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

Wednesday July 16, 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 9:32 a.m.

A. Members Present:

Renee Turner-Bailey, Chairperson, International Union, UAW
Luay Alkotob, MD, Hurley Medical Center
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
Douglas Weaver, MD, Henry Ford Health System
David Wohns, MD, Spectrum Health
Karen Yacobucci, Allegiance Health

B. Members Absent:

Duane DiFranco, MD, Blue Cross Blue Shield of MI

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 June 18, 2014

Motion by Ms. Yacobucci and seconded by Dr. Weaver to approve the minutes as presented. Motion Carried.

IV. Review of Agenda

Motion by Dr. Alkotob and seconded by Dr. Wohns to accept the agenda as presented. Motion Carried.

V. Presentation on Michigan Cardiac Catheterization

Paul Delamater, Michigan State University (MSU) gave an overview and analysis of the current Cardiac Catheterization Services within the state of Michigan (see Attachment A).

VI. Sub-Committee Updates

A. Science and Prevalence

Dr. Ghafari gave a presentation on the science and prevalence of PCI (see Attachment B).

Discussion followed.

Break from 11:12 a.m. – 11:28 a.m.

B. Quality & Access

Ms. Yacobucci gave an update on the sub-committee's initial findings and discussion.

C. Cost

Dr. Saab gave an overview of the initial findings of the cost sub-committee (see Attachment C).

VII. Public Comment

Dennis McCafferty, Economic Alliance for Michigan (EAM)

VIII. Next Steps and Future Agenda Items

Dr. Brahamajee has a contact at University of Michigan who works with BMC^2 and will work on a presentation including the matrix and data reported to BMC^2.

Dr. Wohns is working with Dr. Greg Dehmer who has given a verbal commitment to speak to the SAC and is trying to target the September meeting date.

IX. Future Meeting Dates - August 14, 2014, September 10, 2014, October 8, 2014, November 6, 2014, and December 17, 2014.

Ms. Rogers gave an overview of the process of making recommendations and drafting language.

X. Adjournment

Motion by Dr. Nallamothu and seconded by Dr. Wohns to adjourn the meeting at 12:24 p.m. Motion Carried.

Cardiac Catheterization
Review and Analysis

Paul L. Delamater

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E-mail: delamate@msu.edu

Executive Summary

This document provides background information on Cardiac Catheterization, focusing on utilization and access in Michigan. The intended purpose is to provide the Michigan Department of Community Health (MDCH), the Certificate of Need (CON) Commission, and the Cardiac Catheterization Standard Advisory Committee (SAC) with information that will assist them in determining whether to modify the Review Standards, most notably on the issue of whether therapeutic cardiac catheterization (more narrowly, elective Percutaneous Coronary Intervention (E-PCI)) should be allowed at facilities without onsite Open Heart Surgery (OHS) services.

Geographic access to diagnostic and therapeutic cardiac catheterization services appears, currently, to be quite high for Michigan's adult population. Currently, 96% of Michigan's adult population has 60 minute (travel time) access to diagnostic services, while 93% have 60 minute access to primary and elective PCI services. 84% of the state's adult population has 30 minute access to a diagnostic service location, while 78% and 75% have 30 minute access to primary PCI and elective PCI locations, respectively. If the Review Standards were modified such that the 14 facilities without OHS services were allowed to perform E-PCI procedures, the gains in access would be minimal. Slightly greater than 83% of the state's adult population would experience no gain in access to E-PCI services. Further, less than 1% of Michigan's adult population would have an increase in access of more than 20 minutes.

Overview

Cardiac catheterization, as defined in the CON Review Standards, is *a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart.* Diagnostic catheterization is largely an information retrieval procedure, although it is also used to administer medication. Therapeutic catheterization is differentiated via the presence of an interventional procedure such as a percutaneous coronary intervention (PCI) while the catheter is in place. Therapeutic catheterization procedures can be further subdivided into those that are considered *primary* (P-PCI), which are performed on patients experiencing an acute myocardial infarction with confirmed ST elevation (also referred to as STEMI patients) and those that are performed on an *elective* basis (E-PCI) for non-STEMI patients.

Michigan has regulated cardiac catheterization services via the CON Program since 1985. Presently, cardiac catheterization services are categorized into 3 distinct levels of service: diagnostic, primary therapeutic, and elective therapeutic. Each level of services has unique and specific service requirements. Prior

to 2003 in Michigan, therapeutic catheterization procedures were not separated into primary/elective and could only be performed at facilities having open heart surgery (OHS) services. However, a provision was added in the 2003 update of the Review Standards (effective August 4, 2003) allowing facilities with diagnostic cardiac catheterization service, but not having an OHS service, to perform P-PCI procedures if they met specific volume requirements and medical service/staffing conditions. Although P-PCI may now be performed at non-OHS facilities in Michigan, E-PCI procedures continue to be constrained to facilities having OHS services.

A Standard Advisory Committee (SAC) has been seated to review the Cardiac Catheterization Standards. Although the SAC has multiple charges, the charge that appears to be of most interest to Michigan's greater medical community is an examination of whether the Review Standards should be modified to allow elective therapeutic procedures at facilities without onsite OHS services. This document provides information in an effort to assist the SAC and CON Commission in making their decision regarding this potential change (as well as other possible revisions to the Review Standards).

Regulatory Environment

34 states regulate PCI services without onsite surgical backup (OHS) via a CON *or* state health department [1]. Currently, 36 states have some form of CON Program with 26 states specifically regulating cardiac catheterization services [2]. Michigan is one of only five states that currently prohibit E-PCI at facilities without onsite OHS services (see Figure 1). Of these five, Michigan, along with Maine, New Mexico, and South Carolina, does allow P-PCI procedures to be performed at some or all facilities without OHS services. Vermont is the only state that does not allow P-PCI or E-PCI procedures to be performed at facilities without onsite OHS services. Nationally, the overall character of PCI regulation has changed quite dramatically in recent years. In 2007, both P-PCI and E-PCI without onsite surgical backup was allowed in only 28 states (compared to 45 presently), P-PCI only was allowed in 12 (4), and neither P-PCI or E-PCI in 10 (1) [1].

