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

Wednesday October 8, 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 8:38 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 arrived at 8:41 a.m.
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 arrived at 9:05 a.m.
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:

None.

C. Michigan Department of Community Health Staff present:

Tulika Bhattacharya
Sallie Flanders
Natalie Kellogg
Beth Nagel
Tania Rodriguez

II. Declaration of Conflicts of Interests

No conflicts were declared.

III. Review of Minutes September 10, 2014

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

IV. Review of Agenda

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

V. Presentation by Dr. Greg Dehmer

Dr. Dehmer gave background information on Elective PCI without on-site surgery in Michigan (see Attachment A).

VI. Sub-Committee Recommendations and Draft Language

Ms. Yacobucci gave an overview of the sub-committee recommendations and draft language (see Attachment B).

Discussion followed.

Break from 10:35 a.m. – 10:57 a.m.

Motion by Dr. Saab and seconded by Dr. Alkotob to set the initiation and maintenance volume per facility at 200 PCI procedures and an average of 50 procedures per operator within a 3 year time period. Motion carried in a vote of 12-Yes, 0- No, and 0- Abstained.

Motion by Dr. Nallamothu and seconded by Dr. Alkotob to state as a group that it recommends expansion of elective PCI procedures to those hospitals which currently provide primary PCI services under a set of quality and access criteria to be determined. The motion was tabled.

VII. Next Steps and Future Agenda Items

Ms. Yacobucci will be maintaining the master document with all of the recommendations and changes. Ms. Yacobucci stated that subcommittee members will need to have their information to her before October 30, 2014 in order for the Department to send the materials out to the entire CCSAC at least seven days before the meeting.

Dr. Alkotob, Dr. Wohns, and Dr. Saab are writing the proposals concerning de-coupling Elective PCI from Open-Heart Surgery services.

Dr. DiFranco and Dr. Weaver agreed to work on the proposals concerning quality measures.

VIII. Public Comment

Dennis McCafferty, Economic Alliance for Michigan (EAM)

IX. Future Meeting Dates - November 6, 2014 and December 17, 2014.

Chairperson Turner-Bailey laid out a schedule that includes making key decisions at the November meeting and reviewing final language in December.

Ms. Nagel stated the CCSAC recommendations are scheduled to be presented to the CON Commission at the March 18, 2015 meeting.

X. Adjournment

Motion by Dr. Weaver and seconded by Dr. Wohns to adjourn the meeting at 1:14 p.m. Motion Carried.

Elective PCI Without On-Site Surgery in Michigan

Attachment A

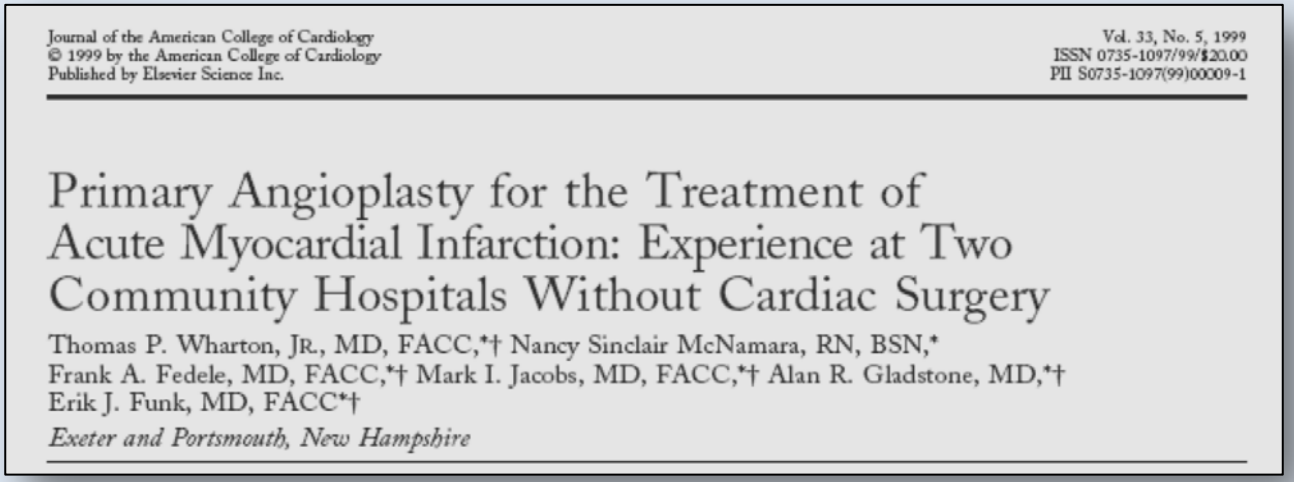
Gregory J. Dehmer, MD, FACC, FACP, FAHA, MSCAI
Medical Director, Cardiovascular Services, Central Texas Division
Baylor Scott & White Healthcare
Professor of Medicine
Texas A&M University Health Science Center College of Medicine

I have no financial conflict of interest with this topic
I perform PCIs at facilities with and without on-site surgery in Texas

History of PCI Without On-Site Surgery

Attachment A

This started with primary PCI for STEMI



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ISSN 0735-1097/99/$20.00
PII S0735-1097(99)00009-1

Primary Angioplasty for the Treatment of Acute Myocardial Infarction: Experience at Two Community Hospitals Without Cardiac Surgery

Thomas P. Wharton, JR., MD, FACC,*† Nancy Sinclair McNamara, RN, BSN,*
Frank A. Fedele, MD, FACC,*† Mark I. Jacobs, MD, FACC,*† Alan R. Gladstone, MD,*†
Erik J. Funk, MD, FACC*†
Exeter and Portsmouth, New Hampshire

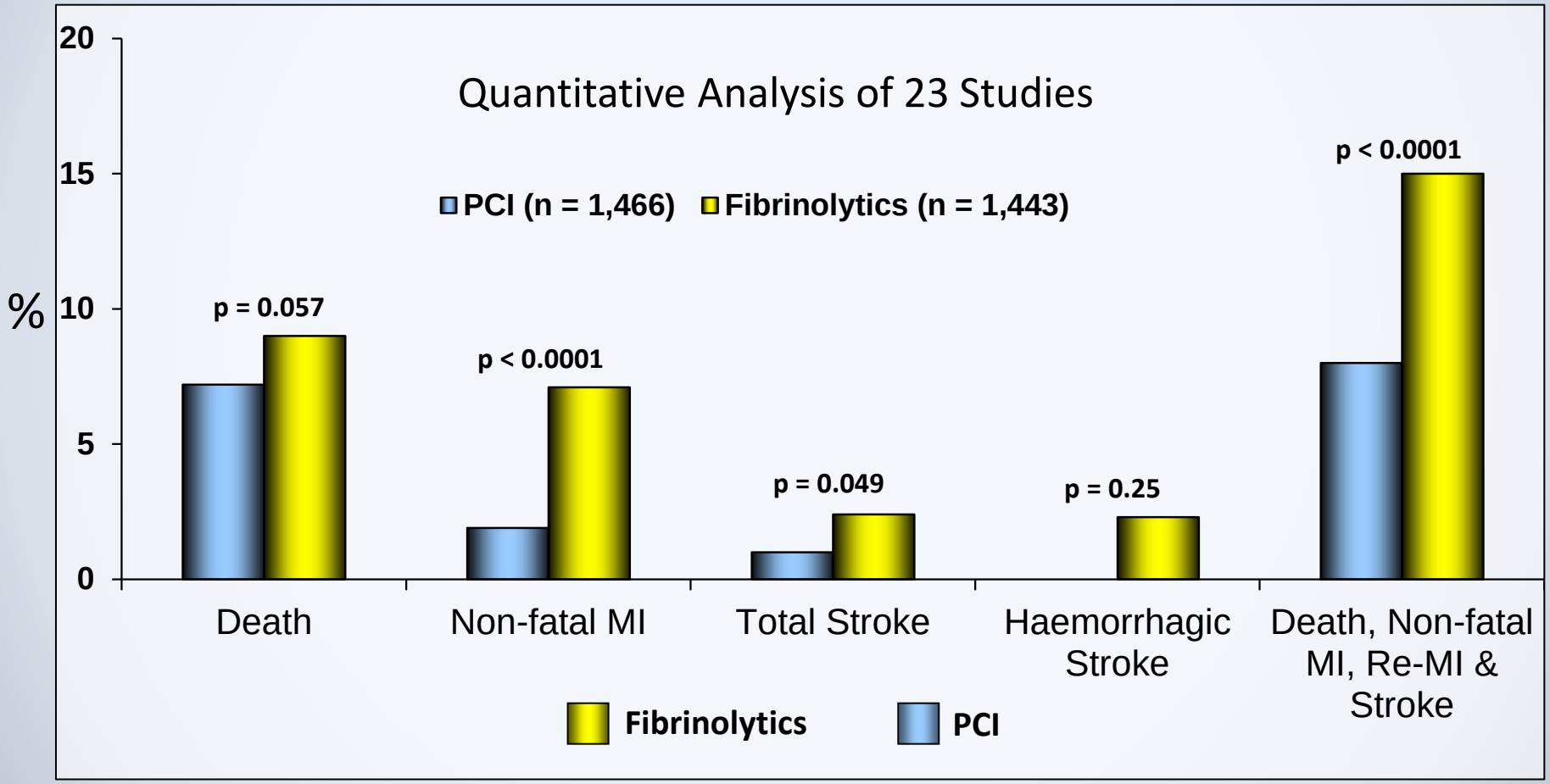
Developed from the belief that PCI was better than lytics
AND
a desire to provide primary PCI rapidly to their local community

Wharton TP, et al. *JACC* 1999;33(5):1257-65.

2003: PCI vs. Lytics

Attachment A

The "*Game Changer*"



Keeley EC, et al. *Lancet* 2003;361:13–20.

The Argument for Elective PCI at Hospitals Without On-Site Surgery

Attachment A

- Improved experience (& volume) for the cath lab
  - Not enough MIs to sustain a cath lab
  - *"Practice makes perfect"*
- Improved access
  - More than just miles and mountains; social issues
  - Improved access = improved outcomes
- Clinical advantages
  - Obviate the need for a transfer and second procedure
  - Sheath issues, contrast use and fluoroscopy times
- Avoid additional delays in care
- Enhanced continuity of care
  - Important for the primary care physician
- Economic advantages
  - Transport expenses, family expenses

2006: The Community Hospital Model

- Mayo series: 1007 patients (722 elective, 285 primary)
  - Rigorous case selection protocol
  - Experienced operators with adequate case volume
  - Real-time oversight
- Matched to cases at the main facility with surgery

Elective (n=722)	With Surgery	Without Surgery	
Procedure success	95%	97%	0.046
In-hospital death	0.01%	0.03%	0.56
Emergency CABG	0.1%	0%	0.24
Primary (n=285)			
Procedure success	96%	93%	0.085
In-hospital death	1%	4%	0.05
Emergency CABG	0%	0%	ns

No difference in mortality or event-free survival after 4 years

Ting HH, et al. *JACC* 2006;46(8):1713-21.

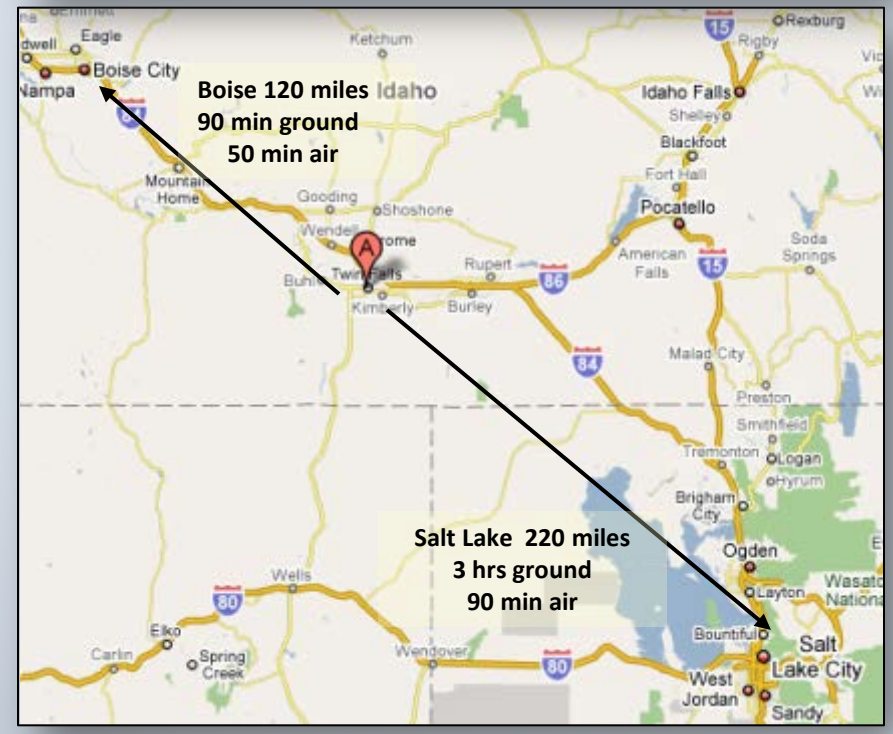
A "Classic Case" of a Geographically Isolated Hospital Performing PCI Without On-Site Surgery

Reviews

Percutaneous Coronary Interventions in a Rural Hospital without Surgical Backup: Report of One Year of Experience

DANIEL C. BROWN, M.D., FACC, STANLEY MOGELSON, M.D., FACC, REED HARRIS, D.O., FACC, DAVID KEMP, M.D., FACC, MARLYS MASSEY, B.S., R.N.

Department of Cardiology, Magic Valley Regional Medical Center, Twin Falls, Idaho, USA



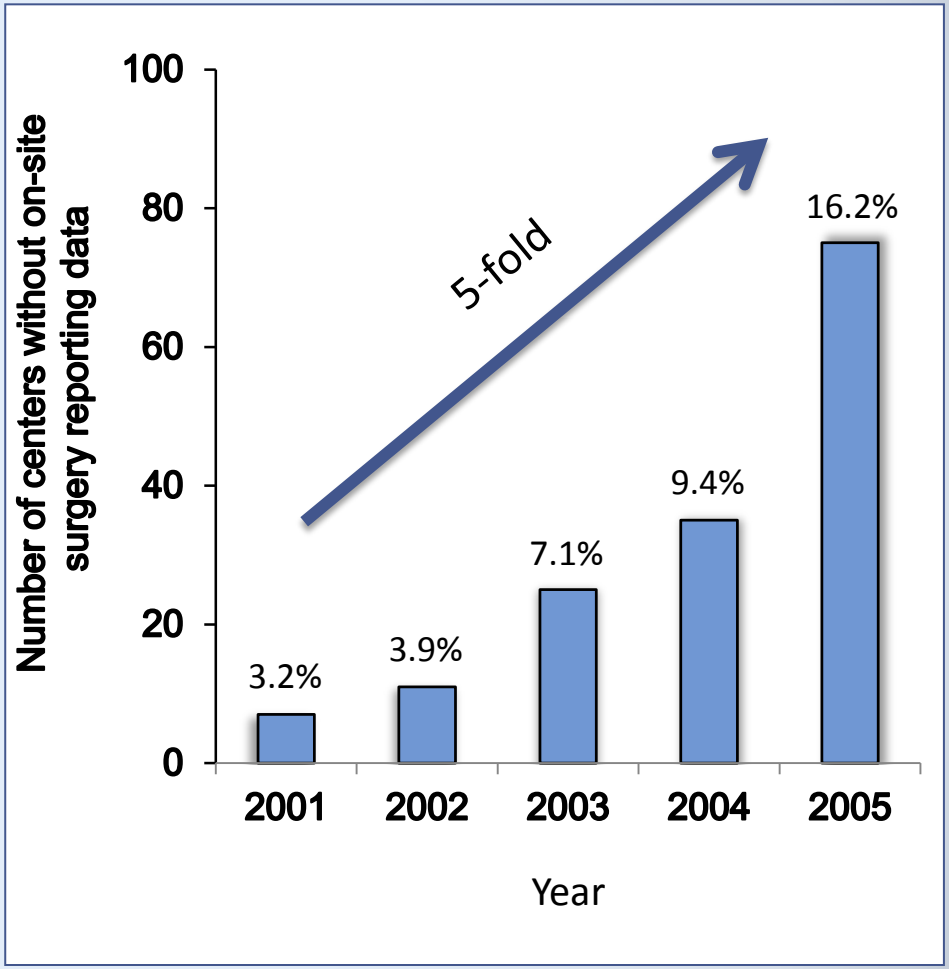
- Twin Falls, Idaho
- 186 bed hospital
- Serves a population of 170,000

Magic Valley Regional Medical Center
Twin Falls, Idaho

Brown DC, et al. Clin Cardiol 2006;29:337-40

2007: Growth of PCI Without On-site Surgery

- 2001 – 2005: Rapid increase in the number of sites performing PCI without on-site surgery
- This was occurring **despite** ACC/AHA/SCAI Guideline recommendations (2005)
  - Primary PCI without onsite surgery – IIb
  - Elective PCI without onsite surgery - III



Data from the NCDR

Dehmer GJ, et al. *Am J Cardiol* 2007; 99:329-32.

