MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CARDIAC CATHETERIZATION
STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Thursday, October 19, 2017

South Grand Building
333 S. Grand Ave,
1st Floor, Grand Conference Room
Lansing, MI 48933

APPROVED MINUTES

I. Call to Order

Chairperson David called the meeting to order at 9:30 A.M.

A. Members Present:

Ernest Balcueva – American Heart Association
Shukri David, MD, Chairperson – Ascension | Michigan
Simon Dixon, MD – Beaumont Hospital
Hitinder S. Gurm, MD – University of Michigan
Henry E. Kim, MD – Henry Ford Health System
Ryan D. Madder, MD – Spectrum Health
Theodore L. Schreiber, MD – Detroit Medical Center
Kristopher J. Selke, DO – Mercy Health & St. Joseph Mercy Health System
Ibrahim Shah, MD – McLaren Greater Lansing
Sunita Vadakath, MD – MidMichigan Health

B. Members Absent:

Lynne F. Carter, MD – Blue Cross Blue Shield of Michigan
Michele L. Davis – Electrical Workers' Joint Board of Trustees

C. Michigan Department of Health and Human Services Staff present:

Tulika Bhattacharya
Amber Myers
Beth Nagel
Tania Rodriguez

II. Declaration of Conflicts of Interests

No conflicts were declared.

III. Review of Agenda

Motion by Dr. Schreiber, seconded by Dr. Kim to approve the agenda with the following changes: Remove both agenda items V. and remove VI. and both will be deferred until next meeting. Motion Carried.

IV. Review and Approval of September 14, 2017 Minutes

Motion by Dr. Schreiber, seconded by Dr. Kim to approve the minutes as presented. Motion Carried.

V. Discussion of Compliance in regard to Physicians having to demonstrate 100 diagnostic procedures.

Dr. Madder presented on the topic. (See Attachment A)

Discussion followed.

Motion by Dr. Madder, seconded by Dr. Selke to accept the language changes on the presentation slide (slide #5) with one change: under Section 10(2)(f)(iii), include "sessions" after "catheterizations." Motion Carried in a vote of 10- Yes, 0- No, and 0- Abstained.

Motion by Dr. Schreiber, seconded by Dr. David to add a requirement that each physician doing diagnostic-only left heart catheterization sessions and/or coronary angiography must perform 50 sessions per year and where not met, the local institution would initiate a robust quality oversight process. If a physician is doing right heart only procedures, then they are not required to meet this volume requirement. Motion Carried in a vote of 7- Yes, 3- No, and 0- Abstained.

VI. Discussion of Charge #7: Consider requirements for replacing a cardiac catheterization service from on existing licensed hospital to another existing licensed hospital.

Dr. Shah presented on the topic. (See Attachment B)

Discussion followed.

Motion by Dr. Shah, seconded by Dr. Gurm to make the addition to the standards as presented. Motion Failed in a vote of 1-Yes, 9 - No, and 0- Abstained.

VII. Next Steps

Madder, Dixon, Gurm will form a small sub-committee to bring back a recommendation regarding Therapeutic Cardiac Catheterization volume requirements and exclusion of certain procedures in Section 10(2)(d).

VIII. Future Meeting Dates

November 9, 2017 & December 20, 2017.

IX. Public Comment

None.

X. Adjournment

Meeting adjourned at 12:17 P.M.

Attachment A

SPECTRUM HEALTH

Physician Volumes:

Issues Raised During Cardiac Cath Compliance Reviews

Dr. Ryan Madder, MD, FACC
Section Chief, Interventional Cardiology
Medical Director, Cardiac Cath Lab
Frederik Meijer Heart & Vascular Institute
Spectrum Health

Review

Department has been reviewing all Cardiac Cath programs across the State to determine if they are in compliance with ALL of the Project Delivery Requirements in the Standards.

Through this process we have learned how some provisions of the Standards are interpreted and will be enforced.

Believe some provisions in the Project Delivery Requirements need modifications to ensure appropriate and consistent enforcement.

Physician Volume Requirements: Diagnostic

"Sec. 10(2)(f) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physicians:

- (i) are trained consistent with the recommendations of the American College of Cardiology;
- (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
- (iii) have each performed a minimum of **100** adult diagnostic cardiac catheterizations in the **preceding 12 months**"

Problems with the current diagnostic requirements

- Confusion by the Department on what this section actually requires
- Lack of clarity regarding “other evidence” of appropriate training
- No scientific data to support an annual minimum volume of 100 diagnostic cardiac caths

2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update
A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents

3.5.1.1 Operators Performing Diagnostic Procedures
Because of the low risk of diagnostic cardiac catheterization, it is difficult to arrive at any consensus as to what would constitute a minimum caseload. There are no data supporting the prior recommendation of at least 150 diagnostic cases per year (1). Previously, this has been simply convention. The minimum laboratory diagnostic caseload may vary widely depending on arbitrary requirements such as the presence of the CON process or state department of health regulations. It falls upon the director of the laboratory to ensure that all cardiac catheterization studies are appropriately indicated, performed, and interpreted (76). A maximum number of procedures that an operator should be performing is also controversial, an area where there are essentially no data. This emphasizes the dependence on the QA process to monitor physician and laboratory behavior appropriately.

Physician Volume Requirements: Diagnostic

"Sec. 10(2)(f) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if ~~the~~ these two staff physicians:

- (i) are trained consistent with the recommendations of the American College of Cardiology;
- (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
- (iii) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding 12 months"

The annual case load for a physician means adult diagnostic cardiac catheterization procedures performed either during a diagnostic-only session or during a therapeutic session by that physician in any combination of hospitals.

