Invasive Cardiac Services Advisory Committee (ICSAC)
April 17, 2014
3:30-5:30 p.m.
Minutes

Members Present:
Madeleine Biondolillo, MD, Chairperson
Clifford Berger, MD
Julie Bonenfant, RN
Anuj Goel
Alice Jacobs, MD
Aaron Kugelmass, MD
Anthony Marks, MD
Laura Mauri, MD
Frederic Resnic, MD
Kenneth Rosenfield, MD
James Waters, MD

Members Absent:
Daniel Engelman, MD
Daniel Fisher, MD
Jean-Pierre Geagea, MD
Sharon McKenna, RN
Karen Nelson
Sharon-Lise Normand, PhD

Department of Public Health (DPH) Staff Present:
Carol Balulescu, Office of General Counsel
Nancy Murphy, Office of Health Planning
Darrell Villaruz, Office of Health Planning

Others Present:
Edward Loughery, MD, Beverly Hospital
Lorraine O'Grady, Mass. Chapter ACC Administrative Office
William Pezzolo, Donoghue Barrett & Singal
Liz Tassinari, RN, Beverly Hospital

Madeleine Biondolillo, MD, Chairperson, began the meeting at 3:44 p.m., when a quorum was in attendance. She welcomed everyone to this second meeting of the Committee and proceeded to introductions.

She then reviewed the agenda for the meeting, noting that Carol Balulescu of the DPH Office of General Counsel would be presenting agenda item number 4, Conflict of Interest, instead of Alexandra Rubin, who had been scheduled to present this topic.

Dr. Biondolillo reviewed the operating rules for the Committee meeting. She noted that any votes other than approval of the previous meeting's Minutes would be done by consensus. She welcomed the participation and commentary from the members of the public in attendance, but reminded the group to limit comments to the issues under consideration by the Committee.

Dr. Biondolillo reviewed the members' Guiding Principles, including the prioritization of patient safety as the primary consideration in all decision-making, use of evidence-based decision making, the sharing of knowledge and making recommendations that members believe will benefit the system as a whole, and making decisions that reflect expert consensus on mechanisms to effect high quality care and best outcomes at all times. The issues are being viewed on a macro level and do not reflect on current providers or facilities.

Dr. Biondolillo noted that the Commissioner of DPH is well aware of the time the subgroup has spent working on their recommendations, which are critical for health planning particularly in light of federal and state cost containment efforts. She thanked Dr. Marks for his leadership of the subgroup, the subgroup members for their contributions, as well as Dr. Waters, who also attended some of the meetings and participated in the discussions.

Moving to agenda item three, Dr. Biondolillo asked if there were any comments on the October 25, 2013 ICSAC meeting Minutes. Hearing none, she asked for a motion to approve the Minutes. Dr. Berger made the motion to approve the Minutes and Dr. Resnic seconded the motion. The Minutes were unanimously approved.

Attorney Carol Balulescu then presented information on the Conflict of Interest Law. She distributed a summary of the law and asked the members to complete the acknowledgement of receipt (the last page of the document) and return it to Nancy Murphy. The members are considered special state employees, so certain restrictions/prohibitions that would apply to regular state employees, such as having a second paid job if the responsibilities of the second job are incompatible with the state job, do not apply. Attorney Balulescu addressed the appearance of a conflict. She stated that when dealing with general matters, members are not required to recuse themselves from the discussion. She noted that members are always able to abstain from a discussion and vote if they feel uncomfortable. They do not need to indicate why they are abstaining. She closed by stating that members may call the State Ethics Commission directly to confidentially discuss any concerns they may have about a potential conflict of or appearance of a conflict of interest. Attorney Balulescu is also available for consultation. Members may contact her through Nancy Murphy or Dr. Biondolillo.

Dr. Biondolillo reviewed the membership of the PCI Oversight Subgroup, their charge and their meeting schedule. They met four times since the last ICSAC meeting. She again thanked the members for their time and the energy they brought to the discussions.

Dr. Biondolillo reviewed the number of cardiac catheterization services by type (i.e., with cardiac surgery on site, perform non-emergency angioplasty, perform primary angioplasty, perform diagnostic cardiac catheterization procedures only) in Massachusetts. She noted that there is one hospital with a diagnostic only cardiac catheterization service that has an application pending with DPH to provide primary angioplasty. The application was filed in October under the existing guidelines. However, because PCI policy was in development, it has been made clear to that hospital that there is no guarantee that a mechanism or process to apply to provide non-emergency angioplasty will be available to the hospital.

