Call to Order

Chairperson Eagle called the meeting to order @ 9:31 a.m.

A. Members Present:

   Dagmar Raica, Marquette General Health System
   Roland Palmer, Vice-Chairperson, Alliance for Health
   Kim Eagle, MD, Chairperson, University of Michigan Health System
   Douglas W. Weaver, MD, Henry Ford Health System
   Theodore Schreiber, MD, Detroit Medical Center
   Bart Berndt, Lakeland Regional Medical Center
   Fouad Ashkar, Garden City Hospital
   Barry Lewis, DO, Botsford General Hospital
   Frank D. Sotille, MD, Crittenton Hospital Medical Center
   Kevin Donovan, Muskegon Construction
   Arthur L. Riba, MD, Oakwood Healthcare, Inc.
   David Dobies, MD, Genesys Regional Medical Center
   Basil Dudar, MD, FACC, Beaumont Hospitals
   John Heiser, MD, West MI Cardiothoracic Surgeons, PLC
   Barton Buxton, Ed.D, Lapeer Regional Medical Center
   Elizabeth J. Pielsticker, MD, Michigan Heart PC
   Robert Goodman, MD, MHSA, FACEP, Blue Cross Blue Shield/Blue Care Network arrived @ 10:20 a.m.
   Michelle Link, Bronson Methodist Hospital

B. Members Absent:

   Lawerence O. Wells, Michigan League for Human Services

C. Michigan Department of Community Health Staff present:

   Jessica Austin
II. Declaration of Conflicts of Interests

No conflicts of interests declared.

III. Review of Minutes

Motion by Buxton and seconded by Dr. Schreiber to accept the draft minutes as presented. Motion Carried.

IV. Review of Agenda

Motion by Buxton and seconded by Ashkar to approve the modified agenda. Motion Carried.

V. Presentation by Dr. Weaver on the following topics:

A. Wennberg Paper (See Attachment A)
B. International Standards as They Relate to Cardiac Procedure Volumes (See Attachment A)
C. 2006 Article by Mauro Moscucci, “Characterizing Risk Adjusted Mortality Based on Operator Volume for the State of Michigan.” (See Attachment A)
D. PCI without Surgical Backup State Regulatory Framework (See Attachment B)
E. Coronary Revascularization Trends (See Attachment C)

Discussion followed.

Chairperson Eagle asked Dr. Schreiber to comment on New York’s regulations. (See Attachment D)

Break @ 10:39 a.m. - 10:55 a.m.

VI. Presentation by Dr. Eagle on:

A. State Hospital PCI Volumes per Site, and State Operator Volumes per Year based on Blue Cross Blue Shield of Michigan Data (See Attachment E)

Discussion followed.
VII. Presentation by Larry Horvath on:

A. Status of state monitoring of hospital volume requirements and other requirements in Michigan regulations (See Attachment F)
B. Report of review of previous minutes of the last CON commission which established a number of 48 primary PCIs as a minimum volume requirement per institution per year (See Attachment F)

Discussion followed.

VIII. Presentation by Dr. Riba on:

A. Review of paper by Jeremy Buckley, Brahmajee Nallamothu and others as it relates to access to primary PCI in the state of Michigan (See Attachment G).

Discussion followed.

IX. Presentation by Dr. Schreiber on:

A. “Long-Term Outcome of a Routine versus Selective Invasive Strategy in Patients with Non-ST-Segment Elevation Acute Coronary Syndrome- A Meta Analysis of Individual Patient Data” Journal of the American College of Cardiology, Vol.55 No.22 2010 (See Attachment H)

Discussion followed.

X. Presentation by Dr. Sotille on:

A. Review of what procedures are being done by hospitals of different geographic locations, and size, in the state of Michigan (See Attachment I)

Discussion followed.

Motion by Dr. Weaver and seconded by Mr. Buxton to approve, in principle, the concept of allowing elective PCI without on-site surgical back up and draft language to assist the SAC as it continues its discussion on the topic.

Discussion followed.

Motion Carried by a vote of 9-Yes, 8-No, and 1-Abstain.

Dr. Weaver volunteered to draft potential language for discussion.

XI. Public Comment
XII. Next Steps and Future Agenda Items

A. Dr. Weaver will provide a presentation of information available from the ACTION registry about quality of care relating to availability of PCI.

B. Dr. Lewis will provide a presentation and lead discussion of equivalents.

C. Chairperson Eagle will provide a presentation on information from the GRACE Registry examining the relation between outcomes of patients with acute coronary syndromes and availability of on-site cath labs.

XIII. Future Meeting Dates

A. February 8, 2011
B. March 10, 2011
C. April 6, 2011
D. May 4, 2011

XIV. Adjournment

Motion by Mr. Buxton and seconded by Dr. Dobies to adjourn the meeting @ 12:55 p.m. Motion Carried.
Cardiac Catheterization SAC
January 11, 2011

W. D. Weaver, M.D
Additional Data, Summary of the Experience and Recommendations for PCI without on site Surgery

Outcomes—mortality, Major Adverse Cardiac Events and Bleeding

Operator Volume and Outcomes

Current status and experience

Suggested guidelines
Data on Relationship of Volume and Outcomes

• Background - MEDPAR Data for Medicare beneficiaries
  - 178 centers, 8168 off-site and 943 centers, 617,686 on-site procedures, 1999-2001
  - 75% of the off-site hospitals did <25 cases/yr; 50% did <11 cases/yr and only 3% did >100 cases/yr
  - Analysis adjusted for patient characteristics using the administrative data available
  - The no-on-site patients more likely to be admitted emergently, have acute MI and to have undergone primary or rescue PCI

Why the increase—possibly....
  - These were very low volume centers—in the < 50 cases/yr only 6 cases of non-primary PCI per yr
  - Inability to adequately adjust for clinical differences

Recent Data on Relationship of Volume and Outcomes

• Background
  - 465 centers, 308,161 procedures, 2004-06, NCDR
  - 72% of off-site programs did <200 cases /yr
  - 42% of the off-site did <36 STEMIs
  - no program did just elective PCI
  - Successful PCI 95 and 94% respectively

Complications

<table>
<thead>
<tr>
<th></th>
<th>OFF-SITE</th>
<th>ON SITE</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ALL</td>
<td>5.1%</td>
<td>5.5%</td>
<td>NS</td>
</tr>
<tr>
<td>• Mortality</td>
<td>0.8%</td>
<td>0.8%</td>
<td>NS</td>
</tr>
<tr>
<td>• Emergency CABG</td>
<td>0.2%</td>
<td>0.3%</td>
<td>NS</td>
</tr>
</tbody>
</table>

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Recent Data on Relationship of Volume and Outcomes

- **Background - Mayo Clinic Experience**
  - 3 centers, 150 and 160 beds 3025 procedures, 2000-07
  - Average 164 and 193 cases/yr; operator volume 87-167 PCI cases/yr
  - Matched analysis to cases done at St Mary’s Hospital
  - no program did just elective PCI
  - Successful PCI 97, 97 and 97% respectively

- Results achieved with “integrated” hub and spoke system

<table>
<thead>
<tr>
<th>Complications</th>
<th>OFF-SITE</th>
<th>ON SITE</th>
<th>P</th>
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</thead>
<tbody>
<tr>
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<td>0.8%</td>
<td>0.8%</td>
<td>NS</td>
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<tr>
<td>Mortality</td>
<td>0.2%</td>
<td>0.4%</td>
<td>NS</td>
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<tr>
<td>Emergency CABG/Death</td>
<td>0.2%</td>
<td>0.6%</td>
<td>NS</td>
</tr>
</tbody>
</table>

Recent Data on Relationship of Volume and Outcomes

• Background - Swedish Angioplasty Registry
  - 24 centers, 8838 off-site and 25,525 on-site procedures, 2000-03
  - Average 307 and 812 cases/yr;
  - no program did just elective PCI

• Successful PCI 97% and 97% respectively

<table>
<thead>
<tr>
<th>Complications</th>
<th>OFF-SITE</th>
<th>ON SITE</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality-all</td>
<td>1.4%</td>
<td>2.2%</td>
<td>&lt;0.001*</td>
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<tr>
<td>Mortality –UA/NSTEMI</td>
<td>1.2%</td>
<td>1.0%</td>
<td>NS</td>
</tr>
<tr>
<td>Mortality-stable</td>
<td>0.4%</td>
<td>0.2%</td>
<td>NS</td>
</tr>
<tr>
<td>Emergency CABG</td>
<td>0.1%</td>
<td>0.2%</td>
<td>NS</td>
</tr>
</tbody>
</table>

* Adjusted for more STEMI at on-site hospitals—P=NS

Carlsson, J. et al. Heart 2007;93:335
Operator Volume and Outcomes

• Background - Michigan BCBS PCI Consortium
  - 14 centers, 18,504 procedures, 2002, 165 operators
  - The current ACC Guidelines suggest that operators do 75 cases or more per year
  - Looked at outcomes by quintiles of volume—

• Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Quintile 1</th>
<th>Quintile 2</th>
<th>Quintile 3</th>
<th>Quintile 4</th>
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<td>Death</td>
<td>2.0</td>
<td>1.7</td>
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<td>1.1</td>
<td>1.4</td>
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<tr>
<td>MI</td>
<td>1.5</td>
<td>1.5</td>
<td>1.4</td>
<td>1.4</td>
<td>1.3</td>
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<td>Stroke</td>
<td>0.0</td>
<td>0.5</td>
<td>0.5</td>
<td>0.4</td>
<td>0.3</td>
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<tr>
<td>Emergent CABG</td>
<td>0.8</td>
<td>1.2</td>
<td>0.6</td>
<td>0.3</td>
<td>0.3</td>
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<tr>
<td>MACE</td>
<td>7.4</td>
<td>6.1</td>
<td>5.0</td>
<td>4.2</td>
<td>4.2</td>
</tr>
</tbody>
</table>

For the less than 75 vs. > 75—only CABG was sig diff (0.8 vs 0.4, p=0.02)
Other Volume and Outcome Studies

• Background—ACC NCDR
  - 410 centers, 289,059 procedures, 2005
  - Hospitals divided into quartiles <400, 400-700, 700-1000, >1000
  - No difference in outcomes after adjustment

  Nallamouthu, B. et al. J Am Coll Cardiol 2006

• Background—New York State Registry
  - 11 off-site centers 1735 PCIs; 40 on-site centers 8817 PCIs
  - Avg volume 221 vs 189; for STEMI 23 vs 17
  - Used propensity scores to match patients

• Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Death -30 d</th>
<th>Same day CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.3</td>
<td>0.2</td>
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<tr>
<td></td>
<td>1.9</td>
<td>0.7</td>
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<td></td>
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<td>0.046</td>
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</table>

  72% vs 54% of operators met >100 PCI; and 54% vs. 26% met the primary PCI criteria suggested by Dehmer


• Background—Seattle Acute MI Registry
  - 1062 patients—no difference in outcome off-site vs on site

  Weaver, D. J Invasive Cardiol 1997, 2:20
Data on Relationship of Volume and Outcomes

- Bleeding Complications
- 768 centers, 1,025,226 procedures-NCDR study
- Post PCI Bleeding was weakly related to case volume

Rao et al, JACC
Summary

• With the data that we have so far, it appears that outcomes from sites without on-site surgery are similar to those that have on-site surgery.

• Now looking at experience and suggested guidelines for programs.
Program Requirements for Elective-PCI with no-onsite CV surgery

Adapted from Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions

Dehmer et al, Catheterization and Cardiovascular Interventions 2007;
Current Status of PCI Without On-Site Surgical Backup

- PCI not allowed without on-site backup (n=1)
- Only primary PCI (n=7)
- Both primary and elective PCI allowed (n=27)
- Both allowed as part of a demo project or study (n=7)

Source: SCAI Expert Consensus Document
Feb 2007, updated 2010
# Global Status of PCI Without On-Site Surgery

## Table of Countries

<table>
<thead>
<tr>
<th>Being Performed</th>
<th>Not Being Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>Brazil</td>
</tr>
<tr>
<td>Canada</td>
<td>Bahrain</td>
</tr>
<tr>
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<td>Belgium</td>
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<td>Vietnam</td>
<td>Syria</td>
</tr>
<tr>
<td></td>
<td>Thailand</td>
</tr>
</tbody>
</table>

## Countries Not Being Performed
- Bahrain
- Belgium
- Greece
- Malaysia

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Source: SCAI Expert Consensus Document

Released February 5, 2007   Full document available at:  www.scai.org
Suggested Qualifications

• Only operators whose outcomes are equivalent to national outcomes
  – **Must participate** in NCDR Cath Registry
    • PCI success, complications, peri-procedural MI
  – **Must participate** in institutional Quality Improvement Program
  – **Must participate** in appropriate CME-be Board certified
  – Initial program **operators experienced**
    • More than 500 PCIs after fellowship
    • Those with less need to be monitored
    • Volume of >100 cases per year

Dehmer et al, Catheterization and Cardiovascular Interventions 2007
Facility Qualifications

- 24/7 facility—both STEMI and elective
- Well trained and experienced personnel
- Balloon pump and ventilator capable
- Written agreements and protocols for transfer
  - Tested twice each year
- Ability to transfer images on-line and obtain consultation from the supporting hospital
- Data collection and benchmarking
- Case loads of > 200/year after 2 years
  - If less than that—program should be closed unless it fits a particular geographically challenged area; if less than 150 and primary PCI less than 36, programs should close without exception

Dehmer et al, Catheterization and Cardiovascular Interventions 2007
Patient Selection

• Selection/Exclusion Criteria must be developed
  – Decompensated heart failure without acute ischemia, recent stroke, advanced malignancy, known clotting disorders, EF less than 25%, Left main disease unprotected by prior surgery, lesions that jeopardize >50% of myocardium, diffuse disease and excessive tortuosity, degenerated vein grafts, substantial thrombus, aggressive measures to open chronic total occlusions, inability to protect major side branches

Dehmer et al, Catheterization and Cardiovascular Interventions 2007
Requirements for Back-up

- Surgeon must have privileges at the institution
- Agreement to receive patients at all hours-signed by both hospital senior executives
- Rigorous protocol for transfer
- Transport must be possible to be initiated within 20 minutes
- Transferring MD obtains consent for surgery
- Consent procedure for PCI acknowledges that no surgery on site is available and transfer may be necessary
- Regular review of all cases undergoing transfer
Program Monitoring

• Collect and participate in the NCDR registry to obtain benchmarked data
  – Cases and outcomes
  – Appropriate Use criteria

• Each facility should establish and impartial and objective review body eg Director of CV Services, Chief Medical Officer, Cath and Surgical Director of the transfer support hospital

• Additional Oversight by an independent and impartial organization-the program should be fair, impartial and not burdensome--? Workgroup of the ACC state Chapter

Dehmer et al, Catheterization and Cardiovascular Interventions 2007
The Case for PCI without on-site Surgery in Michigan

• Elective PCI is moving to become an out-patient procedure
  ▪ Already the case in several states and insurers
  ▪ In healthcare reform and with Accountable Care Organizations-this will also become the norm in Michigan

• Incidence and the death rate from CVD is very high in Michigan

• Michigan is now the exception-most states and most countries have adopted PCI without on-site surgery

• Reduce the cost
  ▪ Coupling the diagnostic cath and the PCI is lower cost
  ▪ Surgery programs to support elective PCI are expensive—staff, training, perfusion, anesthesia, dialysis, surgical critical care

