

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

Tuesday January 11, 2011

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

APPROVED MINUTES

I. 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:

Lawrence O. Wells, Michigan League for Human Services

C. Michigan Department of Community Health Staff present:

Jessica Austin

William Hart Jr.
Sallie Flanders
Tania Rodriguez
Brenda Rogers
Natalie Kellogg

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 Nallamotheu 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

- A. Dennis McCafferty, Economic Alliance for Michigan (EAM)

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

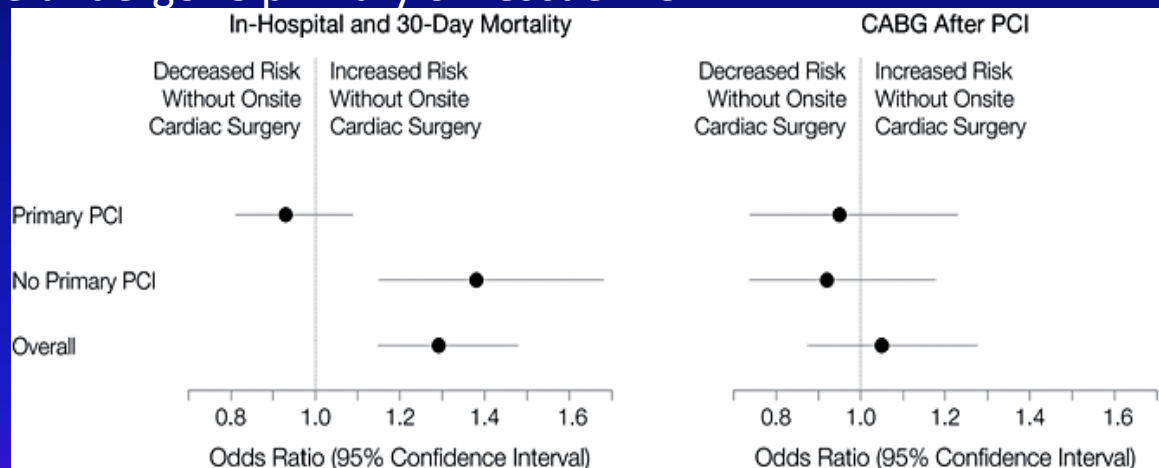
Current status and experience

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....

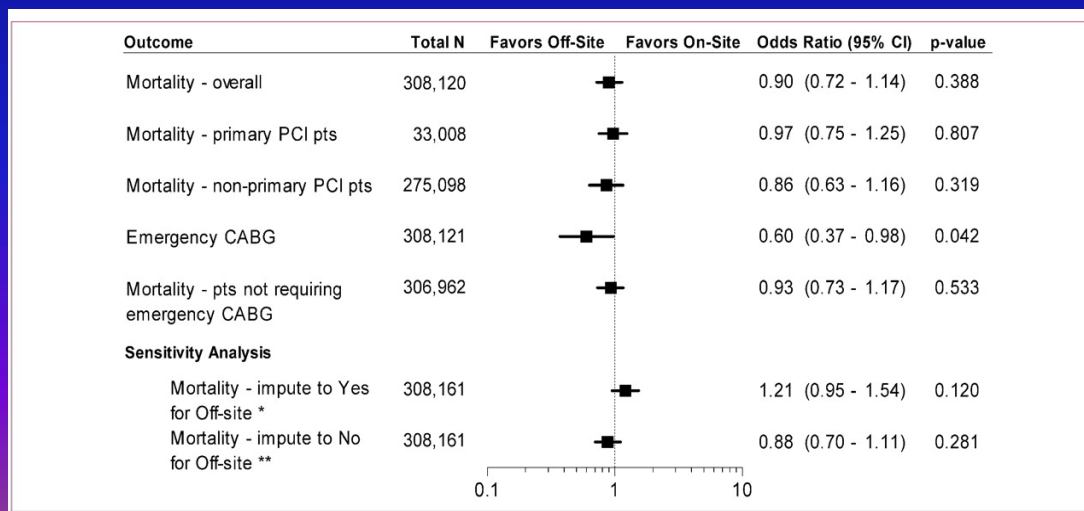
- These were very low volume centers-in the < 50 cases/yr only 6 cases of non-primary PCI per yr
- Inability to adequately adjust for clinical differences

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	OFF-SITE	ON SITE	P
•ALL	5.1%	5.5%	NS
•Mortality	0.8%	0.8%	NS
•Emergency CABG	0.2%	0.3%	NS



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

•Complications	OFF-SITE	ON SITE	P
•MACE	0.8%	0.8%	NS
•Mortality	0.2%	0.4%	NS
•Emergency CABG/ Death	0.2%	0.6%	NS

Recent Data on Relationship of Volume and Outcomes

- Background-Swedish Angioplasty Registry

- 24centers, 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

- Complications

	OFF-SITE	ON SITE	P
•Mortality-all	1.4%	2.2%	<0.001*
•Mortality –UA/NSTEMI	1.2%	1.0%	NS
•Mortality-stable	0.4%	0.2%	NS
•Emergency CABG	0.1%	0.2%	NS

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

Carlsson, J. et al. Heart
2007;93:335

Operator Volume and Outcomes

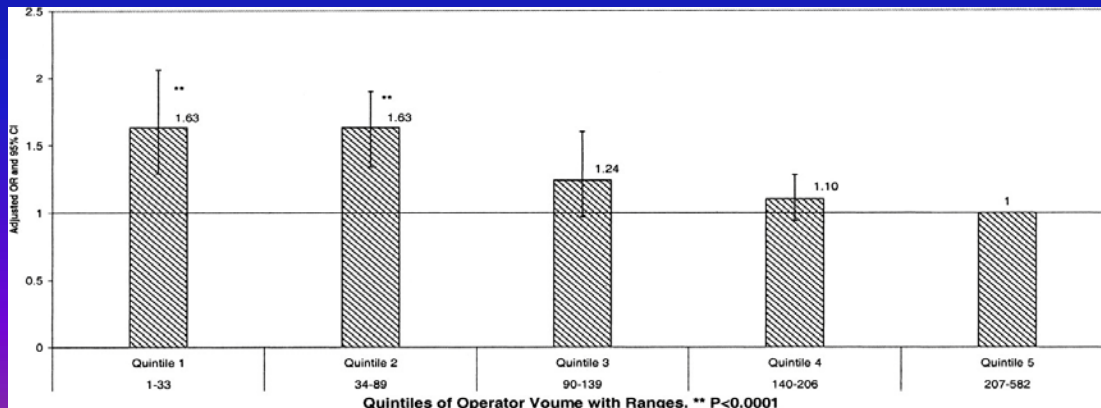
- Background-Michigan BCBS PCI Consortium

- 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

Death	2.0	1.7	1.5	1.1	1.4	NS
MI	1.5	1.5	1.4	1.4	1.3	NS
Stroke	0.0	0.5	0.5	0.4	0.3	NS
Emergent CABG	0.8	1.2	0.6	0.3	0.3	<0.001
MACE	7.4	6.1	5.0	4.2	4.2	<0.001