The Gap Between Guidelines and Reality

The 2005 PCI
Guidelines Update
Primary PCI = IIb
Elective PCI = III

The 2007 PCI
Focused Update
No additional comments

REALITY

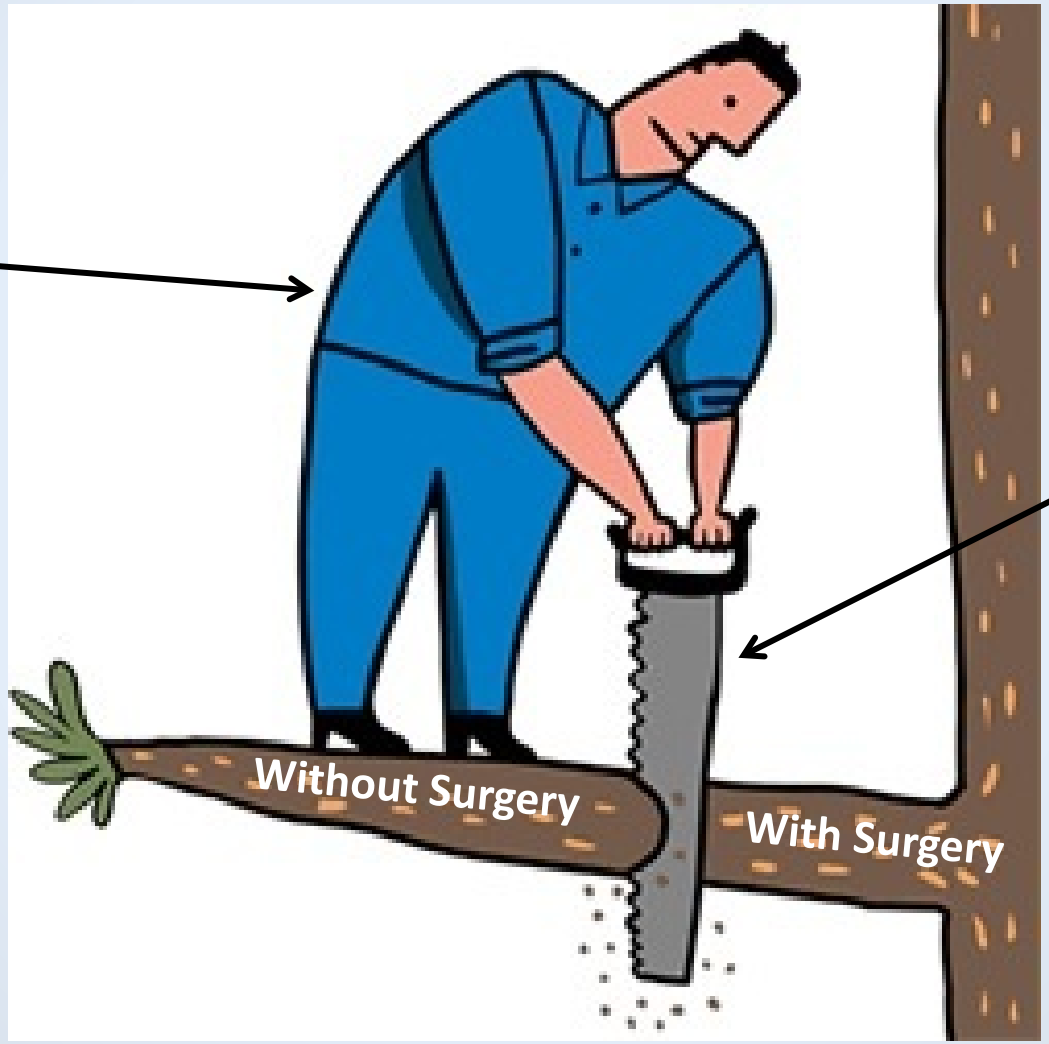
"As with many areas in interventional cardiology, these recommendations may be subject to revision as clinical data and experience increase"

So how did the cardiologist performing PCI without on-site surgery feel?

The Predicament

Attachment A

The Cardiologist



The Guidelines

2007: First SCAI Expert Consensus Document

Attachment A

The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions

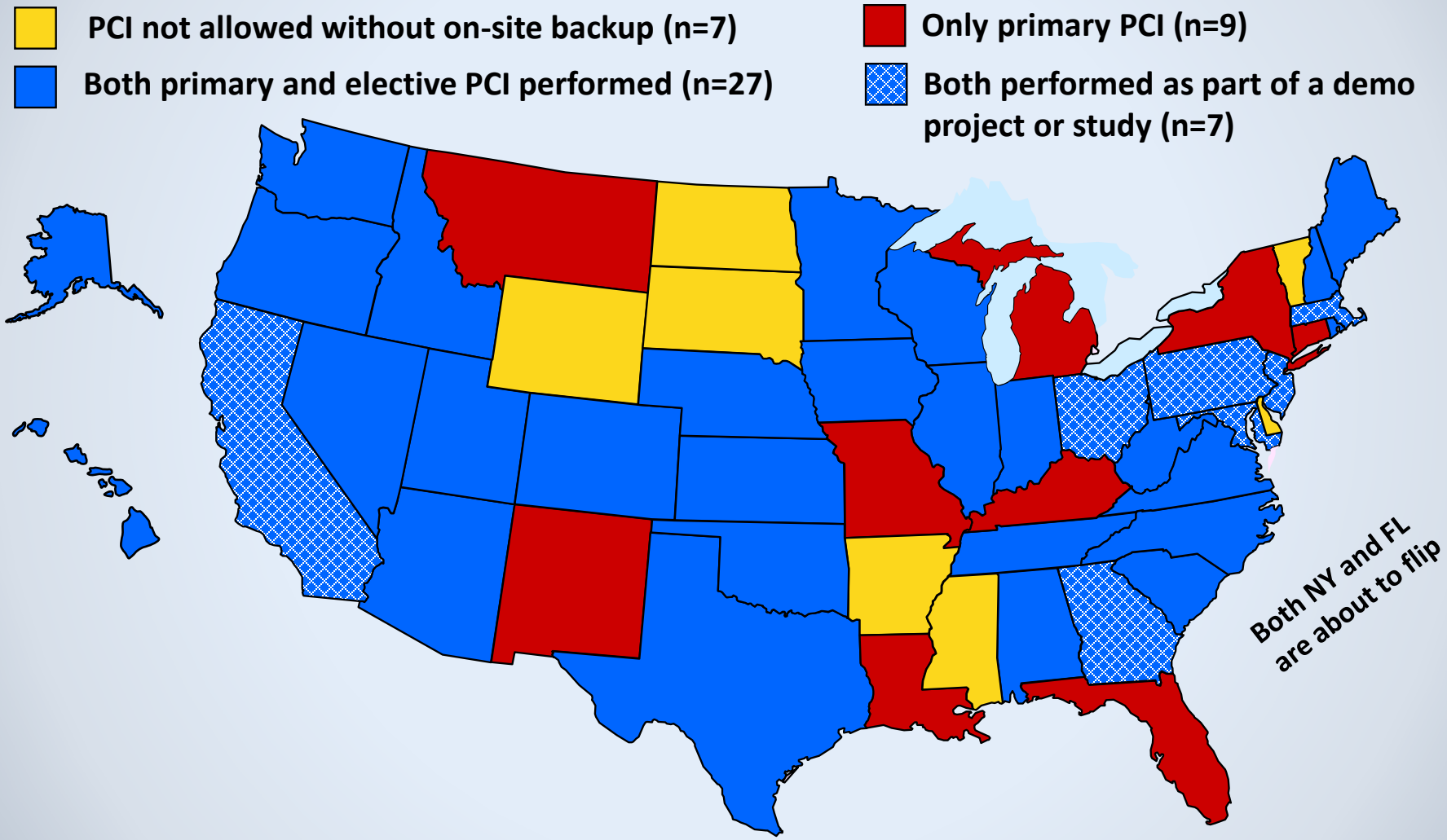
Gregory J. Dehmer,[1]* MD, James Blankenship,[2] MD, Thomas P. Wharton Jr.,[3] MD, Ashok Seth,[4] MD, MBBS, DSc, Douglass A. Morrison,[5] MD, PhD, Carlo DiMario,[6] MD, David Muller,[7] MD, Mirle Kellett,[8] MD, and Barry F. Uretsky,[9] MD

1. Provided an environmental scan of the global use of PCI without on-site surgery
2. Review of the existing literature
3. Examined existing guidelines from US and abroad
4. Established criteria for the operation of programs performing PCI without on-site surgery

Dehmer GJ, et al. Catheter Cardiovasc Intervent 2007;69(4):471-8.

The Status of PCI Without On-Site Surgery in 2007

Attachment A



Dehmer GJ, et al. Catheter Cardiovasc Intervent 2007;69(4):471-8.

Global Status of PCI Without On-Site Surgery

Attachment A

Being Performed			Not Being Performed
Argentina	Australia	Brazil	Bahrain
Canada	Czech Rep.	Egypt	Belgium
England	France	Germany	Greece
Guatemala	Hong Kong	India	Malaysia
Indonesia	Israel	Italy	
Japan	Lebanon	Mexico	
Netherlands	Oman	Pakistan	
Panama	Philippines	Poland	
Russia	Saudi Arabia	Singapore	
South Korea	Spain	Syria	
Taiwan	Thailand	Turkey	
Vietnam			

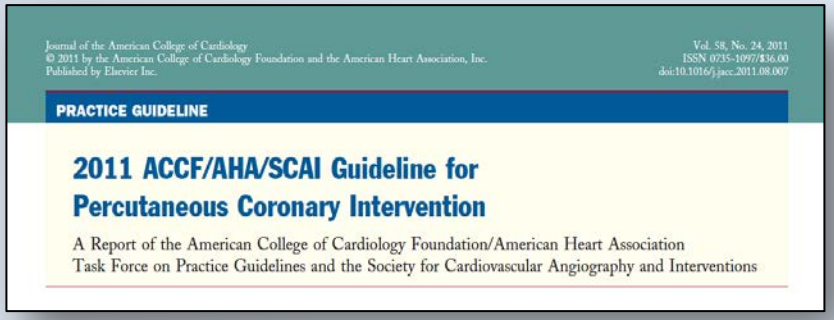
Source: SCAI Expert Consensus Document

Dehmer GJ, et al. Catheter Cardiovasc Intervent 2007;69(4):471-8.

2011: The Guidelines Change

Attachment A

4 years later . . . . .



Hospitals without onsite surgery

Primary PCI = IIa

Elective PCI = IIb (with a plan)

Elective PCI = III (without a plan)

4.8. PCI in Hospitals Without On-Site Surgical Backup: Recommendations

CLASS IIa

1. Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished (351,352). *(Level of Evidence: B)*

CLASS IIb

1. Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (352–354). *(Level of Evidence: B)*

CLASS III: HARM

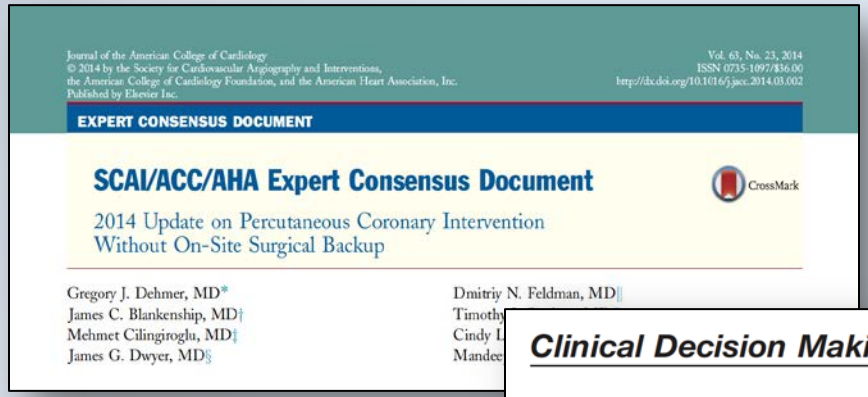
1. Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. *(Level of Evidence: C)*

2007 SCAI Document

Levine GN, et al. JACC 2011;58:e44-122.

2014: Second Expert Consensus Document (SCAI/ACC/AHA)

Attachment A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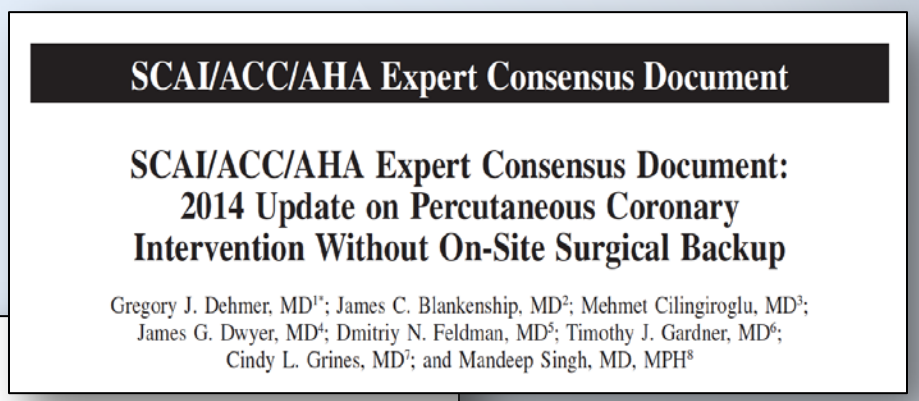
EXPERT CONSENSUS DOCUMENT

SCAI/ACC/AHA Expert Consensus Document

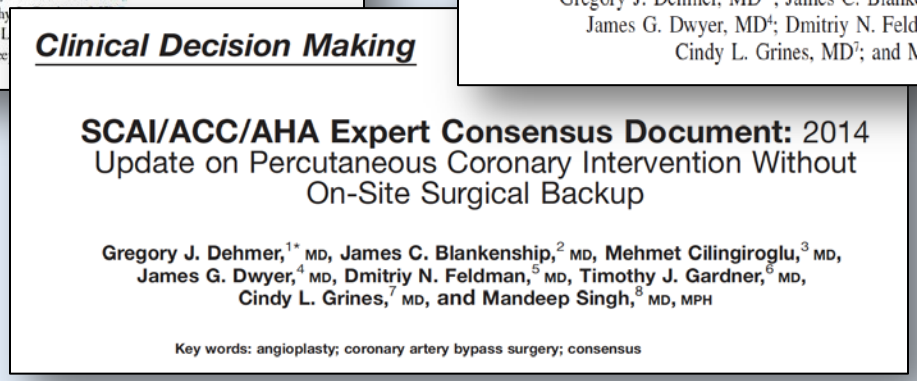
2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Gregory J. Dehmer, MD*
James C. Blankenship, MD†
Mehmet Cilingiroglu, MD‡
James G. Dwyer, MD§
Dmitriy N. Feldman, MD‖
Timothy
Cindy L
Mandee


SCAI/ACC/AHA Expert Consensus Document

SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Gregory J. Dehmer, MD[1*]; James C. Blankenship, MD[2]; Mehmet Cilingiroglu, MD[3]; James G. Dwyer, MD[4]; Dmitriy N. Feldman, MD[5]; Timothy J. Gardner, MD[6]; Cindy L. Grines, MD[7]; and Mandeep Singh, MD, MPH[8]


Clinical Decision Making

SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Gregory J. Dehmer,[1*] MD, James C. Blankenship,[2] MD, Mehmet Cilingiroglu,[3] MD, James G. Dwyer,[4] MD, Dmitriy N. Feldman,[5] MD, Timothy J. Gardner,[6] MD, Cindy L. Grines,[7] MD, and Mandeep Singh,[8] MD, MPH

Key words: angioplasty; coronary artery bypass surgery; consensus

Supported by all 3 major organizations

1. Determine current trends and prevalence of PCI without on-site surgery in the US
2. Summarize new literature since 2007
3. Review existing guidelines from the US and abroad
4. Outline “best practices” for performing PCI without on-site surgery
5. Evaluate the role of PCI without on-site surgery in the current US healthcare system

Circulation 2014;129:2610-26. JACC 2014;63:2624-41. CCI 2014;84:169-87.

Current Use of PCI Without On-Site Surgery in the U.S.

States	2007	2013
Both elective and primary PCI allowed	34	45
Primary PCI only	9	4
Not allowed	7	1

CPORT-E States ?

Only primary PCI allowed in Michigan, New Mexico, Maine and South Carolina

PCI not permitted without on-site surgery in Vermont

2007 data: SCAI ECD on PCI without on-site backup
2013 data: ACC Governors, Industry sources, physician contacts

New Studies

Meta-analysis of 15 studies
Both primary and elective PCI
Examined –
- Mortality
- Need for emergency CABG

Percutaneous Coronary Intervention at Centers With and Without On-site Surgery

Attachment A

A Meta-analysis

JAMA 2011;306:2487-94.

Mandeep Singh, MD, MPH
David R. Holmes Jr, MD
Gregory J. Dehmer, MD
Ryan J. Lennon, MS
Thomas P. Wharton, MD
Michael A. Kutcher, MD
Thomas Aversano, MD
Charanjit S. Rihal, MD

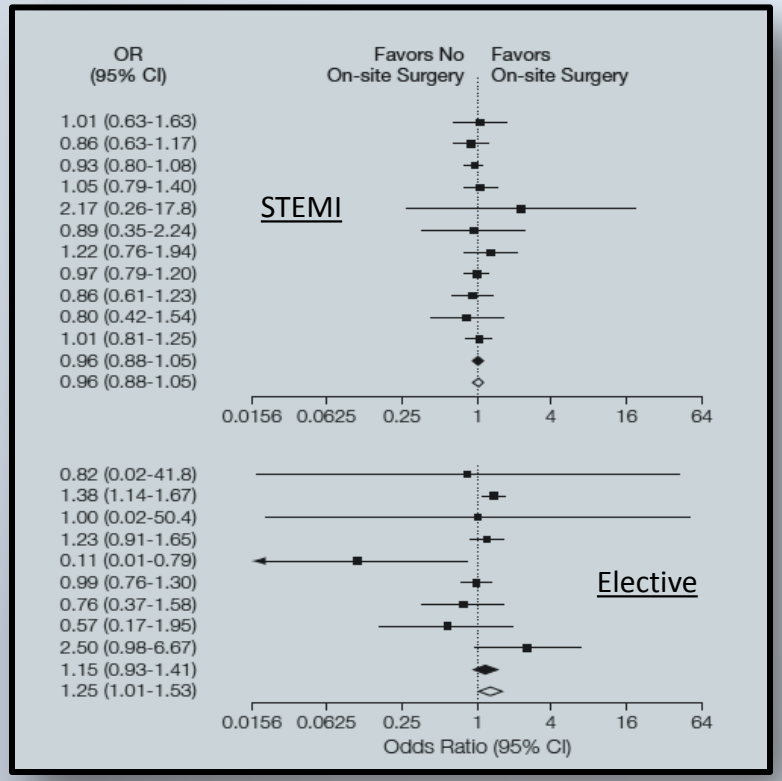
Context Percutaneous coronary interventions are performed at centers without on-site surgery, despite current guidelines discouraging this.

Objective To assess literature comparing rates of in-hospital mortality and emergency coronary artery bypass grafting surgery at centers with and without on-site surgery.

Data Sources A systematic search of studies published between January 1990 and May 2010 was conducted using MEDLINE, EMBASE, and Cochrane Review databases.