• Improve surgical outcomes
  ▪ Creating small and dividing surgical programs is not good for patients and programs-just to support reasonable size PCI programs
## Effect of the Current Regulation on Cardiac Surgery Volumes

<table>
<thead>
<tr>
<th>Facility No.</th>
<th>Hospital</th>
<th>Approved</th>
<th>Open Heart Surgery</th>
<th>Therapeutic Cardiac Cath</th>
<th>Therapeutic Peripheral Cath</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>09-0050</td>
<td>Bay Medical Center</td>
<td>1998</td>
<td>437</td>
<td>2901</td>
<td>207</td>
<td>3108</td>
</tr>
<tr>
<td>83-0450</td>
<td>Sinai-Grace Hospital</td>
<td>1999</td>
<td>118</td>
<td>366</td>
<td>90</td>
<td>456</td>
</tr>
<tr>
<td>50-0070</td>
<td>St. John Macomb Hospital</td>
<td>2001</td>
<td>217</td>
<td>1833</td>
<td>226</td>
<td>2059</td>
</tr>
<tr>
<td>50-0110</td>
<td>Henry Ford-Macomb, Clinton Twp</td>
<td>2001</td>
<td>222</td>
<td>780</td>
<td>100</td>
<td>880</td>
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<tr>
<td>63-0070</td>
<td>Crittenton Hospital</td>
<td>2002</td>
<td>97</td>
<td>624</td>
<td>101</td>
<td>725</td>
</tr>
<tr>
<td>63-0160</td>
<td>William Beaumont Hospital - Troy</td>
<td>2003</td>
<td>287</td>
<td>633</td>
<td>0</td>
<td>633</td>
</tr>
<tr>
<td>56-0020</td>
<td>Mid-Michigan Medical Center</td>
<td>2006</td>
<td>246</td>
<td>1443</td>
<td>595</td>
<td>2038</td>
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<tr>
<td>38-0010</td>
<td>Allegiance Health (Jackson)</td>
<td>2006</td>
<td>148</td>
<td>1398</td>
<td>375</td>
<td>1773</td>
</tr>
</tbody>
</table>

Open Heart Programs Required to Meet 300 Volume Requirement (225 = 75% or substantial compliance)
Over-Supply Leading to Further Inefficiencies

Competitive Strategy Often Trumping Cost, Quality Considerations

- **20%** Incremental cost increase associated with low-volume CABG sites
- **3%** Incremental cost increase associated with low-volume surgeons
- **15%** Relative reduction of in-hospital mortality for CABG if performed in high-volume centers

**Distribution of CABG Programs by Volume Cohort**

*Medicare Volumes, 1998 Versus 2009*

![Graph showing distribution of CABG programs by volume cohort]


1 Low-volume sites defined as those with hospital annualized median volume for CABG <215 patients; physician annualized median volume for CABG <79 patients.

2 High-volume centers defined as those performing >600 CABG per year.

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The Case for PCI without on-site Surgery in Michigan

• Whether we like it or not—people want regular procedures done nearby in the hospital where they have a relationship, medical records and their regular doctor and easy access to their families
  - Coronary PCI is not an out of the ordinary procedure
    700,425 In-pt PCI and 207,495 Open heart procedures 2008 (AHRQ data)

• Healthcare reform is going to bring far greater integration than we have seen in the past
  - Hospital systems are now going to provide services where it makes sense because their market updates are being reduced and they now have to behave like integrated systems—the need for regulation of facilities will decrease

• The data and worldwide experience shows this is a reasonable thing to do
  - Our contribution is to provide some guidance on the minimum requirements—
Why and How Should We do This?

Why

• It brings care closer to patients and in some cases will make an outcome difference
• It is cheaper—the current CON has caused the proliferation of low volume and high cost surgical centers—Many sites will have adequate PCI volumes but low CABG volumes and for CABG surgery-volume is associated with outcome

Cost of Initiating New OHS Services

• Allegiance Health (Jackson) 2008, final costs $5,520,780
• MidMichigan Medical Center 2007, final costs $3,129,855
• William Beaumont-Troy initiated in 2004, final costs $12,233,071
• Crittenton initiated in 2004, final costs $1,111,013
• Henry Ford Macomb, 2001, final costs $1,400,000

** Modified based on Dehmer, NCDR, Swedish and Hannon findings
Annual Personnel Costs for OHS and Cardiac Cath
Example: Henry Ford Macomb

- Highly Skilled Personnel Required (a limited resource)
  - Open Heart personnel
    - FTE Requirements- Additional 31.9
    - FTE Annual Salaries- $1,700,956
  - Therapeutic Catheterization personnel
    - FTE Requirements- Additional 7.6
    - FTE Annual Salaries- $500,100

Source: Henry Ford Macomb CON # 000116 (2000)
Cost Impact

The practice of transferring patients from a non-OHS facility to complete a Therapeutic Cath after a Diagnostic procedure adds on average approximately $4,000 to the cost of the procedure. This includes the impact of the diagnostic cath, the cost of transfer (900 per patient) and the therapeutic cath.

The patient also gets 3 co-pays—approximately $700.
The data showing that CONs change procedure volumes and costs are inconclusive.
Why and How Should We do This?

• How Should it be Done?

  ▪ Each site participates in a registry and it includes measures of outcome and appropriate use of the procedure
  ▪ Telemedicine capability to review cases with surgery center
  ▪ A risk stratification tool—STS or SYNTAX used and recorded prior to any procedure to insure appropriate triage to CABG
  ▪ The site should do 200 or more cases per year by year 2 unless geographically challenged; mandatory closure if less than 150 cases, closure if less than 200 in 3 years**
  ▪ The operators should be Board Certified, have a lifetime of 500 cases, do a minimum of 75 cases each year and do primary PCIs**
  ▪ The site should have a data management person to insure timely and accurate reports are made available to the registry and reviewing bodies
  ▪ Each site should have its own internal review body including a responsible cardiac surgeon and the CMO
  ▪ There should be an external impartial oversight body
  ▪ The annual results should be made public-transparency

** Modified based on Dehmer, NCDR, Swedish and Hannon findings
PCI Without Surgical Backup State Regulatory Framework

**Alabama (Certificate of Need Law Applies to Cath Labs)**

Primary and elective PCI permitted.

**Alaska (Certificate of Need Law Applies to Cath Labs)**

Primary and elective PCI permitted. The following requirements are contained within the certificate of need process. **A facility offering primary PCI without surgical backup** must have a proven and tested transportation plan that will assure that a patient in an emergency will be in a cardiac surgical operating room within 90 minutes. A facility performing elective PCI must be either in a hospital with on-site surgery, attached to a hospital with on-site surgery, or meet the following conditions: accreditation by JCAHO, membership in the ACC NCDR National Cardiovascular Data Registry, the laboratory director must have performed 500 PCIs during his/her career and a minimum of 75 PCIs during the previous two years and must maintain a certificate of “Added Qualifications” in Interventional Cardiology from the American Board of Internal Medicine., the laboratory must maintain a mortality standard of less than 3 per 1000 diagnostic caths and less that 1 per 100 PCI procedures, and the laboratory must demonstrate that the facility has the capability of providing immediate tranvenous pacemakers in the event of cardiac arrest.

**Arizona (No Certificate of Need Law)**

Primary and elective PCI permitted.

**Arkansas (Certificate of Need Law Applies Only to Nursing Facilities)**

Primary and elective PCI permitted.

**California (No Certificate of Need Law)**

A law enacted in 2009 permits six hospitals to add elective PCI without surgical backup. The bill supported by both the California chapter of the ACC and the national ACC sunsets December 31, 2013. The measure was held in the Senate Health Committee until ACC CEO Jack Lewin wrote to the Chair of the Senate Health Committee clarifying that while ACC guidelines called for PCI to be performed when surgical backup was available, the ACC supported limited trials of elective PCI for the specific purpose of gathering additional data regarding the efficacy of elective PCI without surgical backup.

**Colorado (No Certificate of Need Law)**

Primary and elective PCI permitted.

**Connecticut (Certificate of Need Law Applies to Cath Labs)**

Primary and elective PCI permitted.
PCI Without Surgical Backup State Regulatory Framework Page 2

**Delaware** (Certificate of Need Law Applies to Cath Labs)

PCI not allowed without on-site surgical backup

**Florida** (Certificate of Need Law Applies to Cath Labs)

In January, 2009 Florida regulators adopted (following extensive hearings and extended comment periods) a two-level hospital licensure system for adult cardiovascular services under the authority of the Certificate of Need program Chapters 408.031 through 408.0455. **Level 1** permits community hospitals meeting the following specific criteria to offer elective and emergent PCI services: cardiologists must be experienced interventionalists who have performed a minimum of 75 interventions within the previous 12 months; the hospital must have performed a minimum of 36 emergency interventions annually in order to continue to provide the service; formal transfer arrangements must be developed with a hospital with adult open-heart surgery programs to ensure the safe transfer of a patient to that hospital within 60 minutes. **Level 2** facilities provide open heart services.

**Georgia** (Certificate of Need Law Applies to Cath Labs)

In 2005, Georgia regulators permitted 10 hospitals to participate in a national clinical trial to allow community hospitals to provide elective & emergent PCI without surgical backup. In July, 2009 16 additional hospitals were granted approval to do primary & elective without participation in the C-PORT trial. Those hospitals must meet numerous standards including the following: Provide documentation that the facility can perform a minimum of 200 PCIs per year by the beginning of the third year of the program; have at least one interventional cardiologist on staff who has performed 75 PCI procedures the previous year; provide documentation that the interventional cardiologist is board certified or is in the process of seeking board certification in interventional cardiology from the American Board of Internal Medicine; agree to report annually its data to the National Cardiovascular Data Registry.

**Hawaii** (Certificate of Need Law Applies to Cath Labs)

Elective Primary and PCI permitted.

**Idaho** *(No Certificate of Need Law)*

Primary and Elective PCI permitted.

**Illinois** (Certificate of Need Law Applies to Cath Labs)

Primary and Elective PCI permitted.

**Indiana** *(No Certificate of Need Law)*

Primary and elective PCI permitted.
PCI Without Surgical Backup State Regulatory Framework -- Page 3

Iowa (Certificate of Need Law Applies to Cath Labs)
Primary and elective PCI permitted.

Kansas (No Certificate of Need Law)
Primary and elective PCI permitted.

Kentucky (Certificate of Need Law Applies to Cath Labs)
On October 13, 2010 the Kentucky Cabinet for Health and Family Services published an update to the certificate of need standards including cardiac catheterization standards for both primary and “comprehensive” cardiac services on a two-year trial basis. The standards are similar to those found in Florida and Georgia including 200 PCIs per year and ideally 400 PCIs by the end of the second year. Applicants must have performed 300 diagnostic caths during the previous two years. Further details may be found on the Commonwealth of Kentucky CON website: http://chfs.ky.gov/ohp/con/default.html.

Louisiana (Limited Certificate of Need Law Applies Only to Nursing Facilities and ICF-MRs)
Primary and elective PCI permitted.

Maine (Certificate of Need Law Applies to Cath Labs)
Primary PCI permitted.

Maryland (Certificate of Need Law Applies to Cath Labs)
Primary and elective PCI permitted. The Maryland Health Care Commission has created a process where up to six hospitals may participate in the C-PORT project under a waiver from the commission provided certain conditions are met. Many of the requirements are similar to those found in other states discussed in this paper. They include written agreement with a tertiary center for transportation of patients in the case of emergencies, a minimum of three interventional cardiologists at the facility, a minimum volume of 100 PCIs in the first year and 200 PCIs in the second year, Further information may be obtained by consulting COMAR (Code of Maryland Administrative Requirements) 10.24.05 available on the Maryland Health Care Commission website http://mhcc.maryland.gov/

Massachusetts (Certificate of Need Law – Does not apply specifically to cath labs)
Primary and elective PCI permitted.

Michigan (Certificate of Need Law Applies to Cath Labs)
Primary PCI permitted.
Minnesota (No Certificate of Need Law)
Primary and elective PCI permitted.

Mississippi (Certificate of Need Law Applies to Cath Labs)
PCI not permitted without surgical backup.

Missouri (Certificate of Need Law Applies to Cath Labs)
Primary and elective PCI permitted.

Montana (Certificate of Need Law Applies to Cath Labs)
Primary and elective PCI permitted.

Nebraska (Certificate of Need Law Applies only to Long-term Care)
Primary and Elective PCI permitted.

Nevada (Certificate of Need Law Applies to Health Services)
Primary and elective PCI permitted

New Hampshire (Certificate of Need Law Applies to Health Care Facilities)
Primary and elective PCI permitted.

New Jersey (Certificate of Need Law Applies to Cath Labs)
Primary and elective PCI permitted.

New Mexico (No Certificate of Need Law)
Primary PCI permitted.

New York (Certificate of Need Law Applies to Cath Labs)
Engaged in project to allow 10 facilities to perform primary PCI. Regulatory changes signed in November, 2009 will allow elective PCI & prohibit the addition of diagnostic only labs.

North Carolina (Certificate of Need Law Applies to Cath Labs)
Primary and elective PCI permitted. Criteria and standards spelled out in the regulations 10A NCAC 14C.1601 refer to the ACC/SCAI Consensus Document on Cardiac Catheterization Laboratory Standards (June, 2001)
North Dakota *(No Certificate of Need Law)*

Primary and Elective PCI permitted.

Ohio *(Certificate of Need Law Applies only to Long-term Care Facilities)*

Primary and elective PCI permitted (under a C-PORT waiver). Ohio cardiologists have expressed concern to the ACC state team that the future for elective PCI without surgical backup is uncertain since the C-PORT program expires this year. Maryland will also be affected since their elective PCI is sanctioned through C-PORT waivers.

Oklahoma *(Certificate of Need Law Applies Only to Long-term Care Facilities and Psychiatric and Chemical Dependency Projects)*

Primary and elective PCI permitted.

Oregon *(Certificate of Need Law Applies Only to New Hospital or New Skilled Nursing or Intermediate Care Service or Facility)*

Primary and Elective PCI permitted.

Pennsylvania *(No Certificate of Need Law)*

Beginning in 2001, 10 programs granted exceptions to pilot to provision of both primary and elective PCI without Surgical backup. In 2009 5 new programs were approved if they qualified for the C-PORT trial.

Rhode Island *(Certificate of Need Law Applies to Cath Labs)*

Primary and elective PCI permitted.

South Carolina *(Certificate of Need Law Applies to Cath Labs)*

Primary PCI permitted.

South Dakota *(No Certificate of Need Law)*

Primary and elective PCI permitted.

Tennessee *(Certificate of Need Law Applies to Cath Labs)*

Primary and elective PCI permitted.