There was a brief discussion of the nine of twelve diagnostic only services that perform well below the minimum diagnostic volume required in the DPH hospital licensure regulations. Dr. Jacobs asked why these hospitals are allowed to continue to provide this level of service. Dr. Biondolillo responded that it is difficult to close a service unless there are significant quality issues identified. It was noted that none of these hospitals have applied to perform primary angioplasty.

Dr. Biondolillo reviewed the statewide maps of cardiac catheterization services by type that the Committee saw at their last meeting. Dr. Biondolillo reviewed the total statewide PCI volume from 1998 through 2012. There has been a twenty-seven percent decrease in PCI volume between the peak volume in 2005 and 2012 (most recent DPH volume available).

Dr. Biondolillo noted that the PCI Oversight Subgroup reviewed the recent consensus document on PCI without on-site surgical backup that was issued jointly by the Society for Cardiovascular Angiography and Interventions (SCAI), American Heart Association (AHA) and the American College of Cardiology Foundation (ACCF). The subgroup specifically reviewed Tables V and VI regarding case selection and patient and lesion characteristics that could be unsuitable for non-emergency procedures at facilities without cardiac surgery on site. The subgroup agreed that nothing in those tables conflicted with the inclusion/exclusion criteria for non-emergency angioplasty for the former MASS COMM non-surgery-on-site hospitals that DPH issued in July 2013.

Dr. Biondolillo also highlighted the language from the consensus document that the Subgroup included in its Coronary Angioplasty Services Background document that had been distributed to the ICSAC. In the consensus document the SCAI/AHA/ACCF reaffirmed language from the 2011 ACCF/AHA/SCAI PCI Guidelines that "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site surgery…"

Dr. Biondolillo presented state fiscal year 2012 and 2013 PCI volume from Mass-DAC data. The hospitals were de-identified. These data show several hospitals below or slightly above the 200 PCI volume minimum in the hospital licensure regulations. It should be noted, however, that the inclusion/exclusion criteria for the former MASS COMM community hospitals were broadened beginning in August, 2013. As a result, PCI volume at those sites will likely increase in fiscal year 2014.

Dr. Biondolillo presented operator PCI volume as well for fiscal years 2012 and 2013. The DPH hospital licensure regulations include an operator PCI volume minimum of 75 PCIs per year, consistent with previous national guidelines. The most recent national guidelines recommend a minimum of 50 PCIs per year, averaged over two years. Using Mass-DAC data, sixty-eight percent of the operators in Massachusetts who performed PCI procedures performed seventy-five or more PCIs in both fiscal years 2012 and 2013. Eighty-four and seventy-nine percent performed forty-five or more PCIs per year in fiscal years 2012 and 2013, respectively. Dr. Biondolillo summarized that the total volume of PCI procedures is dropping and this is having an impact on institutional as well as individual operator volume. She added that DPH does have risk mitigation strategies in place.

Dr. Biondolillo presented a map of Massachusetts indicating the areas that are within 15 miles of a PCI-capable hospital. Fifteen miles was used as a surrogate for a thirty minute ambulance ride. Approximately eighty-six percent of the Massachusetts population lives within 15 miles of a PCI-capable hospital. Dr. Kugelmass commented on western Massachusetts, where many people live in excess of fifteen miles from a PCI-capable hospital. Because of local highway access, i.e. the Mass. Turnpike, he noted that the blue circles (indicating access) could be extended further to the east and west of Springfield. Baystate Medical Center serves the Pittsfield area with the STEMI program. He indicated that with that in mind the estimated eighty-six percent statewide access may be closer to ninety or ninety-two percent. The North Adams/Williamstown area and near the Quabbin Reservoir, which limits highway access, remain outside an area with timely access to a PCI-capable hospital.

Dr. Biondolillo commented that the Secretariat is conducting state health planning, which involves looking at inventory, capacity and determining unmet needs. An important factor in health planning is consideration of geographic idiosyncrasies such as those noted by Dr. Kugelmass.