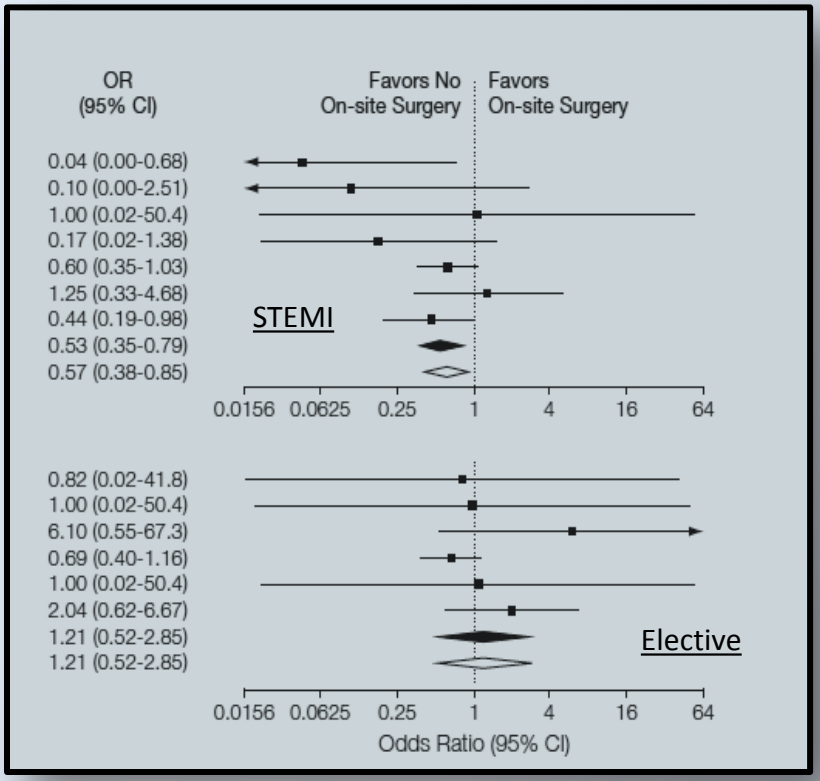
Study Selection English-language studies of percutaneous coronary intervention performed at centers with and without on-site surgery providing data on in-hospital mortality and emergency bypass were identified. Two study authors independently reviewed the 1029 articles originally identified and selected 40 for analysis.

Mortality



No increased risk of mortality or Em-CABG at facilities without on-site surgery

Emergency CABG



New Studies

CPORT-E: Randomized trial of Elective PCI
Randomized 3:1; non-inferiority trial
14,149 pts. without on-site surgery
4,718 pts. with on-site surgery
Strict protocol for operators and facilities
Endpoints: 6 week mortality; 9 month MACE

Attachment A

The NEW ENGLAND JOURNAL of MEDICINE
NEJM 2012;366:1792-802.

ORIGINAL ARTICLE

Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery

Thomas Aversano, M.D., Cynthia C. Lemmon, R.N., B.S.N., M.S., and Li Liu, M.D., for the Atlantic CPORT Investigators

Table 3. **Trial Outcomes.***

Outcome	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	Difference in Rate (Asymptotic One-Sided 95% CI)	P Value	
				Noninferiority	Superiority
	no./total no. (%)		*percentage points*		
Primary end point (intention-to-treat population)					
Death at 6 wk	132/14,149 (0.9)	46/4718 (1.0)	−0.04 (−0.31 to 0.23)	0.004	
9-mo outcomes					
Death	454/14,149 (3.2)	150/4718 (3.2)			
TVR	915/14,149 (6.5)	255/4718 (5.4)			0.01
Q-wave myocardial infarction	434/14,149 (3.1)	144/4718 (3.1)			
Major adverse cardiac event	1716/14,149 (12.1)	529/4718 (11.2)	0.92 (0.04 to 1.80)	0.05	
Exploratory analyses (intention-to-treat population)					
Major adverse cardiac event, including withdrawal and loss to follow-up	2026/14,149 (14.3)	653/4718 (13.8)	0.48 (−0.48 to 1.44)	0.01	
CABG as initial procedure not included in TVR definition					
TVR	873/14,149 (6.2)	218/4718 (4.6)			<0.001
Major adverse cardiac event	1678/14,149 (11.9)	495/4718 (10.5)	1.37 (0.51 to 2.23)	0.21	
TVR according to stent type					
DES only	484/10,074 (4.8)	120/3343 (3.6)			0.005
BMS only	223/2790 (8.0)	53/877 (6.0)			
Both DES and BMS	39/596 (6.5)	8/156 (5.1)			
Balloon only	138/550 (25.1)	34/162 (21.0)			
Per-protocol analyses					
Death at 6 wk	129/13,967 (0.9)	38/4508 (0.8)	0.08 (−0.18 to 0.34)	0.03	
TVR	860/13,967 (6.2)	202/4508 (4.5)			<0.001
Major adverse cardiac event at 9 mo	1676/13,967 (12.0)	467/4508 (10.4)	1.64 (0.77 to 2.51)	0.42	

Mortality at 6 weeks
No SOS = 0.9%
SOS = 1.0%
Not Inferior

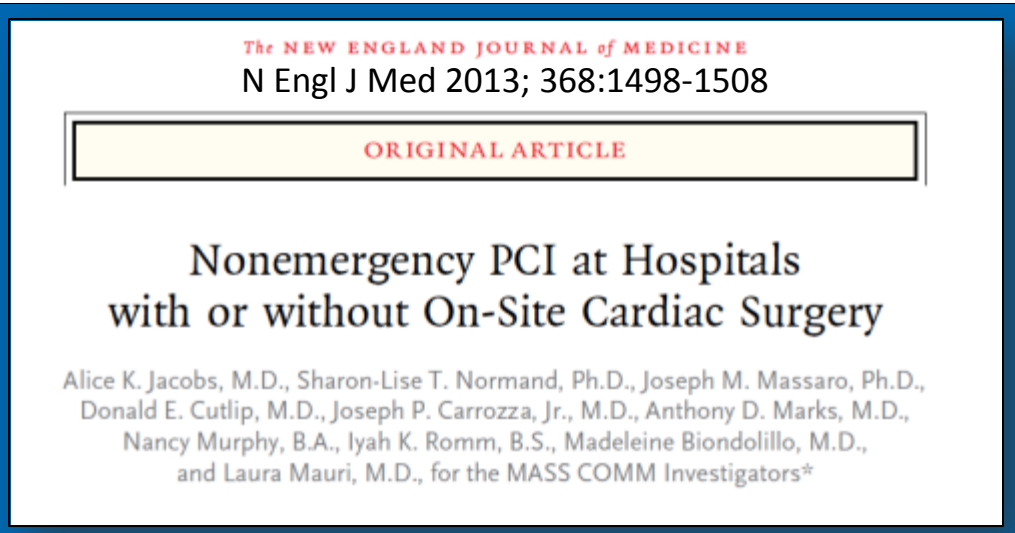
MACE at 9 months
No SOS = 12.1 %
SOS = 11.2%
Not inferior

TVR
No SOS = 6.5%
SOS = 5.4%
Higher at no SOS facilities

New Studies

Attachment A

MASS-COMM: Randomized trial of Elective PCI in Massachusetts
Randomized 3:1 ratio; non-inferiority trial
2,774 pts. without onsite surgery
917 pts. with onsite surgery
Strict protocol for operators and facilities
Co-primary endpoints:
MACE at 30 days (safety)
MACE at 12 months (effectiveness)
MACE = death, MI, repeat revasc, stroke


The NEW ENGLAND JOURNAL of MEDICINE
N Engl J Med 2013; 368:1498-1508

ORIGINAL ARTICLE

Nonemergency PCI at Hospitals with or without On-Site Cardiac Surgery

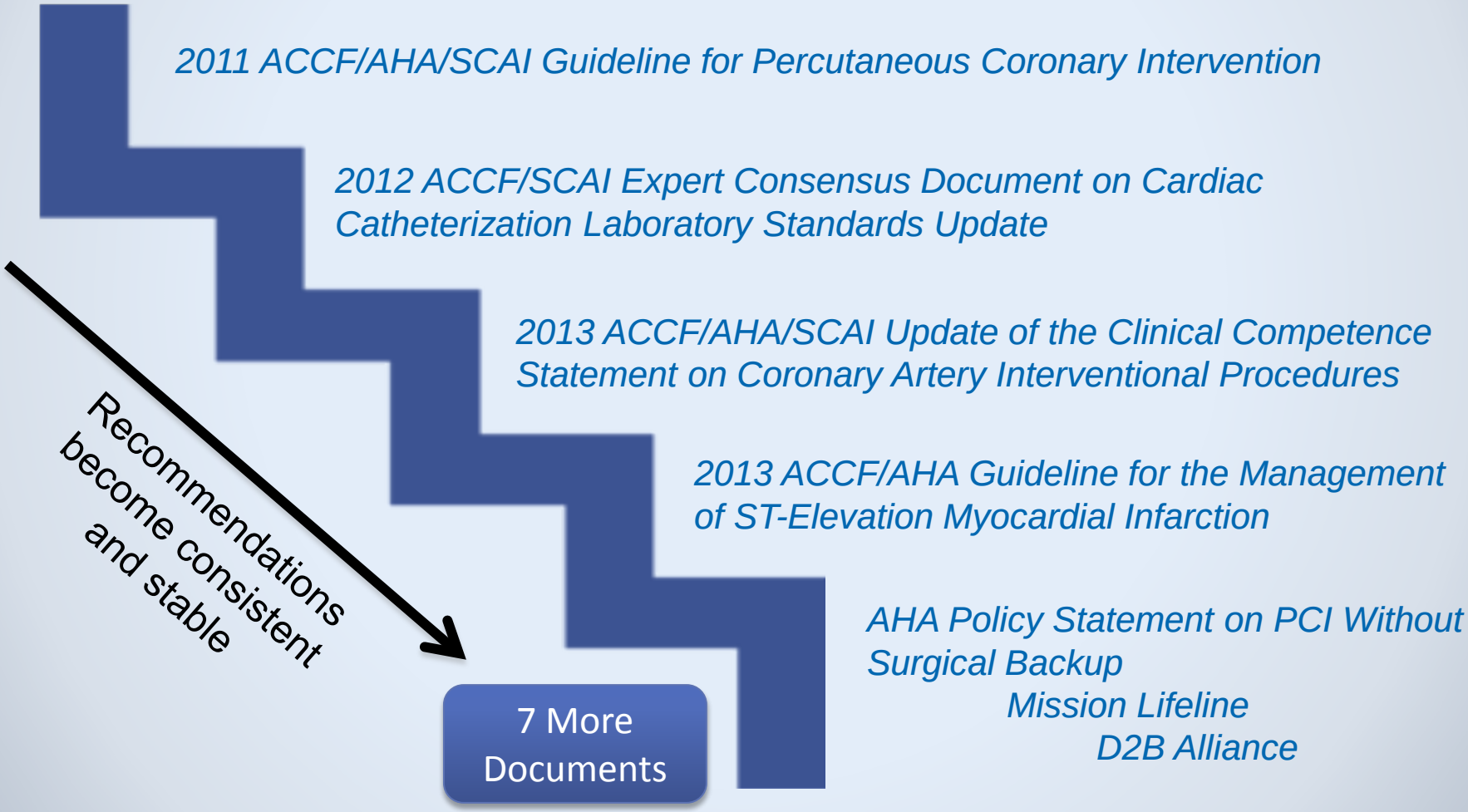
Alice K. Jacobs, M.D., Sharon-Lise T. Normand, Ph.D., Joseph M. Massaro, Ph.D., Donald E. Cutlip, M.D., Joseph P. Carrozza, Jr., M.D., Anthony D. Marks, M.D., Nancy Murphy, B.A., Iyah K. Romm, B.S., Madeleine Biondolillo, M.D., and Laura Mauri, M.D., for the MASS COMM Investigators*

	Without on-site surgery	With on-site surgery	Result
MACE at 30 days	9.5%	9.4%	Not inferior
MACE at 12 months	17.3%	17.8%	Not inferior
Ischemia-driven TVR and TLR	Not inferior at 30 days or 12 months		
Stent thrombosis	Not inferior at 30 days		

Evolution of Recommendations

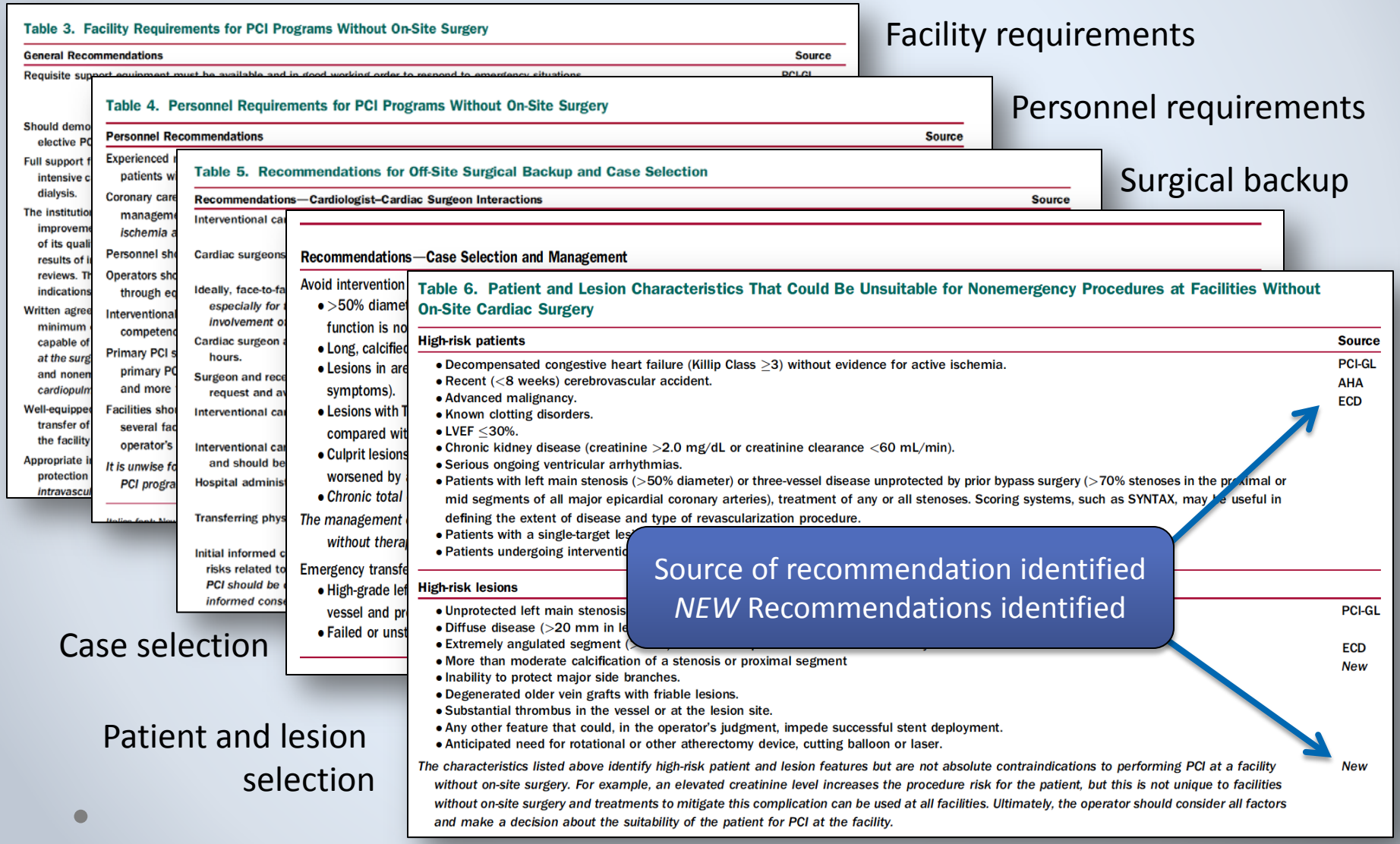
Attachment A

2007 SCAI Expert Consensus Document



Best Practices for PCI Without On-Site Surgery

Attachment A



Facility requirements

Personnel requirements

Surgical backup

Case selection

Patient and lesion selection

Source of recommendation identified

NEW Recommendations identified

Defining Geographic Isolation (by Time)

2011 PCI Guideline says . . .

It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

The problem is . . .

"In the same geographic area" or "geographic isolation" has never been clearly defined.

	Door to ECG < 10 min	Summon cath team from home ≤ 30 min	Artery open in lab < 30 min	Artery open in receiving cath lab < 30 min
Has PCI program	8	≤ 30; stabilize pt.	≤ 30	
No cath lab	8	≤ 30; stabilize pt.	≤ 30	≤ 30
		Time in ED before transport	Transport time	

In the ***ideal*** situation, 30 minutes saved

If PCI Without On-Site Surgery is Safe, What's the Question?

What is the role of PCI without on-site surgery in US healthcare today . . . . . and in Michigan?

Key Questions:

1. Have we improved access?
2. Are we maintaining quality?

* * * * * * * * * * * * * * * * * * * *

Are we just developing more PCI labs.

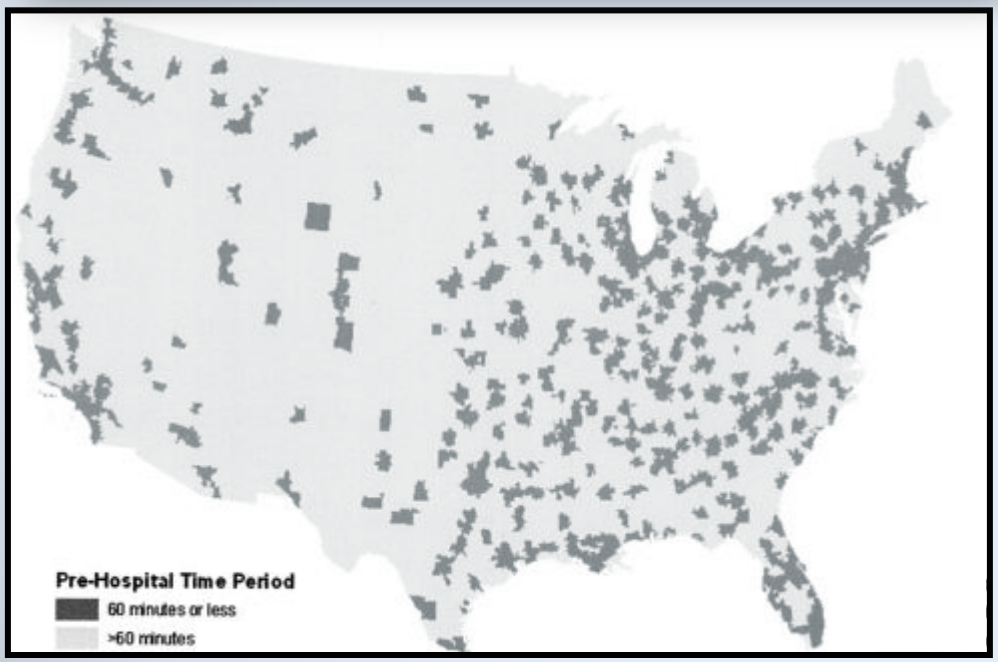
Have We Improved Access?