Texas *(No Certificate of Need Law)*

Primary and elective PCI permitted.
PCI Without Surgical Backup State Regulatory Framework -- Page 6

**Utah (No Certificate of Need Law)**
Primary and elective PCI permitted.

**Vermont (Certificate of Need Law Applies to Cath Labs)**
PCI not permitted without surgical backup.

**Virginia (Certificate of Public Need Law Applies to Cath Labs)**
Primary and elective PCI permitted.

**Washington (Certificate of Need Law Applies to Cath Labs)**
Primary and elective PCI permitted. *A law amending the state CON law was enacted in 2008 to create a special CON for elective PCI. The measure was sponsored by Representative Dawn Morrell, a cardiac nurse, who at the time was vice-chair of the House health panel. She worked with both the ACC state team and the SCAI in crafting her legislation* which passed overwhelmingly. To be granted a CON for elective PCI in Washington a facility must meet standards set forth in 11 sections of the Washington regulatory code. The conditions are similar to those specified in other states including the performance of 300 PCIs by the end of the third year of operation of the program and continuing every year thereafter; Physicians participating in the elective PCI program must demonstrate that they performed 75 PCIs for the previous three years prior to the application request; quality standards are specified in general including benchmarking outcomes against state or national quality of care indicators for elective PCIs. Further information may be obtained by consulting the Washington administrative code WAC 246-310-700 through WAC 246-310-745 available at [http://apps.leg.wa.gov/wac](http://apps.leg.wa.gov/wac)

**West Virginia (Certificate of Need Law Applies to Cardiac Cath Labs)**
West Virginia has a detailed process for approving regulations. First, the regulatory body (the West Virginia Health Care Authority in this case) must propose, hold hearing and approve regulations. Then the final regulation is sent to the legislature which must pass a bill including the body of the regulation and send it to the governor for his approval. The governor may veto any portion of the regulation (similar to a line item veto) and send it back to the Health Care Authority for revision. On March 19, 2007 Governor Joe Manchin approved new cardiac catheterization standards for the state designed to give West Virginians living in rural areas access to cardiovascular services. The certificate of need for cardiac catheterization implemented 3 tiers of service: Tier 1 -- must demonstrate a minimum diagnostic cath volume threshold; after one year of diagnostic caths, can apply to offer primary PCI under Tier 2. Hospitals that offer primary PCI for at least 2 years may apply to offer elective PCI under Tier 3. Further details are available on the West Virginia Health Care Authority website: [http://www.hcawv.org/CertofNeed/conHome.htm](http://www.hcawv.org/CertofNeed/conHome.htm)

**Wisconsin (Wisconsin’s Con Law is limited to long-term care)**
Primary and elective PCI permitted.
Wyoming *(No Certificate of Need Law)*

Primary and elective PCI permitted.
Kim, Tania-
Below are the details regarding "definitions" and descriptions from the regs of New York State, incl. standalone PCI programs. We should include these as well for the January SAC meeting materials.
Thanks,
Ted

From: Schreiber, Theodore
Sent: Saturday, December 25, 2010 09:12
To: Schreiber, Theodore
Subject: Emailing: Viewing Section 405.29 - Cardiac Services.htm

Effective Date: 11/04/2009
Title: Section 405.29 - Cardiac Services

405.29 Cardiac Services

(a) Definitions. For the purposes of this section, the following terms shall have the following meanings:

(1) Adult patient means a patient 18 years of age or older at the time of admission;

(2) Pediatric patient means a patient who has not reached their eighteenth birthday at the time of admission to the hospital;

(3) Cardiac Surgery Center means a general hospital that is approved through the certificate of need process to perform surgery on the heart and great vessels, and is approved for and provides cardiac diagnostic and interventional services including, but not limited to percutaneous coronary interventions (PCI) and diagnostic cardiac angiography procedures. Heart transplant procedures may only be performed at Cardiac Surgery Centers that are also approved as heart transplant centers in accordance with standards at Section 709.9 of this Title and approved for organ sharing by the United Network for Organ Sharing (UNOS). Cardiac Surgery Centers must operate in compliance with this Section, and must meet the construction provisions of Part 711 and
Part 712 of this title. Cardiac Surgery Centers may be approved to serve adult patients (Adult Cardiac Surgery Centers) and or pediatric cardiac patients (Pediatric Cardiac Surgery Centers). However, separate certificate of need approvals are required for Adult and Pediatric Cardiac Surgery Centers in accordance with standards at Section 709.14 of this Title.

(4) Cardiac Catheterization Laboratory Center means a general hospital approved through the certificate of need process to perform catheter based procedures in specially equipped laboratories. Such laboratories are rooms with specialized radiological equipment and supplies used primarily to perform cardiac based angiographic or electrophysiological (EP) procedures on the heart or great vessels. Cardiac Catheterization Laboratory Centers may be approved to serve adult and or pediatric cardiac patients, but separate certificate of need approvals are required in accordance with standards at Section 709.14 of this Chapter for each service. Cardiac Catheterization Laboratory Centers must operate in compliance with standards set forth in this section. Cardiac Catheterization Laboratory Centers are further categorized by the procedures performed as defined below:

(i) A PCI Capable Cardiac Catheterization Laboratory Center Cardiac Catheterization Laboratory Center performs percutaneous coronary and other percutaneous procedures to diagnose and treat abnormalities of the heart or great vessels in adult patients. Such PCI Capable Cardiac Catheterization Laboratory Centers may be approved with or without cardiac surgery at the same hospital site, however, those with no cardiac surgery on site must meet additional criteria at subparagraph 405.29(c)(8)(i) of this section;

(ii) A Diagnostic Cardiac Catheterization Service performs catheter based angiographic procedures on the heart or great vessels and is strictly limited to the diagnosis of abnormalities in adult patients. Such hospitals must maintain an affiliation with a Cardiac Surgery Center as specified in subparagraph 405.29(c)(8)(i) of this section, and are subject to annual review by DOH to determine the continuing operation of the center. Catheter based interventional procedures, such as percutaneous coronary intervention, are prohibited at Diagnostic Cardiac Catheterization Service hospitals;

(iii) A Cardiac EP Laboratory Program shall be located in a Cardiac Catheterization Laboratory Center and is approved through the certificate of need process to perform catheter based cardiac electrophysiology (EP) procedures. Such programs may be approved with or without cardiac surgery at the same hospital site, however, those with no cardiac surgery on site must meet additional criteria at paragraph 405.29(e)(5) of this section.

(iv) A Pediatric Cardiac Catheterization Laboratory Center shall be located at a Cardiac Surgery Center approved through the certificate of need process to provide cardiac surgery to pediatric patients and is approved to perform catheter based diagnostic and interventional procedures on pediatric patients; and
(5) Cardiac Reporting System is a New York State reporting system that gathers demographic, clinical, procedural and outcomes information from Cardiac Surgery Centers and Cardiac Catheterization Laboratory Centers on every patient who has undergone a surgical procedure or a percutaneous interventional procedure on the heart or great vessels. The Cardiac Reporting System includes separate reporting modules to capture procedure specific data elements for the procedure (cardiac surgery or percutaneous interventions) and age group (adult or pediatric) involved.

(b) State Cardiac Advisory Committee. There shall be a State Cardiac Advisory Committee consisting of physicians and other professionals with expertise in cardiac care appointed by the Commissioner of Health. The State Cardiac Advisory Committee shall, at the request of the Commissioner, consider any matter relating to Cardiac Services including, but not limited to review of existing and prospective services, and shall advise the Commissioner thereon.

(c) General Provisions.

(1) Cardiac Catheterization Laboratory Center services shall be limited to general hospitals.

(2) Hospitals shall not admit patients for cardiac surgery or cardiac catheterization laboratory procedures unless the hospital is approved to provide such services.

(3) Hospitals that provide cardiac surgery, Diagnostic Cardiac Catheterization Service, interventional cardiac laboratory services including percutaneous coronary intervention (PCI) and other percutaneous cardiac interventions, or cardiac electrophysiology (EP) must comply with subdivision 405.22 (a) of this Part.

(4) Review and Approval. Site visits to and or data and record reviews from existing and prospective new centers by the Department, members of the Cardiac Advisory Committee or other designees of the Commissioner shall be made as indicated, as an adjunct to initial approval and or for consideration of continued approval. Such site visits and reviews shall include, but not be limited to, evaluation of data, review of service specific quality of care, and compliance with minimum workload standards as set forth in this section.

(5) Closure.

(i) Failure to meet one or more statutory or regulatory requirements or inactivity in a program for a period of 6 months may result in actions to include: probationary status, withdrawal of approval as a Cardiac Surgery Center and or Cardiac Catheterization Laboratory Center.

(ii) Voluntary Closure. The hospital must give written notification, including a closure
plan to the Department at least 60 days prior to planned discontinuance of Cardiac Surgery or Cardiac Catheterization Laboratory Center Services. No Cardiac Surgery Center and no Cardiac Catheterization Laboratory Center shall discontinue operation without first obtaining written approval from the Department.

(6) Notification of significant changes. A hospital must notify the Department of Health in writing within 7 days of any significant changes in its Cardiac Surgery Center or Cardiac Catheterization Laboratory Center services including, but not limited to, any temporary or permanent suspension of services; departure of or change in the physician program director; if the program is without a physician credentialed to perform one or more of the procedures or services of the Cardiac Surgery Center or Cardiac Catheterization Laboratory Center; or inability to meet workload requirements.

(7) Data collection and reporting. Data as deemed necessary by the Commissioner shall be maintained for cardiac patients treated by the hospital and submitted upon request to the Department of Health in a format specified by the Department. Such data shall include, but not be limited to data documenting appropriate case selection and or appropriate access to care and, Cardiac Reporting System data for Cardiac Surgery Centers and Cardiac Catheterization Laboratory Centers.

(8) Quality Assurance. There shall be an organized quality assurance program for cardiac surgery and cardiology that requires participation by all clinical members of the cardiac surgery team and or cardiac laboratory team and includes: monitoring of volume and outcomes; morbidity and all case mortality review; regular multidisciplinary conferences including all health professionals involved in the care of cardiac patients; medical/nursing audit; utilization review, pre hospital and post hospital care review, and a system that assesses pre-operative risk and evaluates outcome trends. Quality improvement efforts must recognize that patients move through multiple systems of care (EMS, Emergency Department, catheterization laboratory etc.) and optimum quality improvement efforts must include participation from as many systems as possible to address those issues at the juncture of systems of care.

(i) In addition, Cardiac Catheterization Laboratory Centers located in hospitals with no cardiac surgery on-site must enter into and comply with a fully executed written agreement with a New York State Cardiac Surgery Center. The agreement will include provisions that address, at a minimum:

(a) Cardiac Surgery Center representatives shall participate in the affiliated Cardiac Catheterization Laboratory Center hospital's quality assurance committee and other reviews of the quality of cardiac care provided by the affiliated Cardiac Catheterization Laboratory Center and in the provision of recommendations for quality improvement of cardiac services. Each Cardiac Surgery Center and each affiliated Cardiac Catheterization Laboratory Center hospital shall take actions necessary, including but not limited to entering into a written agreement to authorize such participation by the Cardiac Surgery
Center representatives in the affiliated Cardiac Catheterization Laboratory Center hospital's quality assurance committee and for purposes of such participation, the Cardiac Surgery Center representative or representatives shall be deemed members of the affiliated Cardiac Catheterization Laboratory Center hospital's quality assurance committee. Cardiac Surgery Center representatives may only access confidential patient information for quality assurance committees as set forth in the affiliation agreements and these regulations. Members of hospitals' quality assurance committees must maintain the confidentiality of patient information and are subject to the confidentiality restrictions of Public Health Law Section 2805-m and other applicable confidentiality restrictions as provided by law. The Cardiac Surgery Center representative(s) shall participate in the review of information and data for quality improvement purposes as described in the agreement which may include:

(1) Statistical data and reports used in quality improvement activities;

(2) the affiliated Cardiac Catheterization Laboratory Center hospital's quality improvement program, policies, and procedures;

(3) care provided by medical, nursing, and other health care practitioners associated with the cardiac services;

(4) appropriateness and timeliness of patient referrals and of patients retained at the affiliated Cardiac Catheterization Laboratory Center hospital who met criteria for transfer to the Cardiac Surgery Center hospital; and

(5) adverse events or occurrences including death and major complications for patients receiving cardiac care at the affiliated Cardiac Catheterization Laboratory Center hospital.

(b) Joint cardiology/cardiac surgery conferences to be held at least quarterly, with a focus on continuous quality improvement to include review of: all cardiac laboratory related morbidity and mortality, review of a random selection of uncomplicated routine cases, patient selection, rates of normal outcomes for diagnostic studies performed, rates of studies needed to be repeated prior to intervention, quality of the studies conducted, rates of patients referred for and receiving interventional procedures subsequent to the diagnostic cardiac catheterization procedure, and the number and duration of cardiac catheterization laboratory system failures;

(c) A mechanism for a telemedicine link between the Cardiac Catheterization Laboratory Center and the Cardiac Surgery Center that provides the capability for off-site review of digital studies, and a commitment on the part of each hospital to provide timely treatment consultation by appropriate physicians on an as needed basis;

(d) The Cardiac Surgery Center's involvement in developing privileging criteria for
physicians performing cardiac catheterization procedures at the hospital with no cardiac surgery on-site;

(e) Development and ongoing review of patient selection criteria and review of implementation of those criteria. The process shall include a comprehensive review of the appropriateness of treatment for a random selection of cases;

(f) Consultation on equipment, staffing, ancillary services, and policies and procedures for the provision of cardiac catheterization laboratory procedures;

(g) A pre-procedure risk stratification tool which ensures that high risk and or complex cases are treated at a Cardiac Surgery Center;

(h) Procedures to provide for appropriate patient transfers between facilities;

(i) An agreement to notify the Department of any proposed changes to the initial agreement and to obtain Department approval prior to the change; and

(j) An agreement to jointly sponsor and conduct annual studies of the impact that the Cardiac Catheterization Laboratory Center service has on costs and access to cardiac services in the hospital's service area.

(ii) The Department's Cardiac Surgery Center reviews, as specified at paragraph 405.29 (c)(4), shall include review of the quality of the services the Cardiac Surgery Center has provided to each of the Cardiac Catheterization Laboratory Centers with which it has a written agreement as specified at subparagraph 405.29(c)(8)(i); and

(iii) Cardiac Surgery Centers with one or more affiliated Cardiac Catheterization Laboratory Centers shall provide professional education and training for physicians, nurses and other staff of the affiliated centers for which it provides quality of care review. Education and training shall be designed to update and enhance staff knowledge and familiarity with relevant procedures and technological advances.

(9) The hospital must have written policies and procedures clearly delineating medical equipment vendor activities in the hospital including restrictions on vendor participation in clinical services.

(10) Cardiac Surgery Centers shall be approved to operate as PCI Capable Cardiac Catheterization Laboratory Centers without a separate certificate of need (CON) approval, but must operate in compliance with standards at 405.29 (e) (1) and 405.29 (e) (2) of this Title.

(11) Hospitals with approved cardiac catheterization laboratories approved prior to July 1, 2009 to perform PCI with no cardiac surgery on site shall be approved to operate as
PCI Capable Cardiac Catheterization Laboratory Centers without a Certificate of Need approval but must operate in compliance with standards at 405.29(e)(1) and 405.29(e)(2) of this Title.

(12) Hospitals with approved cardiac catheterization laboratories approved prior to July 1, 2009 to perform cardiac electrophysiology procedures shall be approved to operate as Cardiac EP Laboratory Programs without a Certificate of Need approval but must operate in compliance with standards at 405.29(e)(1) and 405.29(e)(5) of this Title.

(d) Cardiac Surgery Center Criteria. The following criteria apply to Cardiac Surgery Centers approved to perform adult and or pediatric cardiac surgery. The cardiac surgery services must be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of medical practice:

(1) Direction. The physician director is responsible for the overall quality of the cardiac surgical program and carries out this responsibility through the administrative structure of the institution, including but not limited to the governing body. The hospital must notify the Department of Health within 7 days of any change in the cardiac surgery program director, together with the name and curriculum vitae of the new director. The director shall be a qualified physician board certified in Thoracic Surgery or meet accepted equivalent training and experience.

