairperson, began the meeting at 2:10 p.m. with comments welcoming the attendees to this newly convened Committee and proceeded to introductions.

Carol Balulescu of the DPH Office of General Counsel presented the second agenda item regarding the Open Meeting Law. She distributed a copy of the Open Meeting Law Guide, which was prepared by the Office of Attorney General. Members were instructed to review the Guide and complete the "Certificate of Receipt of Open Meeting Law Materials", which is included as the last page of the Guide. The signed forms are to be returned to Nancy Murphy by November 8, 2013. In summarizing the materials, Ms. Balulescu commented that for this public body to comply with the requirements a notice of the meeting must be posted, the group must deliberate in public and may only deliberate when there is a quorum present. For this group of 17 members, a quorum is 9 members. If the committee decides to create a subgroup, the open meeting law requirements apply as well, although a quorum would be a majority of the subgroup members. There will be no remote participation available to this Committee or any subgroups.

Dr. Biondolillo commented that the goal of the group is to have open, fair deliberations and the Department wishes to engage in broad discussion. She then presented additional basic operating rules of the committee. They included:

1) Designees: Should a member be unable to attend a meeting, the member may send a designee, if the member has informed the Chairperson in writing in advance of the meeting. The designee may not vote, nor is a designee counted for the purposes of a quorum. A member may only designate one person as his/her designee.

2) Voting will be done by consensus.

3) A member of the public may only participate in the discussion at the invitation of the Chairperson.

The Department anticipates that the ICSAC will meet at least yearly, but it is likely it will meet more frequently to start. Any subgroups that are created will meet more frequently.

Dr. Biondolillo reviewed the "Guiding Principles for the ICSAC". These include the primary concern of patient safety with decisions reflecting expert consensus on how to prioritize good outcomes and high quality care over time. The goal is to develop recommendations that benefit the system as a whole, not a particular member's interests, using evidence-based decision-making. The Chairperson summarized by stating that quality, access, safety, openness and fairness are at the heart of all communications.

(Laura Mauri, MD joined the meeting at 2:30 p.m. Dr. Biondolillo briefly left the meeting.)

Kara Murray presented the overview of topics to be addressed by the Committee. These include:

- Developing a Model for Oversight/Monitoring of Facilities Performing Percutaneous Coronary Interventions (PCI)
- Volume Minimums
- Expansion of PCI to other facilities.

When Ms. Murray asked if there were additional topics the members might consider, Dr. Rosenfield commented that the current public data reporting should be integrated in the discussion of oversight and monitoring.

(Dr. Biondolillo returned to the meeting. Anuj Goel left the meeting at 2:35.)

Nancy Murphy presented a brief chronology of the Massachusetts cardiac catheterization/PCI regulatory framework. Prior to 1997, cardiac catheterization services were regulated through the Department's Determination of Need (DoN) process. In 1997, the Department adopted hospital licensure regulations for cardiac catheterization services and removed cardiac catheterization from the list of services subject to the DoN process. Under the licensure regulations, only hospitals with cardiac surgery on site may perform PCIs. In 1997, the Department also began the primary angioplasty special project. Through this project certain hospitals without cardiac surgery on site are allowed to perform primary angioplasty on patients presenting with ST-elevation acute myocardial infarction (STEMI).

Subsequent to legislation in 2000 and the recommendation of the Cardiac Care Quality Advisory Commission, the Department adopted hospital licensure regulations that required hospitals performing angioplasty and/or cardiac surgery services to collect and submit outcome data to the Massachusetts Data Analysis Center (MassDAC), using national American College of Cardiology and Society of Thoracic Surgeons' data instruments. Hospitals began submitting the cardiac surgery data in 2002 and the angioplasty data in 2003.

In 2006, the MASS COMM Trial was created. Through this randomized clinical trial, certain hospitals without cardiac surgery on site were allowed to perform non-emergency angioplasty procedures. Harvard Clinical Research Institute (HCRI) oversaw the data collection and monitored compliance with the Trial's protocol. The randomized trial concluded in September 2011. The Trial's Post-Randomization Phase Cohort Study (entering patient data in a registry) ended in July 2013. The participating hospitals have been allowed to continue to perform non-emergency angioplasty under less restrictive inclusion/exclusion criteria, developed by clinical experts. One of the purposes of this Committee is to develop a recommendation to the Department for the monitoring and oversight of PCI.