Health Services and Outcomes Research

Driving Times and Distances to Hospitals With Percutaneous Coronary Intervention in the United States

Implications for Prehospital Triage of Patients With ST-Elevation Myocardial Infarction

Brahmajee K. Nallamothu, MD, MPH; Eric R. Bates, MD; Yongfei Wang, MS; Elizabeth H. Bradley, PhD; Harlan M. Krumholz, MD, SM



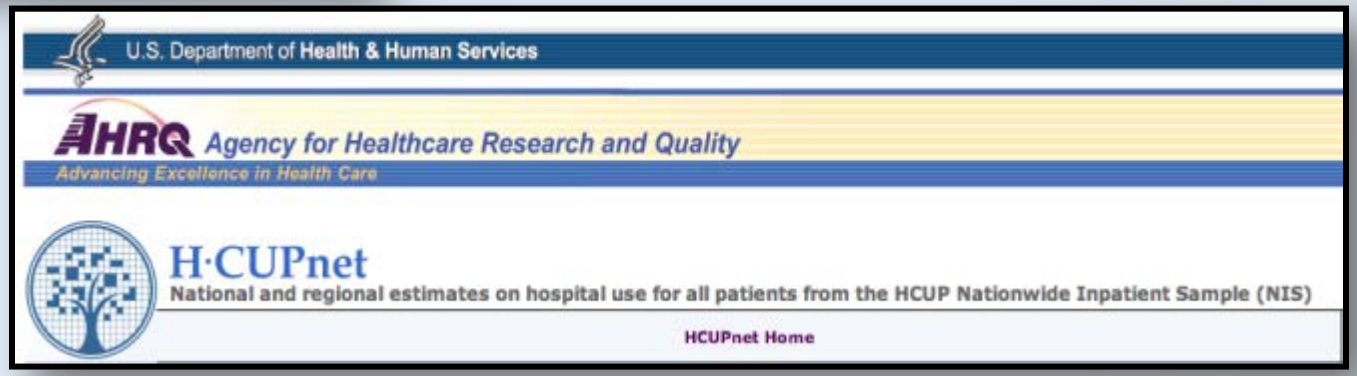
How Close is the Nearest PCI Hospital?

- In 2001, 4609 Acute care hospitals; 1176 (25%) PCI capable
- Median time to a PCI hospital was 11.3 (IQR 5.7 – 28.5) minutes
- Median distance to a PCI hospital was 7.9 (IQR 3.5 – 22.4) miles
- **79% of the adult population live within 60 minutes of a PCI hospital**
- ~ 3/4 would experience a < 30 minute delay by bypassing a non-PCI hospital and going directly to a PCI facility
- Greater times to PCI facilities in rural areas

Nallamothu B, et al Circulation 2006;113:1189-95.

What Happened from 2001 to 2006?

American Hospital Association®

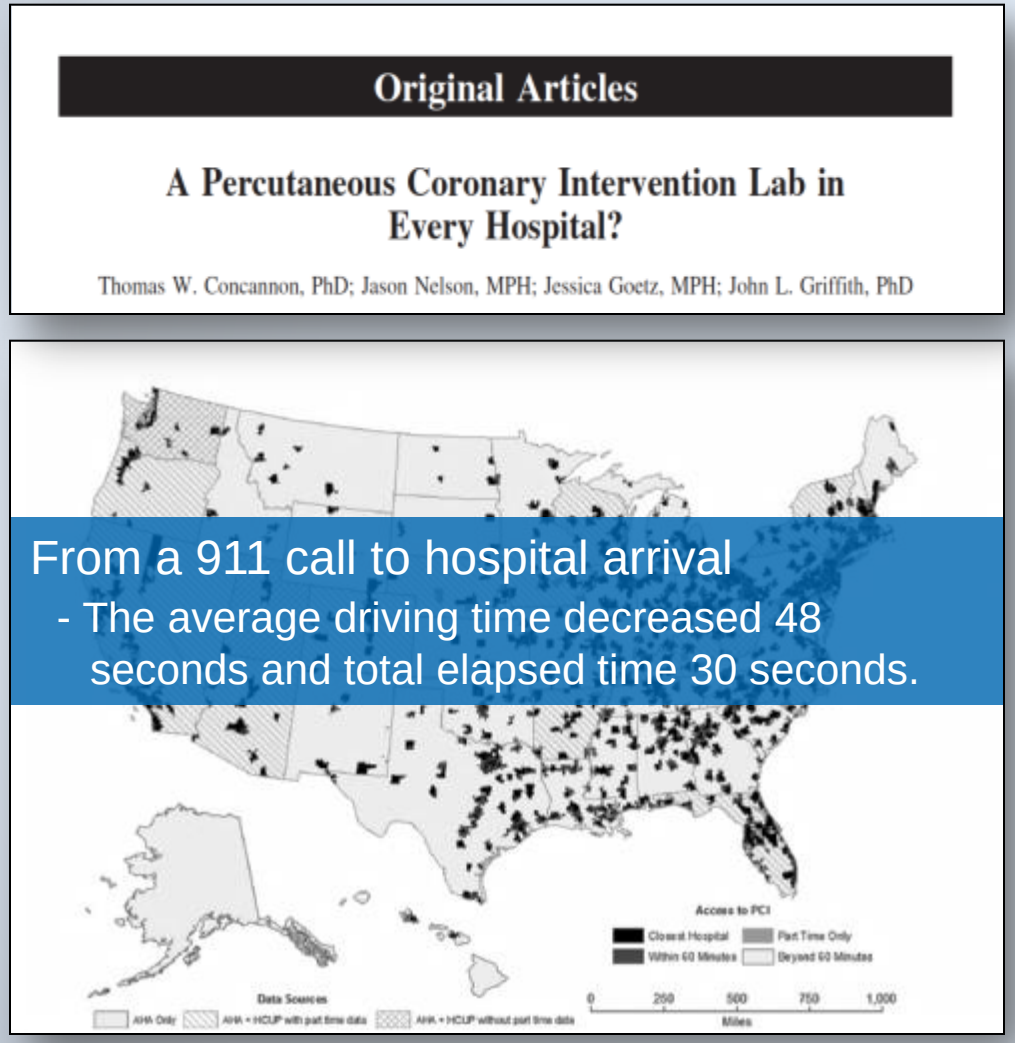


According to data from the American Hospital Association cross-referenced with the AHRQ – HCUP inpatient sample, the number of PCI-capable labs increased by . . . .

519 – a 44% relative increase

Concannon TW, et al. Circ Cardiovasc Qual Outcomes 2012;5:14-20.

Have We Improved Since 2001?



Original Articles

A Percutaneous Coronary Intervention Lab in Every Hospital?

Thomas W. Concannon, PhD; Jason Nelson, MPH; Jessica Goetz, MPH; John L. Griffith, PhD

From a 911 call to hospital arrival
- The average driving time decreased 48 seconds and total elapsed time 30 seconds.

Access to PCI
Closest Hospital
Part Time Only
Within 60 Minutes
Beyond 60 Minutes
Data Sources
AHA Only
AHA + HCUP with part time data
AHA + HCUP without part time data
0 250 500 750 1,000
Miles

- In 2001, 1176 US hospitals were PCI-capable and 79% of the adult population lived within 60 minutes of a PCI hospital
- **From 2001 to 2006 the number of PCI capable hospitals grew by 44% to 1695 (n=519)**
- Using the same population estimate (% of population within 60 minutes of a PCI hospital) access grew from 79.0% to . . . .

79.9%
< 1% increase

Concannon TW, et al. Circ Cardiovasc Qual Outcomes 2012;5:14-20.

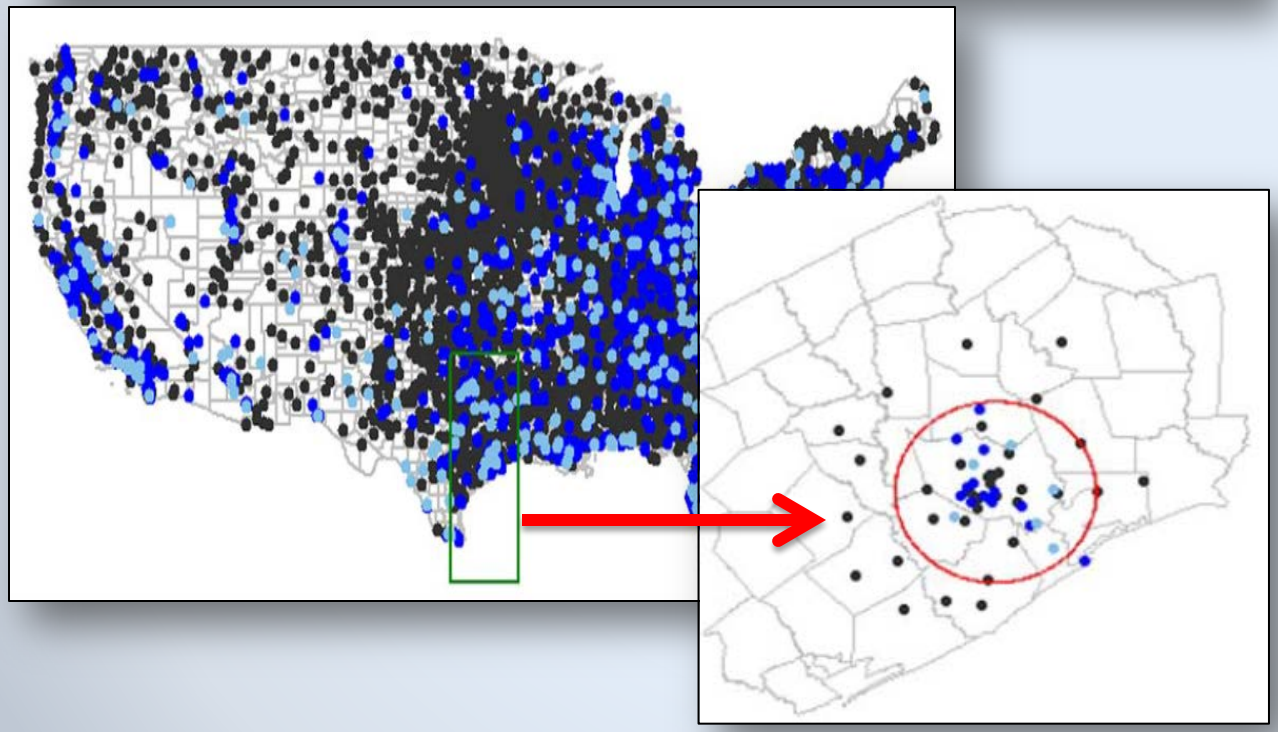
Where Are We Building New Cath Labs?

Attachment A

Health Services and Outcomes Research

Expansion of Invasive Cardiac Services in the United States

Jill R. Horwitz, PhD, JD, MPP; Austin Nichols, PhD, MPP;
Brahmajee K. Nallamothu, MD, MPH; Comilla Sasson, MD, MS; Theodore J. Iwashyna, MD, PhD



- From 1996 to 2008 - 387 new PCI facilities
- An existing PCI facility within 40 miles increased the odds of a new facility opening by 79%
- Hospitals are most likely to open a new PCI facility when neighboring hospital already offer PCI services.

- No PCI in 1997
- PCI in 1997
- New PCI in 2008

Horwitz JR et al. Circulation 2013;128:803-10.

Attachment A

Original Article

Evidence of Systematic Duplication by New Percutaneous Coronary Intervention Programs

Thomas W. Concannon, PhD; Jason Nelson, MPH; David M. Kent, MD; John L. Griffith, PhD

From 2004 to 2008 there was a relative increase of 16.5% in PCI-capable hospitals, yet the percentage of the US population with projected access to timely PCI grew by only 1.8%

New PCI programs were more likely to be introduced in areas that:

- *already had a PCI program with more competition for market share,*
- *near populations with higher rates of private insurance,*
- *in states that had weak or no regulation of new cardiac cath labs,*
- *and in wealthier and larger hospitals.*

Conclusions: *Our data show that new PCI programs were systematically duplicative of existing programs*

Concannon TW, et al. Circ Cardiovasc Qual Outcomes 2013;6:400-08.

PCI Centers per 1 Million Population

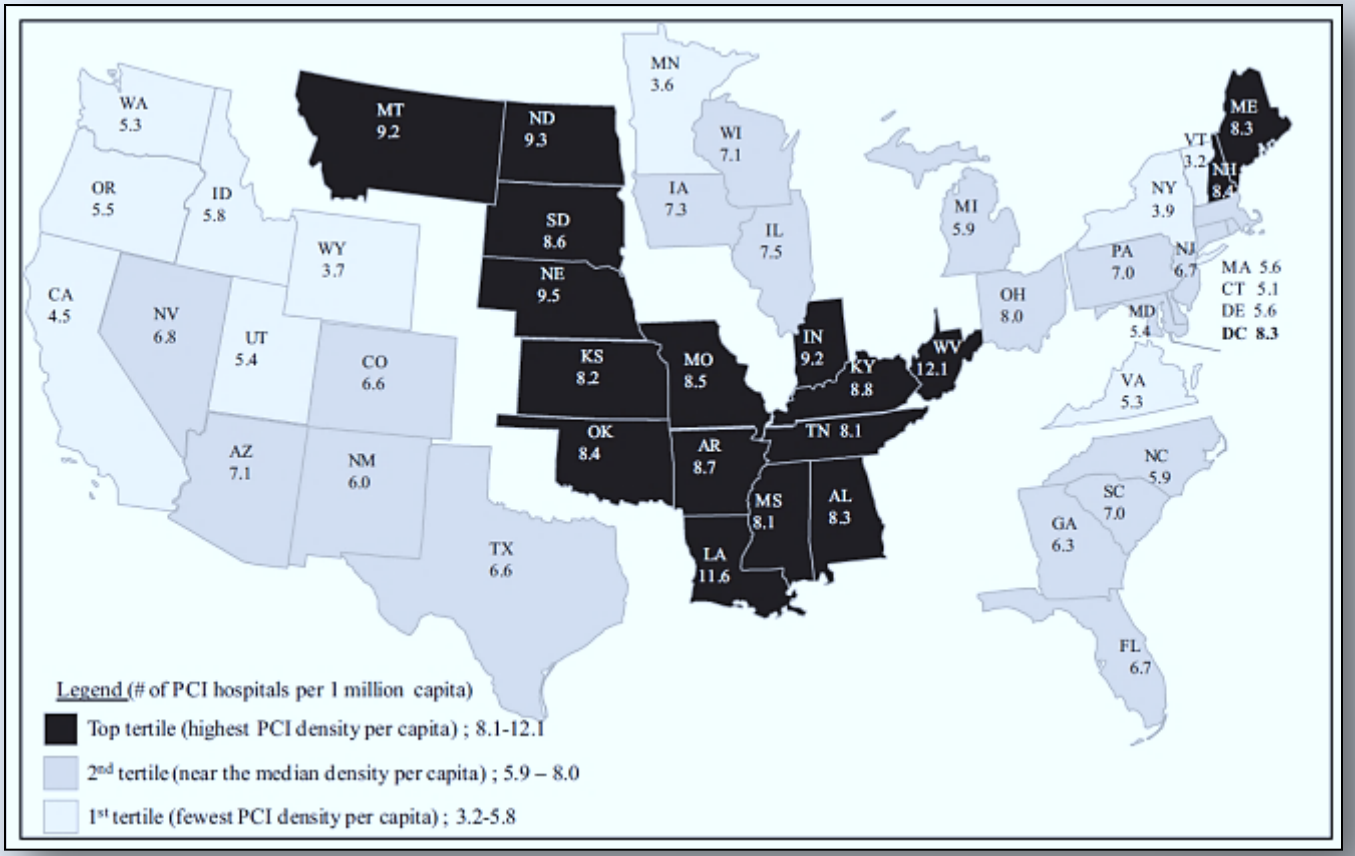
Attachment A

Data (2003 – 2011) from American Hospital Association, US Census and CDC

PCI centers: ↑ 20.2%
39% of hospitals

US population: ↑ 8.3%

MI prevalence:
↓ 4.0 to 3.7%

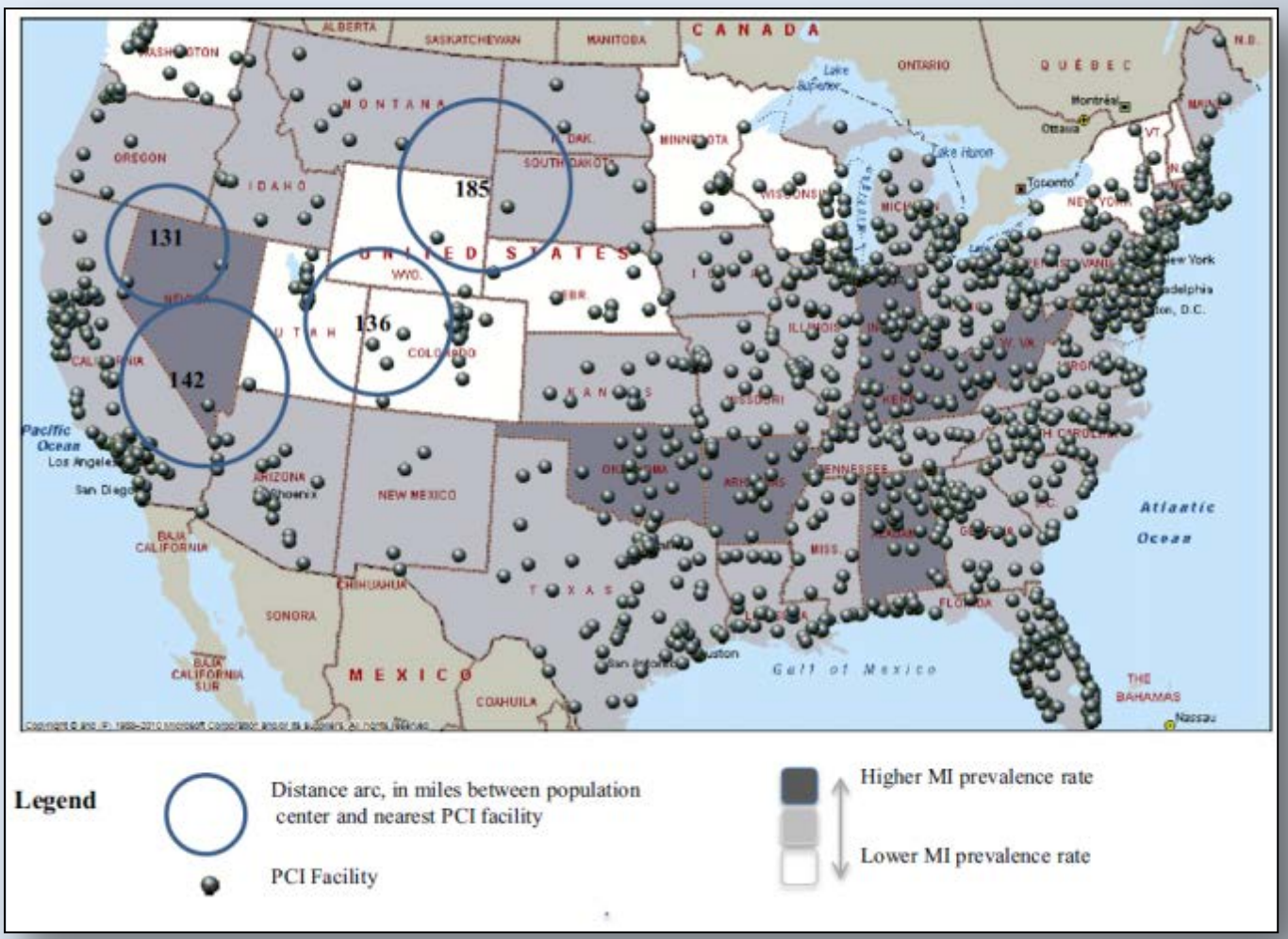


Langabeer JA, et al. J Am Heart Assoc 2013;2:000370.

