MICHIGAN DEPARTMENT OF COMMUNITY HEALTH (MDCH)
CARDIAC CATHETERIZATION
STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Thursday November 6, 2014

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call to Order

Chairperson Turner-Bailey called the meeting to order at 9:34 a.m.

A. Members Present:

Renee Turner-Bailey, Chairperson, International Union, UAW
Luay Alkotob, MD, Hurley Medical Center
Duane DiFranco, MD, Blue Cross Blue Shield of MI
Georges Ghafari, MD, Beaumont Health System
Ginny Latty, Covenant Healthcare
Brahmajee Nallamothu, MD, University of Michigan Health System
Meg Pointon, UAW Retiree Medical Benefits Trust
Fadi Saab, MD, Metro Hospital Frank Tilli, MD, Genesys Regional Medical Center
Frank V. Tilli, MD, Genesys Regional Medical Center
Douglas Weaver, MD, Henry Ford Health System
David Wohns, MD, Spectrum Health
Karen Yacobucci, Allegiance Health

B. Members Absent:

None.

C. Michigan Department of Community Health Staff present:

Tulika Bhattacharya
Sallie Flanders
Natalie Kellogg
Beth Nagel
Tania Rodriguez

Brenda Rogers

II. Declaration of Conflicts of Interests

No conflicts were declared.

III. Review of Minutes October 8, 2014

Motion by Ms. Pointon and seconded by Dr. DiFranco to approve the minutes as presented. Motion Carried.

IV. Review of Agenda

Motion by Ms. Yacobucci and seconded by Dr. Saab to accept the agenda as presented. Motion Carried.

V. Proposals Developed by Sub-Committee

Ms. Yacobucci gave an overview of the document drafted by the various sub-committees (see Attachment A).

A. CCSAC Discussion of Proposals

Discussion followed.

Break from 11:00a.m. - 11:21 a.m.

Motion by Dr. Difranco and seconded by Dr. Ghafari to add patient safety and quality criteria for elective PCI which includes:

a. The number of patients treated with and without STEMI
b. The proportion of PCI with emergency CABG or required emergent transfer
c. Risk and reliability adjusted patient mortality for both STEMI and non-STEMI procedures
d. PCI appropriate use in elective-non acute MI cases
e. Rates of ad-hoc multi-vessel PCI procedures in the same session

The language will also be inserted within the CON Cardiac Catheterization Standards so it applies to all facilities that apply for initiation of services. Language will also be added in the project delivery requirements requiring the Department to request BMC^2 (or like organization) recommendation for a slate of objective quality metrics to include, but not necessarily be limited to those listed under patient safety and quality criteria together with a threshold value for each metric, representing minimally acceptable performances for the year. If the Department does not receive the slate of objective quality metrics

and thresholds within 60 days of request then the Department will defer to the measures listed in the standard and place the performance threshold at a level of the 25th percentile. The Department will notify facilities who fail to meet the metric thresholds and require the facilities to:

a. Submit a corrective action plan within three months of notification
b. Demonstrate that performance has improved to meet or exceed all applicable objective quality metric thresholds within 12 months.
c. The Department will take compliance action as deemed appropriate per the public health code MCL 333.22247.

Allow for de-coupling of open heart surgery services with PCI and include language that supports initiation of elective PCI if the facility already has primary PCI services, or meets geographical criteria listed as follows:

a. That at least 50% of the projected PCI cases will be performed for patients residing at least 60 miles from any existing adult therapeutic cardiac catheterization services, or;
b. That that at least 75% of the projected PCI cases will be performed for patients residing at most 60 miles from only a single existing adult therapeutic cardiac catheterization service.

The motion failed in a vote of 6 - Yes, 6 - No, and 0 - Abstained.

Results as follows:

Renee Turner-Bailey- Yes
Luay Alkotob, MD- Yes
Duane DiFranco, MD- Yes
Georges Ghafari, MD- Yes
Ginny Latty, - No
Brahmajee Nallamothu, MD- No
Meg Pointon - No
Fadi Saab, MD- Yes
Frank V. Tilli, MD- No
Douglas Weaver, MD- Yes
David Wohns, MD- No
Karen Yacobucci- No

B. Public Comment

Dennis McCafferty, Economic Alliance for Michigan (EAM)
Stephen LeMoine, Oakwood Heart and Vascular

Motion by Dr. Weaver and seconded by Dr. Saab, to add the following patient safety and quality criteria for elective PCI:

a. The number of patients treated with and without STEMI
b. The proportion of PCI with emergency CABG or required emergent transfer
c. Risk and reliability adjusted patient mortality for both STEMI and non-STEMI procedures
d. PCI appropriate use in elective- –non -acute MI cases
e. Rates of ad-hoc multi-vessel PCI procedures in the same session