Physician Volume Requirements: Therapeutic

"Sec. 10(2)(d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, a minimum of 50 adult therapeutic cardiac catheterization procedures per year in the second 12 months after being credentialed to and annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals."

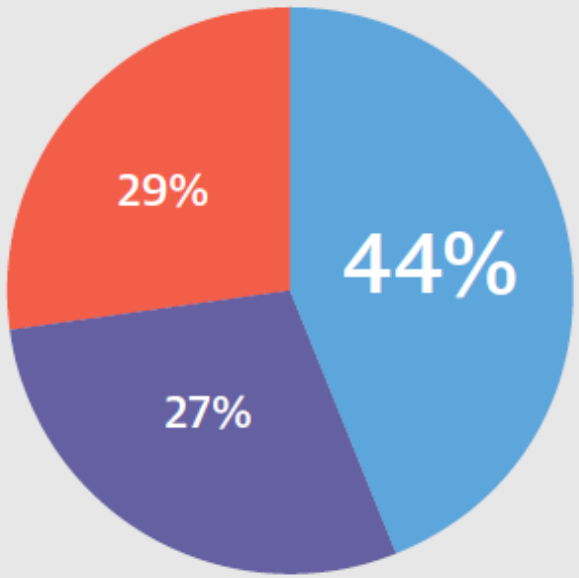
CENTRAL ILLUSTRATION Procedure Characteristics and In-Hospital Outcomes by Operator Volume

Attachment A

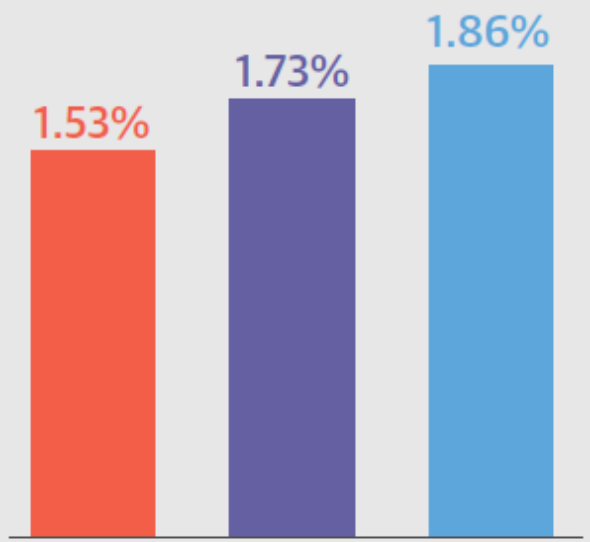
Percutaneous Coronary Intervention (PCI) operator procedure volumes, mortality rates, and characteristics

- High-volume operators: > 100 PCIs/year
- Intermediate-volume operators: 50–100 PCIs/year
- Low-volume operators: Under recommended minimum of 50 PCIs/year

Breakdown of operator groups



Mortality following PCI (%)



Characteristics of low-volume operators:

- Operated at lower volume hospitals
- More frequently performed emergency PCI and PCI for STEMI
- Less frequently used radial access
- Greatest volume of contrast dye; longest fluoroscopy times

Fanaroff, A.C. et al. J Am Coll Cardiol. 2017;69(24):2913-24.

Nearly one-half of all operators were low-volume operators (performed <50 percutaneous coronary interventions [PCI] per year). Compared with intermediate- (50 to 100 PCIs per year) and high-volume operators (>100 PCIs per year), low-volume operators worked at lower volume hospitals, performed more emergency PCIs and primary PCIs for ST-segment elevation myocardial infarction (STEMI), less frequently used radial access, and used more radiographic contrast dye and fluoroscopy minutes. Although in-hospital mortality was low (1.6% overall), it was higher for low- and intermediate-volume operators than for high-volume operators.

Therapeutic

Physician Volume Requirements:

Current language provides no opportunity for a facility to take appropriate action when a physician falls below volume without being automatically considered out of compliance.

Does not provide an opportunity for an exception under appropriate circumstances

- Retirement
- Medical leave
- Maternity/paternity leave
- Leadership positions

Utilizing an average over 3 years would provide some flexibility to account for a low year.

Physician Volume Requirements: Therapeutic

"Sec. 10(2)(d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, ~~a~~ an ~~minimum~~ average of at least 50 adult therapeutic cardiac catheterization procedures per year averaged over the most recent 3 years starting in the second 12 months after being credentialed. ~~to~~ ~~and~~ This three year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals. For physicians who are retiring out of the catheterization laboratory, these physicians will be exempt from maintaining a minimal therapeutic procedural volume of 50 annual cases for the final two years of their career."

CCSAC Charge #7

Ibrahim Shah, MD, FACC
McLaren Greater Lansing

Charge # 7

- Consider Requirements for replacing a cardiac catheterization service from one existing licensed hospital to another existing licensed hospital

Background

- Almost all of the 15 covered clinical services except Cardiac Catheterization Services and Open Heart have replacement language that allows facilities to replace within a certain mile radius.
- This will allow the department to maintain consistency and uniform application of the standards across every modality.

Proposal for charge # 7

- An applicant proposing to replace an existing Cardiac Catheterization Service to a new site shall demonstrate the following:
  1. The existing Cardiac Catheterization Service to be replaced has been in operation for at least 36 months as of the date an application is submitted to the Department.
  2. The proposed new site is a hospital licensed under Part 215 of the Code.
  3. The Proposed new site is within 10-mile radius of the existing site.
  4. The existing Cardiac Catheterization Service to be replaced performed at least the applicable minimum volume requirement set forth in Section 10(4) on the date an application is deemed submitted by the department.