Michigan Analysis

Data and Methods

Facility locations and corresponding service capabilities were mapped using the CON Annual Survey and additional data supplied by the MDCH CON Program. The facilities were subset from MSU's Michigan hospital database and stratified by their category of service provision. Patient utilization data were culled from the CON Annual Surveys and the Michigan Inpatient Database (MIDB), an exhaustive record of inpatient hospitalizations in Michigan. The roads data and network-based travel time model used for the analysis are described in [3].

US Census blocks were used as the underlying data to represent population distribution, containing both the total population and the adult population (aged 18+) in each block in 2010. The block data were converted to geographic centroids (point locations) where each point represents a block's location and population (statewide, there are 207,522 blocks with a population greater than 0). The census block

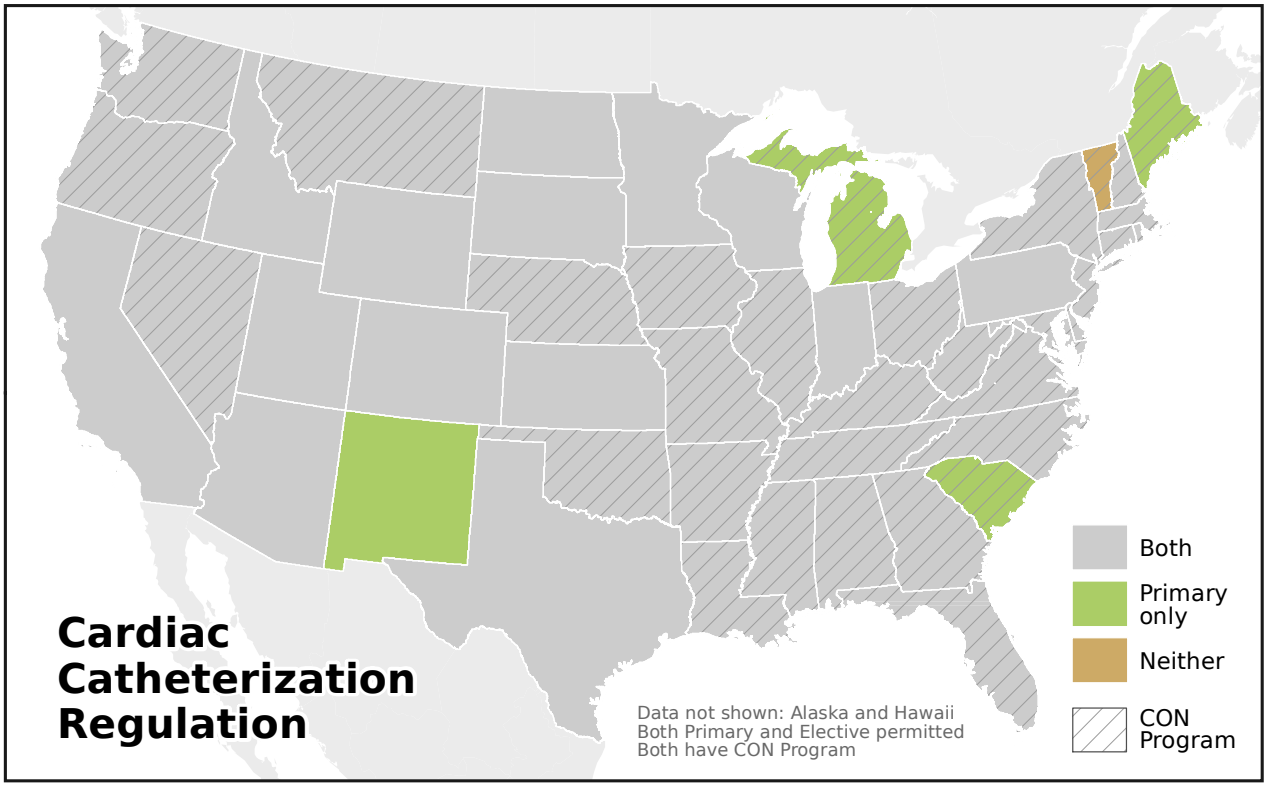


Figure 1. State-based primary and elective PCI regulations. Reported as the PCI services that providers, without onsite OHS capabilities, may provide. The PCI regulation data are mapped from the survey results in [1, via personal communication]. Regulations include those implemented via state CON programs or health departments. CON program data are mapped from [2].

population date were used to estimate the population for all Zip Codes ($n = 908$) in Michigan and calculate population weighted centroid locations for each.

Inpatient hospitalizations for PCI procedures were gathered from the 2012 Michigan Inpatient Database (MIDB). Any adult patient record with an ICD 9 CM procedure code of 00.66 (Percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy), 36.06, or 36.07 (Insertion of non-drug (or drug) eluting coronary artery stent) was extracted for analysis. These data were further subdivided into P-PCI and E-PCI based on the presence of a myocardial infarction as a diagnosis during the hospitalization (ICD 9 CM "414.xx") and the service level of the hospital. Finally, the utilization data were aggregated by the residence of the patient (Zip Code), resulting in the total number of adult P-PCI and E-PCI inpatient discharges from each Michigan Zip Code at each Michigan hospital.

Travel time information was joined with the PCI utilization data. The travel time measurements were calculated by measuring the total time required to travel along the road network from each Zip Code centroid location to each facility providing PCI services. Thus, for each Zip Code hospital pair, the resulting data contained the number of discharges along with the travel time.

To measure *potential* access to cardiac catheterization services, For each cardiac catheterization facil-

ity, travel time service areas were constructed at 10-minute intervals, from 10 to 60 minutes. To determine statewide geographic access, the block population data (both total population and adult population) were overlain with the travel time service areas. The population falling in each travel band was summed by travel time.

Utilization

As reported in the 2012 CON Annual Survey, there are 62 locations providing adult (for patients aged 18+) cardiac catheterization services in Michigan, with 190 total laboratories. Of the 62 facilities reporting adult cardiac catheterization services in 2012, 33 have OHS services and thus can perform diagnostic, P-PCI, and E-PCI procedures. Of the remaining 29 facilities, 14 facilities provide diagnostic and P-PCI services. The remaining 15 facilities only perform diagnostic catheterization procedures. The facilities in Michigan are mapped in Figure 2.

90,690 diagnostic and 67,331 therapeutic catheterizations were performed statewide in 2012. Total utilization of cardiac catheterization has been relatively stable over the last four years, as shown in Table 1 (although there is an unexplained increase in 2011).