PCI Centers and MI Prevalence Rate

Attachment A

The 4 distance arcs on the map show the greatest potential access difficulties in terms of transport times and would appear to benefit the most from a regionalized transfer system using air ambulances



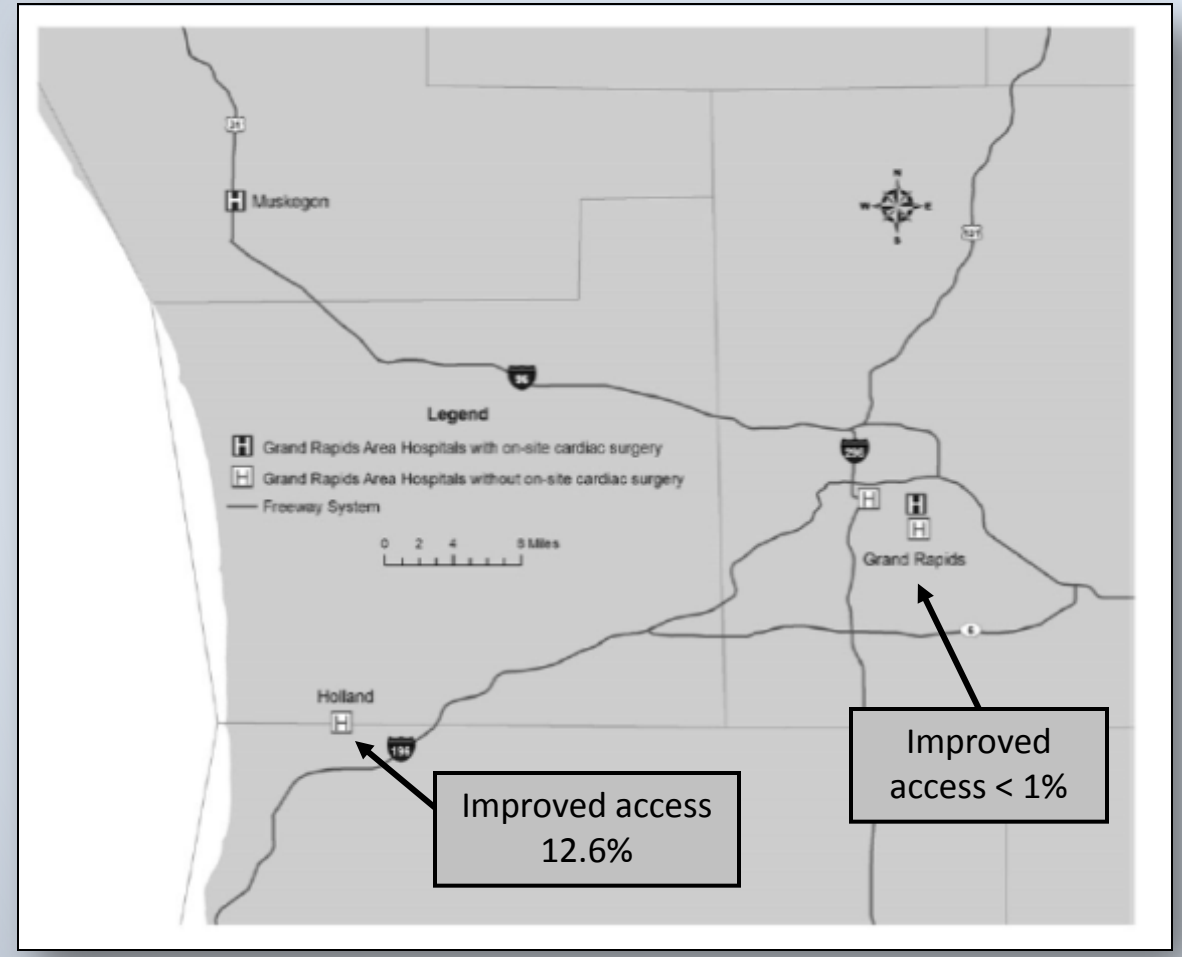
Langabeer JA, et al. J Am Heart Assoc 2013;2:000370.

Improved Access in Michigan?

Primary percutaneous coronary intervention expansion to hospitals without on-site cardiac surgery in Michigan: A geographic information systems analysis

Attachment A

Jeremy W. Buckley, MD,[a] Eric R. Bates, MD,[a] and Brahmajee K. Nallamothu, MD, MPH[a,b] *Ann Arbor, MI*



- In 2005, the state expanded PPCI to 12 hospitals without on-site surgery
- **99.7%** of the population lives within 20 miles of a hospital capable of lytic Rx and/or PPCI
- **72.6%** lived within 20 miles of a PPCI facility with on-site surgery
- Expansion of PPCI to 12 hospitals without surgery increased access to **4.8%** of the population
- Geographically isolated hospitals (> 20 miles from a PPCI facility) accounted for most of the access improvement

Buckley JW, et al. Am Heart J 2008;115:669-72

Improved Access in Michigan?

Paul L Delamater, PhD
Department of Geography
Michigan State University

July 16, 2014
Cardiac Catheterization
Standard Advisory Committee

Potential Gain in Access

- Changing the Standards to allow elective PCI at facilities without OHS would result in very small increases in geographic access
  - Statewide, less than 17% of the adult population would have more than a 9 minute improvement in access due to increased number of facilities
    - Less than 5% would have an improvement of more than 19 minutes
    - Less than 1% would have an improvement of more than 29 minutes

Attachment A

Is This Where PCI is Headed?

CHICAGO SUN-TIMES.com

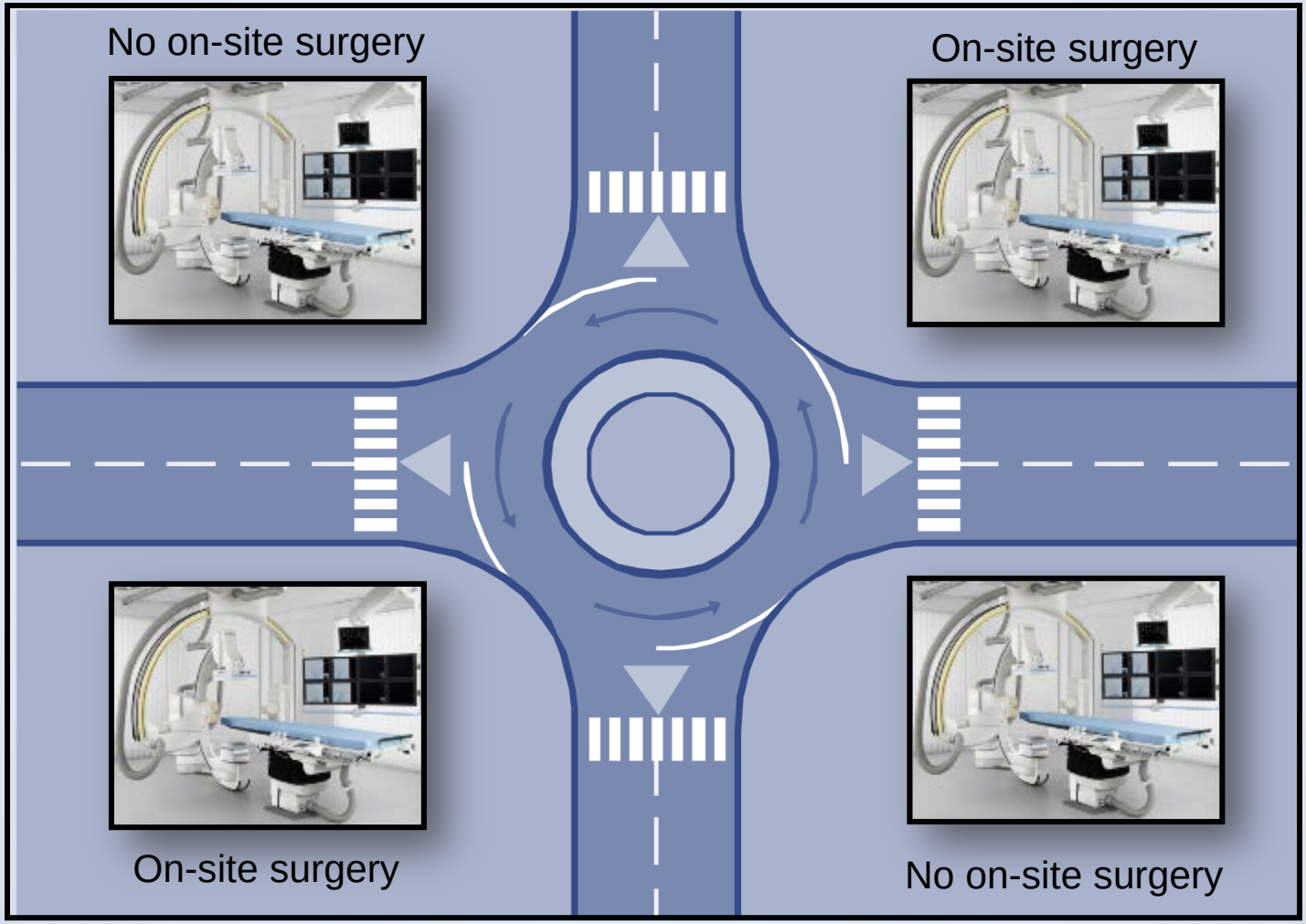
Updated: March 1, 2012 12:29PM

To the average Chicagoan, the drugstore chains Walgreen (WAG) and CVS Caremark (CVS) could be clones. The stores have similar layouts and merchandise. Even the color schemes look alike.

And in their core markets, they both are determined to make their stores unavoidable. They provide saturation coverage, sometimes across the street from each other.

2014 – Are we setting up PCI . . . in all the wrong places

Attachment A



Why So Many New PCI Programs?

Attachment A

1. Medicare payments to hospitals for invasive cardiac procedures have generally remained favorable, although physician reimbursement has decreased

2. PCI programs bring prestige to an institution, and STEMI is one of the most prestigious diseases for treatment

   JAMA 2011;306:2507-2509; Soc Sci Med 2008;66:182-8.

3. With the push to develop rapid STEMI care, EMS is likely to bypass a facility in favor of a PCI capable hospital with the loss of downstream revenue from additional testing in patients not having a STEMI.

With decreasing facility and physician PCI procedure volumes, are we maintaining quality

Are We Maintaining Quality in PCI?

Attachment A

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CLINICAL COMPETENCE STATEMENT

ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

A Report of the American College of Cardiology Foundation/American Heart Association/ American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures)

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*American College of Cardiology Foundation representative; †Society for Cardiovascular Angiography and Interventions representative; ‡American Heart Association representative

J Am Coll Cardiol 2013; 62:357-96

Defining Quality and Competency in PCI

- Selecting appropriate patients
- Achieving risk-adjusted outcomes that are comparable to national benchmarks
  - Procedure success, adverse event rates
- Using reasonable resources
- Achieving quality procedure execution (use of evidence based therapies)
- Providing an acceptable patient experience

Is procedure volume the right a metric for assessing competency and quality?

Volume vs. Outcome Relationships

Common sense & the volume outcome relationship

- If you have no volume you can't assess outcome
- It's hard to assess outcomes when volume is small
  - Sample size, wide confidence intervals
  - Distorted percentages
- The larger the volume, the more reliable your assessment of outcome will be
  - Narrow confidence intervals
- Doing a PCI that should not have been done in the first place is not the way to add volume to a facility
  - Inappropriate, unnecessary procedures

Is There an Operator Volume vs. Outcome Relationship?

The Competency Document says . . . .

Identified 9 studies examining the relationship between individual operator and procedural outcomes in the stent era.

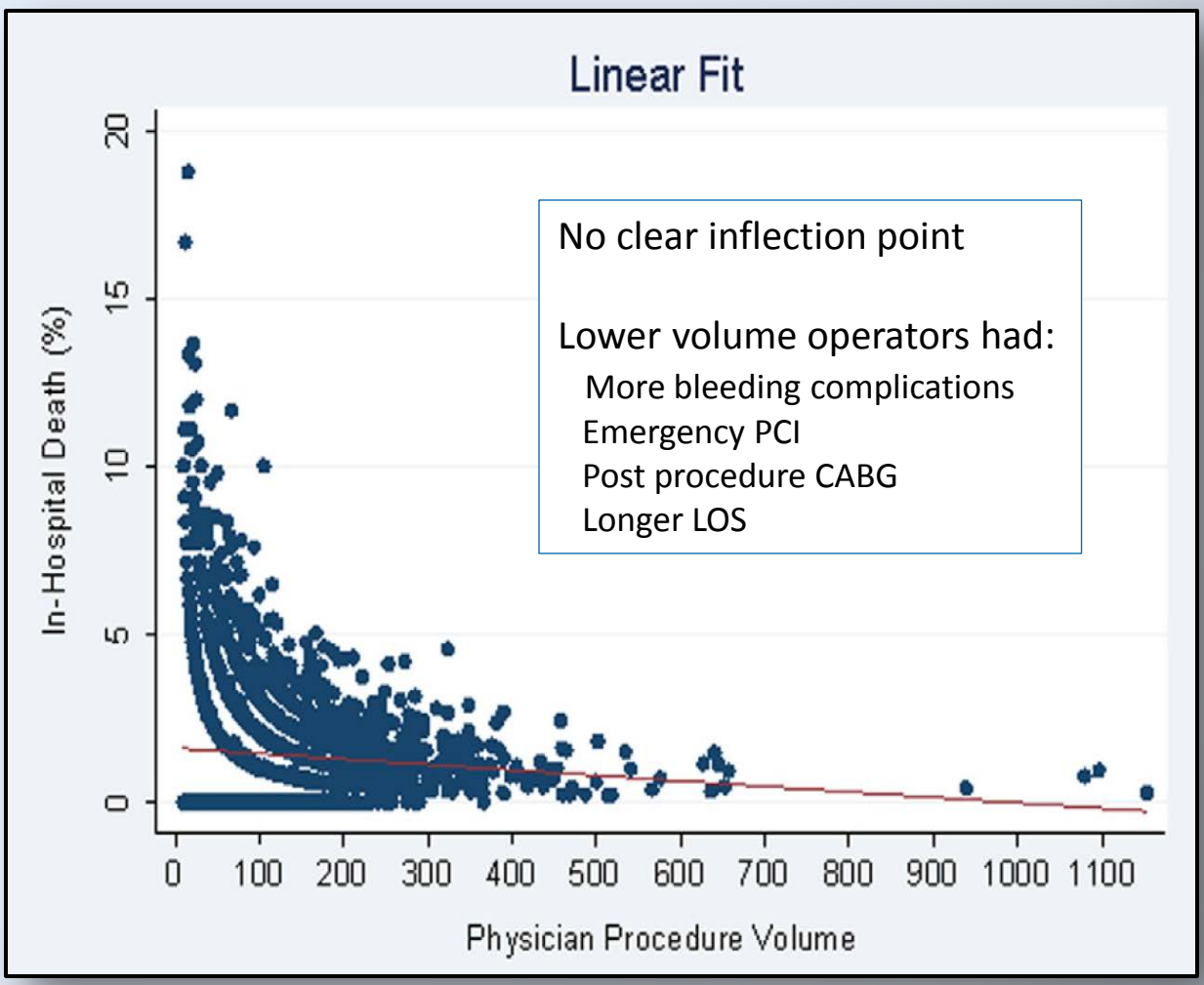
- 4 showed the existence of a relationship between low operator volume and increased adverse outcomes, predominantly urgent CABG; 1 showed a modest correlation with in-hospital mortality
  - The 3 largest (each > 100,000 subjects) supported the existence of such a relationship

Hannan EL et al Circulation 2005;112:1171-9
McGrath PD, et al. JAMA 2000;284:3139-44.
Minges KE, et al. Circulation 2011;124:16550

Is There an Operator Volume vs. Outcome Relationship?