Dr. Biondolillo reviewed the reporting requirements associated with the current oversight of angioplasty services. The requirements and the collected data vary depending on the hospital characteristics, i.e., provide cardiac surgery, participated in MASS COMM Trial,

or provide primary angioplasty without cardiac surgery on site. She then summarized the challenges associated with this oversight. These include:

- the administrative burden on providers who must submit data to multiple programs;
- the time delay (weeks to months) for receipt of patient data;
- the Department's limited ability to track compliance with explicit program requirements, i.e., inclusion/exclusion criteria; and
- insufficient peer review, including but not limited to problems recruiting reviewers for MassDAC chart adjudication.

Dr. Biondolillo added that the Department would like to eliminate administrative burden where it can, but noted the balance required by the Bureau-wide inspection functions. Department inspectors are not always on site and therefore the Department needs supplemental methods to monitor for safety and quality. In the post-MASS COMM Trial era, the Department hopes there will be active participation in a peer review process.

Dr. Rosenfield commented that the Committee will be setting the precedent for the long term. He noted the review fatigue that members of the MassDAC adjudication committees have experienced and recommended that there should be some compensation for participation on these review committees.

Dr. Resnic commented on the potential for risk aversion, i.e., physicians becoming more averse to taking the highest risk patients, who have the most to gain. This risk aversion affects patient access to care as interventionalists become more conservative. He asked if the group should address risk adjustment.

Dr. Berger suggested that whatever the group recommends, it should be rolled into the MassDAC process for public reporting. Dr. Rosenfield agreed, but added that the process should be provider driven and the American College of Cardiology should be involved.

Dr. Bolman noted that the Society of Thoracic Surgeons is also discussing peer review in lieu of surgeon-specific reporting. The Society should be ready to submit a document to the State in the next month. He agreed that the process should be provider driven.

Dr. Kugelmass commented that smaller communities become insular and interfacility exposure provides education. Random adjudication and peer review is sound.

Dr. Mauri added that one cannot completely adjust for risk and that there needs to be some element of peer review. She agreed that interfacility review is important. She added that there is no way to totally monitor for appropriateness because the review process only evaluates the patients who got the procedure, not those who did not.

Dr. Rosenfield noted there is the Hawthorne effect of peer review, which occurs when an individual changes his or her behavior when he or she knows that it will be reviewed by peers. There is still a question of how to make sure patients are not being left out. Dr.

Mauri suggested one way to assess the issue is to review a sample of acute MI and shock patients and see if they had a PCI or not.

Dr. Marks commented that he would like to see a requirement that hospitals participate in the peer review; that participation is not optional. He suggested a random sampling and open discussion of cases from every hospital performing PCI. Dr. Berger noted that this would require many hours to review.

Dr. Rosenfield commented that UC-Davis has a small group that is paid to perform this type of review. If a facility wants to perform PCI it should be willing to support quality assurance through random sampling. Dr. Kugelmass noted that he has conducted peer review and has considered a way to do this in Massachusetts. He noted that the process should not be punitive, but should be educational. He added that each case may take at least an hour or require multiple reviewers. There needs to be interaction between the peer review function and the enforcement function.

Dr. Resnic summarized the MassDAC committee review process for PCI operators. Any operator identified as an outlier with a higher than expected 3-year mortality rate has his/her case mortalities reviewed. The operator is then accorded one of three levels:

1. review does not indicate identifiable issues in case selection, procedural technique, medical care or follow-up;
2. review does not exclude possible concerns regarding patient selection, technique, errors in judgment or errors in aftercare or follow-up; and
3. review raises serious concerns regarding patient technique, errors in judgment or errors in aftercare.

Information regarding the operators with higher than expected mortality rates is shared with the Department as well as the Board of Registration in Medicine. This system could be replicated at the facility level.

The group reviewed the facility and operator volume minimums in the DPH hospital licensure regulations for cardiac catheterization services and the volume minimum for primary angioplasty performed by hospitals participating in the special project. The Department posed the following questions for consideration relative to volume minimums:

- Should operator/facility experience affect compliance with volume minimums?
- What steps could be taken when an operator/facility fails to meet the volume minimums?