Table 1. Cardiac catheterization utilization in Michigan, 2009–2012. Data gathered from the 2009–2012 CON Annual Surveys. Diagnostic and Therapeutic include peripherals and are reported as the number of *sessions*. These data include Children's Hospital of Michigan, which provides only pediatric services.

Year	Facilities	Labs	Diagnostic	Therapeutic
2009	64	187	93,142	61,050
2010	63	186	93,764	59,094
2011	62	193	104,490	64,759
2012	63	192	90,690	67,331

Analysis of the MIDB data identified 44,876 PCI procedures in 2012. This figure is lower than the 67,331 total "therapeutic" sessions reported in the CON Survey data; the discrepancy is a result of two factors, 1) PCI procedures, as defined here, are a subset of the therapeutic catheterizations reported to the CON Annual Survey and 2) that some PCI procedures were likely performed on an outpatient basis. Furthermore, some patients had multiple PCI procedure codes (e.g., 36.06 *and* 00.66). Thus, the total number of unique discharges was 21,122 in 2012, with 11,819 having an identified P-PCI procedure and 9,303 with an E-PCI procedure.

Figure 3 shows the distance decay curves for PCI utilization in Michigan. This figure shows the percentage of the overall patient population that traveled each distance (or further) along the y axis. For example, all patients having a PCI procedure traveled more than 0 minutes for the procedure; therefore, at 0, the graph shows 100% (e.g., 47.2% of hospitalizations for E-PCI were 20 minutes or more from the patient's residence and 29.01% for P-PCI were 30 minutes or more). As the figure shows, travel for P-PCI appears slightly less than E-PCI (especially for distances less than 30 minutes), although the differences appear to be quite small (generally, less than 3% of the cumulative hospitalizations). Notably,

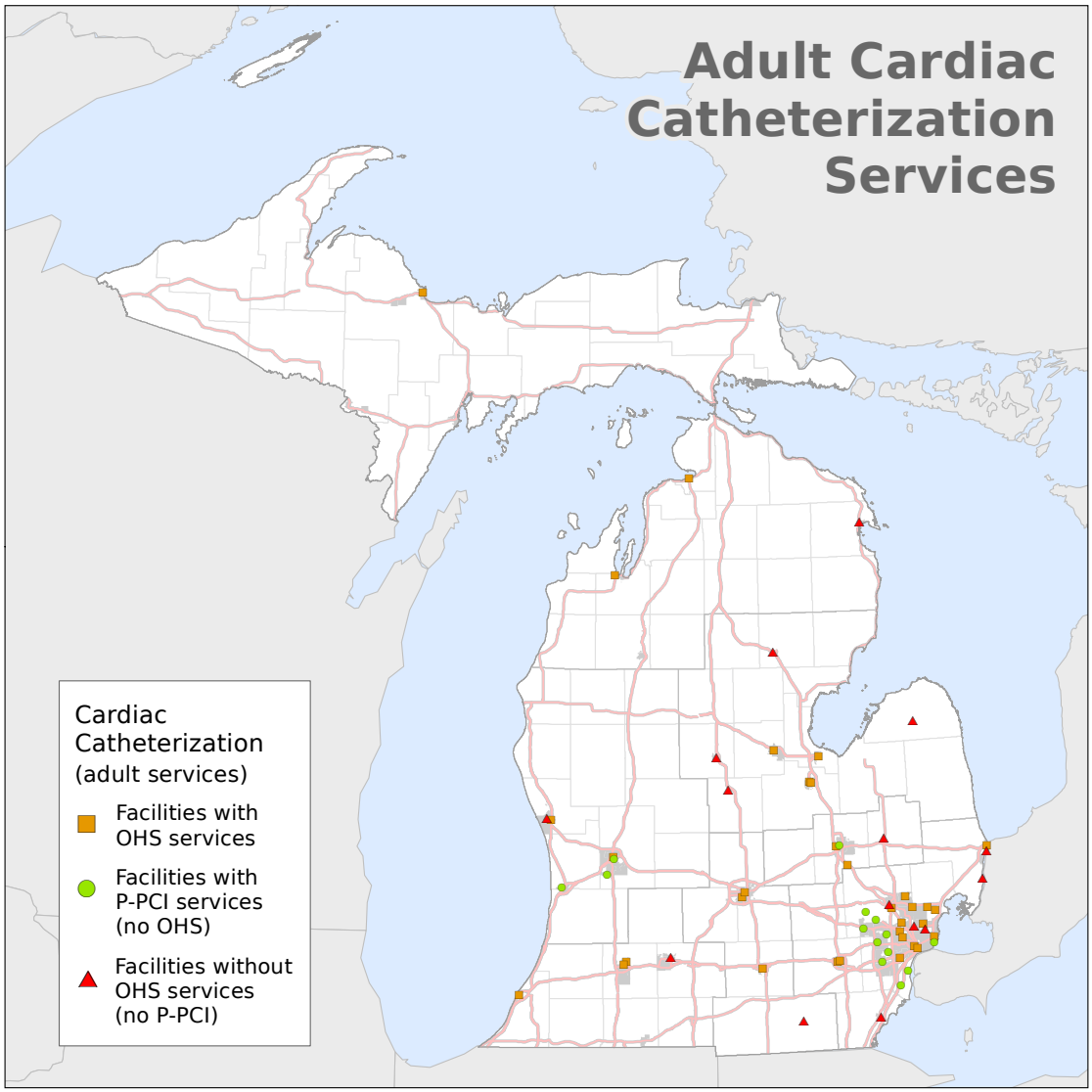


Figure 2. Locations of cardiac catheterization services in Michigan.