Dr. Rosenfield noted that thrombolytics are probably available to ninety-nine percent of the population. Dr. Kugelmass added that western Massachusetts has an acute MI program, where data are shared with the emergency rooms and local EMS. Through this sophisticated network using ‘lytics’ and direct transfers for STEMI patients with standardized communication protocols, he added, they achieve 90-120 minute door-to-balloon times.

Dr. Biondolillo then asked Dr. Marks, who chaired the subgroup, to present the Background to the Coronary Angioplasty Services Proposal. Dr. Marks stated that the

document reflects the work of the whole subgroup and was reviewed line by line. The focus was patient safety and consideration of the other guiding principles as outlined earlier in this meeting. The document was drafted with an understanding of and attention paid to the national guidelines. The subgroup also has an understanding of the volume issues and that there is a relationship between volume and outcomes. He reviewed the historical context of cardiac catheterization services in Massachusetts and how they have evolved over the past twenty years, from an innovative service subject to the DPH Determination of Need Regulations, to a service regulated through hospital licensure regulations, to the primary angioplasty special project and then the MASS COMM Trial that have brought angioplasty procedures to certain community hospitals. He reviewed the General Considerations, including decreasing PCI volume and the impact any new programs would have on existing programs and the need for ongoing monitoring of the PCI programs. He then reviewed the proposal's requirements for all hospitals providing PCI.

Dr. Biondolillo then presented the Specific Recommendations of the subgroup. She noted that there was consensus that PCI quality and outcomes are affected by volume. She reiterated that potentially more than eighty-six percent of the Massachusetts population has reasonable access to PCI. With the volume decreasing and agreement that any new programs would further dilute the volume of existing programs, the subgroup put forward recommendation one that **"there is currently no demonstrable need for additional emergency or non-emergency PCI programs in the Commonwealth, and that any additional PCI centers would have an adverse impact on the existing quality of PCI performed in the Commonwealth."**

Part two of the recommendation states that **if there are changes to the current state of PCI volume or services in Massachusetts** (that is, conditions that potentially create a "need"), any new PCI programs should be considered solely on the basis of evaluating a patient-based need assessment through a comprehensive review of:

a. Geographic need for PCI services, through a demonstration of lack of availability of emergency PCI services within a 30 minute ambulance drive from the proposed facility and a facility that currently provides this service;
b. A detailed program proposal to DPH which would assure quality and safety of the PCI procedures performed at the proposed center; and
c. An impact assessment, to be performed by DPH and in conjunction with the ICSAC, to assess the potential impact of any new PCI program on existing PCI programs in Massachusetts, in terms of quality, safety and procedural volumes.

Dr. Biondolillo asked if there were any comments or concerns, or if anyone disagreed with the recommendations.

Mr. Goel asked if part two of the recommendation contradicted part one.

Dr. Resnic commented that the ICSAC makes a recommendation to DPH, but the Department retains its authority to allow waivers, e.g., for a geographically isolated population. Dr. Biondolillo agreed with Dr. Resnic that the Department always has the

right to waive one of its requirements in the interest of patient needs. She added that the recommendations are not in opposition, and that there might be a time or circumstance that *for the reasons of patient access or safety* - not for market share, not being about a new ACO - that a new program might be considered. Recommendation number 2 creates a mechanism for the Department to look at such a case.

Dr. Jacobs asked how the Department would make a decision on timely access to primary PCI.

Dr. Marks said they would assess the impact on institutional volume when you are looking at eighty-six percent of the population that have timely access to primary angioplasty.

Dr. Rosenfield commented that, for example, in northwestern Massachusetts, if Baystate Medical Center wanted to set up a program and rotate staff through, that would increase access. Dr. Biondolillo noted that in western Massachusetts there is a clinical care network involving medical therapy in lieu of PCI due to geographical isolation and relatively limited access to the service. Dr. Jacobs added that the network will not go away, but the funding will. Dr. Kugelmass responded that Baystate is doing the data collection for the network services in western Massachusetts. Dr. Rosenfield added that his point was in that corner of the state, there may be some benefit to adding a service if there is a mechanism to enact it.

Dr. Biondolillo reminded the group that the recommendation mentions there is no *demonstrable* need. Mr. Goel sought clarification that that would mean despite the recommendation, if a hospital thinks there is a need it could present its case. Dr. Biondolillo clarified:

1) The current state is that there is no need for new PCI programs. She added, that being said, anyone can make a request to DPH if circumstances change such that need becomes demonstrable, i.e., population growth, nearby programs closing, etc.