This language should also be inserted within the CON Cardiac Catheterization Standards so that it applies to all facilities that apply for initiation of services and all current facilities will be subject to the new reporting criteria when they apply for expansion or replacement. Language will also be added in the project delivery requirements requiring the Department to request that BMC^2 (or like organization) recommend a slate of objective quality metrics to include, but not necessarily be limited to those listed under patient safety and quality criteria together with a threshold value for each metric, representing minimally acceptable performances for the year. If the Department does not receive the slate of objective quality metrics and thresholds within 60 days of request then the Department will defer to the measures listed in the standard and place the performance threshold at a level of the 25^{th} percentile. The Department will notify facilities who fail to meet the metric thresholds and require the facilities to:

a. Submit a corrective action plan within three months of notification
b. Demonstrate that performance has improved to meet or exceed all applicable objective quality metric thresholds within 12 months.
c. The Department will take compliance action per MCL 333.22247.

Allow for de-coupling of open heart surgery with PCI and include language that supports initiation of elective PCI if the facility already has primary PCI services or meets the geographical criteria listed as follows:

a. That at least 50% of the projected PCI cases will be performed for patients residing at least 60 miles or 60 minutes from any existing adult therapeutic cardiac catheterization services, or;
b. That at least 75% of the cases projected will be performed for patients residing at most 60 miles or 60 minutes from only a single existing adult therapeutic cardiac catheterization services.

The motion carried with a vote of 9 - Yes, 3 - No, and 0 - Abstained.

Results are as follows:

Renee Turner-Bailey- Yes
Luay Alkotob, MD - Yes

Duane DiFranco, MD - Yes
Georges Ghafari, MD - Yes
Ginny Latty, - No
Brahmajee Nallamothu, MD - Yes
Meg Pointon - Yes
Fadi Saab, MD - Yes
Frank V. Tilli, MD - No
Douglas Weaver, MD - Yes
David Wohns, MD - No
Karen Yacobucci - Yes

VI. Next Steps and Future Agenda Items - December 17, 2014

Ms. Nagel stated that the Department has some technical issues with the language as it was proposed and passed. The Department will come back with some alternate proposals that aim to keep the same concepts, but operationalizing it in a different way.

Chairperson Turner-Bailey stated that at the December 17, 2014 meeting the committee members will be reviewing the language that the Department brings back. The SAC will present their recommendations at the March 2015 Commission meeting.

VII. Public Comment

VIII. Future Meeting Dates –- December 17, 2014

IX. Adjournment

Motion by Dr. DiFranco and seconded by Dr. Weaver to adjourn the meeting at 1:16 p.m. Motion Carried.

CARDIAC CATHETERIZATION SERVICES

STANDARD ADVISORY COMMITTEE (SAC) Draft Charge

Approved by the CON Commission Chairperson as delegated by the CON Commission on January 28, 2014

(original charge in black; consensus in red
proposal 1 in blue; proposal 2 in green)

At a minimum, the Cardiac Catheterization Services SAC should consider reviewing and recommending any necessary changes to the Cardiac Catheterization Services Standards regarding the following:

1. Determine if elective therapeutic cardiac catheterization's **(limited to PCI's)** should be allowed at facilities that do not provide on-site open heart surgery services by considering the recommendations of national organizations.

   Cost and Access do not suggest that there is a need. Research indicates that Quality is not compromised when these services are provided without open heart surgical back up.

   Vote: Decouple (in favor/opposed)

   If it is recommended that the services should be allowed:

   a. consider the impact of cost, quality and access under the current standards in **determining need** for this service;

Proposal 1	Proposal 2
The following shall replace the existing Section 3(2)(d) respecting requirements for initiation of adult therapeutic cardiac catheterization services: The applicant shall project a minimum	**Launch a PILOT program (Duration 3 years) allowing the 14 primary angioplasty sites (plus any facility with Open Heart Surgery that wants to close their OHS program) that are currently in**

of 200 Adult PCI procedures in the category of adult therapeutic cardiac catheterizations (PCI) based on data from the most recent 12-month period preceding the date the application was submitted to the Department. **Respecting these projected PCIs, the applicant will further project that either of the following two requirements will be satisfied based on these same data:** 1. **That at least 50% of the projected PCI cases will be performed for patients residing at least 60 miles from any existing adult therapeutic cardiac catheterization service, or;** 2. **That at least 75% of the projected PCI cases will be performed for patients residing at most 60 miles from only a single existing adult therapeutic cardiac catheterization service.**	**good standing with regards to their quality metrics and outcomes to perform elective angioplasty without surgical back up (This will be determined based on their outcomes reported in BMC2). The current proposal is designed to address topics discussed in CON meetings. Multiple cardiology bodies accept the metrics addressed in this document.** **Allow current Primary PCI programs (14 institutions), plus any facility with Open Heart Surgery that wants to close their OHS program, to Pilot an elective angioplasty program with the current conditions: (see quality and safety section)**