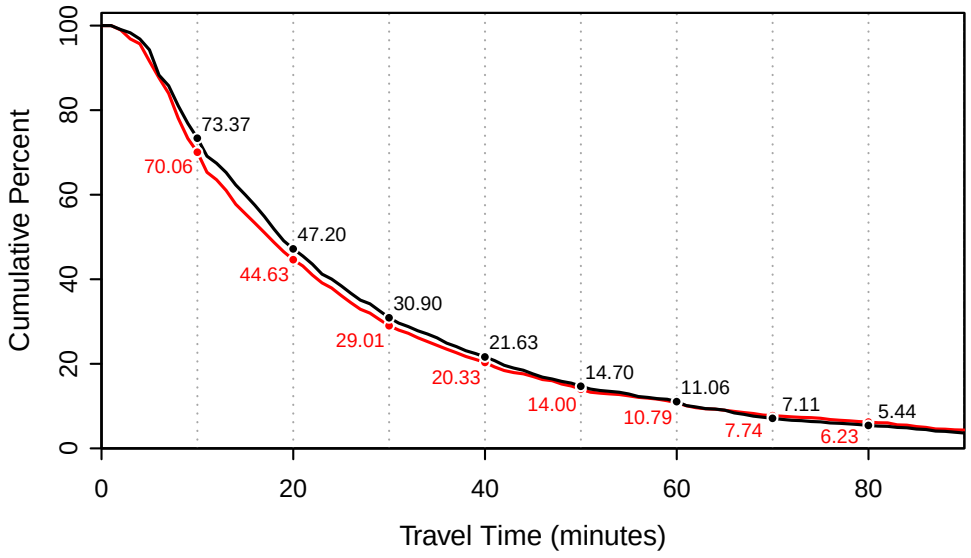


Figure 3. Distance decay of inpatient discharges for P-PCI (red) and E-PCI (black) for Michigan residents at Michigan hospitals.

the inpatient hospital utilization data show that patients currently travel about the same distance for these procedure classes, not further for E-PCI procedures than P-PCI procedures.

Access to Cardiac Catheterization Services

Geographic access, for both the overall state population and the adult population, was calculated for each of the three categories of cardiac catheterization service (diagnostic, P-PCI only, and E-PCI). The results can be found in Tables 2–4 and Figures 4–6.

Table 2. Geographic access to diagnostic cardiac catheterization services in Michigan. Travel time for the total population (**Pop**) and adult population (**Pop (18+)**). **%** is percent of the population and **C%** is the cumulative percent (e.g., 75.49% of the overall population resides within 30 minutes or less of a diagnostic service location).

Minutes	Pop	%	C%	Pop (18+)	%	C%
10	4,643,997	46.99	46.99	3,551,848	47.11	47.11
20	2,457,818	24.87	71.85	1,858,348	24.65	71.76
30	1,256,237	12.71	84.56	947,199	12.56	84.32
40	622,870	6.3	90.87	472,836	6.27	90.59
50	336,792	3.41	94.27	260,683	3.46	94.05
60	176,930	1.79	96.06	138,517	1.84	95.89
60+	388,996	3.94	100	310,141	4.11	100

Table 3. Geographic access to primary PCI services in Michigan.

Minutes	Pop	%	C%	Pop (18+)	%	C%
10	4,242,919	42.93	42.93	3,241,704	43	43
20	2,351,836	23.8	66.72	1,775,673	23.55	66.55
30	1,159,833	11.73	78.46	871,340	11.56	78.1
40	739,411	7.48	85.94	558,456	7.41	85.51
50	451,085	4.56	90.50	350,197	4.64	90.16
60	275,718	2.79	93.29	214,787	2.85	93
60+	662,838	6.71	100	527,415	7	100

Table 4. Geographic access to elective PCI services in Michigan.

Minutes	Pop	%	C%	Pop (18+)	%	C%
10	3,216,080	32.54	32.54	2,458,262	32.6	32.6
20	2,609,615	26.4	58.94	1,982,236	26.29	58.9
30	1,635,452	16.55	75.49	1,230,336	16.32	75.21
40	943,308	9.54	85.03	708,921	9.4	84.62
50	525,494	5.32	90.35	406,156	5.39	90
60	290,709	2.94	93.29	226,137	3	93
60+	662,982	6.71	100	527,524	7	100