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

Death -30 d	2.3	1.9	NS
Same day CABG	0.2	0.7	0.046

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

Hannan E, et al. Circ Cardiovasc Interv 2009;2:519

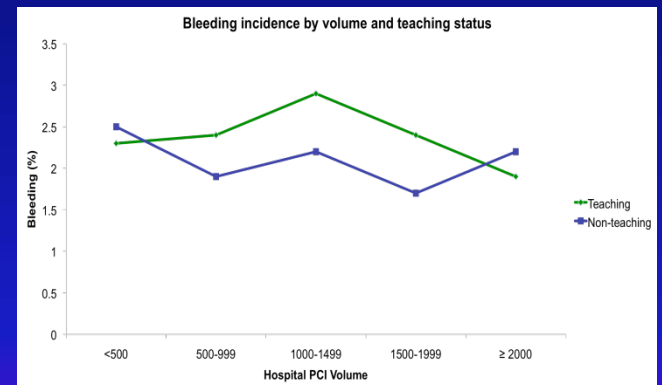
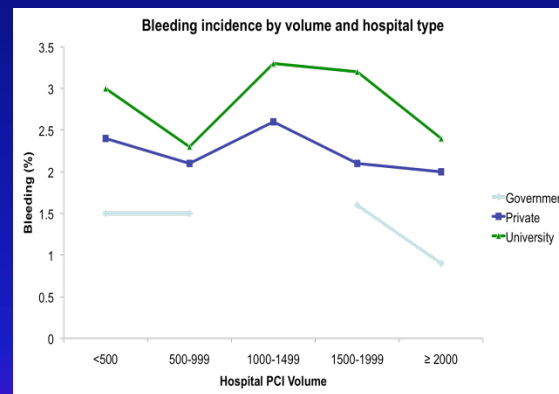
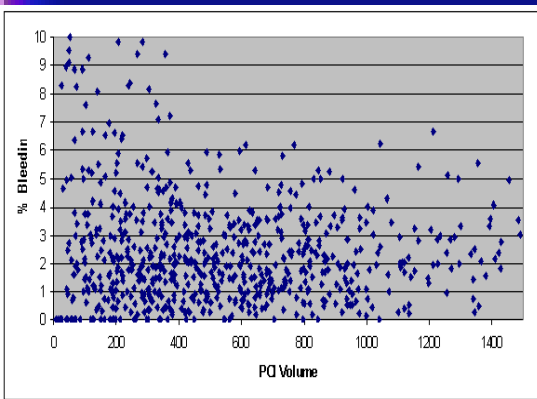
•Background—Seattle Acute MI Registry

- 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



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*

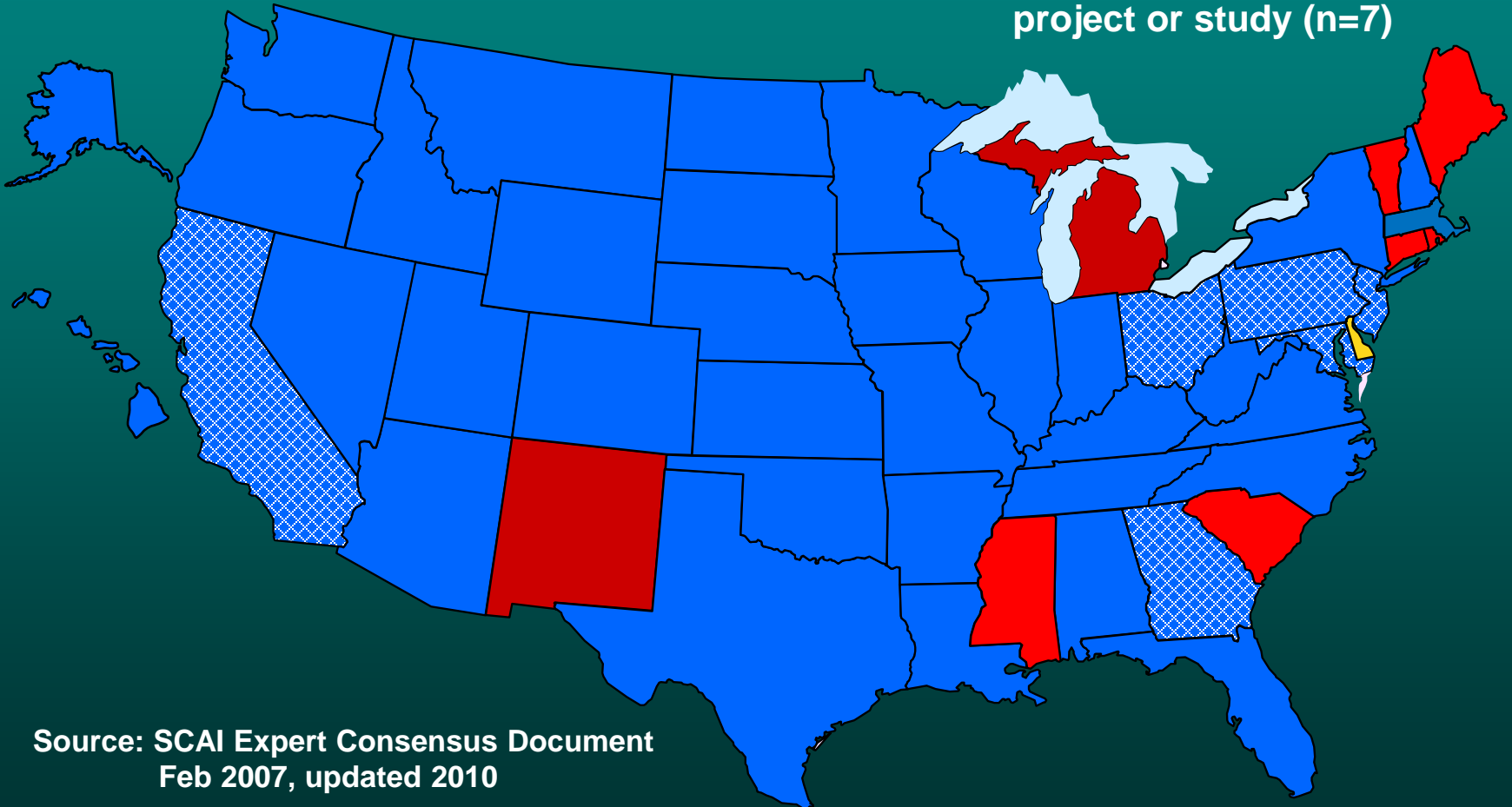
Program Requirements for Elective-PCI with no-onsite CV surgery

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 Attachment A

- 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



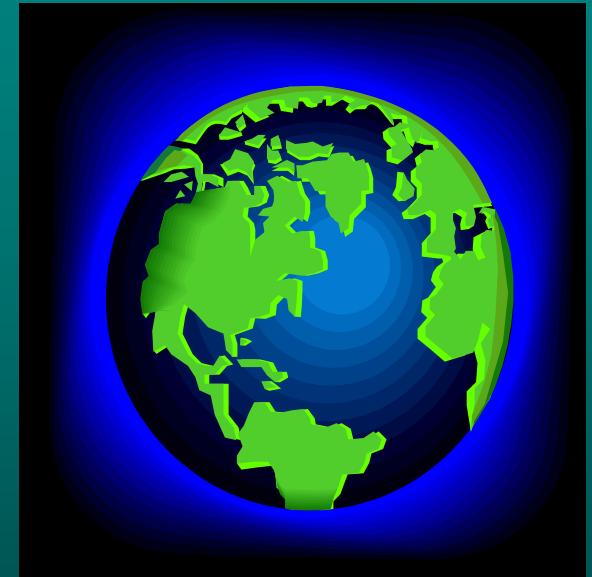
TEXAS A&M
HEALTH SCIENCE CENTER
COLLEGE OF MEDICINE



SCOTT & WHITE

Global Status of PCI Without On-Site Surgery Attachment A

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



Source: SCAI Expert Consensus Document

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

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

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

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 an 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

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

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

Open Heart Programs Required to Meet 300 Volume Requirement (225 = 75% or substantial compliance)

