Invasive Cardiac Services Advisory Committee (ICSAC)
Percutaneous Coronary Intervention (PCI) Oversight Subgroup Meeting
March 3, 2014
5-7 p.m.
Minutes

Attendance

Subgroup Members:
Cliff Berger, MD
Aaron Kugelmass, MD
Anthony Marks, MD
Laura Mauri, MD
Frederic Resnic, MD
Kenneth Rosenfield, MD

Department of Public Health (DPH) Staff:
Nancy Murphy
Tammy Thomas

Although there was a quorum present at 5:00, the start of the meeting was delayed to wait for the arrival of two other members of the subgroup. Madeleine Biondolillo, MD was not able to attend this meeting. Nancy Murphy began the meeting at 5:22 pm by welcoming everyone and ensuring everyone had the necessary materials.

Anthony Marks, Chairperson of the Subgroup, then addressed the first agenda item: Review/Approval of the February 6, 2014 Meeting Minutes. The Minutes were unanimously approved.

The conversation then proceeded to the second agenda item: Guidelines for non-emergency angioplasty. The discussion focused at first on the FY2012 cardiac catheterization service volume data (de-identified by hospital) that had been distributed prior to this meeting, as was requested at the last meeting. It was noted that there are four programs performing over 1000 PCIs and several in the 500 range (total PCI). Of the four performing fewer than 200 PCIs, three perform a good number of ST- Elevation Myocardial Infarction (STEMI) PCI procedures.

Cliff Berger asked if any of the facilities are relatively new to performing PCI. Ms. Murphy responded that the most recent approval for primary PCI was in 2010. Four of the ten community hospitals performing PCI perform fewer than 200 PCIs. Ms. Murphy noted that the 2012 volume precedes the end of the MASS COMM Trial Post-Randomization Cohort Phase. According to Mass-DAC PCI volume data for July-September 2013, which was annualized and compared to the DPH FY12 volume for the former MASS COMM community hospitals, it is estimated that there was a 17% increase in the PCI volume at these hospitals in FY13. The group agreed this seemed as expected, in part due to the broadening of the inclusion/exclusion criteria and patients no longer deciding not to have a PCI at the community hospital due to the chance of being randomized to the tertiary facility (as occurred during the Trial).

Aaron Kugelmass noted that the 17% increase is not exactly "a gold rush". He commented on the 'cannibalization' of existing programs that would occur with new programs, adding that the it could come from the lower volume hospitals. He raised the concern of dilution of volume.

Dr. Berger asked where do you draw the line?

Dr. Kugelmass asked what the goal was of opening additional non-emergency PCI programs back in 2006. Was it to improve access?

Laura Mauri responded that it was in part to support primary PCI at these sites. It was agreed that the rationale was partly academic, economic, and driven by patient centeredness. The result was that these lower volume centers drew volume from the higher volume centers.

Dr. Mauri noted that the subcommittee's goal is to counsel DPH regarding what is in the best interest of patients and how to ensure safety, access and better outcomes. She added that looking at patients pre-MASS COMM and under the MASS COMM Trial there was not a big shift in how far patients had to travel.

Dr. Marks moved to agenda item 2b. regarding a plan for mapping. Ms. Murphy provided preliminary maps that DPH is developing regarding PCI services and Mass. population as well as rates of PCI, based on 2010-2012 hospital discharge data. Dr. Berger noted that non-emergency PCI patients who are not admitted will not be included in these data.

Dr. Berger offered to provide the American Heart Association maps showing regional transport times/distances.

Dr. Marks then turned the group's attention to the page two of the draft "Recommendations" document, asking for comment on the paragraph stating there is sufficient access to non-emergency PCI care.

Dr. Mauri asked about the dynamic of the western part of the state. Dr. Kugelmass explained that the population west of the Quabbin Reservoir is shrinking and aging. He added that nobody in the western half of the state is not getting timely angioplasty. A program in the far western portion is not viable. They do not have the volume to support a program, but nobody is not able to get care, although it may be a little further away.

(Dr. Rosenfield arrived at 5:35 p.m.)

The question is do we need more programs, is there a lack of primary PCI? There is rapid access and transport and a well-developed system for STEMI and reperfusion. It may be acceptable for certain rural areas to have a low annual volume, but there is no area in Massachusetts that is "very rural", especially considering programs in neighboring states. Is a program needed to benefit the population or is it needed to pursue a hospital's economic rights?

(Dr. Resnic arrived at 5:45 p.m.)

Dr. Berger commented that the concern is whether the existing programs will suffer.

Dr. Rosenfield asked if an existing cardiac surgery program is closed, should that hospital still be able to provide non-emergency PCI? He recommended that the guidelines should have a paragraph about that. This would be shifting volume from the categorization of an SOS to a non-SOS site, but not diluting volume at other sites.