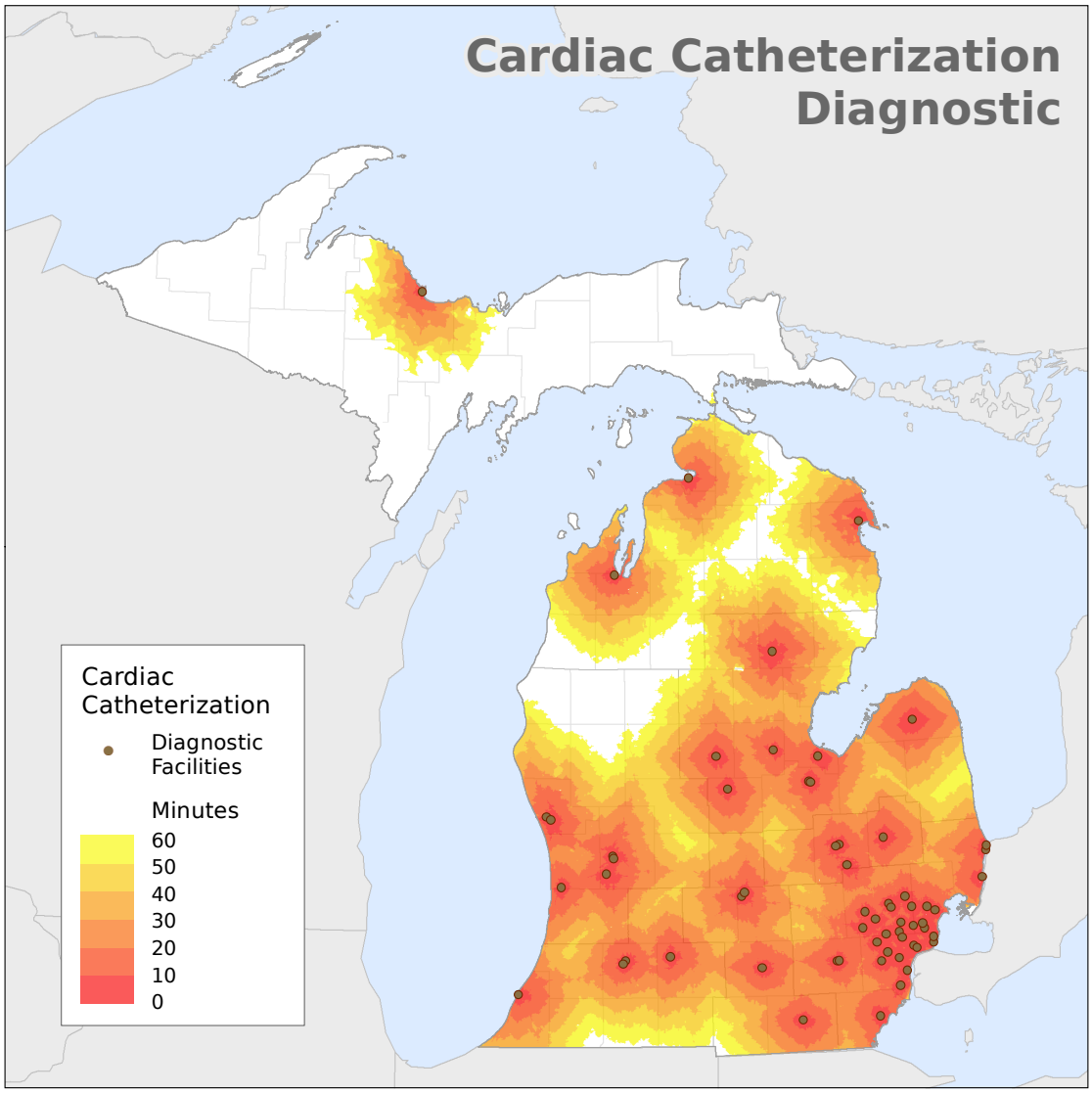


Figure 4. Geographic access to diagnostic cardiac catheterization services in Michigan.

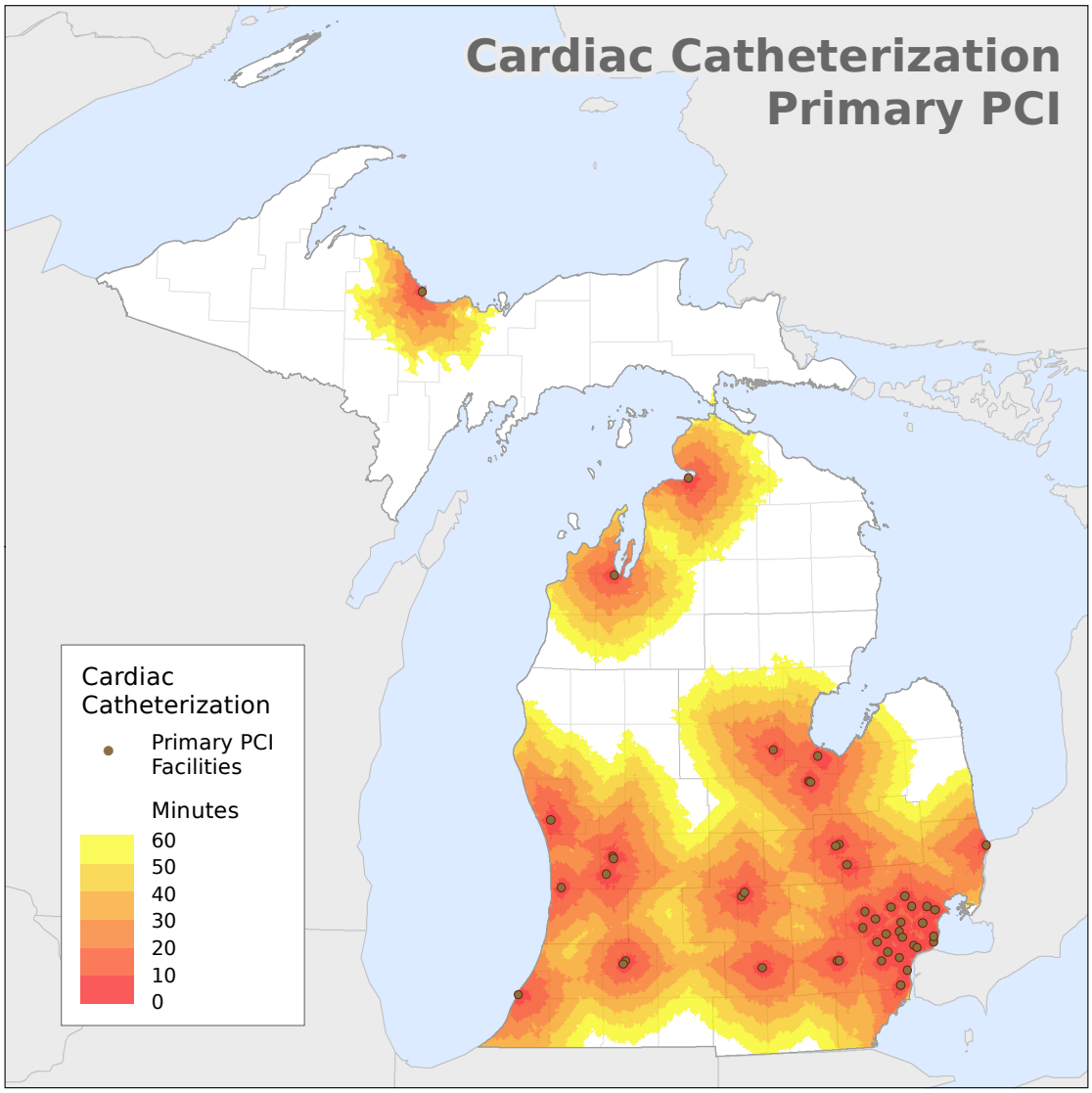


Figure 5. Geographic access to primary PCI services in Michigan.