- Study cohort:
  - 3,649 physicians
  - 345,526 PCIs
  - 543 hospitals
- Adjusted for:
  - Pt. demographics
  - Comorbidities
  - Cardiac Status
  - Hospital volume

- After multivariable adjustment, in-hospital mortality was 14% higher for those performing < 75 PCIs/year compared with ≥ 75/year (absolute difference = 0.3%)

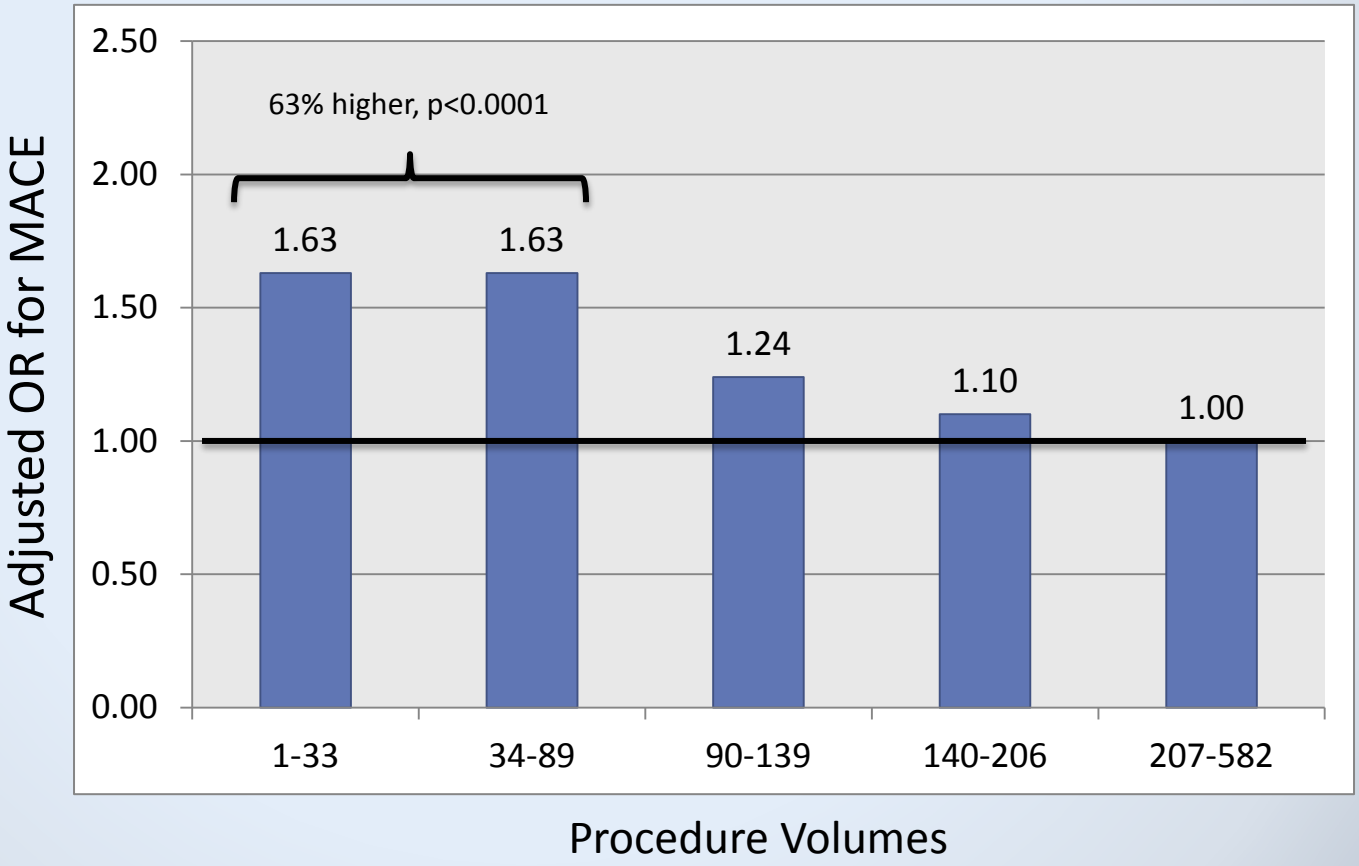


Minges KE, et al. Circulation 2011;124:16550

Is There an Operator Volume vs. Outcome Relationship?

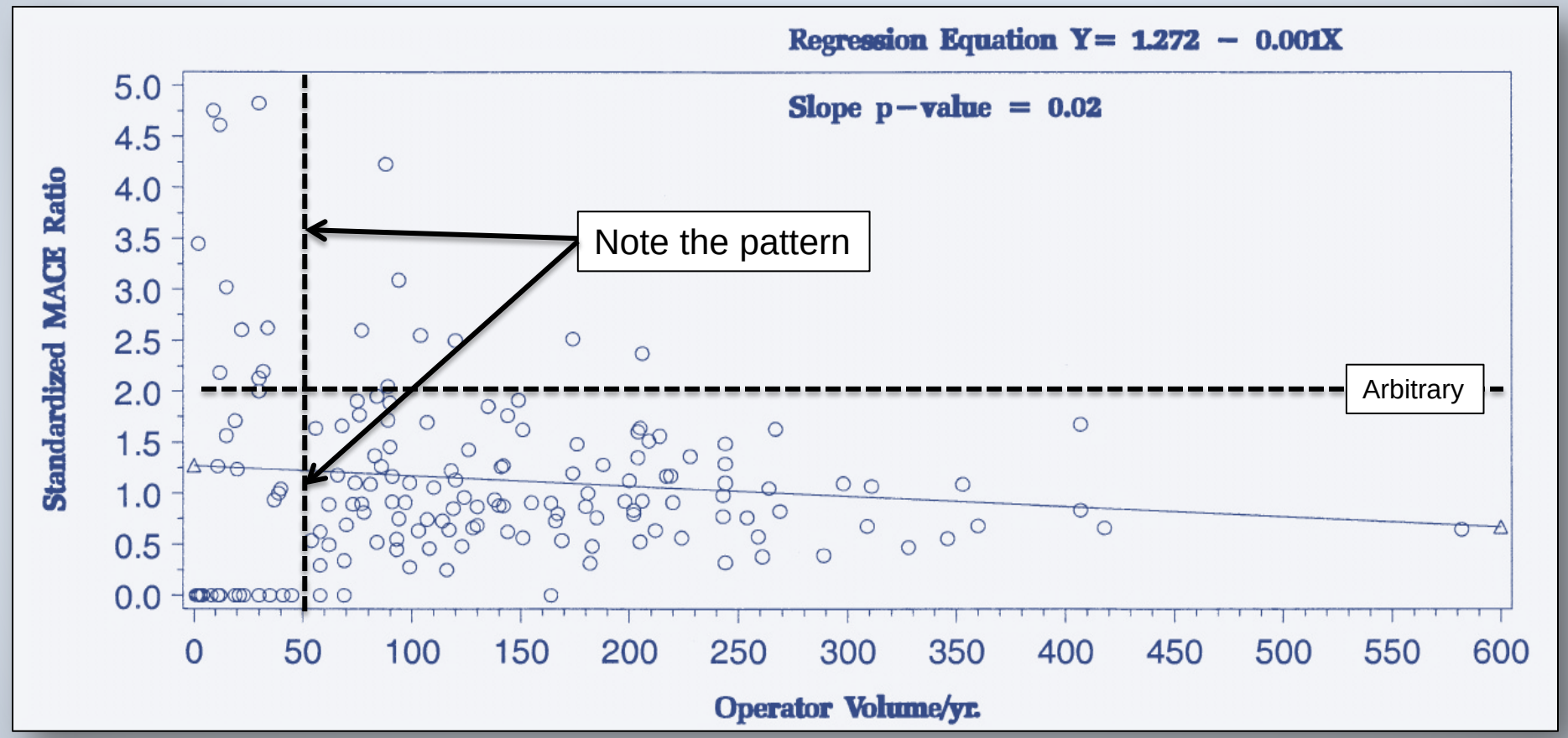
- **Study cohort:** 165 physicians; 18,504 PCIs; 14 hospitals
- **Adjusted for:** Age, gender Hx of CHF, CABG, vascular disease, COPD, emergency procedure, elevated Cr, LVEF < 50%, lesion type, LM disease, 3v disease, thrombus present, cardiac arrest, MI, shock, VT/VF and unstable angina

Death alone was not significant



Moscucci M, et al. J Am Coll Cardiol 2005;46(4):625-32.

Is There an Operator Volume vs. Outcome Relationship?



MACE = Major adverse cardiac events

Moscucci M, et al. J Am Coll Cardiol. 2005;46(4):625-32.

The Reality
How many PCIs did you do last year doctor?

Attachment A

Answer: Not as many as you think, and the number is going down; peaked in 2004
Reasons: Decreased restenosis due to DES, better medical therapy and adherence to guidelines, FFR, the AUC, too many interventionalists, fear of prosecution for overuse, etc . . .

In the 2008 FFS **Medicare data**: 378,372 PCI performed by 6,443 interventionalists.
30% of PCI were performed by operators doing < 40 PCIs/year (ave. = 29 PCIs)
61% of operators performed < 40 PCIs/year

PCI volume	Physicians in cohort	% Total	Aggregate PCI performed by cohort	% Total	Cohort average volume
1–40	3,929	61.0	112,679	29.8	29
41–200	2,329	36.1	213,345	56.4	92
>200	185	2.9	52,348	13.8	283
	6,443		378,372		

[a]PCI, percutaneous coronary intervention.

Maroney J, et al. Catheter Cardiovasc Interv. 2013; 81:34-9.

Overall, it is the opinion of the writing committee that the available evidence does not send a loud signal supporting a consistently strong relationship between operator caseload and mortality (58,84–86). In part, this is a function of the extremely low procedural-related mortality that now exists for PCI. The preponderance of data available is related to clinical outcomes other than mortality and does suggest a possible relationship between operator volume and emergency CABG surgery and other PCI complications. On the basis of available data and the judgment of the writing committee involving all of these considerations, the writing committee recommends interventional cardiologists perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency. The writing committee acknowledges that this number is established primarily by expert opinion derived from the interpretation of substantial data from multiple sources (each with inherent limitations). Because of the limitations of these data, the writing committee believes operators performing <50 PCIs/year should not be denied privileges or excluded from performing coronary interventions based solely on their procedural volume. The committee acknowledges that there are low-volume operators who provide excellent clinical care and achieve excellent outcomes. In instances where operators are performing <50 PCIs annually, the writing committee strongly encourages both institutions and operators to carefully assess whether their performance is adequate to maintain competence. Other metrics are needed, in addition to volume and risk-adjusted outcomes, which have very wide confidence intervals at low procedure volumes, and thus are difficult to assess accurately. The committee suggests that each facility develop alternative pathways for the evaluation of low-volume operators. These pathways may be established and monitored by an independent institutional committee (consisting of physicians and relevant healthcare personnel) or an external review organization. The writing committee emphasizes that volume is but 1 of several factors that should be considered when assessing an individual operator's competence. Other factors to consider for low-volume operators include (but are not limited to): performance of additional noncoronary cardiovascular interventional procedures, lifetime experience, ABIM certification in interventional cardiology, attendance at educational symposiums, CME credits, and simulation courses.

What Does the Document Say?

Attachment A

The Key Points:

- The available evidence <u>does not support a strong relationship between operator volume and mortality</u>
  - In part, related to current low overall mortality
- The preponderance of data related to outcomes other than mortality suggest a <u>possible relationship between operator volume and other complications</u>
- **The new minimum number is 50 PCIs/year**
  - This is based on primarily on expert opinion
- Because of the limitations of these data, operators performing < 50 PCIs/year should not be denied privileges
- Each facility should have an internal mechanism (quality program) to evaluate low volume operators or use an external review organization

J Am Coll Cardiol 2013; 62:357-96

Volume-Outcome Relationship Confirmed

Attachment A

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association®

Impact of Annual Operator and Institutional Volume on Percutaneous Coronary Intervention Outcomes: A 5-Year United States Experience (2005 - 2009)

Apurva O. Badheka, Nileshkumar J. Patel, Peeyush Grover, Vikas Singh, Nilay Patel, Shilpkumar Arora, Ankit Chothani, Kathan Mehta, Abhishek Deshmukh, Ghanshyambhai T. Savani, Achint Patel, Sidakpal S. Panaich, Neeraj Shah, Ankit Rathod, Michael Brown, Tamam Mohamad, Frank V. Tamburrino, Saibal Kar, Raj R. Makkar, William W. O'Neill, Eduardo De Marchena, Theodore Schreiber, Cindy L. Grines, Charanjit S. Rihal and Mauricio G. Cohen

Healthcare Cost and Utilization Project (HCUP) Inpatient Sample: 457,498 PCIs
Operator and institutional values separated into quartiles

Outcomes significantly worse in the lowest quartile

	Operator Volume			
Outcome	**> 100**	**45-100**	**16-44**	**≤ 15**
In-hospital all cause mortality	0.59%	0.87%	1.15%	1.68%
In-hospital mortality and peri-procedural complications	5.51%	6.40%	7.75%	10.91%

Published on line 9/4/14

Is There an Facility Volume vs. Outcome Relationship?

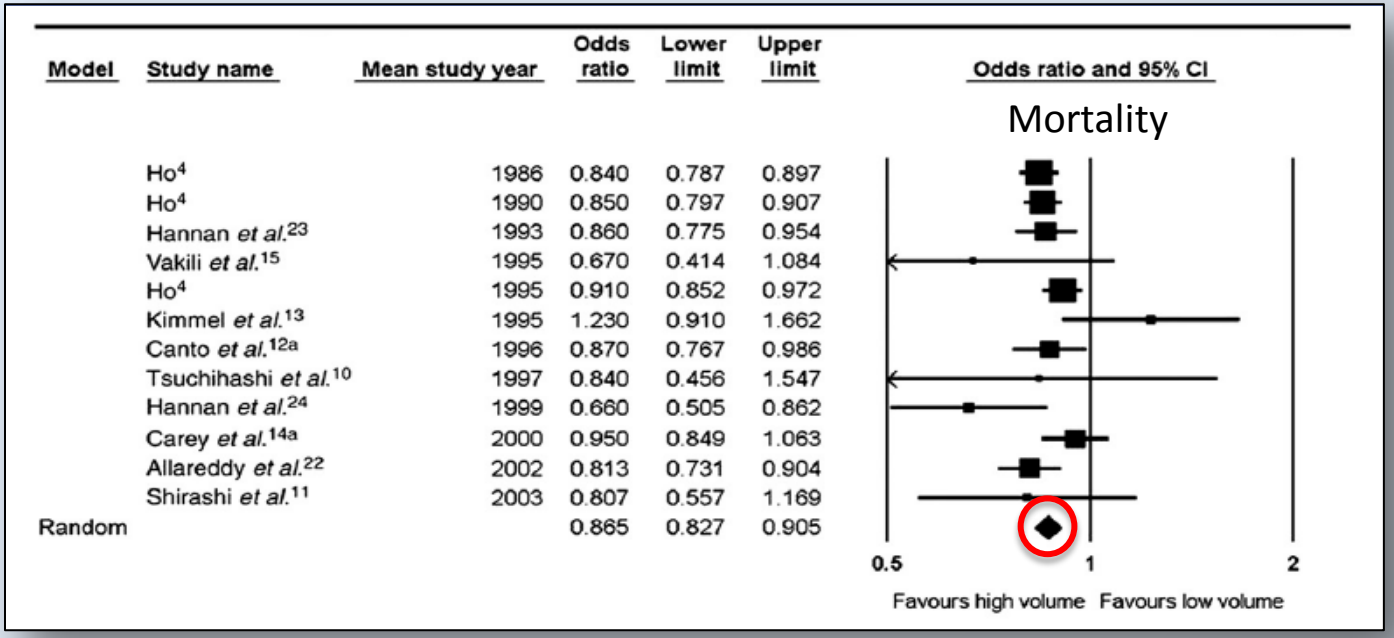
Attachment A

The Competency Document says . . . .

Identified 17 studies examining the relationship between facility volume and procedural outcomes.

Of the 8 studies during the balloon angioplasty era, all but 1 showed a relationship between hospital volume and facility volume with lower volumes associated with the need for in-hospital CABG (6 studies) or in-hospital mortality (4 studies)

More recent data (12 sites)



Post PM, et al. Eur Heart J 2010;31:1985-92

What Does the Document Say?

Overall, the preponderance of data suggests that hospitals in which fewer coronary interventions are performed have a greater incidence of adverse events, notably death and CABG surgery for failed intervention, than hospitals performing more procedures. This relation is supported by earlier studies in the PTCA era (46,69–74), contemporary studies in the stent era (57,58,75–81), and a recent meta-analysis (82). The writing committee recognizes the wide variability of institutional volume thresholds used in the different studies and the complexity and multitude of factors influencing PCI outcomes. However, it is important to note that a signal exists suggesting that an institutional volume threshold <200 PCIs/year appears to be consistently associated with worse outcomes across the various studies (Online Appendix 1) (58,75,80). Full-service (both primary and elective PCI) laboratories performing <200 total cases annually require additional considerations. Many such low-volume laboratories do not have onsite surgery and were developed to provide PPCI services to underserved or geographically isolated populations; a situation that the 2011 PCI guideline acknowledges may be acceptable. Elective PCI is often performed in these facilities to increase the volume of procedures and thus maintain facility and operator proficiency. There are also some laboratories that provide only PPCI service to similar populations. Such facilities must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger-volume facilities. The continued operation of low-volume laboratories that are not serving isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should close. This becomes increasingly relevant in an era of declining procedural volumes and expanded care delivery models for patients with STEMI (83).