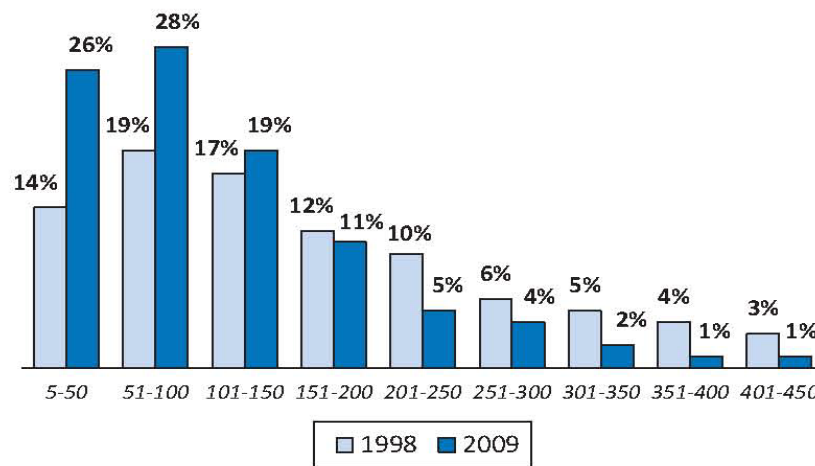
Over-Supply Leading to Further Inefficiencies

Competitive Strategy Often Trumping Cost, Quality Considerations



- 20%** Incremental cost increase associated with low-volume CABG sites¹
- 3%** Incremental cost increase associated with low-volume surgeons
- 15%** Relative reduction of in-hospital mortality for CABG if performed in high-volume centers²

Distribution of CABG Programs by Volume Cohort
 Medicare Volumes, 1998 Versus 2009



¹ Low volume sites defined as those with hospital annualized median volume for CABG <215 patients; physician annualized median volume for CABG <70 patients.

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

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Source: Auerbach A, et al., *Archives of Internal Medicine*, 2010, 170: 1202; Post P, et al., *European Heart Journal*, 2010, 31: 1985-92; Cardiovascular Roundtable research and analysis.

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

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

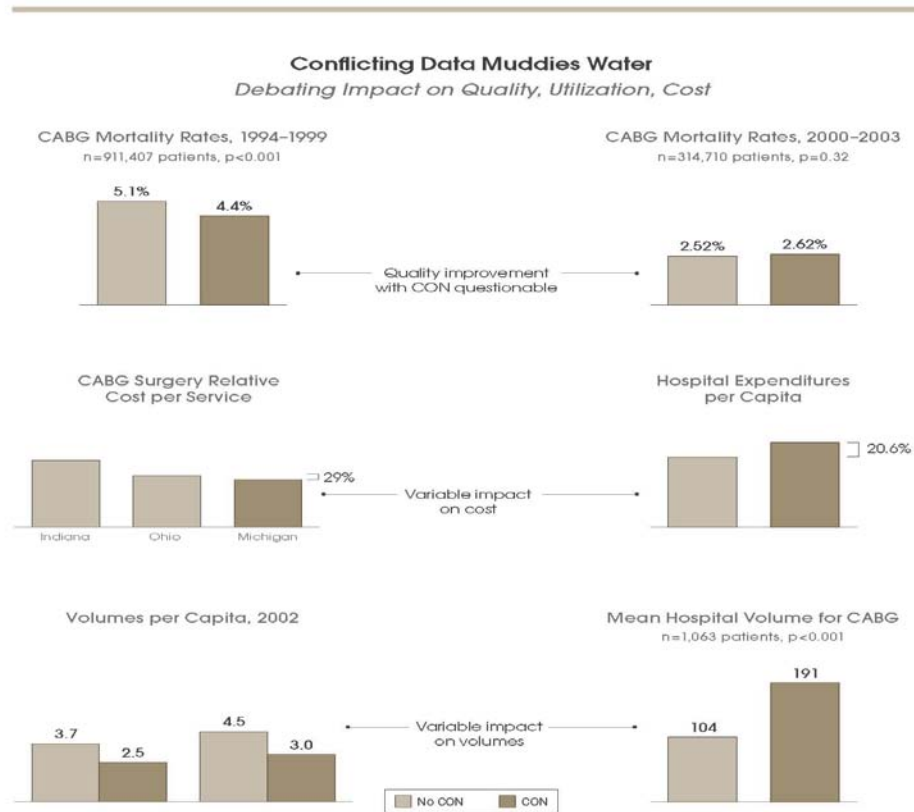
Source: Henry Ford Macomb CON # 000116 (2000)

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-approx
\$700

The data showing that CONs change procedure volumes and costs are inconclusive



Source: Daimler-Chrysler Corporation, 2000, available at: <http://www.dhss.mo.gov/CON/conbenefits.pdf>, accessed September 25, 2008; DiSesa V, et al., "Contemporary Impact of State Certificate-of-Need Regulations for Cardiac Surgery," *Circulation*, 2005, 114: 2122-2129; Ho V, et al., *American Heart Journal*, 2009, 154: 767-775; Lanning J, et al., *Journal of Regulatory Economics*, 1991, 3: 137-154; Vaughan M, et al., *JAMA*, 2002, 288: 1859-1866.

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 than 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.

PCI Without Surgical Backup State Regulatory Framework -- Page 4

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)

PCI Without Surgical Backup State Regulatory Framework -- Page 5

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>

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>

Wisconsin (*Wisconsin's Con Law is limited to long-term care*)

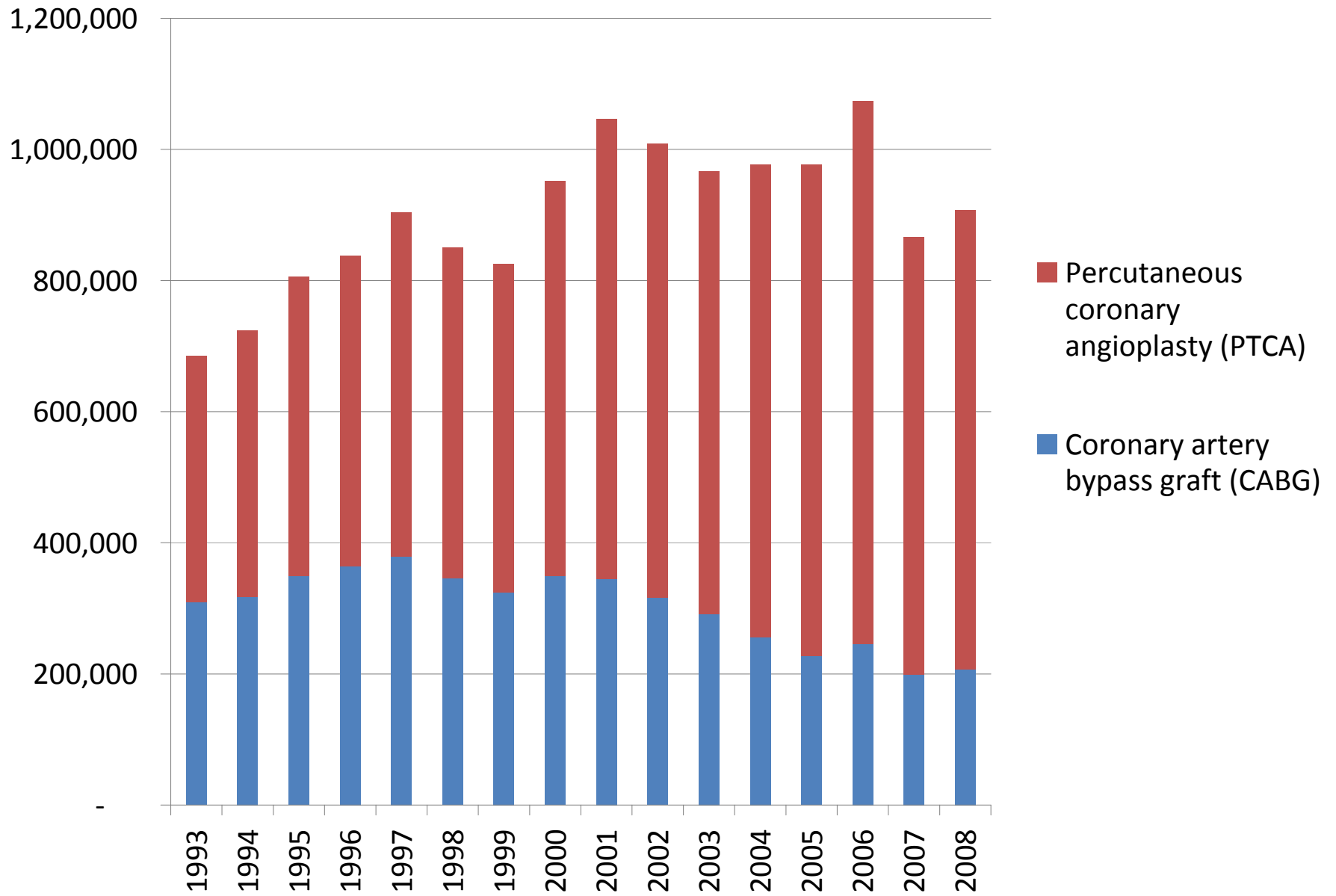
Primary and elective PCI permitted.