2) If there are changes to the current volume or PCI services or if there is demonstrable geographic need for emergency PCI services, Recommendation #2 outlines the process for DPH, in conjunction with the ICSAC, to assess the impact of a proposed center on existing programs.

Dr. Marks stated that the subgroup had considered the concern of the difficulty of providing a STEMI program without the financial support provided by additional non-emergency procedures.

Julie Bonenfant asked if only the northwest part of the state would be able to make a case of geographic need, when according to the map, areas of less than optimal access appear to exist on the Cape. The group agreed that the northwest part of the state was only used as an example of where there might be geographic need.

Dr. Kugelmass added that in populated areas, transport times are often faster than the 30 minute (15 miles on the map) window. The map is a representation.

Dr. Biondolillo then asked for a consensus vote. She asked if anyone disagreed with recommendations one and two, which stated:

1. Therefore, based on the issues noted above, it is the opinion of this committee that sufficient access to emergency and non-emergency PCI care exists today in the Commonwealth via the high concentration of PCI-capable hospitals, particularly in eastern Massachusetts. The current low average volume performed at PCI hospitals in Massachusetts significantly challenges the capability of these centers to maintain adequate technical experience for staff. Therefore, it is the opinion of the ICSAC PCI Subcommittee that there is currently no demonstrable need for additional emergency or non-emergency PCI programs in the Commonwealth, and that any additional PCI centers may have an adverse impact on the existing quality of PCI performed in the Commonwealth.

2. If there are changes to the current state of PCI volume or services in Massachusetts, new emergency and/or non-emergency PCI programs should be considered solely on the basis of evaluating a patient-based need assessment for PCI services through a comprehensive review of the following:
    a. Geographic need for PCI services, through a demonstration of lack of availability of emergency PCI services within a 30 minute ambulance drive from the proposed facility and a facility that currently provides this service;
    b. A detailed program proposal to the DPH that would assure quality and safety of PCI procedures performed at the proposed center; and
    c. An impact assessment, to be performed by DPH and in conjunction with ICSAC, to assess the potential impact of any new PCI program on existing PCI programs in Massachusetts, in terms of quality, safety and procedural volumes.

No members disagreed. The recommendations were unanimously approved.

Dr. Resnic then presented the Background for agenda item 5b – Refinement of PCI Public reporting Parameter and Recommendations. He acknowledged the subgroup. He acknowledged the benefits of the current reporting of risk adjusted outcomes. Through this proposal the subgroup does not wish to dilute the benefits of the current Mass-DAC data collection, adjudication and analysis.

Based on the long term track record with public reporting that Massachusetts and New York have, the subgroup agreed with the evidence that risk aversion is real and has a detrimental effect on patients who might benefit most from high risk PCI but do not undergo the procedure.

Dr. Resnic referred to the SHOCK Trial, in which New York became an independent risk factor for mortality for patients presenting in cardiogenic shock. He added that we do not know about patients who do not receive the treatment. According to a 2013 AHA scientific statement, there is a low rate of early angiography despite clear evidence of ischemia.

Other data from Massachusetts have shown a decline in patients *treated* in cardiogenic shock. In addition, that only academic medical centers have been identified as negative outliers indicates a limitation of the hierarchical methodologies that require a certain volume. These centers are also not able to transfer patients out. If a community hospital transfers a PCI patient to a tertiary facility and the patient dies at the tertiary facility, the death is not attributed to the community hospital, but to the tertiary facility where the patient died. It has been hard to define what the quality issue is for the outliers. The question therefore is is the signal robust enough on its own?

Dr. Biondolillo presented the following two recommendations to strengthen the PCI public reporting process:

1. *Continue to collect, adjudicate, analyze and interpret PCI clinical outcomes data for ALL PCI cases, as is done today*. These internal Mass-DAC analyses would be shared with the DPH on a regular basis to identify trends and potential outliers for further investigation. However, the publicly released Mass-DAC PCI quality report, should exclude (from "numerator" and "denominator") all patients at uniquely high risk, that are poorly controlled for in any risk-adjustment methodology.

   Specifically, all patients presenting with the following diagnoses should be adjudicated, and if verified, excluded from the analysis used in the preparation of the PCI public 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 PCI 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.