(i) The Director shall:

(a) Continuously monitor the performance of all surgeons working in the cardiac surgical program, including each individual surgeon’s annual case load and level of competence. The director shall advise the Chief of Service, Hospital Medical Director and Credentials Committee on requirements for credentialing and privileging within the cardiac surgery department and will provide assessments of compliance with standards of care, policies and guidelines as part of the credentialing and privileging process;

(b) In conjunction with the medical staff, monitor the quality and appropriateness of cardiac related patient care and ensure that identified problems are reported to the quality assurance committee and are resolved; and

(c) Assure the timely and accurate reporting of the cardiac surgery component of Cardiac Reporting System data to the Department.

(2) Structure and Service Requirements. Hospitals providing cardiac surgery services shall be adequately staffed and equipped for cardiac diagnostic and therapeutic services including, but not limited to cardiac surgery, percutaneous coronary interventions (PCI) and diagnostic cardiac catheterization and, in addition, provide the following:

(i) For Adult Cardiac Surgery Centers:
(a) Cardiac Surgical intensive care, organized, staffed and available on a 24 hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required by adult cardiac surgery patients, and

(b) Coronary Care organized, staffed and available - on a 24-hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required of complex cardiac conditions, and

(c) PCI Capable Cardiac Catheterization Laboratory Center services meeting standards at 405.29(e)(1) and 405.29(e)(2).

(ii) For Pediatric Cardiac Surgery Centers: age appropriate intensive care, organized, staffed and available on a 24-hour basis by clinical personnel trained and equipped to meet the needs of pediatric patients undergoing cardiac surgery, and Pediatric Cardiac Catheterization Laboratory Center services meeting standards at 405.29(e)(1) and 405.29(e)(4).

(iii) For all Cardiac Surgery Centers:

(a) Operating Rooms adequately staffed and equipped for the needs of the Cardiac surgery patient;

(b) Preoperative and post operative care areas to serve the needs of the surgery patient;

(c) A qualified cardiac surgeon must be immediately available for consultation. The surgeon must remain available (arrive on-site within 20 minutes of being called) after each cardiac surgery procedure. The surgeon must remain available until at least such time that the patient is evaluated on post operative day one and for a clinically appropriate period of time thereafter to handle cardiac surgery emergencies;

(d) The hospital must assure that a cardiac surgery team is immediately mobilized for handling cardiac surgery emergencies. In the event that a patient must return on an emergency basis to the operating room, appropriate resources shall be immediately available in order to have the patient in the operating room and the team ready within 20 minutes of an identified surgical emergency. There shall be written documentation of a triage protocol including identification of specific responsibilities;

(e) Non-invasive cardiac diagnostic equipment and capabilities;

(f) In addition, the hospital shall provide clinical support services in keeping with generally accepted standards. Such services shall be integrated and available on an inpatient basis, but there shall also be adequately and appropriately organized outpatient services to preclude unnecessary hospitalization and ensure continuity of care;
(g) Cardiac surgery conferences shall be held no less than 10 times per year at which the staff reviews the studies of a statistically significant number of cases. Records of these conferences indicating attendance, cases reviewed and decisions on patient management shall be maintained; and

(h) The hospital shall attempt to determine and document the status of the patient at 30 days post surgery for those who are no longer inpatient and throughout the hospital stay for those who are discharged from the cardiac surgery service to another service within the hospital. Status shall include living or deceased and other pertinent criteria as determined by the Commissioner.

(3) Staffing. All personnel shall be qualified for their responsibilities through appropriate training and educational programs.

(i) Physicians shall all be residency trained and board certified, or meet accepted equivalent training and experience for physicians in their respective specialty and shall be appropriately credentialed and privileged as part of the medical staff, and shall be available in sufficient numbers and on a 24 hour basis to meet the needs of the cardiac surgery patients. Such specialists shall, at a minimum include:

(a) Cardiothoracic surgeons in sufficient numbers to meet the ongoing needs of the patients, and each of whom performs a minimum of 50 cardiac surgeries per year. Review by the physician director shall be conducted and provided to the Chief of Service, Hospital Medical Director and Medical Staff Credentials Committee for all physicians whose annual volume is below 50 cardiac surgeries to determine what actions are deemed necessary. In addition, for programs approved to perform pediatric cardiac surgery, cardiac surgeons with advanced training and or with significant experience in pediatric cardiac surgery to meet the needs of the pediatric patients;

(b) Anesthesiologist(s), who have acceptable minimum experience with cardiac surgical procedures;

(c) Specialists with expertise in critical care and the care of post cardiac surgery patients;

(d) Cardiologists to care for adults and, for programs approved to care for pediatric patients, pediatric cardiologists, with expertise in children's cardiovascular diseases, each of whom meet qualifications in accordance with generally accepted standards from recognized specialty organizations; and

(e) Complement of additional physicians shall be in keeping with generally accepted standards to meet the needs of cardiac surgery patients and shall include, but not be limited to practitioners, readily available for consultation in additional specialties, including hematology, pulmonology, neurology, nephrology and clinical pharmacology.
(ii) Nurses. Nursing personnel shall be certified in advanced cardiac life support (ACLS) or meet acceptable equivalent training and experience and shall include:

(a) A registered professional nurse, with 24-hour accountability, in charge of coordinating the care of post cardiac surgery patients and in charge of staffing levels for the unit;

(b) Registered professional nurses, licensed practical nurses and nursing assistants in such ratios that are commensurate with the type and amount of nursing needs of the patients.

(iii) Nurse Practitioners, Advanced Practice Nurses and or Registered Physician Assistants may be utilized when these specialists are appropriately credentialed and privileged on the medical staff.

(iv) The Cardiac Surgery Center shall have perfusionists who have special training and experience in an active program of open heart surgery, including a thorough background in sterile techniques, perfusion physiology, and the use of monitoring equipment and must demonstrate, through a formal review process, competencies in these areas. The operator may be a specially trained physician, nurse, or technician, at the discretion of the director of the center.

(v) The Cardiac Surgery Center shall have a data manager who has special training in the clinical criteria used in the cardiac surgery module of the Cardiac Reporting System as provided by the Department or its designee, is designated and authorized by the hospital and shall work in collaboration with the physician director to ensure accurate and timely reporting of Cardiac Reporting System data to the Department. In addition to the data manager, relevant medical and administrative staff must be trained in the use of the Cardiac Reporting System and the specific data element definitions involved.

(4) Patient Selection Criteria and Limitations. Criteria shall be adopted by the Cardiac Surgery Center to be used as indications of appropriate case selection. Such criteria shall be in keeping with generally accepted standards and, at a minimum, shall provide the following limitations:

(i) The hospital shall not perform heart transplantation unless the hospital is a Cardiac Surgery Center approved for heart transplantation and approved for organ sharing by UNOS;

(ii) The hospital shall not electively admit patients for implantable ventricular assist devices unless the hospital is a Cardiac Surgery Center approved for heart transplantation or has an agreement with at least one New York State heart transplantation center that provides for appropriate consultation and expertise for such cases;
(iii) The hospital shall not admit patients under the age of 18 for cardiac surgery unless the hospital is a Cardiac Surgery Center approved for pediatric cardiac surgery or unless the patient’s diagnosis indicates a condition, such as acquired heart disease, that can be most appropriately treated in an adult program with pediatric trained personnel and pediatric consultative services. Such exceptions must be supported by written documentation of consultation with a pediatric cardiologist; and

(iv) Cardiac Surgery Centers approved to perform pediatric cardiac surgery that are not also approved as Adult Cardiac Surgery Centers shall not admit patients over the age of 18 for cardiac surgery unless the procedure will be performed to treat a congenital anomaly and the hospital can meet the additional clinical needs of the patient.

(5) Minimum workload standards. There shall be sufficient utilization of a Cardiac Surgery Center to insure both quality and economy of services, as determined by the Commissioner. An institution seeking to maintain approval shall present evidence that the annual minimum workload standards have been achieved and maintained. The following annual minimum workload standards must be achieved within two years following initiation of the service to ensure both quality and economy of services:

(i) Adult Cardiac Surgery Centers shall maintain an annual minimum of 100 procedures on adult patients; and

(ii) Pediatric Cardiac Surgery Centers shall maintain an annual minimum of 75 pediatric cardiac surgery procedures excluding the number of isolated Patent Ductus Arteriosus (PDA) repairs. The annual minimum volume shall be deemed to be met when two or more Pediatric Cardiac Surgery Centers, at least one of which must perform a minimum of 75 pediatric cardiac surgery procedures a year (excluding isolated PDA repairs), join in a coordinated program based on a fully executed written agreement, approved by the Commissioner, and the combined volume of the collaborating Pediatric Cardiac Surgery Centers (excluding the number of PDA repairs) is greater than 100 procedures a year. The agreement between the collaborating hospitals must include, at a minimum, information on: quality improvement, peer review and coordination of care of patients between the coordinated Pediatric Cardiac Surgery Centers. The agreement must specify that the Department will be provided 60 day prior written notice of any proposed change, termination or expiration of the agreement. Changes must be found acceptable to the Department prior to implementation and any proposed termination or expiration of the agreement will result in termination of the coordinated Pediatric Cardiac Surgery Center program.

(6) Waiver of minimum workload standards. The Commissioner may waive the workload requirements upon a satisfactory showing by a Cardiac Surgery Center as determined by the Commissioner upon seeking advice from Cardiac Advisory Committee representatives that the quality of care provided is adequate as supported, at a minimum, by a review of cases and outcome trends conducted by the Department, and:
(i) There are extenuating circumstances precluding compliance with the workload requirements; and or

(ii) There is documented evidence that need for cardiac surgery in the hospital's geographical service area would be substantially unmet if the program were closed.

(e) Cardiac Catheterization Laboratory Center Criteria

(1) The following criteria apply to all Cardiac Catheterization Laboratory Centers. Cardiac Catheterization Laboratory Center services must be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of medical practice.

(i) Direction. The physician director is responsible for the overall quality of the Cardiac Catheterization Laboratory Center and must have the appropriate authority to carry out those responsibilities through the support of the Chief of Cardiology, the Medical Director of the hospital and the hospital administration. The hospital must notify the Department within 7 days of a change in the directorship of the Cardiac Catheterization Laboratory Center, together with the name and curriculum vitae of the new director;

(ii) Qualifications of the Director. The director must be Board certified in Internal Medicine and the subspecialty of Cardiac Disease or meet equivalent standards, be experienced in the performance of procedures specific to type of Cardiac Catheterization Laboratory Center services provided, have good management skills and must be appropriately credentialed and privileged as a member of the medical staff;

(iii) The Director shall:

(a) Continuously monitor the performance of all cardiologists working in the Cardiac Catheterization Laboratory Center, including but not limited to, each cardiologist's annual case load requirement and level of competence. The director shall advise the Chief of Service, the Hospital Medical Director and the Credentials Committee on requirements for credentialing and privileging in the Cardiac Catheterization Laboratory Center and shall provide assessments of compliance with standards of care, policies and guidelines as part of the credentialing and privileging process;

(b) In conjunction with the medical staff, monitor the quality and appropriateness of cardiac related patient care and ensure that identified problems are reported to the quality assurance committee and are resolved; and

(c) For centers approved as PCI Capable Cardiac Catheterization Laboratory Centers, assurance of the timely and accurate reporting the Cardiac Catheterization Laboratory Center module of the Cardiac Reporting System data to the Department.
(iv) Structure and Service Requirements:

(a) All Cardiac Catheterization Laboratory Centers must provide diagnostic services, including but not limited to diagnostic radiology, clinical laboratory, and invasive and noninvasive cardiac diagnostic procedures. Such services shall be available on an inpatient and outpatient basis;

(b) All Cardiac Catheterization Laboratory Centers must have a process in place that allows for appropriate transfer of cases to a higher level of care to handle cardiac emergencies;

(c) Cardiac Catheterization Laboratory Centers approved to provide care to adult patients must provide Coronary Care organized, staffed and available on a 24-hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required of complex cardiac conditions;

(d) Cardiac Catheterization Laboratory Centers approved to perform pediatric procedures must provide age appropriate intensive care, organized, staffed and available on a 24-hour basis by clinical personnel trained and equipped to meet the needs of pediatric patients undergoing cardiac laboratory procedures;

(e) Cardiology conferences shall be held no less than 10 times per year at which the staff reviews the studies of a statistically significant number of cases. Records of these conferences indicating attendance, cases reviewed and decisions on patient management shall be maintained;

(f) Records of the disposition of the cases shall be maintained in compliance with standards set forth in section 405.10 of this Title;

(g) The number of patients referred annually for surgery and the center(s) to which they are referred shall be maintained and readily available upon request from the Department of Health;

(h) Statistics shall be kept on the number of normal invasive cardiac diagnostic studies performed, and written criteria shall be adopted and used for determining when a study is to be considered abnormal. Such criteria shall be in keeping with generally accepted standards of medical practice; and

(i) The hospital shall ensure high quality imaging and radiation protection for patients and personnel in accordance with Section 405.15 of this Title.

(j) In addition to standards at 405.29(c)(8)(i), for Cardiac Catheterization Laboratory Centers approved under a co-operator agreement as set forth in section 709.14(d)(1)(ii)
(n), the written and signed co-operator agreement between a Cardiac Surgery Center and the Cardiac Catheterization Laboratory Center without cardiac surgery on site must be maintained and must specify that the department shall be provided 60 day prior written notification of any proposed change, termination or expiration of the agreement, any changes must be found acceptable to the Department prior to implementation and any proposed termination or expiration shall require prior submission of a plan of closure to the Department. The agreement shall provide for an integration of expertise and resources from the Cardiac Surgery Center that would support a high quality program at the hospital without cardiac surgery on site, and shall delineate responsibilities of each institution. The agreement shall further provide that the parties agree that termination or expiration of the agreement shall result in closure of the co-operated Cardiac Catheterization Laboratory Center.

(v) Staffing. All personnel shall be qualified for their responsibilities through appropriate training and educational programs.

(a) Physicians shall all be board certified, or meet accepted equivalent training and experience for physicians in their respective specialty, and shall be appropriately credentialed and privileged as part of the medical staff. Such specialists shall, at a minimum, include a cardiologist and or pediatric cardiologist depending upon the age group(s) served; a cardiac angiographer whose basic medical training is in keeping with generally accepted standards;

(b) Nurses with appropriate education and training shall be regularly assigned to the center; and

(c) Additional healthcare personnel as needed, each of whom is qualified through appropriate training and education to serve the needs of Cardiac Catheterization Laboratory Center patients.

(vi) Patient Selection Criteria.

(a) The hospital shall not admit patients under the age of 18 for a cardiac laboratory procedure unless the hospital is an approved Pediatric Cardiac Catheterization Laboratory Center or unless the patient's diagnosis indicates a condition, such as acquired heart disease, that can be most appropriately treated in an adult program with pediatric trained personnel and pediatric consultative services, or except as provided in 405.29(e)(5)(iii) (c). Such exceptions must be supported by written documentation of consultation with a pediatric cardiologist;

(b) Pediatric Cardiac Catheterization Laboratory Centers that are not also approved as adult cardiac services programs shall not admit patients over the age of 18 for a cardiac laboratory procedure unless the procedure will be performed to diagnose or treat a congenital anomaly and the hospital can meet the additional needs of the patient;
(c) The hospital shall not admit adult patients for percutaneous coronary intervention or other percutaneous cardiac interventions unless it is an approved PCI Capable Cardiac Catheterization Laboratory Center; and

(d) The hospital shall not provide Cardiac EP Laboratory Program services unless it is an approved Cardiac Catheterization Laboratory Center with an approved Cardiac EP Laboratory Program.

