

Minutes of Meeting

Tertiary Care Advisory Committee

Date: 21 August 2007

Time: 1:00 PM

Location: Conference Room 401

ATTENDANCE:

Council: Present: Gregory Allen, DO, John Flynn, Catherine Graziano, RN. PhD, Sam Havens, Robert S.L. Kinder, MD, Joan Kwiatkowski, Gus Manocchia, MD, Robert J. Quigley, DC (Chair), Ed Quinlan

Staff: Valentina D. Adamova, Jay Buechner, PhD, Michael Dexter, Linda M. Tetu-Mouradjian, RN, Donald C. Williams and Harvey Zimmerman

Public: (see attendance attached)

1. Call to Order and Approval of Minutes

The meeting was called to order at 1:00 PM. The chairman noted that the conflict of interest forms were available to any member who may have a conflict. A motion was made, seconded and passed by a vote

nine in favor and none opposed to approve and accept the 17 July 2007 minutes.

The Chairman requested a motion for the extension of time for the availability of minutes pursuant to the Open Meetings Act. A motion was made, seconded and passed by a vote nine in favor and none opposed that the availability of the minutes for this meeting be extended beyond the time frame provided for under the Open Meetings Act. Those members voting in favor of the motion were: Allen, Flynn, Graziano, Havens, Kinder, Kwiatkowski, Manocchia, Quigley and Quinlan.

2. General Order of Business

The Chairman announced that representatives from area hospitals would be presenting information on their experience in providing Primary Percutaneous Coronary Intervention services. He then introduced the first of two speakers David O. Williams, MD representing Lifespan. Dr. Williams presented information on the current knowledge of Acute Coronary Occlusion and Lifespan's experience with this condition. Topics covered included: The Pathogenesis of ST Elevation MI's (STEMI), The Impact of Reperfusion and the Influence of Duration of Occlusion, Selection of Patients for Primary Catherization Intervention (PCI), PCI versus Fibrinolysis, Change in Care Patterns, Expected Outcomes and The STEMI PCI Center at Lifespan.

During his presentation Dr. Williams emphasized a number of important factors that needed consideration when performing emergency PCI procedures including: when fibrolytic therapy was combined with PCI, results were instantaneous, it took seconds to open occluded arteries and reduce cardiac damage, additionally the use of cardiac catheterization allows physicians to observe a patient's response to the intervention as you can see what is happening. However he emphasized the significance of watching the "clock" with respect to from the time a patient walks in the door to balloon time. He stressed that heart attack size is related to patient outcomes.

Dr. Williams also talked about treatment for acute MI from a historical perspective beginning with lytic therapy. He stressed that although lytic therapy is important in reducing mortality from acute MI it was fraught with risks and guess work. Some risks mentioned were bleeding and stroke (disability). Additionally for lytic therapy to be effective it needs to be infused within 30 minutes and takes 90 minutes to take effect. Unlike primary PCI, physicians had to guess whether the therapy was effective.

Dr. Williams noted that ACC/AHA guidelines state when possible primary PCI is preferred under appropriate circumstances especially where angioplasty is available over fibrolysis. PCI is preferred over lytic therapy as a treatment strategy when it can be done in a timely fashion and in an institution where all the support services are

available. A member asked Dr. Williams whether the information he presented was consistent with the current ACC/AHA guidelines. He stated they were. He also pointed out that the mortality relationship to outcome was dependent on the patient's symptoms and the time that had lapsed from symptom onset to balloon inflation which if prolonged increases the risk of mortality. The acceptable range at present from door to balloon time is 90 minutes.

Dr. Williams stated that primary PCI was the more current practice used for STEMI patients compared to fibrinolysis because it yields better clinical outcomes. He stressed that institutions should choose one method (primary PCI or lytic therapy) over the other but not both. One of his reasons for advocating choosing one intervention over the other was due to the intensity of setting up primary PCI services in hospital settings. Policies and procedures must be written, enforced and continuously improved based on objective data collection and analysis. Some factors to consider include: which patients are eligible for primary PCI procedures (some or all STEMI patients) and what time frames from door to balloon must be implemented.

In addressing the time from door to balloon issues, Dr. Williams pointed out that there were several ways patients arrived at the hospital ED which included walk-ins, driven by family, sent by other hospitals, and 911 rescue. Additionally he stressed the point that it is imperative to diagnose and get eligible patients to the cardiac

catherization lab within 90 minutes. He stated performing primary PCI is protocol driven. That essential consistency is important and a level of competence is equally important throughout the entire patient encounter. He stressed that a primary PCI program must be monitored through data collection and analysis with constant feedback to providers for quality assurance and compliance.

Dr. Williams also emphasized that to perform primary PCI required a highly trained and skilled group who were familiar with handling emergency PCI and managing the complications of Myocardial Infarction. In addition he stated that hospitals interested in performing primary PCI would need an operating committee that oversees the operation and executes continuous performance monitoring with the team, ED, and EMS staff. At Lifespan (RIH) primary PCI performance indicators showed poor results in 2004 yet in 2005 all (100%) of the primary PCI procedures performed were under 120 minutes. Currently the time allowed for primary PCI is 90 minutes from door to balloon inflation.