2. Prior to the release of the annual PCI public report, and after the exclusion of the extreme risk cases as noted in item #1 above, any institutional "negative outlier" would be thoroughly reviewed by an external independent programmatic peer review organization (e.g., American Medical Foundation (AMF) or Accreditation for Cardiovascular Excellence (ACE)), with the context of their findings regarding the

presence (or absence) of an underlying clinical quality issue included in the PCI public report.

Dr. Biondolillo noted that while Massachusetts has an excellent system for the purposes of quality improvement we must always take a look at the process. With experience over time we can refine the approach to ensure we are driving toward quality outcomes.

Dr. Biondolillo again thanked the PCI Oversight Subgroup for their thoughtful consideration. She noted that the impact of recommendation number one (excluding approximately 3.3% of the total PCI patients from the public report) is included on page two of the Background information. She added that although Dr. Normand of Mass-DAC was unable to attend today's meeting, she has been apprised and is aware of the recommendation.

She asked for comments from the group. Dr. Jacobs stated that in New York, for OHCA with impaired neurologic status, only neurologic death patients were excluded. Dr. Mauri commented that the proposal is to exclude these patients on presentation; you do not know the ultimate cause of death on presentation. Dr. Jacobs stated that there are known characteristics that are associated with little chance for neurologic recovery in patients with OHCA. With public reporting, if futility is involved, the physician is less likely to take the patient to the cath lab which is appropriate. Dr. Rosenfield commented that this involves a small number of patients. Dr. Berger commented on the subtlety of cardiovascular versus neurologic death, adding that most trials default to cardiovascular death. Dr. Jacobs added that the New York data criteria for neurologic death were well done. She accepted no change to the recommendation, aware that this is not a major issue, but thought it was important to discuss and emphasize when NOT to perform PCI. The committee agreed.

Dr. Rosenfield raised the issue of different definitions for cardiogenic shock, e.g., ACC and Mass-DAC's guidance. Based on the discussion, an edit was suggested for recommendation 2b to add "as previously defined by Mass-DAC" to the end, so that the recommendation would read:

> b. All patients presenting with ***Cardiogenic shock (CGS)*** at the start of the PCI procedure, as previously defined by Mass-DAC.

Dr. Rosenfield also sought clarification that this was a recommendation to the Commissioner and was a guideline that could be changed.

Dr. Jacobs supported the recommendation, but asked that the meeting Minutes reflect that the committee is cognizant that this may increase the number of patients that may be taken to the cath lab that should not be. Operators should be "mindful of futility". In addition, she noted that similar to the recommendation in the AHA scientific statement concerning public reporting and OHCA, these patients should be carefully analyzed even though not publicly reported.

Dr. Rosenfield asked if it would be appropriate to add a preamble to ensure the operator consider whether it was appropriate to take the patient to the cath lab, i.e., to consider futility.

Dr. Marks noted that there are similar general statements about appropriateness mentioned.

Dr. Rosenfield noted that overutilization in that group is pretty small. Dr. Mauri added that it is not that they will not be analyzed, they just will not be in the public report.

Dr. Rosenfield asked, although Mass-DAC is listed throughout the document, what happens if another entity performs the data collection and analysis for the Department.

Dr. Biondolillo responded that we are talking about current circumstances but guidelines can reflect a change.

The group agreed that "or its successor entity" should be added after the first use of Mass-DAC in the recommendation. Dr. Biondolillo asked for a consensus vote. With that change made, there was no disagreement with the recommendations. The recommendations were unanimously approved.

Dr. Biondolillo reviewed the upcoming priorities of the PCI Oversight Subgroup. The subgroup will review the primary angioplasty special project guidelines for revisions. Dr. Marks added that this is a very dated document that needs to be rewritten. Dr. Biondolillo solicited any thoughts on the guidelines and welcomed members to attend the subgroup meetings.

Dr. Rosenfield made a brief comment on the peer review proposal. As noted in the July 2013 DPH letter closing out the MASS COMM Trial, there is to be additional oversight of all PCI hospitals, not just those without surgery on site. The oversight will be built in the spirit of quality improvement. The next work is to determine how to construct an interfacility peer review program and eliminate unnecessary variation among operators.

Dr. Biondolillo offered her thanks on behalf of the Commissioner of DPH. She added that there will likely be another ICSAC meeting in June, with a couple PCI Oversight Subgroup meetings before that.

The meeting adjourned at 5:30 p.m.