PCI Without Surgical Backup State Regulatory Framework -- Page 7

Wyoming (No Certificate of Need Law)

Primary and elective PCI permitted.

Number of Coronary Revascularizations in United States 1993 - 2008



Tania Rodriguez - FW: Emailing: Viewing Section 405.29 - Cardiac Services.htm

From: "Schreiber, Theodore" <TSchreib@dmc.org>
To: 'Kim Eagle' <keagle@med.umich.edu>, 'Tania Rodriguez' <rodrigueztl@michigan.gov>
Date: 1/2/2011 9:57 AM
Subject: FW: Emailing: Viewing Section 405.29 - Cardiac Services.htm

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 including, but not limited to percutaneous coronary intervention 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' <rodrigueztl@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.

Volume: D

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Report for the State of Michigan

The Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2)

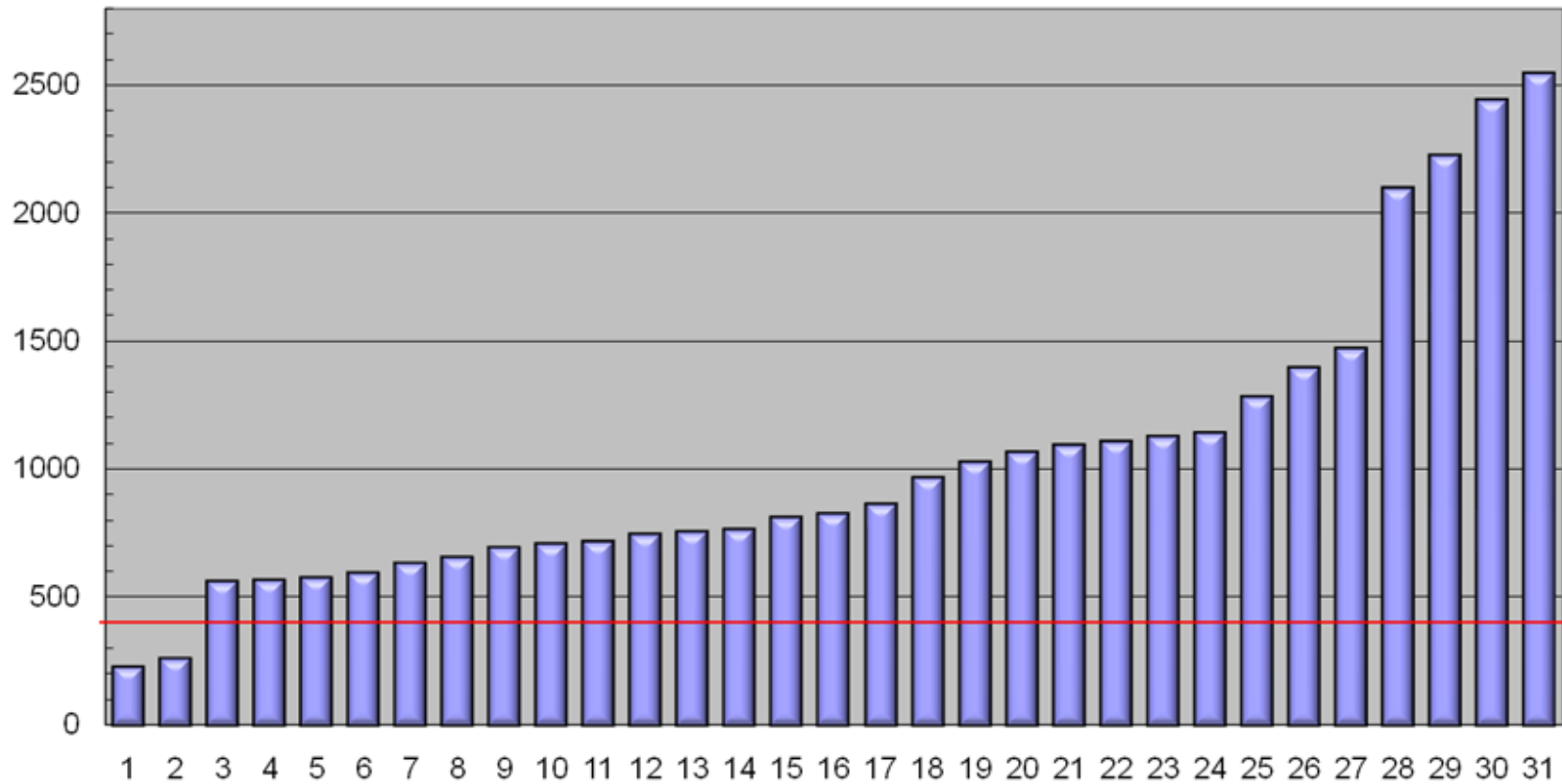
Hitinder Gurm, M.D.
Director, BMC2-PCI
December 17, 2010