Dr. Williams stressed that EMS plays a major role in assessing and reporting MI patients' cardiac status and EKG changes to ED physicians during the course of rescue and transport to the hospital. In addition, Dr. Williams mentioned that he was working with The Miriam Hospital and Sturdy Memorial Hospital in Attleboro to develop primary PCI interventions for those sites and AHA mission lifeline and that the program was working very well with respect to treatment

times including EMS transport.

The Chairman asked Dr. Williams about the type of staff required to perform primary PCI. Dr. Williams stated that it requires a team working 24/7 and the ability to get into the hospital within 30 minutes from the time of the call. He pointed out that team members who consist of ED physicians and coronary care staff trained to care for acutely ill patients carries a designated pager and cell phone and must be able to arrive at the hospital within 30 minutes of receiving the call. The PCI catheterization lab must be available and door to balloon inflation time currently (90 min) is of the essence. He stated the whole process is protocol driven and essential consistency is important as well as a level of competence which is a continuous process.

H. Zimmerman asked how long the catheterization procedure took. Dr. Williams answered generally about 1-2 hours however it is case dependent. S. Havens asked what the relationship was regarding volume to quality outcomes. Dr. Williams stated that for PCI alone 200 cases, STEMI 50 cases yet for Rhode Island Hospital it is over 200 cases. S. Havens brought up the issue regarding the importance of active EMS involvement in these types of cases.

Dr. Williams stated that there was a huge benefit to having EMS involved with patient care early in these cases due to the time savings. Once an EKG is performed on the patient, communications

between ED doctors and EMS can facilitate treatment prior to arrival at the ED. Dr. Williams stated that he and others had provided an education program for EMS last year and that they are equipped to perform the necessary tasks. The Chairman stated that the TCAC made recommendations involving EMS participation in the aforementioned situations 5-6 years ago, and may need to make them again.

The Chairman introduced the second speaker Samuel Shubrooks MD, Administrative Director, Cardiac Catheterization, Lab, Associate Professor of Medicine Harvard Medical School. He presented topics related to Volume versus Quality related to Primary PCI from the Landmark Medical Center (LMC) experience. This included Cardiology Services at LMC, LMC Cardiac Catheterization Laboratory Procedures, Primary PCI Outcomes, Principles for Establishing a PCI Program for Acute STEMI, Percent Door to Balloon Time, Limitations to the Use of Procedural Volume as Measurement of Quality, PCI Operators, New York (NY) State PCI Registry (1998-2000), NY State and Florida Registries 2001, and the ACCF/AHA/SCAI (2007) Update of the Clinical Competence Statement in Cardiac Interventional Procedures.

Dr. Shubrooks pointed out that LMC as of January 2007 had the ability to provide 24/7 Primary PCI services to the community. In addition he explained in detail the elements that are necessary to establish a Primary PCI program. He stated that planning and proper catheterization and imaging facilities were important factors. In addition

to equipment, technologists, nursing staff trained in coronary care, ancillary support and facilities, an experienced catheterization lab director and cardiac surgery back-up were the primary factors that were essential to providing this service.

He stated other considerations would include designing a well thought out plan for transporting patients needing surgical cardiac procedures if on site surgery was not available. He added that the percentage of patients needing urgent cardiac surgery is low about (.5%). Additionally, he added when dealing with acutely ill patients with complications other medical specialties may be needed. He pointed out that other factors that are essential in developing a Primary PCI program would include initial case selectivity, an ongoing QA and review of cases and outcomes, and comparison of outcomes with national benchmarks for example the National Cardiac Data Registry.

He emphasized that high volume hospitals and high volume operators who perform over 75 procedures per year did better overall but high volume operators alone have lower mortality rates in terms of outcomes. He stressed that according to the ACCF/AHA/SCAI (2007) update that procedural volume is a poor substitute for quality and outcomes and it should not replace well controlled analysis of the results and does not ensure quality. There should be an ongoing institutional and operator maintenance of quality. He suggested that participation in a state, regional or national registry is encouraged to

allow measurement of risk adjusted outcomes and compare them with national benchmarks.

S. Havens asked about the current need for consumer transparency regarding Medicare and other payers who are demanding more information and the need to give consumers more data to base their medical decisions. Dr. Shubrooks stated there is a large debate currently in Massachusetts for hospitals to make public reports available to consumers. Dr. Shubrooks stated that he and others are committed to deal with hospitals that are outliers and mentor physicians.

Dr Williams stated that two years ago, in New York, there was a suit related to a hospital on Long Island that released a public report with misinformation. It caused consumers in New York to leave and find surgeons out of state. He said there are no intentional covers ups but a lot of misinterpretation of reports that need to be addressed. This incident resulted in physicians selecting less sick patients to care for when the information in New York became public.

Dr. Williams said he thought it was fair to look at the performance of institutions not individual operators and to look at outliers in the state and country regarding outcomes. J. Kwiatkowski asked both presenters about tracking performance issues and outcomes of surgeons who perform procedures in multiple institutions. Dr. Shubrooks responded that both hospital and operator data are

available. In addition he stated that lead physicians should mentor operators experiencing problems. J. Kwiatkowski asked how many cardiac catheterization labs were at Lifespan and LMC. Dr Williams for Lifespan responded that there were four, and Dr. Shubrooks responded that LMC had two.

Adjournment

The next meeting of the TCAC will be held on September 18, 2007 at 1:00 PM in Room 401. There being no further business the meeting was adjourned at 2:30 PM.

Respectfully submitted,

Linda M. Tetu-Mouradjian, RN