(2) PCI Capable Cardiac Catheterization Laboratory Centers. PCI Capable Cardiac Catheterization Laboratory Centers must meet the following standards:

(i) Structure and Service Requirements

a) PCI Capable Cardiac Catheterization Laboratory Centers must be appropriately staffed and equipped for diagnostic and therapeutic services including but not limited to diagnostic cardiac catheterization and percutaneous coronary and other percutaneous interventions;

b) PCI Capable Cardiac Catheterization Laboratory Centers must maintain capabilities to perform emergency percutaneous coronary interventions for the treatment of ST elevation Myocardial Infarction (STEMI) on a 24 hour a day, 365 days a year basis and must be capable of assembling a dedicated team within 30 minutes of the activation call to provide coronary interventions 24 hours a day and 365 days each year. Exception to this standard shall be made only for temporary and extenuating circumstances and when:

(1) Local Emergency Medical Services have been notified and documentation is in place for triaging patients in need of emergency PCI, and

(2) The Department of Health has been provided with a specific description of the circumstances, documentation of the revised triage arrangements and a timeline for return to the 24 hour provision of services, and has approved the arrangement.

c) The hospital must insure that once an ambulance calls to indicate transport of an emergency cardiac patient, the PCI team is immediately mobilized;

d) The hospital must effectively and efficiently identify patients in need of an emergency percutaneous coronary intervention and must transfer those patients rapidly (within 30 minutes) from the Emergency Department to the cardiac laboratory; and

e) The hospital must have a system documented and in place to ensure effective and efficient identification and transfer of a patient from the cardiac laboratory to a cardiac surgical program either in the hospital or at another hospital.
(ii) Staffing.

(a) Physicians shall all be board certified, or meet accepted equivalent training and experience for physicians in their respective specialty and shall be appropriately credentialed and privileged as members of the medical staff and in sufficient numbers to meet the care needs of the patients;

(b) A minimum of three interventional cardiologists, at least one of whom dedicates the majority of his or her professional time at the facility, must be credentialed and privileged on the medical staff to perform percutaneous coronary interventions. Each interventional cardiologist shall maintain sufficient volume on-site to maintain familiarity with the laboratory and shall perform a minimum of 75 total percutaneous coronary intervention cases per year of which 11 are emergency percutaneous coronary intervention cases, and not all 75 minimum cases or 11 minimum emergency cases must be performed at one site. Review by the physician director shall be conducted and provided to the Chief of Service, Hospital Medical Director and Medical Staff Credentials Committee for all physicians whose volume falls below these minimum volumes to determine actions deemed necessary; and

(c) The PCI Capable Cardiac Catheterization Laboratory Center shall have a data manager who has special training in the clinical criteria used in the PCI module of the Cardiac Reporting System as provided by the Department or its designee, is designated and authorized by the hospital and shall work in collaboration with the physician director to ensure accurate and timely reporting of Cardiac Reporting System data to the Department. In addition to the data manager, relevant medical and administrative staff must be trained in the use of the Cardiac Reporting System and the specific data element definitions involved.

(iii) Patient Selection Criteria. PCI Capable Cardiac Catheterization Laboratory Centers shall adopt criteria for appropriate coronary artery diagnostic and interventional procedures in accordance with generally accepted standards for cardiac patients. For centers with no cardiac surgery on site, patient selection criteria shall be reviewed and approved annually by the affiliated Cardiac Surgery Center in accordance with subparagraph 405.29(c)(8)(i) of this section.

(iv) Minimum workload standards. There shall be sufficient utilization of a center to ensure both quality and economy of services, as determined by the Commissioner. For hospitals that are part of an Article 28 network and multi-site facilities with more than one approved PCI Capable Cardiac Catheterization Laboratory Center, and for PCI Capable Cardiac Catheterization Laboratory Centers operating under a co-operator agreement pursuant to section 709.14(d)(1)(ii)(c)(3)(viii), minimum volume standards are site specific and may not be combined for purposes of achieving minimum workload standards. Any hospital seeking to maintain approval shall present evidence that the
annual minimum workload standards have been achieved by the second full year following initiation of the service and maintained thereafter. Each PCI Capable Cardiac Catheterization Laboratory Center must maintain a minimum volume of 150 percutaneous coronary intervention cases per year including at least 36 emergency percutaneous coronary intervention cases per year. Hospitals with volumes below 400 percutaneous coronary intervention cases per year must comply with the following:

(a) PCI Capable Cardiac Catheterization Laboratory Centers with an annual volume between 300 and 400 percutaneous coronary intervention cases shall undergo a review of cases and outcomes trends conducted by the Department to evaluate the appropriateness and quality of care provided by the center;

(b) PCI Capable Cardiac Catheterization Laboratory Centers with a volume between 150 and 300 percutaneous coronary intervention cases a year must procure the services of an independent physician consultant, acceptable to the Department, who shall conduct an annual review of the appropriateness and quality of percutaneous coronary intervention cases performed at the facility and shall provide a copy of the findings directly to the Department. Findings will be used by the Department to determine whether continued approval or withdrawal of approval best meets the needs of the patients in the region; and

(c) PCI Capable Cardiac Catheterization Laboratory Centers with an annual volume below 150 percutaneous coronary intervention cases a year for two consecutive calendar years, or a volume below 36 emergency percutaneous coronary intervention cases a year for two consecutive calendar years, shall surrender approval to perform percutaneous coronary interventions or have approval to perform the procedure revoked.

(v) PCI Capable Cardiac Catheterization Laboratory Centers with no cardiac surgery on-site must enter into a formal relationship documented by a fully executed written agreement with a Cardiac Surgery Center meeting standards at 405.29 (c)(8)(i).

(3) Diagnostic Cardiac Catheterization Services

As of the effective date of these regulations, no additional Diagnostic Cardiac Catheterization Services shall be approved. Diagnostic Cardiac Catheterization Services hospitals are not approved to perform percutaneous coronary intervention or cardiac surgery, are subject to annual reviews of volume, appropriateness of cases and other quality indicators for diagnostic cardiac catheterization, and must meet the following standards:

(i) Affiliation agreement. The hospital must enter into and maintain a fully executed written agreement with a Cardiac Surgery Center with demonstrated high volume and high quality interventional cardiac services (cardiac surgery and percutaneous coronary interventions). The agreement, must be approved by the Commissioner, and must provide, at a minimum, for the standards at 405.29(c)(8)(i).
(ii) Patient Selection Criteria. Written criteria shall be adopted by the Diagnostic Cardiac Catheterization Service hospital to be used as indications for coronary angiography and or other cardiac invasive diagnostic procedures and shall be available for review during site visits.

(iii) Minimum Workload Standards. There shall be sufficient utilization of a Diagnostic Cardiac Catheterization Service to ensure both quality and economy of services, as determined by the Commissioner. For hospitals that are part of an Article 28 network and for multi-site facilities with more than one approved Cardiac Catheterization Laboratory Center, minimum volume standards are site specific and may not be combined for purposes of achieving minimum workload standards. Any institution seeking to maintain approval shall present evidence that the annual minimum workload standards have been achieved and maintained. Diagnostic Cardiac Catheterization Services shall achieve and maintain an annual minimum volume of 200 angiographic diagnostic cardiac catheterization procedures within two years of initial approval. Such procedures include left and or right heart catheterization with or without the use of contrast visualization and with or without coronary arteriograms, and such procedures exclude:

(a) Placement of permanent or temporary pacemaker or Automatic Implantable Cardioverter Defibrillator (AICD);

(b) Any floating type catheter;

(c) Bundle of His study;

(d) Balloon septostomy;

(e) Radionuclide study;

(f) Right heart catheterization without contrast visualization in adults;

(g) Placement of intra-aortic balloon pump, and

(h) Non-Coronary studies.

(iv) Waiver of Minimum Workload Standards. The Commissioner may temporarily waive the workload requirements upon a satisfactory showing by the hospital that the quality of care provided is adequate as supported, at a minimum, by a review conducted by the Department of cases, outcome trends and appropriateness of care, and that:

(a) there are extenuating circumstances temporarily precluding compliance with the workload requirements, and
(b) there is a documented unmet need in the center's geographical service area that cannot be met by existing PCI Capable Cardiac Catheterization Laboratory Center Laboratory Centers.

(4) Pediatric Cardiac Catheterization Laboratory Centers. In addition to the standards at paragraph 405.29(e)(1) of this subdivision, Pediatric Cardiac Catheterization Laboratory Centers must meet the following standards:

(i) Pediatric Cardiac Catheterization Laboratory Centers are limited to hospitals approved to perform pediatric cardiac surgery and that meet standards at 405.29(d) of this section; and

(ii) During any interventional pediatric cardiac catheterization procedure and for a clinically appropriate period of time following such a procedure, a qualified pediatric cardiac surgeon must be immediately available for consultation and available on-site within 30 minutes, when requested, to perform procedures as needed to meet the patient's needs.

(5) Cardiac EP Laboratory Programs. In addition to the standards at paragraph 405.29(e)(1) of this section, Cardiac EP Laboratory Programs must meet the following standards:

(i) Structure and Service Requirements.

(a) Cardiac electrophysiology laboratories must be adequately staffed and equipped for providing intracardiac electrophysiology procedures;

(b) An ultrasound (echocardiographic) machine must be readily available to the laboratory during all electrophysiology procedures;

(c) The Cardiac EP Laboratory Program must have written protocols utilized for addressing complications including tamponade; and

(d) Cardiac EP Laboratory Programs serving patients between the ages of 12 and 18 with adult cardiac surgery on site, but no pediatric cardiac surgery on site, must maintain pediatric trained personnel.

(ii) Staffing. Staffing for Cardiac EP Laboratory Programs shall include:

(a) Electrophysiologists, board certified or with separate equivalent training and experience each of whom shall maintain an average annual volume of 50 adult cardiac electrophysiology procedures based on review of two years of cases, or 20 pediatric cardiac electrophysiology procedures per year depending on the population served. Review by the physician director shall be conducted and provided to the Chief of Service, Hospital Medical Director and Medical Staff Credentials Committee for all physicians.
whose volume falls below these minimum workload standards to determine what actions are deemed necessary;

(b) Physicians, on staff and immediately available to the laboratory with the expertise to perform local exploration and diagnose and treat tamponade; and

(c) Registered Nurses specifically trained in electrophysiology.

(iii) Patient selection criteria.

(a) Written criteria shall be adopted to be used as indications and contraindications for cardiac electrophysiology procedures in accordance with generally accepted standards of medical care for cardiac patients.

(b) Notwithstanding 405.29(e)(1)(vi)(a) of this section, a hospital with a Cardiac EP Laboratory Program and no cardiac surgery on-site shall not admit patients under the age of 18, patients in need of chronic lead extractions, patients being treated for ventricular tachycardia ablations, and patients being treated for atrial fibrillation ablations for Cardiac EP Laboratory Program services. Additional patient selection criteria for Cardiac EP Laboratory Programs with no cardiac surgery on-site shall be developed in collaboration with a Cardiac Surgery Center with an active Cardiac EP Laboratory Program and the agreed upon criteria shall be documented in writing.

(c) Notwithstanding 405.29(e)(1)(vi)(a) of this section, a hospital with a Cardiac EP Laboratory Program and with adult cardiac surgery on-site, but no Pediatric Cardiac Surgery on-site may perform cardiac electrophysiology procedures on patients between the age of 12 and 18 when the patient's diagnosis and condition can be most appropriately treated in an adult program and when pediatric trained personnel are available to meet the additional needs of the patient and when consultation with a pediatric cardiologist is documented in writing for each pediatric patient.

**Volume: C**

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Tania Rodriguez - FW: Emailing: Viewing Section 709.14 - Cardiac services.htm

From: "Schreiber, Theodore" <TSchreib@dmc.org>
To: 'Tania Rodriguez' <rodriguezt1@michigan.gov>, 'Kim Eagle' <keagle@med.umich.edu>
Date: 1/2/2011 9:53 AM
Subject: FW: Emailing: Viewing Section 709.14 - Cardiac services.htm

Tania and Kim-
Happy new year!
Below are the details of the New York State Regs regarding CONs for PCI programs, incl. standalone programs. They should be included in the materials for our next SAC meeting, and I will be prepared to discuss the salient points.
Ted

From: Schreiber, Theodore
Sent: Saturday, December 25, 2010 09:09
To: Schreiber, Theodore
Subject: Emailing: Viewing Section 709.14 - Cardiac services.htm

Effective Date: 11/04/2009
Title: Section 709.14 - Cardiac services

709.14 Cardiac services. (a) These standards will be used to evaluate certificate of need applications for Cardiac Catheterization Laboratory Center services and Cardiac Surgery Center services. All need determinations are hospital site specific. It is the intent of the State Hospital Review and Planning Council that these standards, when used in conjunction with the planning standards and criteria set forth in section 709.1 of this Part, become a statement of planning principles and decision making tools for directing the distribution of Cardiac Catheterization Laboratory Center services and Cardiac Surgery Center services. These planning principles and decision making tools build on the existing regional resources that have been developed through the regulatory planning process. The goals and objectives of the standards expressed herein are expected to promote access to Cardiac Catheterization Laboratory Center services and Cardiac Surgery Center services, maintain provider volumes associated with high quality care, and avoid the unnecessary duplication of resources while addressing the geographic distribution of services necessary to meet the needs of patients in need of emergency percutaneous coronary interventional (PCI) procedures. Additionally, it is intended that the methodology provide sufficient flexibility to consider additional circumstances that reflect on the need for cardiac services.

(b) Cardiac Surgery Centers. The factors for determining the public need for Cardiac
Surgery Center services shall include, but not be limited to the following:

(1) The planning area for determining the public need for Cardiac Surgery Center services shall include the applicant's designated Health Systems Agency (HSA) region and the use area of the applicant facility. For purposes of determining Cardiac Surgery Center services need, the use area of a facility is defined as the area within a 100 mile radius of the applicant facility.

(2) Planning for Cardiac Surgery Center services shall ensure that, to the extent possible, eighty percent of the total population of each HSA region resides within 100 miles of a facility providing cardiac surgical services.

(3) A facility proposing to initiate an Adult Cardiac Surgery Center must document a cardiac patient base and current cardiac interventional referrals sufficient to support a projected annual volume of at least 500 cardiac surgery cases and a projected annual volume of at least 300 PCI cases within two years of approval. The criteria for evaluating the need for additional Adult Cardiac Surgery Centers within the planning area shall include consideration of appropriate access and utilization, and the ability of existing services within the planning area to provide such services. Approval of additional Adult Cardiac Surgery Center services may be considered when each existing Adult Cardiac Surgery Center in the planning area is operating and expected to continue to operate at a level of at least 500 cardiac surgical procedures per year. Waiver of this planning area volume requirement may be considered if:

(i) the HSA region's age adjusted, population based use rate is less than the statewide average use rate; and

(ii) existing Adult Cardiac Surgery Centers in the applicant facility's planning area do not have the capacity or cannot adequately address the need for additional cardiac surgical procedures, such determinations to be based on factors including but not necessarily limited to analyses of recent volume trends, analyses of Cardiac Reporting System data, and review by the area Health Systems Agency(s); and

(iii) existing cardiac surgical referral patterns within the planning area indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other existing cardiac surgical programs.