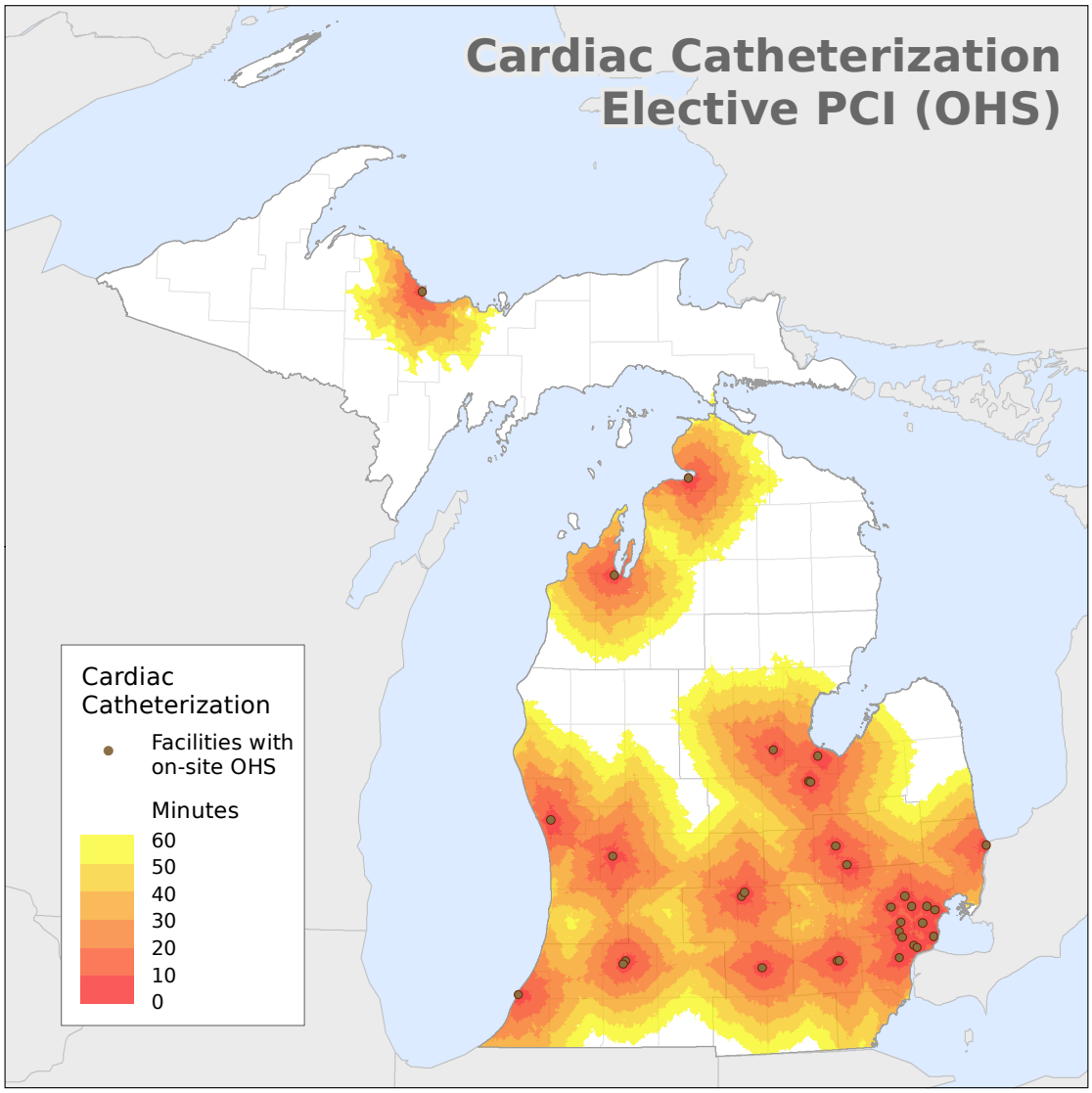


Figure 6. Geographic access to elective PCI services in Michigan.

Potential Changes in Geographic Access

Changes in geographic access to E-PCI services for Michigan residents were considered under a hypothetical scenario in which the 14 hospitals that currently provide P-PCI services without OHS services were allowed to provide E-PCI services. The travel time service areas were overlain and improvements in access were noted (e.g., if a census block had 20–30 minute access under the current regulations, but had 10–20 minute access in the hypothetical scenario, this census block would be considered to have a 10 minute "improvement" in geographic access). Overall, changes to the E-PCI restrictions would only improve geographic access for 16.8% of Michigan's adult population and 17% of the overall population. Thus, over 80% of the adult population would not experience any improvement in access, even if all 14 facilities were to begin providing E-PCI services. The details of this analysis are presented in Table 5 (Appendix A contains a more detailed breakdown of the results), notably showing that only 0.78% of Michigan's adult population (59,001 residents) would see more than a 20 minute gain in access to E-PCI services.

Table 5. Potential changes in geographic access to elective PCI services in Michigan. Changes in access are based on a scenario in which the 14 facilities that perform P-PCI without OHS services would be allowed to perform E-PCI. The column "Change" is the gain in access (e.g., 20–30 minutes to 0–10 minutes would constitute a 20 minute gain in access).

Change	Pop	%	C%	Pop (18+)	%	C%
None	8,206,796	83.03	83.03	6,273,783	83.21	83.21
10	1,242,001	12.57	95.60	935,835	12.41	95.62
20	355,419	3.60	99.20	270,953	3.59	99.22
30	76,372	0.77	99.97	56,664	0.75	99.97
40	3,052	0.03	100.00	2,337	0.03	100.00

Discussion

The small potential increases in geographic access to E-PCI services are similar to the results found by Buckley et al. [4], who studied the gains in access for Michigan's population when the Review Standards were modified to allow P-PCI at facilities without OHS services. Both Buckley et al.'s results and the results provided in this document suggest that the state is well-served by the current configuration of cardiac catheterization facilities and services.

In a 2012 statement, the American Heart Association provided two reasons for opening a new PCI location without onsite OHS surgery services, 1) to provide high quality timely P-PCI services for STEMI patients and 2) to provide local care to patients and families that do not want to travel long distances or want to use a preferred physician [5]. The current debate in Michigan regarding E-PCI services at facilities without OHS services is related to the second reason provided by the AHA. Specifically, this matter appears to hinge on whether the potential positive contributions of allowing E-PCI at facilities without OHS services (i.e., increased safety of E-PCI procedures, a small increase in geographic access

and the ability of hospitals/systems to keep patients "in-house") outweigh the potential negative effects related to service duplication (e.g., overutilization, dilution of procedures and resources, and increased costs).

References

1. Dehmer GJ, Blankenship JC, Cilingiroglu M, Dwyer JG, Feldman DN, et al. (2014) SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. Circulation 129: 2610–2626.

2. National Conference of State Legislatures (2013). CON-Certificate of need state laws. URL http://www.ncsl.org/issues-research/health/con-certificate-of-need-state-laws.aspx.

3. Delamater PL, Messina JP, Shortridge AM, Grady SC (2012) Measuring geographic access to health care: raster and network-based methods. International Journal of Health Geographics 11: 1–18.