Dr. Mauri cautioned that with volume as a trigger for review, smaller institutions will take longer to reach the volume where identification of a problem would be statistically significant. Dr. Rosenfield suggested that an “equalizer” would be review of a certain percentage of angiograms. There must be a standardized review, incorporating physician competency guidelines, PCI Guidelines and Appropriate Use Criteria. He also added that there must be due process, which may eventually lead to out-of-state review.

Dr. Biondolillo asked the group two questions:
1) Does convening a subgroup to develop a process make sense?
2) Should a subgroup have the authority to make a final recommendation to the Department or should the subgroup bring its recommendation back to the larger committee for discussion?

Dr. Berger asked how many PCI operators perform fewer than 75 PCIs. The Department can provide this number based on FY11 data and will soon be able to provide it based on the FY12 data.

Dr. Resnic stated that there is not clear evidence of a cut point, adding that the number of PCIs is declining nationally. Dr. Fisher added that overall volume is down statewide and nationally. Dr. Resnic added that this impacts the training of new interventionalists. Dr. Biondolillo commented that this issue is not something that this group can address. The focus of the group is the quality of patient care. She added that there is some number of procedures that helps ensure operator competency. Dr. Resnic commented that that number should not be below the national standard, which has recently been lowered from 75 to 50 per year, averaged over a two-year period.

There was a discussion of how these national recommendations are determined and how they must apply to all states, not just the more highly regulated states. Dr. Biondolillo concluded that it is not uncommon to exceed national standards.

Dr. Berger suggested that there should be minimum standards and if an operator falls below the minimum, there should be a review. Dr. Rosenfield suggested that even with an operator who exceeds the minimum volume, a few random cases should be reviewed.

Dr. Geagea commented that the patient should be able to expect uniform quality. Dr. Rosenfield added "with some variation". There was also concern regarding institutional minimums eliminating access to where patients' doctors are.

Dr. Kugelmass noted that institutional volume below the recommended 200 PCIs in a facility that provide access in a remote, rural area is different from an urban institution that does not meet the volume minimum.

Dr. Rosenfield mentioned a (currently embargoed) guideline update for PCI without surgery on site that will likely be available in December.

The group then discussed the third issue that the Committee will address: expansion of PCI to other facilities.

Regarding emergency PCI, Dr. Berger commented that the majority of emergency angioplasty patients do not arrive by ambulance, but walk in to the emergency department. A transfer to a PCI-capability facility can take an hour. He added that an emergency PCI program, which must provide coverage 24/7, is unsustainable without the facility also being able to perform non-emergency PCI procedures. He also said that it

may not be necessary for a facility to have experience performing primary PCI before it is allowed to perform non-emergency angioplasty – that a program for starting both was possible.

Dr. Biondolillo added that we need to consider this in the context of federal/state cost containment and accountable care organizations.

Dr. Resnic suggested that that might blur the issues and it is up to the systems to navigate the changing environment. Ms. Bonenfant asked if the Committee would consider lower standards based on a system's needs, not necessarily considering distance to another provider of the service. Dr. Rosenfield added that more programs mean more dilution of the existing services. Dr. Resnic asked two questions:

1) Does geographic isolation affecting patient access warrant a new primary angioplasty service? If the facility can maintain the volume, he suggested it probably is warranted.

2) Should a facility providing primary angioplasty have the ability to mature into providing non-emergency angioplasty procedures?

Dr. Berger commented that it is not viable for a facility to just perform primary angioplasty.

Dr. Marks asked who will make the final decision. Dr. Biondolillo responded that the Commissioner will decide.

Dr. Rosenfield added that recent data show that door-to-balloon time may not be as critical to outcomes. Based on that data, do we need PCI in every rural area?

Dr. Biondolillo brought the discussion back to how do we provide appropriate PCI oversight? How do we structure the process, including peer review and public reporting? She asked if the full Committee needed to meet again or should a subgroup develop a proposal and bring it back to the Committee?

Dr. Rosenfield suggested that there should be an Oversight Subgroup that would also address how to deal with lower volume. Subsequent to review of the subgroup's recommendation the Committee could determine if a separate subgroup was needed to address volume.

Dr. Biondolillo asked for a motion to create a subgroup for oversight. Dr. Rosenfield made the motion. The motion was seconded by Dr. Berger. The Committee voted unanimously to form the Oversight Subgroup. Committee members were instructed to email Nancy Murphy if they are interested in participating in the subgroup.

The meeting ended at 3:48 p.m.