(4) No finding of need for the addition of Pediatric Cardiac Surgery Center services will be made unless each existing Pediatric Cardiac Surgery Center service in the planning area is operating and expected to continue to operate at a level of at least 200 pediatric cardiac surgical procedures per year, and unless such existing Pediatric Cardiac Surgery Center services do not have the further capacity to meet projected need for additional pediatric cardiac surgical procedures. Where public need is established herein, a facility proposing to provide pediatric cardiac surgical services must demonstrate the ability to
perform a minimum of 200 pediatric cardiac surgical procedures per year by the end of the second full calendar year of operation or demonstrate the ability to perform a minimum of 50 cases a year on-site and operate as part of a coordinated program based on a fully executed written agreement, approved by the Commissioner, with another pediatric cardiac surgery program in accordance with standards at 405.29(d)(5)(ii). For hospitals seeking approval as part of a coordinated program, the agreement must be submitted with the certificate of need application and must be approved by the Department prior to initiation of the service.

(5) A facility proposing to provide Adult and or Pediatric Cardiac Surgery Center services shall:

(i) submit a written plan to the Department of Health which, when implemented, will ensure access to cardiac surgical services for all segments of the HSA region's population. Such plan shall provide a detailed plan to reach patients not currently served within the planning area, ensure continuity of care for patients transferred between facilities, and shall otherwise promote planning for cardiac services within the region; and

(ii) propose a hospital based heart disease prevention program that, when implemented, shall include:

(a) Treatment plans for cardiac inpatients with a principal diagnosis of ischemic heart disease. These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(1) protocols shall be developed and implemented for the assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle. Such protocols shall be in keeping with generally accepted standards;

(2) The hospital shall provide patient education that shall include, but not be limited to, information on the importance of assessing risk factors for heart disease in first-degree relatives, and the importance of cardiopulmonary (CPR) training for family members and care givers;

(3) Discharge plans must include:

(i) a request for consent to allow patient medical information to be shared with the patient’s primary care providers;

(ii) patient referral to their primary care provider with documentation of treatments provided by the hospital and follow-up care recommended by the hospital; and

(iii) patient referral to cardiac rehabilitation programs appropriate to their needs.
(b) professional education:

(1) The hospital shall sponsor or co-sponsor at least three professional education programs per year related to heart disease risk assessment and control and that are open to local community based health professionals.

(c) hospital-based heart health promotion:

(1) The program shall implement policies and health programs in the hospital and establish environments that promote heart-healthy behaviors among hospital staff, employees and visitors, including:

(i) prohibiting the sale and use of tobacco products on hospital premises;

(ii) offering and promoting, on a regular basis, healthful choices in hospital cafeterias and patient menus; and

(iii) offering employee wellness and fitness programs that provide opportunities for employees to make healthy choices.

(d) community based heart health promotion:

(1) The hospital shall organize or participate in a consortium of existing community-based organizations and key community leaders to engage in activities to improve cardiac health in the community; and

(2) organize or participate in at least one major community based campaign (not including health fairs) each year related to major heart disease risk factors.

(e) program administration:

(1) Hospitals shall identify a team within their organization to coordinate heart disease prevention activities. Members of the team shall include a broad range of expertise, including but not limited to: community organization, planning, and social marketing, public health skills and health education.

(6) When considering an application to meet public need for Adult and or Pediatric Cardiac Surgery Center services, priority consideration shall be given to the expansion of an existing service as opposed to the initiation of a new Cardiac Surgery Center.

(7) Where public need is established herein, priority consideration will be given to applicants that agree to serve the medically indigent and patients regardless of the source of payment.
(8) Applicants proposing to initiate an Adult and or Pediatric Cardiac Surgery Center service must:

(i) demonstrate the ability to comply with standards set forth in 405.29 (c), 405.29(d), and 711.4(h) of this Title; and

(ii) in addition, a facility providing Pediatric Cardiac Surgery Center services also must comply with the requirements specified in section 711.4(f) of this Title.

(9) All hospitals approved as Adult Cardiac Surgery Centers shall be approved as PCI Capable Cardiac Catheterization Laboratory Centers and must meet standards in Sections 405.29(c), 405.29(e)(1), and 405.29(e)(2) of this Title. All hospitals approved as Pediatric Cardiac Surgery Centers shall be approved as Pediatric Cardiac Catheterization Laboratory centers and must meet the standards at 405.29(c), 405.29(e)(1) and 405.29(e)(4) of this Title.

(c) For the purposes of this section the terms Cardiac Catheterization Laboratory Center, Percutaneous Coronary Intervention (PCI) Capable Cardiac Catheterization Laboratory Center, Cardiac Electrophysiology (EP) Laboratory Program and Pediatric Cardiac Catheterization Laboratory Center shall have the same meanings as in section 405.29 (a)(4) of this Title.

(d) Public need for Cardiac Catheterization Laboratory Centers:

(1) PCI Capable Cardiac Catheterization Laboratory Centers. The factors and methodology for determining the public need for PCI Capable Cardiac Laboratory Centers shall include, but not be limited to the following:

(i) PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with a Cardiac Surgery Center on site. Applicants approved as Cardiac Surgery Centers are approved PCI Capable Cardiac Catheterization Laboratory Centers as provided under section 709.14 (b)(9) of this Part and must meet standards at Sections 405.29(c), 405.29(e)(1) and 405.29(e)(2) of this Title.

(ii) PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on site. Factors for determining public need for PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on-site include, but are not limited to:

(a) The planning area for determining the public need for PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on-site shall be the area within a 1 hour average surface travel time, as determined by the department of
transportation and adjusted for typical weather conditions, of the applicant facility, unless otherwise determined by the Commissioner in accordance with section 709.1(c) of this title;

(b) Evidence that existing PCI Capable Cardiac Catheterization Laboratory Centers within the planning area cannot adequately meet the needs of patients in need of emergency percutaneous coronary interventions due to conditions such as capacity, geography, and or EMS limitations;

(c) Documentation by the applicant must demonstrate the hospital’s ability to provide high quality appropriate care that would yield a minimum of 36 emergency PCI procedures per year within the first year of operation and would yield a minimum of 200 total PCI cases per year within two years of start-up.

(1) Documentation of the number of cardiologists on staff at the proposed site who currently perform percutaneous coronary interventions at other hospital sites and a summary of experience (including the most recent 3 years of volume and outcomes) for each.

(2) Documentation in support of volume projections must include, at a minimum: discharge data indicating the number of patients with a diagnosis of acute myocardial infarction (AMI) and/or other diagnoses associated with PCI, the number of doses of thrombolytic therapy ordered for acute MI patients in the applicant hospital’s emergency department (as documented through hospital pharmacy records), and documentation of transfers to existing PCI Capable Cardiac Catheterization Laboratory Centers for PCI.

(3) Additional documentation that may be submitted in support of projected volume and need for a proposed PCI Capable Cardiac Catheterization Laboratory Center include:

(i) The number of acute care beds at the applicant hospital and the range of acute care services provided;

(ii) Documentation by the applicant of barriers that impact care experienced by specific population groups within the planning area and demonstration of cultural competency at the applicant site specific to the proposed populations to be served by the applicant;

(iii) Documentation by the applicant demonstrating outreach to underserved populations that identifies potential new PCI cases within the service area;

(iv) Emergency department discharge data;

(v) Documentation by the applicant of regional demographics and transport patterns within the applicant's Emergency Medical Service (EMS) Region that impact the provision of cardiac care;
(vi) The geographic distribution of PCI Capable Cardiac Catheterization Laboratory Center services and the ability of such existing centers to serve the patients in the applicant's service area;

(vii) Letters from local physicians quantifying the number of PCI referrals from their practice and the portion of those that would have been treated at the applicant facility if PCI had been available;

(viii) Additional information that may be considered in projecting volume for an applicant from an established Article 28 network, or multi-site facility as defined at section 401.1 of this Title, with an approved Cardiac Surgery Center within its system that is seeking to add a PCI Capable Cardiac Catheterization Laboratory Center at a non-cardiac surgery hospital site within the system and for a co-applicant proposing to operate a PCI Capable Cardiac Catheterization Laboratory Center without surgery onsite, under a co-operator agreement, approved by the department, with an existing Cardiac Surgery Center. Such additional volume projection criteria include documentation by the applicant of the number of patients residing in the service area of the proposed site who have received percutaneous coronary interventions at the Cardiac Surgery Center site and who would have been candidates to receive their procedures at the proposed non-surgery site.

(d) Existing referral patterns indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other existing PCI Capable Cardiac Catheterization Laboratory Centers and one of the following conditions exists:

(1) The proposed PCI Capable Cardiac Catheterization Laboratory Center is located more than one hour average surface travel time, as determined by the department of transportation and adjusted for typical weather and traffic conditions, from the nearest existing PCI Capable Cardiac Catheterization Laboratory Center; or

(2) All existing PCI Capable Cardiac Catheterization Laboratory Centers within one hour average surface travel time of the applicant facility, as determined by the department of transportation and adjusted for typical weather and traffic conditions, perform and are expected to continue to perform at a level of at least 300 PCI procedures per year after the addition of the proposed new program. Evidence for evaluating this expectation shall include, but not be limited to:

(i) Data indicating the number of patients residing in the applicant's primary service area who are currently receiving percutaneous coronary intervention procedures at existing centers and the location of the centers where patients are receiving that care;

(ii) Volume at existing PCI Capable Cardiac Catheterization Laboratory Centers within
one hour of the applicant hospital;

(iii) Analysis provided by the applicant evaluating the portion of its proposed patient case load that would result in a redistribution of cases from existing centers and the portion that would represent new cases from currently under served populations. Such analysis shall include documentation of any outreach programs by the applicant facility that would support projections of new cases.

(e) A written plan submitted by the applicant that demonstrates the hospital’s ability to comply with standards for PCI Capable Cardiac Catheterization Laboratory Centers at sections 405.29(c), 405.29(e)(1) and 405.29(e)(2) of this Title;

(f) A written plan submitted by the applicant that outlines staff training and demonstrates the hospital’s readiness to accommodate the needs of the PCI patients;

(g) A written plan has been submitted by the applicant which would promote access to Cardiac Catheterization Laboratory Center services for all segments of the hospital service area's population. The document shall include:

(1) a description of current and proposed initiatives for improving outcomes for patients with heart disease,

(2) a plan documenting the hospital's ability to maintain a comprehensive program in which high quality interventional procedures are provided as a component of a broad range of cardiovascular care within the hospital and within the community, to include an emphasis on processes of care and a description of how a patient will traverse through the system of care to be offered,

(3) a plan for ensuring continuity of care for patients transferred between facilities,

(4) documentation of outreach to regional EMS councils served by the applicant,

(5) documentation that EMS system capabilities have been taken into consideration in the delivery of cardiac services;

(6) a description of activities that promote planning for cardiac services within the region; and

(7) a description of current and proposed initiatives and strategies for reaching patients not currently served within the area.

(h) Comments and recommendations received from community organizations;

(i) The hospital shall propose and implement a hospital heart disease prevention program
as set forth at section 709.14(b)(5)(ii) of this Part;

(j) Where public need is established herein, priority consideration shall be given to applicants that agree to serve the medically indigent and patients regardless of payment and can document a history of the provision of services to populations that experience health disparities.

(k) Where public need is established herein, priority consideration shall be given to applicants that can demonstrate projected volume in excess of 300 PCI cases a year.

(l) Where public need is established herein, priority consideration will be given to the expansion of an existing service as opposed to the initiation of a new service.

(m) A written and signed affiliation agreement with a New York State Cardiac Surgery Center, acceptable to the department, has been submitted in accordance with standards at Section 405.29(c)(8)(i) of this title.

(n) In addition, hospital applicants proposing to jointly operate a PCI Capable Cardiac Catheterization Laboratory Center at a hospital without cardiac surgery on-site under a co-operator agreement with a Cardiac Surgery Center must:

(1) Submit a written and signed operational agreement between the applicant Cardiac Surgery Center and the applicant hospital without cardiac surgery on site that demonstrates there will be an integration of expertise and resources from the Cardiac Surgery Center that would support a high quality program at the proposed site and that is acceptable to the department. The agreement must specify that the department shall be provided 60 day prior written notification of any proposed change, termination or expiration of the agreement, and any changes must be found acceptable to the Department prior to implementation. The agreement shall further provide that the parties agree that termination or expiration of the agreement shall result in closure of the co-operated Cardiac Catheterization Laboratory Center.

(2) Submit documentation that demonstrates high quality cardiac care is provided at the applicant Cardiac Surgery Center site and that expanding the service to the proposed site would serve as a benefit to patients and the community.

(3) Submit written documentation of governing body approval of the co-operator contract.

(2) Cardiac EP Laboratory Programs. Factors for determining public need for Cardiac EP Laboratory Programs shall include but not be limited to the following:

(i) Each applicant for a Cardiac EP Laboratory Program shall be an approved PCI Capable Cardiac Catheterization Laboratory Center or an approved Diagnostic Cardiac
Catheterization Service operating in compliance with standards at sections 405.29(c) and 405.29(e). Applicants for EP laboratory programs will also be considered in conjunction with requests for approval of PCI Capable Cardiac Catheterization Laboratory Center services.

(ii) Each applicant shall submit documentation, describing how the hospital will comply with standards at 405.29(e)(5) of this Title.

(iii) Each applicant shall submit documentation of existing referrals for cardiac electrophysiology patients treated by cardiologists on staff at the hospital.

(iv) Applicants for cardiac EP Laboratory Programs at hospitals with no Cardiac Surgery Center on-site must submit a copy of the patient selection criteria for the proposed program in accordance with the standards at section 405.29(e)(5)(iii) of this Title.

(v) Hospitals approved as Cardiac Surgery Centers shall be deemed to have demonstrated public need to perform cardiac electrophysiology.

(3) Pediatric Cardiac Catheterization Laboratory Centers. Public need for a Pediatric Cardiac Catheterization Laboratory Center shall be determined only in conjunction with an application for a Pediatric Cardiac Surgery Center and when need has been demonstrated for Pediatric Cardiac Surgery Centers in accordance with standards at Section 709.14(b) of this Part.

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Report for the State of Michigan
The Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2)

Hitinder Gurm, M.D.
Director, BMC2-PCI
December 17, 2010
Introduction

• BMC2 currently collects PCI data on all consecutive cases in 32/33 non–federal hospitals in Michigan where surgical back up is provided.

• Unless otherwise indicated, information contained in this presentation is for calendar year 2009. During that period, BMC2 had 31/33 hospitals in Michigan.

• For the State of Michigan, BMC2 also collects and comprehensively audits all PCI cases for the 11 Primary PCI Hospitals.
• Procedure counts by hospital (blinded) are provided for 2009 (next slide).

• The PCI hospital volume “goal” of 400 procedures per year is shown on the graph in red.

• All but 2 sites met this goal in 2009, 29 of 31.
BMC2 PCI Sites – 2009:
Number of Procedures Per Site

# of Procedures

Hospitals
Primary PCI Hospitals

• There are 11 Primary PCI hospitals in Michigan. These sites provide primary PCI for STEMI but do not perform PCI for other indications and do not provide cardiac surgery on site.

• A count of PCI procedures are provided in a graph (next slide) by site (blinded) for 2009.

• The State of Michigan – CON “goal” of 75 procedures per site is shown in red.

• Two hospitals met this goal in 2009.

• One hospital entered data for only part of 2009.
BMC2 Primary PCI Sites – 2009: Number of Procedures Per Site

Number of Procedures Per Site

<table>
<thead>
<tr>
<th>Hospital</th>
<th># of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>3</td>
<td>40</td>
</tr>
<tr>
<td>4</td>
<td>50</td>
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<td>7</td>
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<td>8</td>
<td>90</td>
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<tr>
<td>9</td>
<td>100</td>
</tr>
<tr>
<td>10</td>
<td>110</td>
</tr>
<tr>
<td>11</td>
<td>120</td>
</tr>
</tbody>
</table>

* Hospital 1 has the lowest number of procedures, while Hospital 11 has the highest number of procedures.
• Slides 10 – 40 provide physician PCI volume (at a given site) for each of the 31 PCI hospitals in Michigan (blinded).