4. Buckley JW, Bates ER, Nallamothu BK (2008) Primary percutaneous coronary intervention expansion to hospitals without on-site cardiac surgery in michigan: A geographic information systems analysis. American Heart Journal 155: 668–672.

5. American Heart Association (2012). Percutaneous coronary intervention (PCI) without surgical back-up policy guidance. URL www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_437472.pdf.

Appendix A

Table 6. Potential changes in geographic access to elective PCI services in Michigan. Changes in access are based on a scenario in which the 14 facilities that perform P-PCI without OHS services would be allowed to perform E-PCI. The column "Change" is the gain in access.

Current	Proposed	Change	Pop	%	Pop (18+)	%
10	10	0	3,216,080	32.54	2,458,262	32.60
20	20	0	1,915,329	19.38	1,452,634	19.27
30	30	0	1,003,193	10.15	754,952	10.01
40	40	0	692,303	7.00	522,849	6.93
50	50	0	441,479	4.47	342,884	4.55
60	60	0	275,574	2.79	214,678	2.85
70	70	0	662,838	6.71	527,415	7.00
Sum		***0***	***8,206,796***	***83.03***	***6,273,674***	***83.21***
20	10	10	694,286	7.02	529,602	7.02
30	20	10	361,415	3.66	267,267	3.54
40	30	10	134,180	1.36	99,610	1.32
50	40	10	42,370	0.43	32,043	0.42
60	50	10	9,606	0.10	7,313	0.10
70	60	10	144	0.00	109	0.00
Sum		***10***	***1,242,001***	***12.57***	***935,944***	***12.41***
30	10	20	270,844	2.74	208,117	2.76
40	20	20	58,168	0.59	43,076	0.57
50	30	20	21,669	0.22	16,196	0.21
60	40	20	4,738	0.05	3,564	0.05
Sum		***20***	***355,419***	***3.60***	***270,953***	***3.59***
40	10	30	58,657	0.59	43,386	0.58
50	20	30	16,924	0.17	12,696	0.17
60	30	30	791	0.01	582	0.01
Sum		***30***	***76,372***	***0.77***	***56,664***	***0.75***
50	10	40	3,052	0.03	2,337	0.03
Sum		***40***	***3,052***	***0.03***	***2,337***	***0.03***

2014 Cardiac Catheterization SAC

Percutaneous Coronary Intervention Without On-site Cardiac Surgical Backup

Historical/Scientific Background

Rationale for on-site surgical backup

- Early 1980s, Emergency CABG rate during PCI was approximately 6.6%. Standard practice was to have operating room and surgical team immediately available at the institution.

NEJM 2012 (Shahian, et al.)

Attachment B

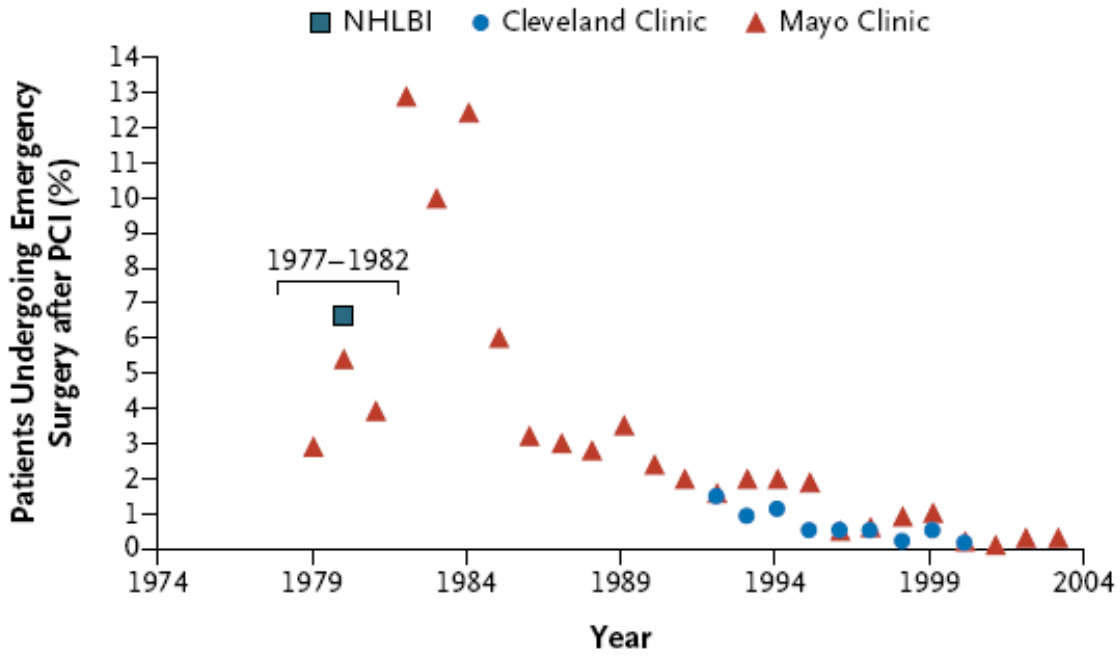


Figure 1. Progressive Decline in Emergency Cardiac Surgery after Percutaneous Coronary Intervention (PCI).

Data are from the National Heart, Lung, and Blood Institute (NHLBI) Registry[1] (overall results from 1977 through 1982, summarized at year 1980), the Cleveland Clinic,[2] and the Mayo Clinic.[3]

Rationale, continued

- More recently, ACC/NCDR registry data for emergency CABG during PCI shows a rate of approximately 0.37%. Standard practice was therefore modified so that surgical backup was no longer required to be on standby.