- 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



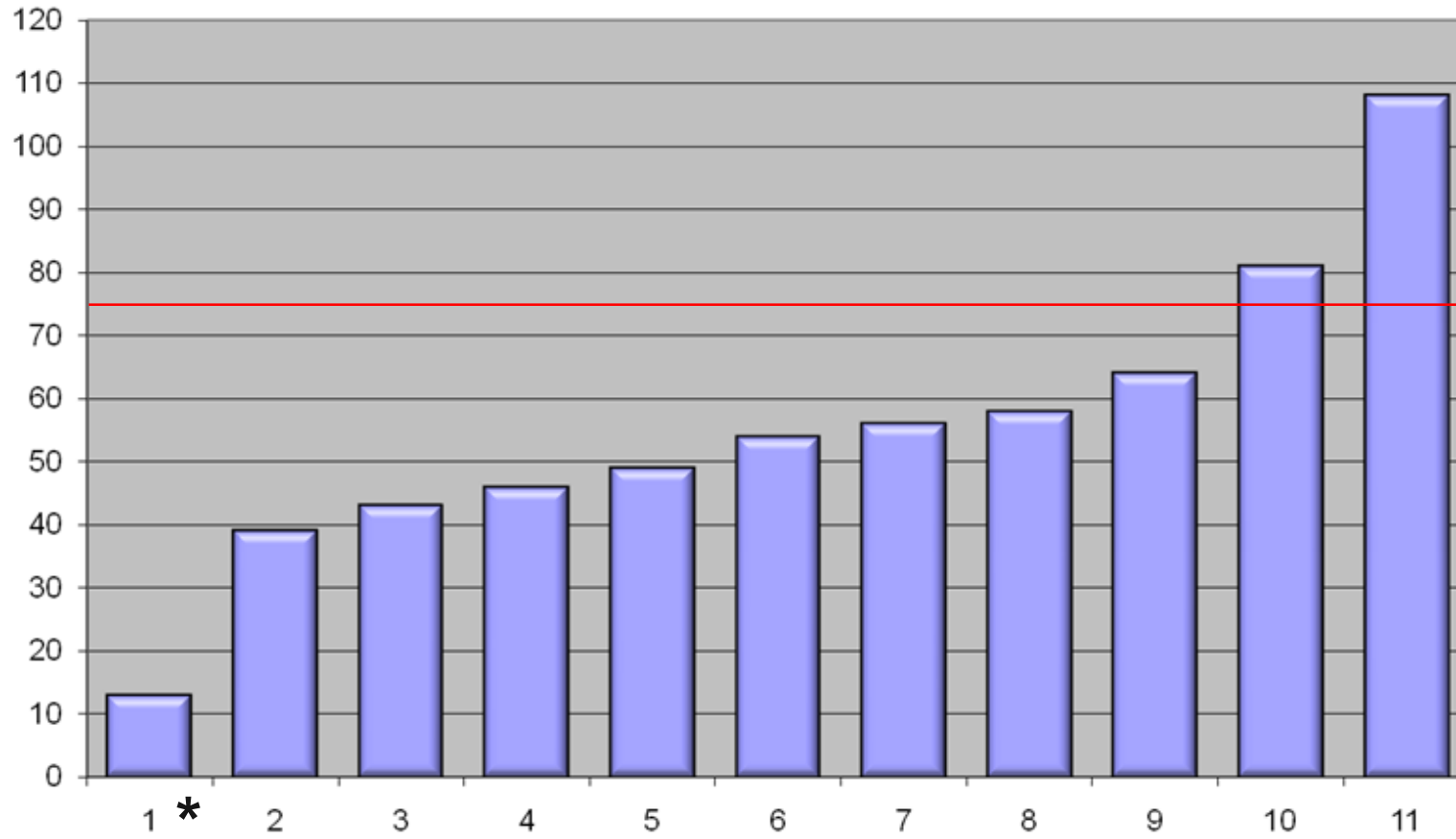
Hospitals

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

of Procedures



Hospital

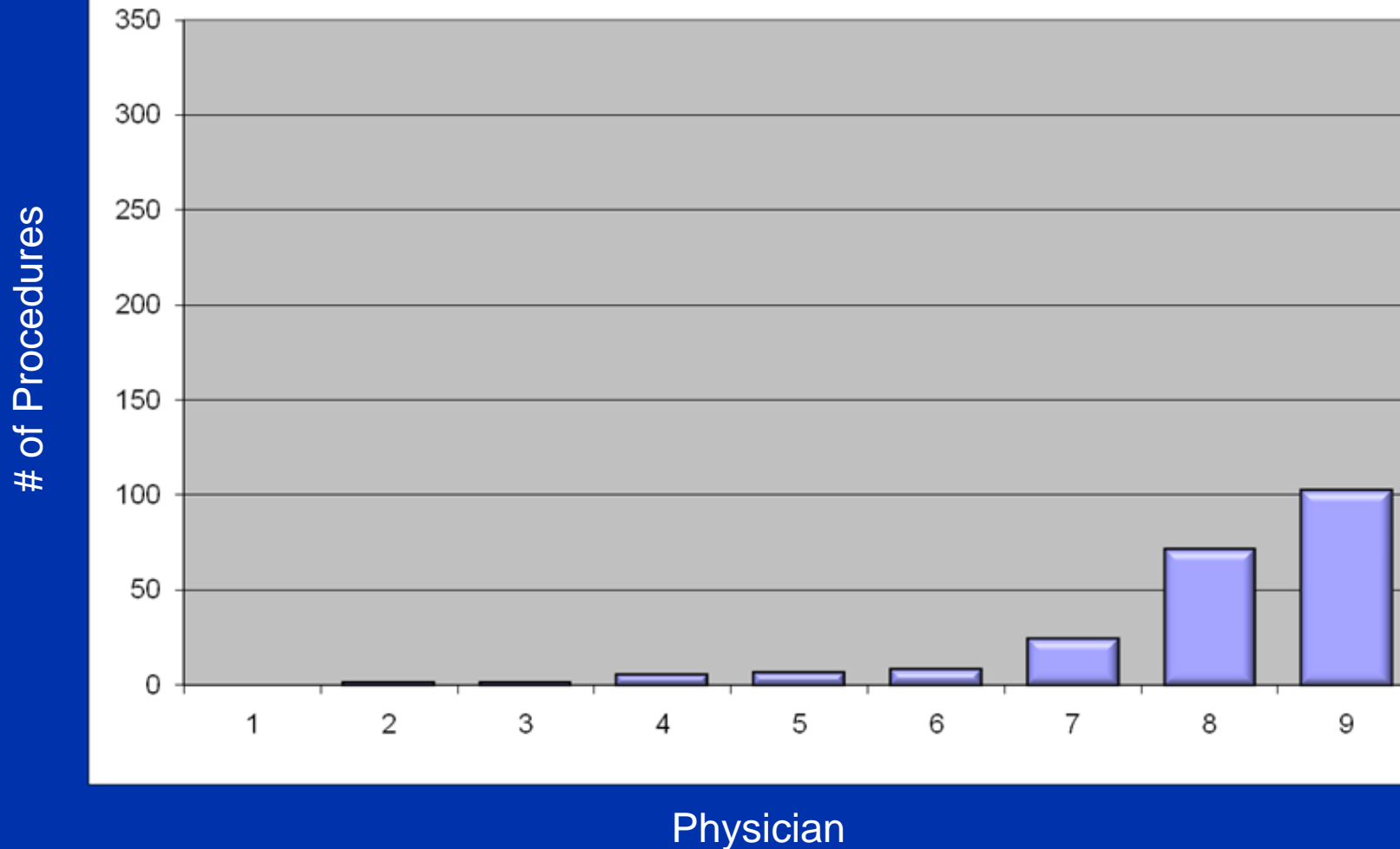
- Slides 10 – 40 provide physician PCI volume (at a given site) for each of the 31 PCI hospitals in Michigan (blinded).
- It is not possible for BMC2 to provide total physician PCI volume irrespective of hospital where the procedure was performed because BMC2 does not possess national identifier information 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

Supporting Information Continued:

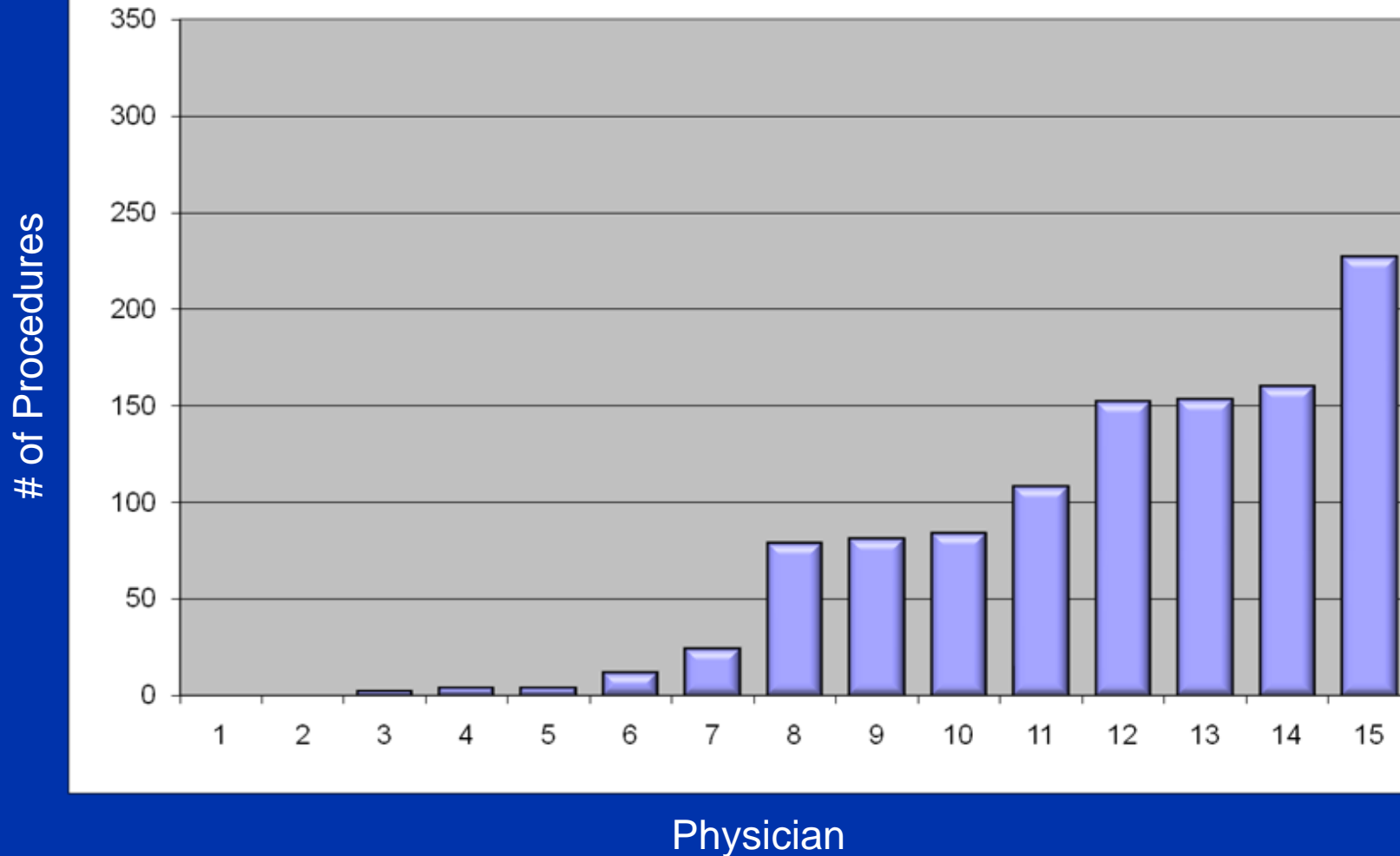
- Slides 10 – 40 provide individual physician PCI volume at each site for 31 PCI hospitals in Michigan.
- Since a physician may work at more than one hospital, these numbers do not reflect the annual total physician experience.

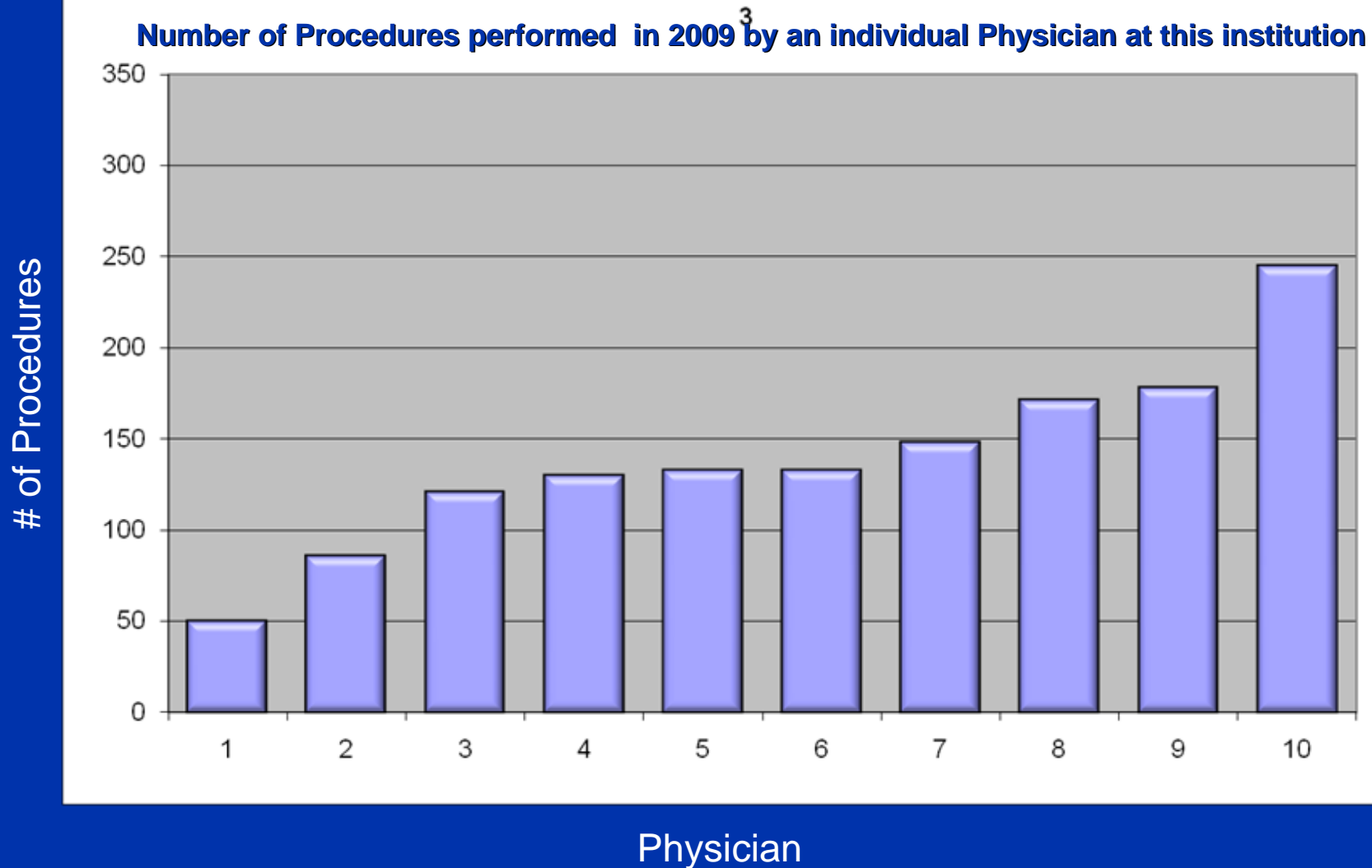
- The median volume per operator across all sites is 57 (inter-quartile range [IQR]=109).
- The mean volume per operator across all sites is 76. (mean=76.6, standard deviation [SD]=83.3)
- The distribution is severely non-normal (Shapiro-Wilk, $p=0.000$), the median is a better measure of central tendency.