Vote: Access Criteria (in favor/opposed)If majority vote is in favor of access crotieria- Motion to approve proposal 1

Vote: 14 Primary PCI and OHS closing are the only eligible for expansion (Pilot) (in favor/opposed)

b. Provide specific criteria for this service including:

Initiation and Maintenance Volumes;

i. *A minimum of 200 procedures per year to initiate and maintain elective PCI without open heart surgical back up (previously approved through SAC Committee vote)*

ii. *Single operator minimum volume of 50 procedures per year over 2 years (previously approved through SAC Committee vote)*

iii. Operators must be at least 2 years out of fellowship

As well as Patient Safety and Quality Criteria

i. All centers must have a quality program with internal QI processes monitoring patient selection and procedures.
ii. All hospitals must have a transfer protocol and emergency plan in place for patient transfers.
iii. Each hospital with an approved CON for primary PCI and/or elective PCI (upon upgrade or expansion) shall report to the MDCH as part of their annual hospital survey, the following information from their most BMC2 (or like registry/quality monitoring program) report at its sole expense:

Proposal 1	Proposal 2
Information collected and utilized internally by this program should include: **a. The number of patients treated with and without STEMI** **b. The proportion of PCI patients with emergency CABG, risk-adjusted acute kidney injury, or post procedure stroke;** **c. Risk-adjusted patient mortality for both STEMI and non-STEMI procedures;** **d. PCI in–hospital risk adjusted rate of bleeding events** **e. Median post–acute LOS for PCI patients with STEMI** **f. PCI appropriate use in**	**Quality metrics will be determined by the quality sub-committee**

elective-non acute MI cases	

Vote: Quality Sub-Committee determines metrics (in favor/opposed)
Vote: Minimal recommended set approved and updated by BMC2 (or like organization) (in favor/opposed)

iv. Each institution will identify a physician champion as the contact point for the BMC2 or like organization.

v. **Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements will conform with SCAI/ACC consensus document. Each facility will bear the sole expense of demonstrating compliance with these criteria in their application.**
Vote: SCAI/ ACC compliance demonstrated in application for new elective programs and renewals (in favor/opposed)

2. Develop language for a second acquisition, similar to that of other standards.

Consistent with previous recommendations above.

3. Develop specific measurable quality metrics in the project delivery requirements similar to that of Open-Heart Surgery (OHS) standards.

	Proposal 1	Proposal 2
i.	**Annually, Michigan Department of Community Health will request of BMC2 (or like organization) a recommendation for a slate of objective quality metrics – to include, but not necessarily be limited to those listed under "Patient Safety and Quality Criteria" section above – together with a threshold value for each metric, representing minimally acceptable performance for the following**	**Quality metrics will be determined by the quality sub-committee** **Clinical and anatomical consideration to exclude patients from elective angioplasty without surgical backup:** **a. Patients with decompensated heart failure** **b. Patients with advanced**

year. ii. If MDCH does not receive the requested slate of objective quality metrics and thresholds within 60 days of request, then MDCH will use the following thresholds and metrics: performance at a level of 25th percentile on each metric listed under "Patient Safety and Quality Criteria" section above. iii. MDCH will notify hospitals who fail to meet any of the minimally acceptable objective quality metric thresholds. MDCH will require these hospitals to: a. Submit a corrective action plan within <u>three (3)</u> months of notification b. Demonstrate that performance has improved to meet or exceed all applicable objective quality metric thresholds within <u>twelve (12) months</u> of notification. iv. MDCH will revoke the CON of hospitals that fail to meet the requirements set forth in iiib.	malignancy and life expectancy less than 1 year c. Patients with recent hemorrhagic stroke (Less than 8 weeks). d. Patients who are unable to tolerate antiplatelet therapy e. Patients with unprotected Left main disease f. Patients that may require hemodynamic support prior to the start of the procedure as decided by the clinician In case any center fails to provide adequate response or adhere to quality measures as defined by the quality sub-committee, the state will be notified.

Deliberate and create motion on quality Vote: (in favor/opposed)

Vote: MDCH actions related to those hospitals who fail to meet any of the minimally acceptable quality thresholds: (in favor/opposed)

iv. If the hospital does not meet minimum state standards with respect to <u>Appropriate Use Criteria</u>, as measured by BMC2 (or like organization), the center will be notified immediately. The

physician champion will be responsible to lead the efforts to develop and submit an action plan **as outlined in iiia and iiib.**

Pediatric language will be incorporated as identified in the document distributed by Renee Turner-Bailey.

4. Consider any technical or other changes from the department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

These adjustments have previously been recommended and approved by Department of Michigan staff related to definitions and geographies.