Timeline of Published Clinical Studies

- April 2000 – C-Port (JAMA 4/2002)
  - Primary PCI/STEMI with no surgery on-site, better than thrombolytics
- October 2004 – MEDPAR database (JAMA 10/2004)
  - Primary PCI with/without surgery on-site have equivalent outcomes
  - Elective PCI without on-site surgical backup showed worse outcomes

Timeline of Published Clinical Studies

- April 2008 – NCDR (JAMA 2009)
  - Registry database comprised of > 300,000 patients demonstrated similar outcomes for primary and elective PCI in hospitals with or without on-site surgical backup
- Nov 2011 – C-Port E (NEJM 5/2012)
  - Randomized trial of 18,000 patients demonstrated similar outcomes for primary and elective PCI in hospitals with or without on-site surgical backup

Timeline of Published Clinical Studies

- Dec 2011 – Meta-analysis (JAMA)
  - 100,000 patients with STEMI
  - 900,000 patients with elective/urgent PCI
    - No difference in outcomes between hospitals with/without surgical backup
- May 2012 –C PORT E (NEJM)
  - Randomized trial 18,000 Elective PCI no SoS
  - No difference at 6wks/9mo
- Mar 2013 – MASSCOM Trial (NEJM)
  - 2,700 patients with elective PCI
  - No difference in outcomes at 30 day/12 month follow-up between hospitals with/without surgical backup

ACC/AHA Classification of Recommendations and Level of Evidence

Attachment B

SIZE OF TREATMENT EFFECT

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT

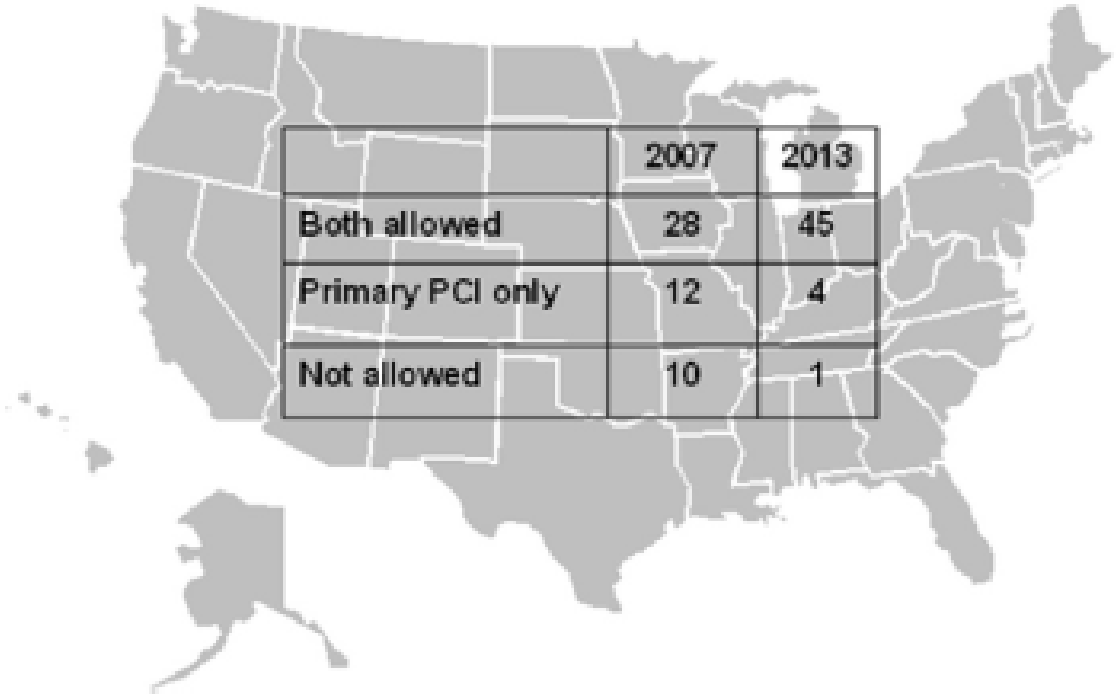
	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* Procedure/ Test / Treatment COR III: No benefit — Not Helpful — No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful — Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care

ACC/AHA Guidelines

- 2005
  - Primary PCI without on-site surgical backup was considered a Class IIb
  - Elective PCI without on-site surgical backup was considered a Class III – contraindicated

- 2011
  - Primary PCI without on-site surgical backup changed to a Class IIa
  - Elective PCI without on-site surgical backup changed to a Class IIb - acceptable

JACC – June 17, 2014



	2007	2013
Both allowed	28	45
Primary PCI only	12	4
Not allowed	10	1

Figure 2. Change in the Availability of PCI Without On-Site Surgery From 2007 to 2013

The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

Additional Observations

- Effects of CON regulations uncertain:
  - No effect on statewide volumes but per hospital volume declined
  - No evidence of reduced procedural mortality
  - Possibly more appropriate care
  - Redundant low volume primary PCI centers cost ineffective
- Volume/Outcomes (controversial)
  - <200 PCIs/yr associated with worse outcomes (and <36 primary PCI)
  - Volumes (<50/operator; 200/institution) predictor of mortality, complications, LOS, costs
- Most of data supporting safety
  - Predated widespread implementation of AUC
  - Predated significant contraction of volume
  - Predated adoption of advanced technologies including cooling, pVADs, etc in cath lab

SCAI/ACC/AHA Expert Consensus Document

- **PCI programs should be evaluated based**
- **on their ability to**:

- Sustain adequate quality metrics
- Provide access to elective and emergency PCI procedures that would otherwise be unavailable in their service area
- Maintain the operator ($\geq$50 PCI, $\geq$ 11 Primary PCI) and institutional (>200, >36 Primary PCI) volumes annually

SCAI/ACC/AHA Expert Consensus Document

Attachment B

- Small PCI programs with large fixed costs are inefficient and unnecessary if they do not improve access in the areas of need
- System-wide efficiency will require central planning on the state or federal level
- ***"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 cardiac surgery"***
- New programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations

SAC Sub-committee Follow Up

Attachment B

- SAC Committee Discussion
  - Quality assurance/quality improvement
  - Operator experience
  - Facility requirements
  - Volume thresholds
  - Access/cost
  - Affordable Health Care Act
- 3/2014 – SCAI/ACC/AHA document
  - Recommendations/criteria for performing elective PCI with no SoS

QUESTIONS

Cost Assessment of PCI

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Cost

1. Definition of Cost
2. Direct and In direct financial Cost
3. Un measured Cost
4. Cost for the payers
5. Cost for the patients
6. Cost of the un-insured or under insured

Points to consider

- Cost associated with patient transfer
- Cost associated with patient repeat procedure
- Cost associated with complication management
- Cost associated with duplicated processes

Hospital Experience

- In 2013, Metro Health Hospital transferred at least 90 patients with the diagnosis of acute coronary syndrome
- On average, immediate cost related to patient transfer and placement in the other institution is estimated at 1200 $.
- This does not cover costs related to other facility caring for the patient
- No information documented regarding cost related to complication management
- Un insured and under insured patients will deal with two bills and two separate costs.