Dr. Rosenfield asked if perhaps every hospital should have to reapply for non-emergency angioplasty; that every hospital should have an equal chance to respond to a Request for Proposal, for example. Dr. Marks responded that there was a process in which the program were chosen and demonstrated ability to provide the service.

Dr. Mauri recommended that that issue be taken off the table. Dr. Rosenfield responded that he is playing devil's advocate; that he does not necessarily agree that each hospital should have to apply, but thinks it should be acknowledged in the guidelines and say that the group does not think it is appropriate. It is up to a new hospital to prove it can meet the criteria.

Dr. Kugelmass noted that if the issue is access, there is no reason to open a new program within 20-30 miles of an existing program. Dr. Berger asked why patients should travel 30 miles.

The group then discussed hospital systems issues and people choosing to stay within the system or not for non-emergency procedures.

The overriding concern is dilution of volume leading to a decrease in quality and safety. The group then proposed developing a two-part recommendation:

1. Currently, there is no need for additional programs; there are concerns about dilution of volume leading to safety and quality concerns; there are no access issues.
2. Circumstances that would allow a new program. Must address:
    a. Access – lack access within 30 minutes to an existing angioplasty center (including neighboring state programs) and
    b. Quality and Safety – achieving sufficient volume (meet volume minimums) to sustain the program, and an impact assessment - regional and statewide effect on quality and safety; cannot adversely affect other PCI programs.

The group discussed "within 30 minutes travel time via emergency ambulance", which had been included in the 2008 STEMI point of entry guidelines, and would be about 20 to 30 miles. The thirty minutes is consistent with the first patient contact to balloon time of 30-60-90 minutes.

The group agreed that there are a large number of low volume angioplasty centers in Massachusetts and any additional programs within 30 minutes run the risk of diluting volume and negatively effecting quality and safety.

Dr. Berger recommended that we need to summarize the volume data for the ICSAC showing that 40% (4/10) of non-SOS hospitals perform fewer than 200 PCIs. Dr. Rosenfield added that it is important to have 2013 data. These data, which Mass-DAC should have, will reflect the volume impact of the end of the MASS COMM Trial.

Dr. Kugelmass suggested that the language in a recommendation state that DPH will follow current society volume guidelines and not include a specific volume number, for that number in the guidelines may change.

Dr. Marks added that the argument flips if a hospital proves it can perform 200 PCIs per year: it doesn't bring any benefit, it is not favorable for the entire state, and is detrimental for quality and safety.

The group recommended limiting primary PCI if within 30 minutes of existing programs.

In summary:

1) Volume is important and here is the volume (include table). The issue of diluting volume of existing programs (whether SOS or non-SOS programs) is important.
2) Access is not an issue. Thirty minutes (i.e., what an ambulance can travel in 30 minutes) is reasonable access for elective procedures.

The group will not address in their recommendation hypotheticals about the island hospitals. This will address on an ad hoc basis if one of the hospitals presents a request.

Dr. Berger recommended including data regarding operator volume to the ICSAC, e.g., what percent of interventionalists perform fewer than 75 procedures, 60 procedures, 50 procedures. Dr. Rosenfield suggested requesting the raw per site and per operator PCI numbers from Mass-DAC for 2013.

Dr. Marks then walked the group through the Proposal section of the Guidelines. The group agreed to:

1) delete items 2 and 3, addressing new primary and non-emergency PCI programs;
2) revised the language in item 8a. regarding credit for experienced 'second operators', limiting them to no more than 20 credited procedures per year; and
3) revised the language in item 9 regarding the peer review process to be developed and deleting language about payment.

Ms. Murphy will incorporate the subgroup's edits into the guideline document. Dr. Resnic will revise the recommendation document. DPH will distribute the edited documents to the subgroup for comment to be returned to DPH. If there is agreement on the draft proposal and recommendations another meeting of the subgroup will not be needed before it is presented to the ICSAC for consideration.

Dr. Resnic then asked to comment on the Mass-DAC system that has evolved since its inception. He noted that there are duplicative data submissions to NCDR and Mass-DAC that require two separate files, two sets of software and the associated costs. He commented on the reporting cycle issues, e.g., national death indices available two months later than optimal for Mass-DAC's schedule, so they cannot wait for them. He commented on the hurdles to share confidential information, resulting in meetings not being held outside of Mass-DAC's offices.

Dr. Rosenfield added a concern about the publication issue, ownership of the data and shifting costs to the proposer.

Dr. Resnic will draft a document for review at a future meeting.

Ms. Murphy asked the group about availability for an ICSAC meeting in April. The members are available for the proposed date of April 17 from 3-5:00 p.m.

The meeting adjourned at 7:15 p.m.