• It is not possible for BMC2 to provide total physician PCI volume irrespective of hospital where the procedure was performed because BMC2 does not possess national identifier information for all BMC2 physicians.

• Slides 42 and 43 provide a comparison of PCI STEMI and Primary PCI door to balloon times and death for 2007
• Slides 10 – 40 provide individual physician PCI volume at each site for 31 PCI hospitals in Michigan.

• Since a physician may work at more than one hospital, these numbers do not reflect the annual total physician experience.
• The median volume per operator across all sites is 57 (inter-quartile range [IQR]=109).

• The mean volume per operator across all sites is 76. (mean=76.6, standard deviation [SD]=83.3)

• The distribution is severely non-normal (Shapiro-Wilk, p=0.000), the median is a better measure of central tendency.
Number of Procedures performed in 2009 by an individual Physician at this institution
Number of Procedures performed in 2009 by an individual Physician at this institution.

- Physician
- BMC2 PCI
- Hospital #2
- Hospital #2
Number of Procedures performed in 2009 by an individual Physician at this institution

- Physicians 1 to 8 performed fewer than 10 procedures.
- Physicians 9 to 13 performed between 10 and 25 procedures.
- Physicians 14 to 18 performed more than 25 procedures.
Number of Procedures performed in 2009 by an individual Physician at this institution
Number of Procedures performed in 2009 by an individual Physician at this institution

Physician

# of Procedures

0 50 100 150 200 250 300 350

1 2 3 4 5 6 7
Number of Procedures performed in 2009 by an individual Physician at this institution

# of Procedures

Physician
Number of Procedures performed in 2009 by an individual Physician at this institution

<table>
<thead>
<tr>
<th>Physician</th>
<th># of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<tr>
<td>2</td>
<td>75</td>
</tr>
<tr>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>4</td>
<td>125</td>
</tr>
<tr>
<td>5</td>
<td>200</td>
</tr>
<tr>
<td>6</td>
<td>225</td>
</tr>
</tbody>
</table>
Number of Procedures performed in 2009 by an individual Physician at this institution

Physician

# of Procedures
Number of Procedures performed in 2009 by an individual Physician at this institution
BMC2 PCI - Hospital #11

Number of Procedures performed in 2009 by an individual Physician at this institution

Number of Procedures

Physician
Number of Procedures performed in 2009 by an individual Physician at this institution

Physician

# of Procedures

0  1  2  3  4  5  6  7  8  9  10  11  12  13  14  15  16  17  18  19  20  21

12
BMC2 PCI - Hospital #13

Number of Procedures performed in 2009 by an individual Physician at this institution

Physician

# of Procedures

13
Number of Procedures performed in 2009 by an individual Physician at this institution

# of Procedures

Physician
Number of Procedures performed in 2009 by an individual Physician at this institution

Physician
Number of Procedures performed in 2009 by an individual Physician at this institution
Number of Procedures performed in 2009 by an individual Physician at this institution

# of Procedures

Physician

1  2  3  4  5  6  7
Number of Procedures performed in 2009 by an individual Physician at this institution

- 0
- 50
- 100
- 150
- 200
- 250
- 300
- 350

# of Procedures

1 2 3 4 5 6 7 8 9 10 11

Physician
Number of Procedures performed in 2009 by an individual Physician at this institution

Physician

# of Procedures

0 50 100 150 200 250 300 350

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19
Number of Procedures performed in 2009 by an individual Physician at this institution

Physician

# of Procedures

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23

0 50 100 150 200 250 300 350
BMC2 PCI - Hospital #21

Number of Procedures performed in 2009 by an individual Physician at this institution

# of Procedures

Physician
Number of Procedures performed in 2009 by an individual Physician at this institution

- # of Procedures
- Physician
- 0
- 50
- 100
- 150
- 200
- 250
- 300
- 350

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12

- 12 Physicians
Number of Procedures performed in 2009 by an individual Physician at this institution

Physician

# of Procedures

0  50  100  150  200  250  300  350

1  2  3  4  5  6  7
Number of Procedures performed in 2009 by an individual Physician at this institution
BMC2 PCI - Hospital #25

Number of Procedures performed in 2009 by an individual Physician at this institution

<table>
<thead>
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<th>Physician</th>
<th># of Procedures</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
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<tr>
<td></td>
<td>2</td>
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<tr>
<td></td>
<td>3</td>
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<tr>
<td></td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>5</td>
</tr>
</tbody>
</table>
Number of Procedures performed in 2009 by an individual Physician at this institution

- Physician 1: 120 procedures
- Physician 2: 150 procedures
- Physician 3: 180 procedures
- Physician 4: 200 procedures
Number of Procedures performed in 2009 by an individual Physician at this institution

Physician

# of Procedures
Number of Procedures performed in 2009 by an individual Physician at this institution

<table>
<thead>
<tr>
<th>Physician</th>
<th># of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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<tr>
<td>28</td>
<td>300</td>
</tr>
<tr>
<td>28</td>
<td>350</td>
</tr>
</tbody>
</table>

Note: The number of procedures performed in 2009 by individual Physician 28 at Hospital #28 is highlighted.
BMC2 PCI - Hospital #29

Number of Procedures performed in 2009 by an individual Physician at this institution

- # of Procedures
- Physician
Number of Procedures performed in 2009 by an individual Physician at this institution
Number of Procedures performed in 2009 by an individual Physician at this institution

<table>
<thead>
<tr>
<th>Physician</th>
<th># of Procedures</th>
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<tbody>
<tr>
<td>1</td>
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<td>2</td>
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<tr>
<td>9</td>
<td>150</td>
</tr>
<tr>
<td>10</td>
<td>250</td>
</tr>
</tbody>
</table>
• 2007 comparisons of standardized mortality ratios for the PCI and PPCI sites reveal that the PPCI sites have a lower ratio of observed over predicted deaths (statistically not different).

• The 2007 comparison of median D2B times and % < 90 minutes for PCI and PPCI sites reveal that (in 2007) PPCI sites had slightly longer D2B times than PCI sites.
Death in 2007 in BMC2 STEMI Patients vs. Primary PCI Hospital Patients

<table>
<thead>
<tr>
<th>Death Percentage &amp; SMR</th>
<th>Observed</th>
<th>Predicted</th>
<th>Obs/Pred</th>
<th>SMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMC2 Hospitals</td>
<td>4.63</td>
<td>3.73</td>
<td>1.24, 95% CI (1.09-1.38)</td>
<td>1.14</td>
</tr>
<tr>
<td>Primary PCI Hospitals</td>
<td>5.95</td>
<td>5.22</td>
<td></td>
<td>1.14</td>
</tr>
</tbody>
</table>

Observed Death Percent vs. Predicted Death Percent with SMR.
2007 Comparison of PCI STEMI and PPCI Door to Balloon Times

- Median DTB Time (Min)
- DTB Time <90 Min (%)

- BMC2 Hospitals
- Primary PCI Hospitals
CERTIFICATE OF NEED
CARDIAC CATHETERIZATION PROGRAM OVERVIEW

Larry Horvath, Manager
CON Evaluation Section
January 11, 2011

OVERVIEW

- Monitoring and Compliance Activities
- Primary PCI Volume Requirement/Background
- Annual Survey Process & Reports
- Methodology & Volume Requirements
**Follow Up vs. Compliance**

- **Follow up**: The requirement that the facility provide routine updates to the Department and confirmation that the project was completed as proposed. This process ends when the project is operational and deemed 100% complete.

- **Compliance**: The statutory responsibility to verify that the CON holder is meeting the commitments and obligations set forth in the standards, under which the applicant was approved, for the life of the CON.

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**COMPLIANCE**

- MCL 333.22247 (1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

- MCL 333.22247 (2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following…
Compliance Remedies

- Revoke or suspend the CON [MCL 333.22247(2)(a)]
- Reduction in the CON service level (i.e., from 3 CT Scanners to 2 CT Scanners)
- Pursue an injunction to prevent further violation of the terms of the CON [MCL 333.22253]
- Civil fine for the noncompliant time period, not to exceed the total billings. [MCL 333.22247(2)(b)]
- Other remedies deemed appropriate [MCL 333.22247(2)(g)]

MCL 333.22247 continued…

- MCL 333.22247(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.
PRIMARY PCI BACKGROUND

- Ad Hoc Committee:
  - Open Heart Surgery
  - Cardiac Catheterization Services

- Review Standards for primary PCI effective August 4, 2003
  - ACC/AHA Task Force on Practice Guidelines
    - 36 primary angioplasty procedures per year at institutions without onsite cardiac surgical backup
    - Institutions should have a proven plan for rapid and effective PCI as well as rapid access to cardiac surgery in a nearby facility
  - Workgroup discussed a range from 36 to 52 procedures annually, but compromised at 48 procedures

PRIMARY PCI BACKGROUND continued...

- Hospitals offering primary PCI without onsite cardiac surgery
  1. Metro Health Hospital
  2. St Mary’s Medical Center, Grand Rapids
  3. Holland Community Hospital
  4. St Mary’s Mercy Hospital, Livonia
  5. Hurley Medical Center
  6. Henry Ford Wyandotte Hospital
  7. Botsford General Hospital
  8. Garden City Hospital
  9. Oakwood Annapolis Hospital
  10. Huron Valley-Sinai Hospital
  11. Oakwood Southshore Medical Center

Note: MidMichigan (Midland) and Allegiance Health approved for open heart surgery; Battle Creek Health System closed program.
PRIMARY PCI BACKGROUND continued…

Most recent data review:
- Hospital required to provide portions of BMC\textsuperscript{2} data reports directly to department annually
- Department reviews (2009 data):
  - # of PCI Procedures
  - # of Primary PCI Procedures (Range: 39 to 108)
  - % of patients with “door-to-balloon” time:
    - Within 90 minutes (Range: 58.3\% to 92.0\%)
    - Within 120 minutes (Range: 72.1\% to 97.5\%)

ANNUAL SURVEY PROCESS & REPORTS

- The survey is an online tool designed to improve and expedite the data reporting process to the Department as required by the Public Health Code. The information collected is used by the Department in review of CON applications as well as determining compliance with the terms and conditions of approved projects. The survey data is also used by the Commission to develop and revise Review Standards.

www.mi.gov/con
ANNUAL SURVEY REPORTS

Report 060 contains aggregate data by service type (diagnostic, therapeutic) and by sessions, but not equivalencies.

Maps by Service Category
METHODOLOGY & VOLUME REQUIREMENTS

CON-716 form available at www.mi.gov/con

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

Jeremy W. Buckley, MD, Eric R. Bates, MD, and Brahmajeec K. Nallamothu, MD, MPH

Ann Arbor, MI

Background  In 2005, Michigan expanded primary percutaneous coronary intervention (P-PCI) capability to 12 hospitals without on-site cardiac surgery. We determined the potential impact of this expansion on geographic access to P-PCI for patients.

Methods  Geographic information systems using the US Census Survey and hospital data from the state of Michigan were used to construct maps with 20-mile hospital service areas around P-PCI hospitals with and without on-site cardiac surgery. Geographic access was calculated as the percentage of the population living within the hospital service areas of these 2 types of hospitals.

Results  Of 9,938,444 persons in Michigan, 7,694,834 (77.4%) lived within 20 miles of a P-PCI hospital. Thirty centers with on-site cardiac surgery provided access for 7,219,995 persons (72.6%). The 12 P-PCI hospitals without on-site cardiac surgery increased access by 474,839 persons (4.8%). Of these, 3 geographically isolated facilities, which were at least 20 miles away from another P-PCI hospital, accounted for the greatest improvement in geographic access (n = 425,700 [4.3%]), whereas the remaining 9 hospitals increased access by only 49,139 persons (0.5%).

Conclusions  Expansion of P-PCI to hospitals without on-site cardiac surgery in Michigan improved geographic access to a modest extent. [Am Heart J 2008;155:668-72.]
Background

- Primary PCI w/o on-site CS approved in Michigan in 2005
- Permission to 12 hospitals
- Goal: to improve access to timely reperfusion
- Increase “geographic access” vs. overlap of hospital services
Methods

- **Data:** Geographic Information Systems
  - 2000 US census survey → “census tracts”
  - 2004 MDCH Directory of Hospitals
  - American Hospital Association Annual Survey
- **132 Acute Care Hospitals**
  - PPCI with on-site CS 30
  - PPCI w/o on-site CS 12
  - Thrombolytic only 90
Methods (cont.)
Hospital Service Areas

- “Geographically Isolated” if > 20 miles from other PPCIs
- “Access”: % of Michigan population in census tract whose population-based centers were located within the HSA
Results

- Approximately 10,000,000 persons in Michigan
  - 99.7% ≤ 20 miles of PPCI or thrombolytic hospital
  - 72.6% ≤ 20 miles of existing PPCI centers with on-site CS
  - 12 hospital expansion: increased access by 4.8% (only 3 located ≥ 20 miles)
Conclusions/Implications

- Geographic access vs. overlap/duplication of services
- Response of hospitals with existing diagnostic labs only
- Potential reduction of volumes at regional centers and proliferation of low volume operators and programs
- STEMI “Regionalization and Systems of Care”
Where do P-PCI Hospitals

Net Effect of Improving Access to P-PCI within 20 miles of 4.8%
Michigan Primary Percutaneous Coronary Intervention (PCI) Hospitals (1/20/10)
Emergency Preparedness / Trauma Regions

DRAFT (rev 4/8/10)

Hospital PCI Status
- Non-PCI Capable Hospital
- PCI Capable, No Surgical Program
- PCI Capable Hospital
MICHIGAN PRIMARY PCI HOSPITALS WITHOUT SURGICAL BACKUP
AND OPEN HEART HOSPITAL LOCATIONS

<table>
<thead>
<tr>
<th>Origin</th>
<th>Destination</th>
<th>Travel_Miles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metropolitan Hospital</td>
<td>Spectrum Health - Grand Rapids</td>
<td>44.7</td>
</tr>
<tr>
<td>Saint Mary's Mercy Medical Center Grand Rap</td>
<td>Spectrum Health - Grand Rapids</td>
<td>1.1</td>
</tr>
<tr>
<td>Holland Community Hospital</td>
<td>Spectrum Health - Grand Rapids</td>
<td>30.9</td>
</tr>
<tr>
<td>St Mary Mercy Hospital - Livonia</td>
<td>Providence Hospital Medical Center</td>
<td>18.9</td>
</tr>
<tr>
<td>Hurley Medical Center</td>
<td>McLaren Regional Medical Center</td>
<td>2.2</td>
</tr>
<tr>
<td>Henry Ford Wyandotte Hospital</td>
<td>Oakwood Hosp &amp; Med Center - Dearborn</td>
<td>8.9</td>
</tr>
<tr>
<td>Botsford General Hospital</td>
<td>Providence Hospital Medical Center</td>
<td>7.9</td>
</tr>
<tr>
<td>Garden City Hospital</td>
<td>Oakwood Hosp &amp; Med Center - Dearborn</td>
<td>7.9</td>
</tr>
<tr>
<td>Oakwood Annapolis Hospital</td>
<td>Oakwood Hosp &amp; Med Center - Dearborn</td>
<td>8.9</td>
</tr>
<tr>
<td>Huron Valley Sinai Hospital</td>
<td>St. Joseph Mercy Oakland</td>
<td>13.8</td>
</tr>
<tr>
<td>Oakwood Southshore Medical Center</td>
<td>Oakwood Hosp &amp; Med Center - Dearborn</td>
<td>18.7</td>
</tr>
</tbody>
</table>