The Key Points:

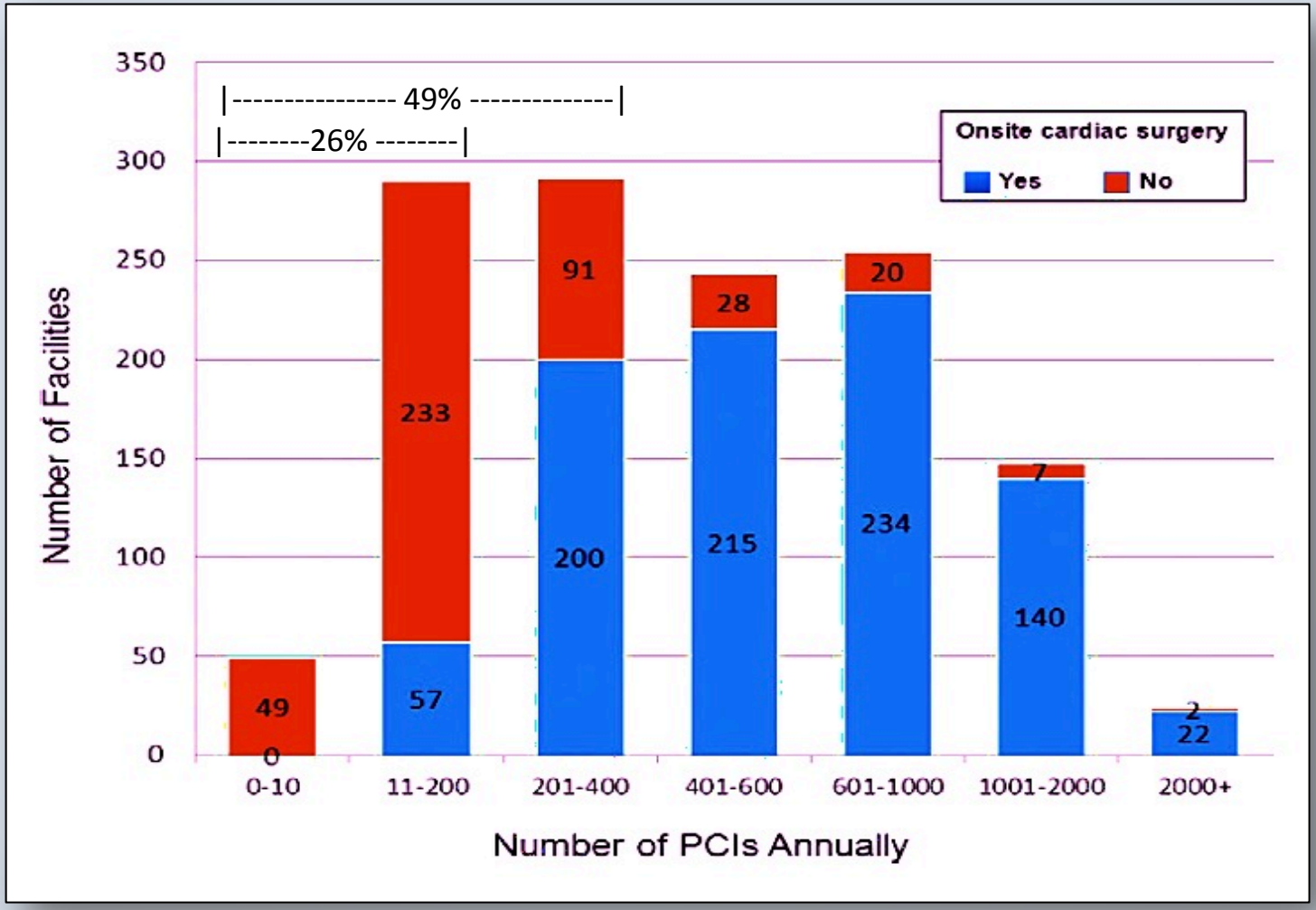
- The preponderance of data suggests that hospitals in which fewer interventional procedures are performed have a greater incidence of adverse events, notably death and CABG surgery than hospitals performing more procedures
- A “signal exists” suggesting that an institutional volume threshold of < 200 PCIs/year appears to be consistently associated with worse outcomes
- Labs performing < 200 PCIs annually “require additional considerations”
- Such facilities must have stringent systems and process protocols with close monitoring of clinical outcomes

J Am Coll Cardiol 2013; 62:357-96

Why is Volume a Concern?

Attachment A

The majority of sites without on-site surgery are low volume



Dehmer, et al. J Am Coll Cardiol 2012; 60:2017-31.

Is There an Operator or Facility Volume vs. Outcome Relationship for STEMI?

Attachment A

The Competency Document says . . . .

Identified 16 studies examining the relationship between facility or operator volume and outcomes in patients undergoing PPCI for STEMI.

- 4 showed no relationship between volume and mortality although 1 showed shorter D-2-B times and greater adherence to guideline-directed therapies in higher volume centers.
  - In the remaining 12 studies, 10 showed a significant inverse relationship between hospital PPCI volume and in-hospital mortality
    - 2 studies showed an inverse relationship between operator PPCI volume and in-hospital mortality; 1 study did not show a relationship

2011 PCI Guidelines: 36/facility and 11/operator annually

J Am Coll Cardiol 2013; 62:357-96

Support for an Volume vs. Outcome Relationship for STEMI

Attachment A

- Study cohort: 7,321 PPCIs
- Examined risk-adjusted mortality rates at:
  high-volume hospitals (>50 PPCI/yr) and by high-volume physicians (>10 PPCI/yr)

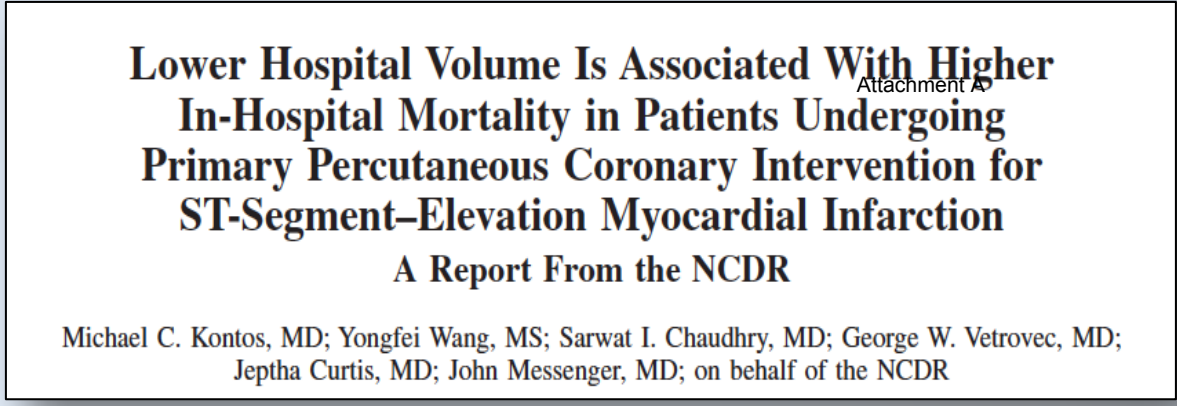
Average Mortality by Hospital and Physician

Physician Volume	Hospital Volume	Patients, n	Observed Mortality*	Risk-Adjusted Mortality Rate†
>10/yr (n = 90)	>50/yr	4,712	3.2 (0.33)	3.8 (0.42)
>10/yr (n = 36)	≤50/yr	526	3.5 (0.90)	4.8 (1.23)
≤10/yr (n = 140)	>50/yr	1,461	4.2 (0.90)	6.5 (2.12)
≤10/yr (n = 97)	≤50/yr	622	6.7 (1.6)‡	8.4 (2.73)§
>20/yr (n = 29)	>50/yr	2,424	2.8 (0.40)	3.5 (4.27)
>20/yr (n = 10)	≤50/yr	106	3.0 (1.9)	2.6 (1.39)
≤20/yr (n = 201)	>50/yr	3,749	4.0 (0.6)	5.7 (1.50)
≤20/yr (n = 123)	≤50/yr	1,042	6.1 (1.2)‖	7.9 (2.16)‖

Greatest differences seen with lower volume physicians at lower volume hospitals
The higher the volume for hospitals or physicians, the better the outcome

Srinivas VS, et al. J Am Coll Cardiol 2009;53(7):574-9.

More Recent Support



Attachment A

Lower Hospital Volume Is Associated With Higher In-Hospital Mortality in Patients Undergoing Primary Percutaneous Coronary Intervention for ST-Segment–Elevation Myocardial Infarction

A Report From the NCDR

Michael C. Kontos, MD; Yongfei Wang, MS; Sarwat I. Chaudhry, MD; George W. Vetrovec, MD; Jeptha Curtis, MD; John Messenger, MD; on behalf of the NCDR

The Key Points:

- Data from the NCDR Cath PCI Registry
  - 87,324 patients; 738 hospitals. Separated into 3 PPCI group:
    - ≤ 36/yr (n=238), > 36 – 60/yr (n=236), > 60/yr (n=224)
    - 54% treated at high-volume hospitals, 15% at low volume hospitals

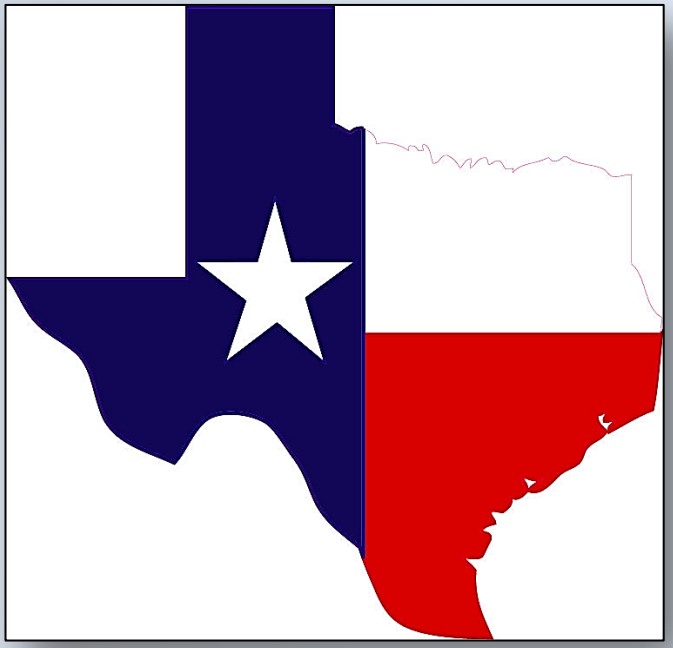
Results:

- Unadjusted mortality was higher in low volume hospitals compared with high volume hospitals (5.6% vs. 4.8%, p<.001)
- This was maintained after multivariate adjustment
- Mortality was not significantly different between intermediate and high volume hospitals
- D2B times shorter at high volume hospitals (72 vs. 77 minutes, p<.0001)

Circ Cardiovasc Qual Outcomes 2013;6(7):574-9.

What About Texas?

Attachment A



Data from Texas Health Care information Collection

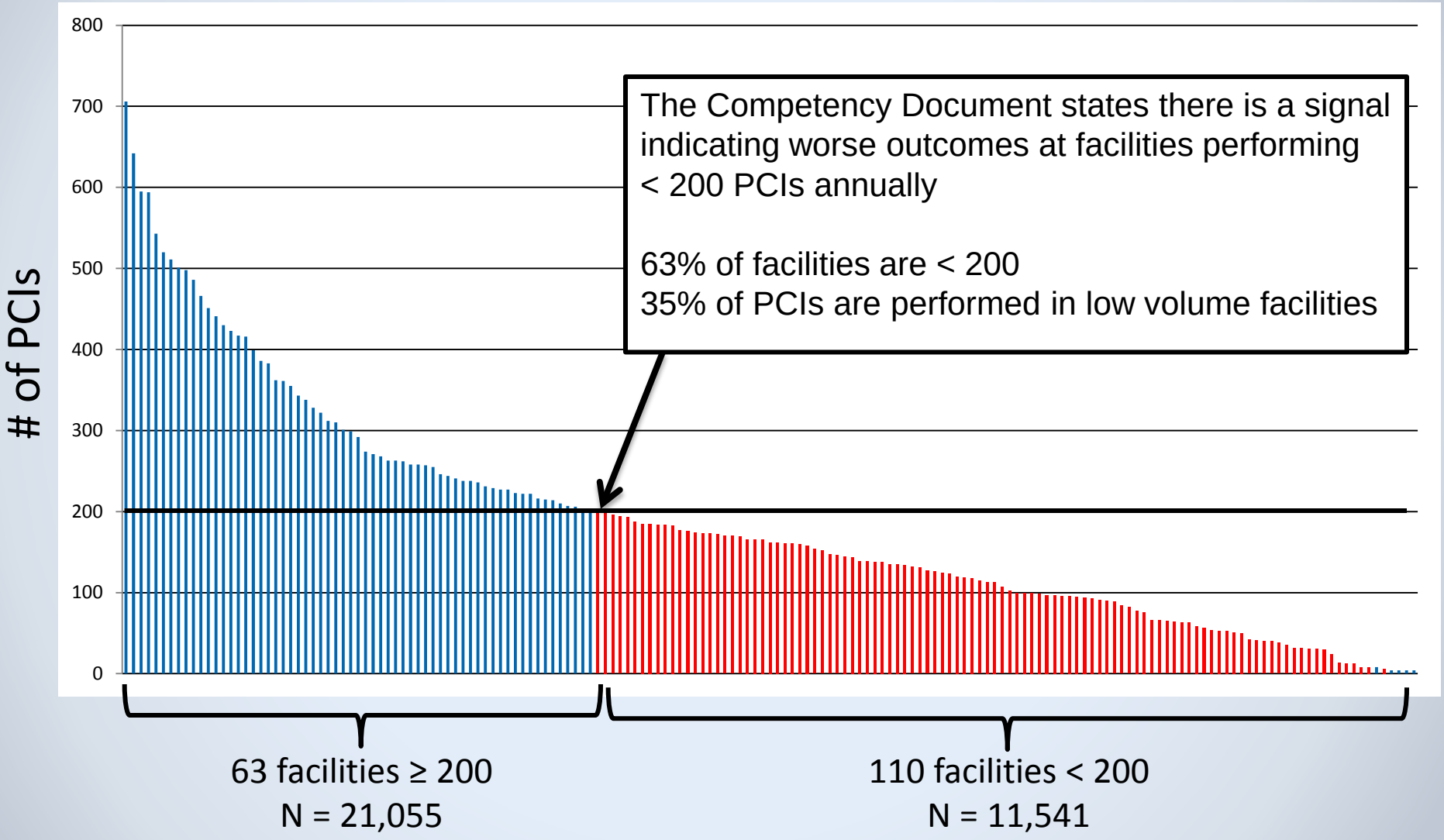
THCIC provides volume and mortality data for CABG and PCI

- CABG: 140 sites; 15,321 surgeries
- PCI: 173 sites; 32,596 PCIs
- PCI/CABG ratio = 2.1 (low)

http://www.dshs.state.tx.us/thcic/

PCI Volume per Facility in Texas

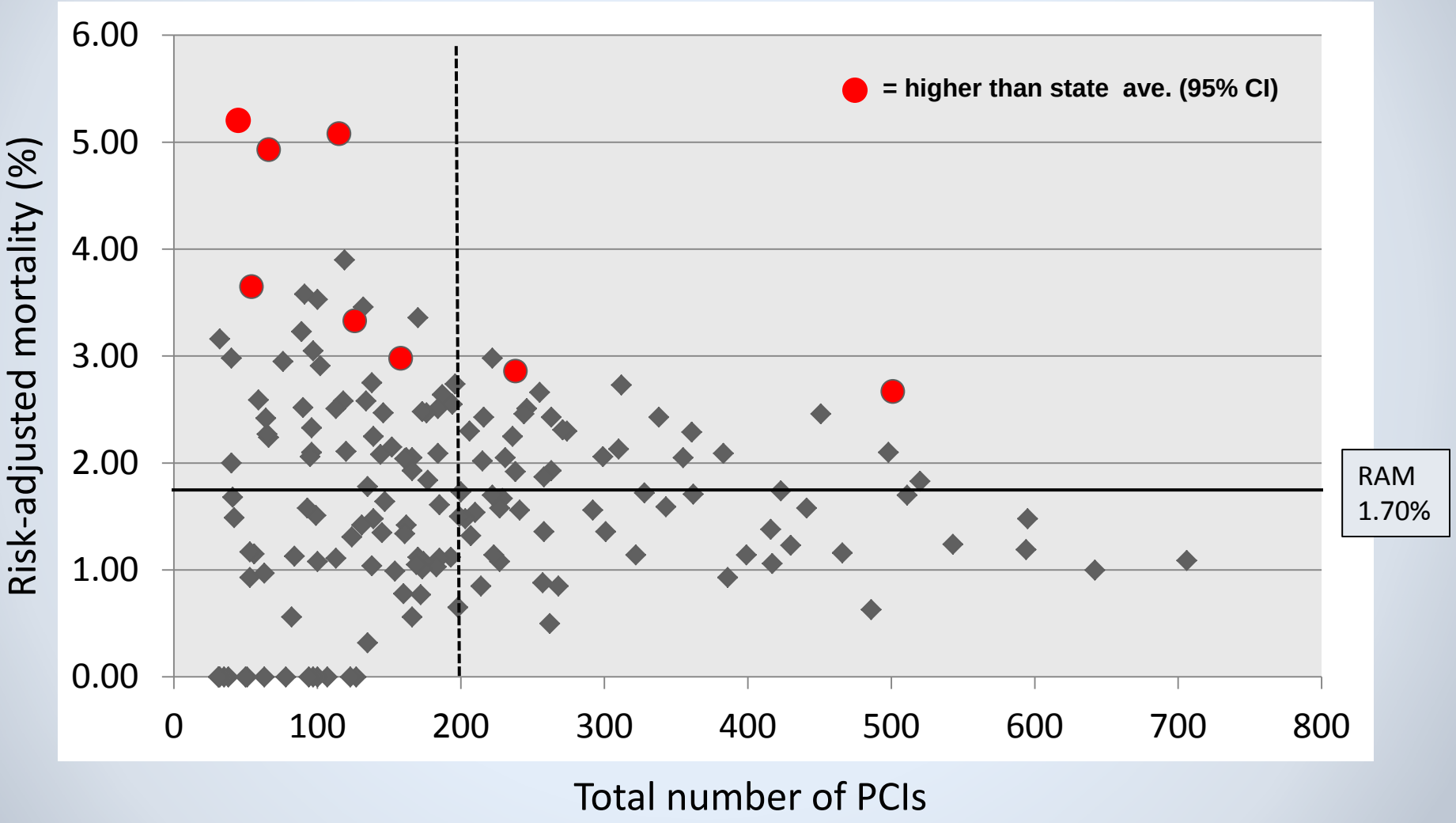
Attachment A



http://www.dshs.state.tx.us/thcic/

Volume vs. Risk-Adjusted Mortality in Texas

Attachment A



http://www.dshs.state.tx.us/thcic/

My Recommendations for Michigan

Attachment A

My simple bottom line:

1. Elective PCI without on-site surgery is safe, so stop worrying about this
2. National data suggests there are too many cath labs and some are in the wrong place, so if you are going to allow this in Michigan, think carefully about how to do this and where these labs should be
3. Volumes per facility and per operator are going down and that's not good
4. Watch all outcomes closely which is increasingly hard as volumes shrink
5. Consider state or external review of low volume programs

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR CARDIAC CATHETERIZATION SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval of the initiation, replacement, expansion, or acquisition of cardiac catheterization services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code, cardiac catheterization services are a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.

(b) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization 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. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.

(c) "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; pediatric diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric therapeutic cardiac catheterizations.

(d) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(e) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(f) "Department" means the Michigan Department of Community Health (MDCH).

(g) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac catheterization services may also perform implantations of cardiac permanent pacemakers and ICD devices.

(h) "Electrophysiology study" means a study of the electrical conduction activity of the heart and characterization of atrial and ventricular arrhythmias obtained by means of a cardiac catheterization procedure. The term also includes the implantation of permanent pacemakers and ICD devices.