Number of Procedures performed in 2009¹ by an individual Physician at this institution

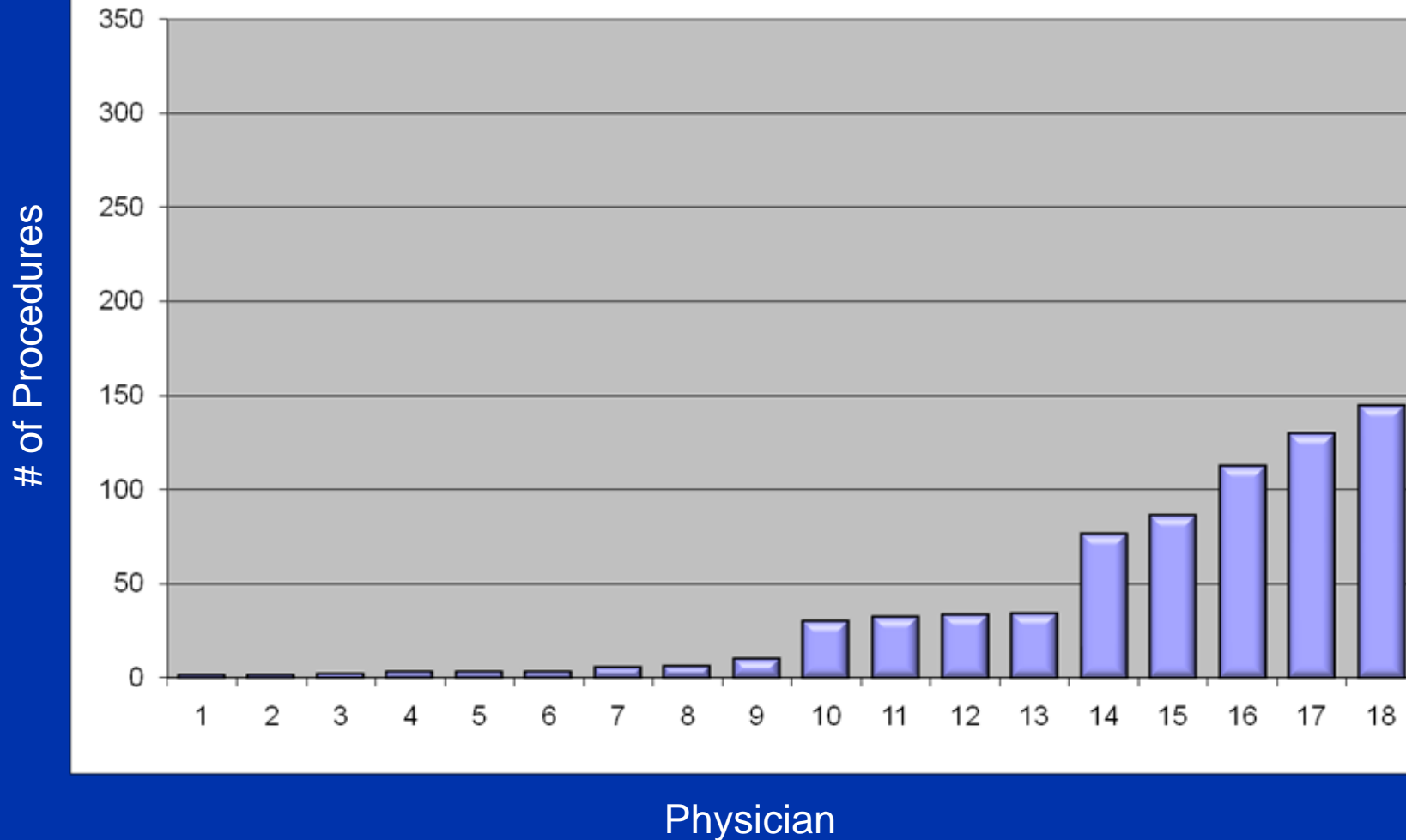


Number of Procedures performed in 2009² by an individual Physician at this institution