LEGEND

H: Open Heart Hospital

△: Primary PCI Hospital

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Note: Distances calculated using mapquest.com
Geographical Access Implications
- Elective PCI

MICHIGAN CARDIAC CATH LOCATIONS

<table>
<thead>
<tr>
<th>Distance between diagnostic labs and Open Heart hospital</th>
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</thead>
<tbody>
<tr>
<td>Origin</td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
<td>Alpena Regional Medical Center</td>
</tr>
<tr>
<td>Battle Creek Health System</td>
</tr>
<tr>
<td>Beaumont Hospitals - Grosse Pointe</td>
</tr>
<tr>
<td>St. John Hospital and Medical Center</td>
</tr>
<tr>
<td>Doctors Hospital of Michigan</td>
</tr>
<tr>
<td>Henry Ford Macomb Hospital - Warren Campus</td>
</tr>
<tr>
<td>Henry Ford West Bloomfield Hospital</td>
</tr>
<tr>
<td>Hurley Medical Center</td>
</tr>
<tr>
<td>Lapeer Regional Medical Center</td>
</tr>
<tr>
<td>Mercy Health Partners Hatcher Campus</td>
</tr>
<tr>
<td>Mercy Hospital Brayton</td>
</tr>
<tr>
<td>PCH Regional Medical Center</td>
</tr>
<tr>
<td>Providence Park Hospital - Novi</td>
</tr>
<tr>
<td>Spectrum Health - Bay City</td>
</tr>
<tr>
<td>St. Joseph Mercy Port Huron</td>
</tr>
<tr>
<td>West Branch Regional Medical Center</td>
</tr>
</tbody>
</table>

LEGEND

- Open Heart Hospital
- Primary PCI Hospital
- Diagnostic Lab

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Note: Distances calculated using mapquest.com
Thank you
Outcomes of Nonemergent Percutaneous Coronary Intervention With and Without On-site Surgical Backup: A Meta-Analysis

Param Puneet Singh, MD,* Mukesh Singh, MD, Updesh Singh Bedi, MD, Sasikanth Adigopula, MD, Sarabjeet Singh, MD, Vamsi Kodumuri, MD, Janos Molnar, MD, Aziz Ahmed, MD, Rohit Arora, MD, and Sandeep Khosla, MD

Despite major advances in percutaneous coronary intervention (PCI) techniques, the current guidelines recommend against elective PCI at hospitals without on-site cardiac surgery backup. Nonetheless, an increasing number of hospitals without on-site cardiac surgery in the United States have developed programs for elective PCI. Studies evaluating outcome in this setting have yielded mixed results, leaving the question unanswered. Hence, a meta-analysis comparing outcomes of nonemergent PCI in hospitals with and without on-site surgical backup was performed. A systematic review of literature identified four studies involving 6817 patients. Three clinical end points were extracted from each study and included in-hospital death, myocardial infarction, and the need for emergency coronary artery bypass grafting. The studies were homogenous for each outcome studied. Therefore, the combined relative risks (RRs) across all the studies and the 95% confidence intervals (CIs) were computed using the Mantel-Haenszel fixed-effect model. A two-sided alpha error less than 0.05 was considered to be statistically significant. Compared with facilities with on-site surgical backup, the risk of in-hospital death (RR, 2.7; CI, 0.6–12.9; \( P = 0.18 \)), nonfatal myocardial infarction (RR, 1.3; CI, 0.7–2.2; \( P = 0.29 \)), and need of emergent coronary artery bypass grafting (RR, 0.46; CI, 0.06–3.1; \( P = 0.43 \)) was similar in those lacking on-site surgical backup. The present meta-analysis suggests that there is no difference in the outcome with regard to risk of nonfatal myocardial infarction, need for emergency coronary artery bypass grafting, and the risk of death in patients undergoing elective PCI in hospitals with and without on-site cardiac surgery backup.

Keywords: onsite backup surgery, percutaneous coronary intervention

INTRODUCTION

Percutaneous coronary interventions (PCI) were introduced for the first time in 1977 by Andreas Gruntzig. Since then, many technologic and pharmacologic advances in PCI have been made. Steerable guidewires, coronary artery stents,2 and new antiplatelet therapies have improved the success rate of PCI procedures and significantly reduced the risk of per-procedural complications needing urgent cardiac surgery. Recent studies have shown that the need for emergency cardiac surgery is now as low as 0.3% to 0.6%.2,3 As a result, the number of procedures has increased worldwide,4 and an increasing proportion of procedures are performed at centers without surgical backup.5,6 Despite major advances in PCI technique, the current American College of Cardiology/American Heart Association/Society of Cardiovascular Angiography and Intervention 2005 guidelines7 for PCI recommend against elective PCI at hospitals without on-site cardiac surgery (Class III indication). Acknowledging this trend, the Society for Cardiovascular Angiography and Interventions recently issued an expert consensus statement that provides practice standards for elective PCI at hospitals...
without on-site cardiac surgery. Because of the conflicting literature on this subject, the question about safety of elective PCI at centers without surgical backup remains unanswered. Hence, a meta-analysis comparing outcomes of nonemergent or elective PCI in hospitals with and without on-site surgical backup was performed.

METHODS

We performed this review in accordance with the Quality of Reporting of Meta-analysis statement and the Consolidated Standards of Reporting Trials Group recommendations.

Literature search

A systematic review of the medical literature was performed to identify studies evaluating the efficacy or adverse outcomes of combination therapy in patients with congestive heart failure, acute myocardial infarction, or high-risk diabetes mellitus. Eligible studies were identified by searching MEDLINE (January 1966–December 2008), EMBASE (January 1980–December 2006), the Cochrane Library (Controlled Trials Register and Database of Systematic Reviews, all years), the National Institute of Health Clinical Trials (http://www.clinicaltrials.gov), and the U.S. Food and Drug Administration web sites (http://www.FDA.gov) and relevant bibliographies.

Study selection

There was a written protocol with explicit inclusion and exclusion criteria, which was followed for all articles that were screened. All titles and abstracts from the results of our computerized search were reviewed by the authors for potential inclusion in our study. We also searched for relevant review articles and their bibliographies for articles. In addition to our computerized search, we manually reviewed the reference list of all retrieved articles to complete our search for randomized, controlled trials comparing outcome of PCI with and without surgical backup. Study selection process is outlined in Figure 1.

Studies were excluded if they did not meet the inclusion criteria. Those studies that were not done in human subjects, not randomized, published in nonpeer-reviewed journals, or with inadequate follow up were excluded from our analysis.

End points and definitions

Three clinical end points were extracted from each study and included: in-hospital death, nonfatal myocardial infarction (MI), and need for emergency coronary artery bypass surgery (CABG). End point definitions were those used in the individual trials. Death was defined as in-hospital mortality from any cause. MI was defined as enzymatic and electrocardiographic changes consistent with MI. Emergency CABG surgery was defined as unplanned surgical revascularization within 48 hours of PCI. All end points were assessed at the end of follow up of the trial.

Data extraction

The two authors (PS, MS) independently screened the titles and abstracts for eligibility. Full articles were retrieved for all titles for which abstracts were not available and for all abstracts that appeared to potentially fulfill the inclusion and exclusion criteria. It was decided that if there was a conflict between the two authors, then the study in question would be brought to the panel of all authors where the decision would be made for its inclusion. Data extraction was done independently by two authors. Each author tabulated important trial characteristics and assessed methodological quality (jaded score), including patient demographics such as age, study population, sample size diabetes, hypertension, and angiographic characteristics.

Statistical analysis

The statistical analysis was performed with the Comprehensive Meta-Analysis software package (Version CM 2.2; Biostat, Englewood, NJ). We calculated odds
ratio for each study outcome to allow for pooling of similar outcomes. All the results are reported as the pooled odds ratio with 95% confidence interval (CI). Chi square test was used to assess heterogeneity. The studies were homogenous for each outcome studied (Table 1). Therefore, the combined relative risks (RRs) across all the studies and the 95% CIs were computed using the Mantel-Haenszel fixed-effect model. A two-sided alpha error less than 0.05 was considered to be statistically significant.

Role of funding source

The funding source had no role in the design, conduct, or reporting of the study or in the decision to submit the manuscript for publication.

RESULTS

Data synthesis and study characteristics

Figure 1 represents the trial selection and inclusion flow diagram. After the initial search based as described previously, a total of 80 articles was considered as potentially relevant. After the title and abstract review, 69 of the 80 were excluded because they were not randomized, non-English trials, or did not meet our inclusion criteria. From the remaining 11, seven were excluded after full text review because there was inadequate follow up, the outcomes measured were different, or the study characteristics did not meet our inclusion criteria. Our search of abstracts from conference proceedings of the American College of Cardiology, American Heart Association, European Society of Cardiology, and Heart Failure Society of America did not reveal any additional studies that satisfied our inclusion and exclusion criteria. Our meta-analysis included the remaining four randomized, controlled trials involving 6817 patients.10–13

Baseline characteristics

Table 2 summarizes the study population characteristics of all the studies included for the analysis. All four studies were large randomized, controlled trials with adequate follow up. Mean duration of follow up was 31 months. Mean age of patients enrolled was 64 years. Allocation sequence generation and concealment were adequately described in all four studies. All the studies had two arms comparing the outcome of patients undergoing elective PCI at two centers with and without on-site cardiac surgery backup. In-hospital death and need for emergency surgery as outcomes were reported in two studies,12,13 whereas non-fatal MI was reported in all four studies included in this meta-analysis.10–13

Clinical outcomes

Angiographic characteristics of patients in the included studies are given in Table 3. The outcomes measured in our analysis were in-hospital death, nonfatal MI, and need for emergent CABG.

In-Hospital Death

Compared with hospitals with surgical capability, there was no difference in the risk of in-hospital death in patients undergoing elective PCI at centers without surgical back up (RR, 2.7; CI, 0.6–12.9; P = 0.18) (Fig. 2).

Table 1. Results of heterogeneity analysis.

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FIGURE 2. Risk of in-hospital death with on-site surgical backup versus no backup.
Nonfatal Myocardial Infarction

The risk of nonfatal MI was similar in both groups of patients without any significant difference (RR, 1.3; CI, 0.7–2.2; \( P = 0.29 \)) (Fig. 3).

Need for Emergent Coronary Artery Bypass Grafting

The risk for need for emergent CABG did not differ between the patients undergoing PCI at centers with and without surgical backup (RR, 0.46; CI, 0.06–3.1; \( P = 0.43 \)) (Fig. 4).

DISCUSSION

Our meta-analysis shows that there is no difference in the incidence of in-hospital mortality, nonfatal MI, and the need for emergency CABG in patients undergoing

### Table 2. General characteristics of the patient population in studies included in meta-analysis.

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<td>722</td>
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<td>NSB 174</td>
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<td>59 (9%)</td>
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MI, myocardial infarction; PCI, percutaneous coronary intervention; TIA, transient ischemic attack; CABG, coronary artery bypass grafting; PVD, peripheral vascular disease; DM, diabetes mellitus; HTN, hypertension; CKD, chronic kidney disease; CHF, congestive heart failure; LVEF, left ventricular ejection fraction; SB, on-site surgical backup group; NSB, no on-site surgical backup group.

FIGURE 3. Risk of nonfatal myocardial infarction with on-site surgical backup versus no backup.

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PCI at centers with and without surgical backup (Fig. 5). Overall, of 6817 patients in all four studies, total in-hospital deaths were 32 (0.47%). In the group with no surgical backup, in-hospital mortality was 0.13% (three of 2315 patients died), whereas in the group with on-site surgical backup, the in-hospital mortality rate was 0.6% (29 of 4502 patients died).

The purpose of cardiac surgical backup for PCI is to provide emergent hemodynamic support and revascularization to salvage complications that cannot be addressed by catheter-based techniques. PCI can be complicated by life-threatening hemodynamic and ischemic emergencies that can be addressed only by the availability of emergency cardiac surgery. The role of on-site cardiac surgical backup is twofold: on-site cardiac surgical backup provides prompt availability of cardiac surgical support in the event of a hemodynamic or ischemic emergency and on-site cardiac surgical backup is a surrogate for an institution’s overall capability to respond to a catheterization laboratory emergency.14 Technical improvements in PCI instruments and techniques have led to the concept that the requirement for emergency cardiac surgery is sufficiently rare that PCI can be performed safely without on-site surgery. This has led to the development of elective angioplasty programs without on-site surgical coverage.

Cardiac surgical backup for PCI has evolved from a formal surgical standby in the 1980s to an informal arrangement of first-available operating room and, in some cases, off-site surgical backup.15–21 With the advent of intracoronary stenting, there has been a decrease in the need for emergency CABG ranging between 0.4% and 2%.2,3,21–28 Not surprisingly, emergency CABG surgery for a patient with an occluded or dissected coronary artery is associated with a higher mortality than elective surgery.21,29–34 Emergency procedures are also associated with high rates of perioperative infarction and less frequent use of arterial conduits. Complex coronary artery disease intervention, hemodynamic instability, and prolonged time to reperfusion are contributing factors to the increased risk of emergency bypass surgery.

A recently published report from analysis of National Cardiovascular Data Registry showed findings similar to our meta-analysis. This National

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<td>3 (2%)</td>
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<td>VG</td>
<td>1 (0.5%)</td>
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<td>263 (8%)</td>
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<td>1.7 ± 1.3</td>
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SB, on-site surgical backup group; NSB, no on-site surgical backup group; SVD, single-vessel disease; DVD, double-vessel disease; TVD, triple-vessel disease; SV, single vessel; MV, multiple vessel; LM, left main; VG, venous graft.
Cardiovascular Data Registry data analysis showed that off-site PCI centers had similar observed procedure success, morbidity, emergency cardiac surgery rates, and mortality in cases that required emergency surgery. The risk-adjusted mortality rates in off-site PCI facilities were comparable to those of PCI centers that had cardiac surgery on-site regardless of whether PCI was performed as primary therapy for ST-elevation MI or in a nonprimary setting.35

Like with any meta-analysis, our analysis has limitations inherent to such analysis. Meta-analyses have inherent methodological limitations in that summary data are pooled from studies of different designs. The study population used in all the trials, although being somewhat similar, is not exactly the same. Although we detected no significant heterogeneity, a meta-analysis cannot replace large, well-conducted randomized trials as evidence for and against an intervention.

Our meta-analysis adds to the current body of literature on PCI by considering between study heterogeneity, bias, consistency of outcomes among studies and inclusion of large recent studies. This meta-analysis shows that there is no difference in the outcome with regard to risk of nonfatal MI, need for emergency CABG, and the risk of death in patients undergoing elective PCI in hospitals with and without on-site cardiac surgery backup.

REFERENCES


14. Williams DO, Riley RS, Singh AK, et al. Restoration of normal coronary hemodynamics and myocardial metab-
Outcome of Nonemergent PCI


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154 Acute Care Hospitals
86 <100 beds 3 have diagnostic labs
3 have pediatric labs
18 diagnostic labs
30 therapeutic labs
11 Primary PCI labs

of the hospitals with greater than 100 beds nine have no l
of hospitals with greater than 150 beds only detroit receiv
convenant medical center are without labs  (55 out of 5