(i) "Hospital" means a health facility licensed under Part 215 of the Code.

(j) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396g and1396i to 1396u.

(k) "Pediatric cardiac catheterization service" means providing cardiac catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies that are offered and provided to infants and children ages 14 and below, and others with congenital heart disease as defined by the ICD-9-CM codes (See Appendix B for ICD-10-CM Codes) of 426.7 (anomalous atrioventricular excitation), 427.0 (cardiac dysrythmias), and 745.0 through 747.99 (bulbus cordis anomalies and anomalies of cardiac septal closure, other congenital anomalies of heart, and other congenital anomalies of circulatory system).

(l) “Primary percutaneous coronary intervention (PCI)” means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block.

(m) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a laboratory based on the type of procedures being performed.

(n) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, percutaneous transluminal coronary angioplasty (PTCA) and coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention.

(2) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Requirements to initiate cardiac catheterization services

Sec. 3. An applicant proposing to initiate cardiac catheterization services shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall demonstrate the following as applicable to the proposed project:

(a) An applicant proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a rural or micropolitan statistical area county shall project a minimum of 500 procedure equivalents including 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(b) An applicant proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a metropolitan statistical area county shall project a minimum of 750 procedure equivalents that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(c) An applicant proposing to initiate a diagnostic cardiac catheterization service with two or more laboratories shall project a minimum of 1,000 procedure equivalents per laboratory that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures per laboratory based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(2) An applicant proposing to initiate an adult therapeutic cardiac catheterization service shall demonstrate the following:

(a) The applicant provides, is approved to provide, or has applied to provide adult diagnostic cardiac catheterization services at the hospital. The applicant must be approved for adult diagnostic cardiac catheterization services in order to be approved for adult therapeutic cardiac catheterization services.

(b) An applicant operating an adult diagnostic cardiac catheterization service has performed a minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterizations during the most recent 12-month period preceding the date the application was submitted to the Department if the service has been in operation more than 24 months.

(c) ~~The applicant has applied to provide adult open heart surgery services at the hospital. The applicant must be approved for an adult open heart surgery service in order to be approved for an adult therapeutic cardiac catheterization service.~~

(d) The applicant shall project a minimum of ~~300 procedure equivalents~~ 200 Adult PCI's per site in the category of adult therapeutic cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(e) That all hospitals seeking a CON for Cardiac Catheterization Services related to both elective and/or primary PCI be required to participate with the BMC2 (or like registry/quality monitoring program) as well as Accreditation for Cardiovascular Excellence (ACE) or an equivalent outside monitor. ACE accreditation will be required for an initial term and then BMC2 will be required as long as the institution is providing PCI services.

(f) That the Michigan Department of Community Health (MDCH) include in its annual survey a question requesting the annual volume number of Primary and Elective PCI procedures performed, from each hospital with an approved CON for Cardiac Catheterization. This numbers of both primary and elective PCI procedures shall be posted separately from the other Cardiac Cath. procedures on the Department's website. This will be accomplished through the registry.

(g) Each hospital with an approved CON for Cardiac Catheterization to perform Primary PCI and/or Elective PCI shall report to the MDCH as part of their annual hospital survey the following information from their most recent BMC2 (or like registry/quality monitoring program) report:

- The proportion of PCI patients with emergency CABG, acute kidney injury, or post-procedure stroke.
- Composite: Proportion of PCI patients with death, emergency CABG or stroke
- PCI in-hospital risk adjusted rate of bleeding events.and major vascular complications
- Median post-acute LOS for PCI patients with STEMI
- All PCI appropriate use criteria.

Performance on all indicators will be above the 50th percentile as compared to NCDR and BMC2. (or like registry/quality monitoring program)

(h) That the MDCH would then be required to take appropriate compliance actions for those Cardiac Catheterization programs that had BMC2 (or like registry/quality monitoring program) Unacceptable Quality scores or Unacceptable Appropriateness. For primary PCI programs applying for elective PCI, data will be collected and reviewed for 12 consecutive months prior to the date of the application. Once approved, In the event that a program does not maintain performance above the 50th percentile, the state will require an action plan within 3 months and demonstrate 50th percentile performance within 12 months or the state shall close the program.

(3) An applicant proposing to initiate a pediatric cardiac catheterization service shall demonstrate the following: **Committee recommends that a pediatric cardiologist review and revise this shaded section to reflect current guidelines.**

(a) The applicant has a board certified pediatric cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory.

(b) The applicant has standardized equipment as defined in the most current American Academy of Pediatrics (AAP) guidelines for pediatric cardiovascular centers.

(c) The applicant has on-site ICU as outlined in the most current AAP guidelines above.
(d) The applicant has applied to provide pediatric open heart surgery services at the hospital. The applicant must be approved for a pediatric open heart surgery service in order to be approved for pediatric cardiac catheterization services.
(e) The applicant shall project a minimum of 600 procedure equivalents in the category of pediatric cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(4) An applicant proposing to initiate primary PCI service without on-site open heart surgery services shall demonstrate the following:
(a) The applicant operates an adult diagnostic cardiac catheterization service that has performed a minimum of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac catheterization procedures during the most recent 12 months preceding the date the application was submitted to the Department.
(b) The applicant has at least two interventional cardiologists to perform the primary PCI procedures and each cardiologist has performed at least ~~75~~ 50 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the Department.
(c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill patients and comfortable with interventional equipment; have acquired experience in dedicated interventional laboratories at an open heart surgery hospital; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency shall be documented annually.
(d) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional equipment.
(e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management. Competency shall be documented annually.
(f) A written agreement with an open heart surgery hospital that includes all of the following:
(i) Involvement in credentialing criteria and recommendations for physicians approved to perform primary PCI procedures.
(ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of primary PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.
(iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient candidates. Competency shall be documented annually.
(iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI cases.
(v) Development and ongoing review of patient selection criteria for primary PCI patients and implementation of those criteria.
(vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care.
(vii) Written protocols, signed by the applicant and the open heart surgery hospital, for the immediate transfer, within 1 hour from the cardiac catheterization laboratory to evaluation on site in the open heart surgery hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. The protocols shall be reviewed and tested on a quarterly basis.
(viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.
(g) A written protocol must be established and maintained for case selection for the performance of primary PCI.
(h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the emergency department to the cardiac catheterization laboratory must be developed and maintained so that door-to-balloon targets are met.
(i) At least two physicians credentialed to perform primary PCI must commit to functioning as a coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day

per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate with administrative and clinical staff in establishing and implementing protocols, call schedules, and quality assurance procedures pertaining to primary PCI designed to meet the requirements for this certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the American College of Cardiology and American Heart Association.

(j) The applicant shall project a minimum of 36 primary PCI cases based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

Section 4. Requirements to replace an existing cardiac catheterization service or laboratory

Sec. 4. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray equipment or a relocation of the service to a new site. The term does not include a change in any of the other equipment or software used in the laboratory. An applicant proposing to replace a cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:

(1) An applicant proposing to replace cardiac catheterization laboratory equipment shall demonstrate the following:

(a) The existing laboratory or laboratories to be replaced are fully depreciated according to generally accepted accounting principles or demonstrates either of the following:

(i) The existing angiography x-ray equipment to be replaced poses a threat to the safety of the patients.

(ii) The replacement angiography x-ray equipment offers technological improvements that enhance quality of care, increases efficiency, and reduces operating costs.

(b) The existing angiography x-ray equipment to be replaced will be removed from service on or before beginning operation of the replacement equipment.

(2) An applicant proposing to replace a cardiac catheterization service to a new site shall demonstrate the following:

(a) The proposed project is part of an application to replace the entire hospital.

(b) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:

(i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

(ii) A minimum of ~~300 procedure equivalents~~ 200 PCI's per site in the category of adult therapeutic cardiac catheterization procedures.

(iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures. **DEFER SHADED AREA TO PEDIATRIC CARDIOLOGIST**

(iv) A minimum of ~~500 procedure equivalents~~ 200 PCI's for a hospital in a rural or micropolitan county with one laboratory.

(v) A minimum of ~~750 procedure equivalents~~ 200 PCI's for a hospital in a metropolitan county with one laboratory.

(vi) A minimum of ~~1,000 procedure equivalents~~ 200 PCI's per cardiac catheterization laboratory for a hospital with two or more laboratories. (the guideline is per facility)

(c) The existing cardiac catheterization service has been in operation for at least 36 months as of the date the application has been submitted to the Department.

Section 5. Requirements to expand a cardiac catheterization service

Sec. 5. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall demonstrate the following:

(1) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:

(a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

(b) A minimum of ~~300 procedure equivalents~~ 200 PCI's per site

(c) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures **DEFER SHADED AREA TO PEDIATRIC CARDIOLOGIST**

(2) The applicant has performed a minimum of ~~1,400 procedure equivalents~~ 400 adult diagnostic and PCI procedures per existing and approved laboratories during the most recent 12-month period preceding the date the application was submitted to the Department.

Section 6. Requirements to acquire a cardiac catheterization service

Sec. 6. Acquiring a cardiac catheterization service and its laboratories means obtaining possession and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for existing angiography x-ray equipment. An applicant proposing to acquire a cardiac catheterization service or renew a lease for equipment shall demonstrate the following as applicable to the proposed project:

(1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the following:

(a) The proposed project is part of an application to acquire the entire hospital.

(b) An application for the first acquisition of an existing cardiac catheterization service after February 27, 2012 shall not be required to be in compliance with the applicable volume requirements in subsection (c). The cardiac catheterization service shall be operating at the applicable volumes set forth in the project delivery requirements in the second 12 months of operation of the service by the applicant and annually thereafter.

(c) FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING CARDIAC CATHETERIZATION SERVICE, EXCEPT THE FIRST APPLICATION APPROVED PURSUANT TO SUBSECTION (B), AN APPLICANT SHALL BE REQUIRED TO DOCUMENT THAT THE CARDIAC CATHETERIZATION SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH THE VOLUME REQUIREMENTS SET FORTH IN SECTION 9 OF THESE STANDARDS APPLICABLE TO AN EXISTING CARDIAC CATHETERIZATION SERVICE ON THE DATE THE APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(2) An applicant proposing to renew a lease for existing angiography x-ray equipment shall demonstrate the renewal of the lease is more cost effective than replacing the equipment.

Section 7. Requirements for a hybrid operating room/~~cardiac catheterization laboratory~~ that is also used for therapeutic cardiac catheterization procedures (OR/CCL)

Sec. 7. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an angiography system permitting ~~minimally~~ invasive therapeutic procedures of the heart and blood vessels with full anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLs at an existing cardiac catheterization service shall demonstrate each of the following:

(1) The applicant operates an open heart surgery service which is in full compliance with the current CON Review Standards for Open Heart Surgery Services.

(2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance with section 4(2) of these standards.

(3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories at the facility, the applicant is in compliance with Section 5 of these standards.

(4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s), the applicant is in compliance with the provisions of Section 4, if applicable.

(5) The applicant meets the applicable requirements of the CON Review Standards for Surgical Services.

(6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

(7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility will not be limited to the number of hybrid ORCCLs within a single licensed facility.

Section 8. Requirement for Medicaid participation

Sec. 8. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 9. Project delivery requirements and terms of approval for all applicants

Sec. 9. An applicant shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.

(b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.

(c) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including complication rates, morbidity and mortality, success rates and the number of procedures performed.

(d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall ideally perform, as the primary operator, a minimum of ~~75~~ **50** adult therapeutic cardiac catheterization procedures per year including no les than 11 primary PCIs annually in a ~~he second 12 months after being credentialed to and annually thereafter~~ a facility that performs 200 total and >36 primary PCI procedures annually. The annual case load for a physician means adult therapeutic PCI cardiac catheterization procedures performed by that physician in any combination of hospitals.

(e) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization procedures per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means pediatric diagnostic cardiac catheterization procedures performed by that physician in any combination of hospitals **DEFER SHADED AREA TO PEDIATRIC CARDIOLOGIST**

(f) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac

catheterizations per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means pediatric therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals **DEFER SHADED AREA TO PEDIATRIC CARDIOLOGIST**

(g) 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.

(h) An adult therapeutic 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 therapeutic cardiac catheterizations; and

(iii) have each performed a minimum of ~~75~~ 50 adult therapeutic cardiac catheterization procedures in the preceding 12 months.

(i) A pediatric cardiac catheterization service shall have an appropriately trained physician on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physician:

(i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;

(ii) is credentialed by the hospital to perform pediatric cardiac catheterizations; and

(iii) has trained consistently with the recommendations of the American College of Cardiology.

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(j) A cardiac catheterization service shall be directed by an appropriately trained physician. The Department shall consider appropriate training of the director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 200 catheterizations per year during each of the five preceding years. The Department may accept other evidence that the director is appropriately trained.

(k) A cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(3) Compliance with the following access to care requirements:

(a) The service shall accept referrals for cardiac catheterization from all appropriately licensed practitioners.

(b) The service shall participate in Medicaid at least 12 consecutive months within the first two years of operation and annually thereafter.

(c) The service shall not deny cardiac catheterization services to any individual based on ability to pay or source of payment.

(d) The operation of and referral of patients to the cardiac catheterization service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

(4) Compliance with the following monitoring and reporting requirements:

(a) The service shall be operating at or above the applicable volumes in the second 12 months of operation of the service, or an additional laboratory, and annually thereafter:

(i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

(ii) ~~300 procedure equivalents~~ 200 PCI's per site in the category of adult therapeutic cardiac catheterization procedures.

(iii) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.

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(iv) ~~500 procedure equivalents~~ 200 PCI's for a hospital in a rural or micropolitan county with one laboratory.

(v) ~~750 procedure equivalents~~ 200 PCI's for a hospital in a metropolitan county with one laboratory.

(vi) ~~1,000 procedure equivalents~~ 200 PCI's per cardiac catheterization laboratory for two or more laboratories.

(vii) 36 adult primary PCI cases for a primary PCI service.

(b) The hospital shall participate in a data collection network established and administered by the Department or its designee. Data may include, but is not limited to, annual budget and cost information, operating schedules, patient demographics, morbidity and mortality information, and payor. The Department may verify the data through on-site review of appropriate records.

(c) The hospital shall participate in a quality improvement data registry administered by the Department or its designee. The hospital shall submit summary reports as required by the Department. The hospital shall provide the required data in a format established by the Department or its designee. The hospital is liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The hospital must become a member of the data registry upon initiation of the service and continue to participate annually thereafter for the life of that service.

(5) Compliance with the following primary PCI requirements, if applicable:

(a) The requirements set forth in Section 3(4).

(b) The hospital shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.

(c) The hospital shall perform a minimum of 36 primary PCI procedures at the hospital in the preceding 12–month period of operation of the service and annually thereafter.

(d) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary PCI sessions.

(e) The hospital shall participate in a data registry, administered by the Department or its designee. The Department or its designee shall require that the applicant submit data on all consecutive cases of primary PCI as is necessary to comprehensively assess and provide comparative analyses of case selection, processes and outcome of care, and trend in efficiency. The applicant shall provide the required data in a format established by the Department or its designee. The applicant shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant shall meet all quality standards outlined in section 3e-h.

Section 10. Methodology for computing cardiac catheterization equivalents

Sec. 10. The following shall be used in calculating procedure equivalents and evaluating utilization of a cardiac catheterization service and its laboratories:

Procedure Type	Procedure equivalent	
	Adult	Pediatric
Diagnostic cardiac catheterization/peripheral sessions	1.5	2.7
~~Therapeutic cardiac catheterization/peripheral sessions~~	~~2.7~~	~~4.0~~
~~Complex percutaneous valvular and other structural therapeutic procedures*~~	~~4.0~~	~~7.0~~
~~* Complex percutaneous valvular sessions includes, but is not limited to, procedures performed percutaneously or with surgical assistance to repair or replace aortic, cardiac valves such as transcatheter aortic valvular implantation (Tavi) procedures, repair structural heart abnormalaties, implant structural heart devices. These sessions can only be performed at hospitals approved with open heart surgery services.~~		

Section 11. Documentation of projections

Sec. 11. An applicant required to project volumes shall demonstrate the following as applicable to the proposed project:

(1) The applicant shall specify how the volume projections were developed. Specification of the projections shall include a description of the data source(s) used and assessment of the accuracy of the data. The Department shall determine if the projections are reasonable.

(2) An applicant proposing to initiate a primary PCI service shall demonstrate and certify that the hospital treated or transferred 36 ST segment elevation AMI cases during the most recent 12-month period preceding the date the application was submitted to the Department. Cases may include thrombolytic eligible patients documented through pharmacy records showing the number of doses of thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an appropriate hospital for a primary PCI procedure.

Section 12. Comparative reviews; Effect on prior CON Review Standards

Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac Catheterization Services approved by the CON Commission on MARCH 18, 2014 and effective on JUNE 2, 2014.

APPENDIX A

Rural Michigan counties are as follows:

Alcona		Oceana
Alger	Huron	Ogemaw
Antrim	Iosco	Ontonagon
Arenac	Iron	Osceola
Baraga	Lake	Oscoda
Charlevoix	Luce	Otsego
Cheboygan	Mackinac	Presque Isle
Clare	Manistee	Roscommon
Crawford		Sanilac
Emmet		Schoolcraft
Gladwin	Montmorency	Tuscola
Gogebic	NEWAYGO	

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry		MONTCALM
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

75 F.R., p. 37245 (JUNE 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX B

ICD-9-CM TO ICD-10-CM Code Translation

ICD-9 Code	Description	ICD-10 Code	Description
426.7	Anomalous Atrioventricular Excitation	I45.6	Pre-Excitation Syndrome
427	Cardiac Dysrythmias	I47.0-I47.9	Paroxysmal Tachycardia
		I48.0-I48.92	Atrial Fibrillation and Flutter
		I49.01-I49.9	Other Cardiac Arrhythmias
		R00.1	Bradycardia, Unspecified
745.0 through 747.99	Bulbus Cordis Anomalies and Anomalies of Cardiac Septal Closure, Other Congenital Anomalies of Heart, and other Congenital Anomalies of Circulatory System	P29.3	Persistent Fetal Circulation
		Q20.0-Q28.9	Congenital Malformations of the Circulatory System

"ICD-9-CM Code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification**,** prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.

"ICD-10-CM Code" means the disease codes and nomenclature found in the International Classification of Diseases - 10th Revision - Clinical Modification, National Center for Health Statistics.