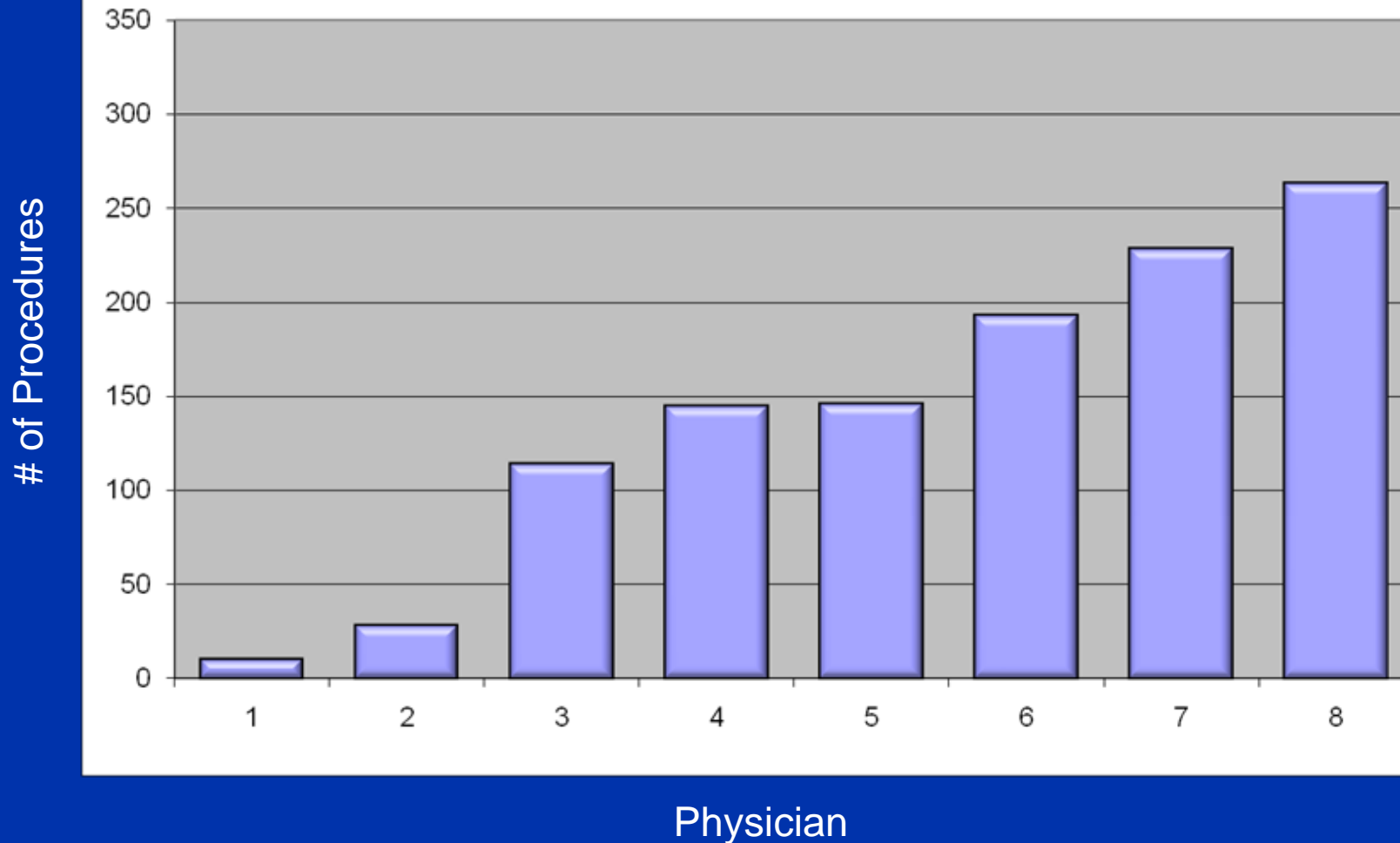




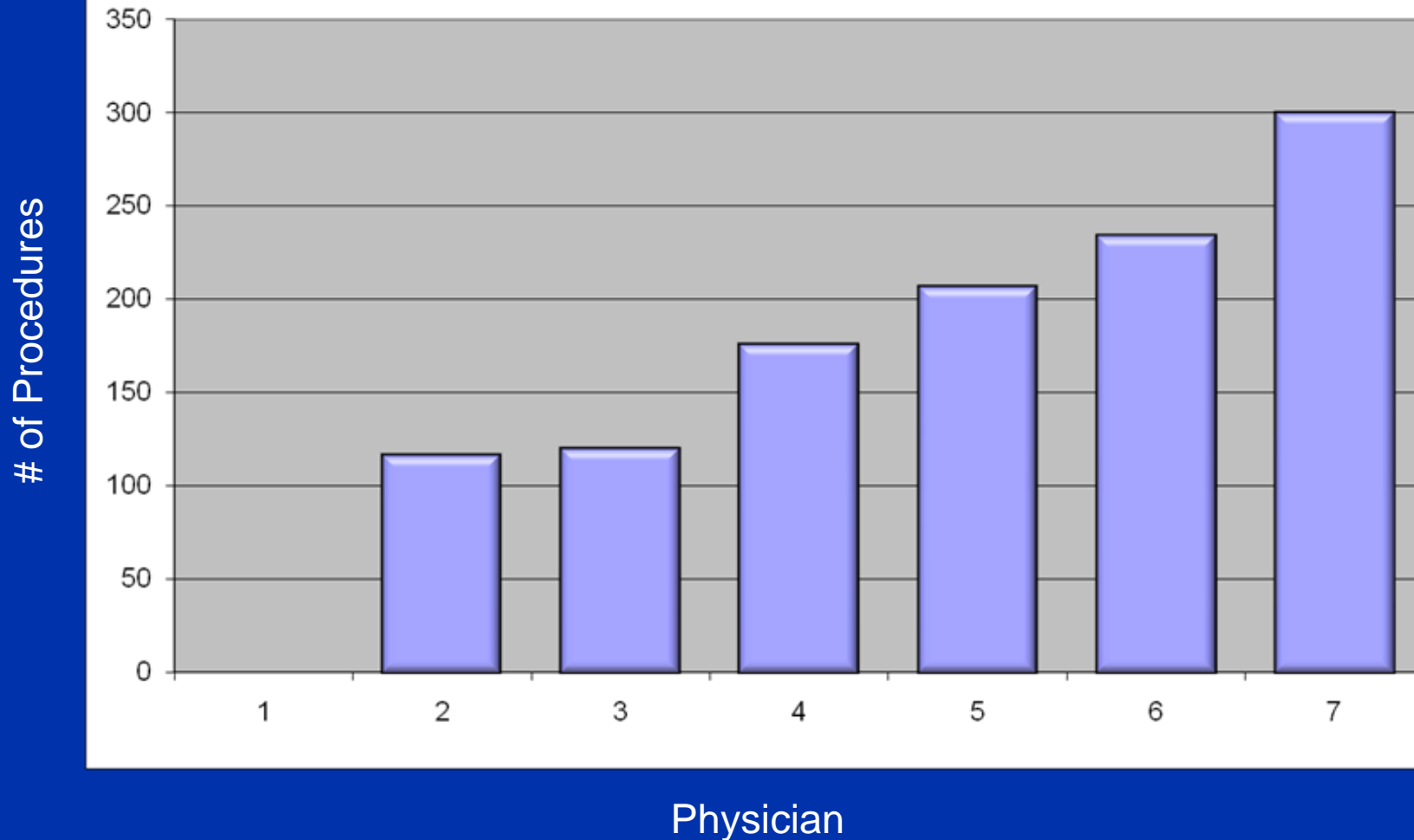
Number of Procedures performed in 2009⁴ by an individual Physician at this institution



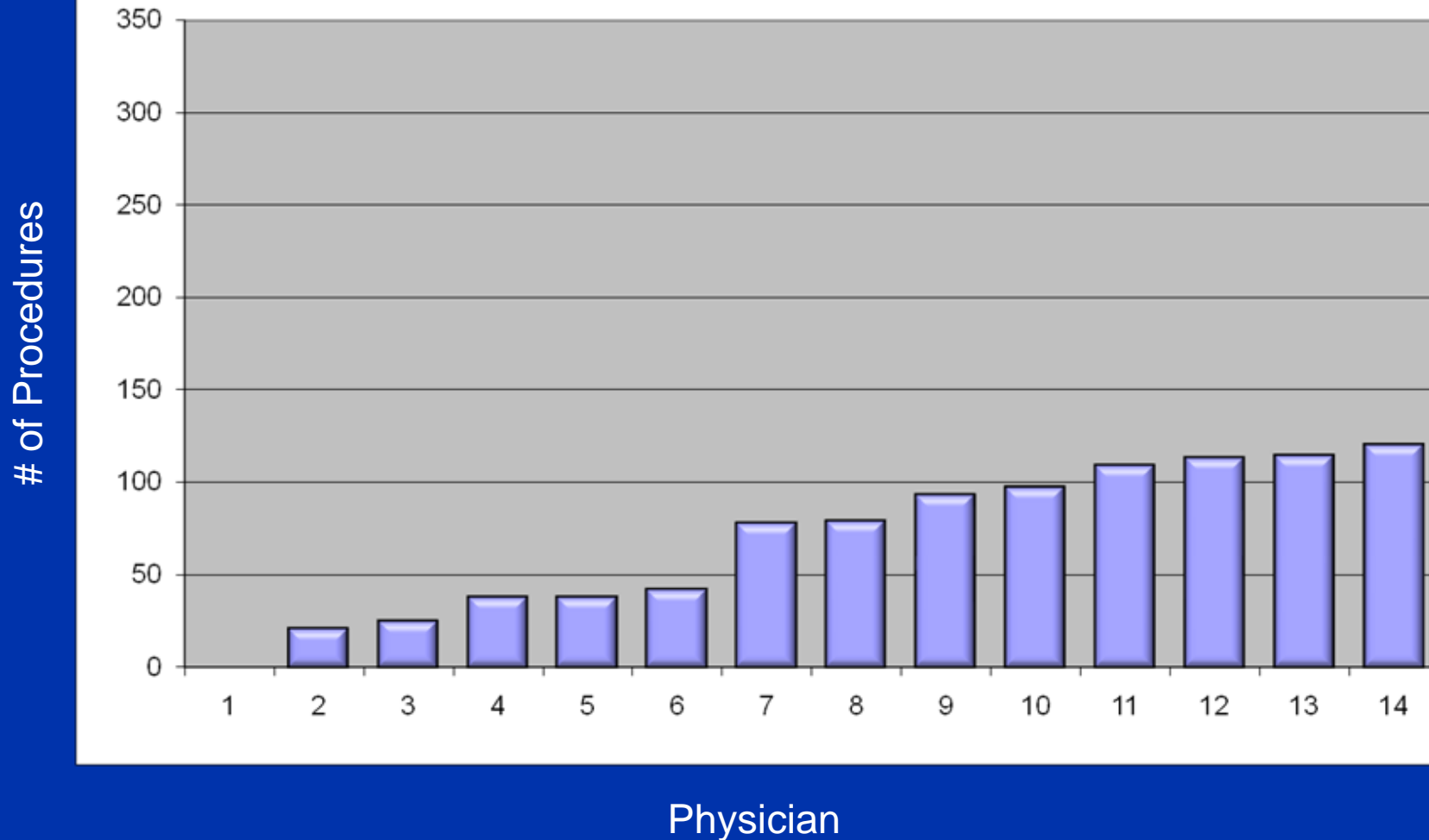
Number of Procedures performed in 2009 by an individual Physician at this institution



Number of Procedures performed in 2009⁶ by an individual Physician at this institution

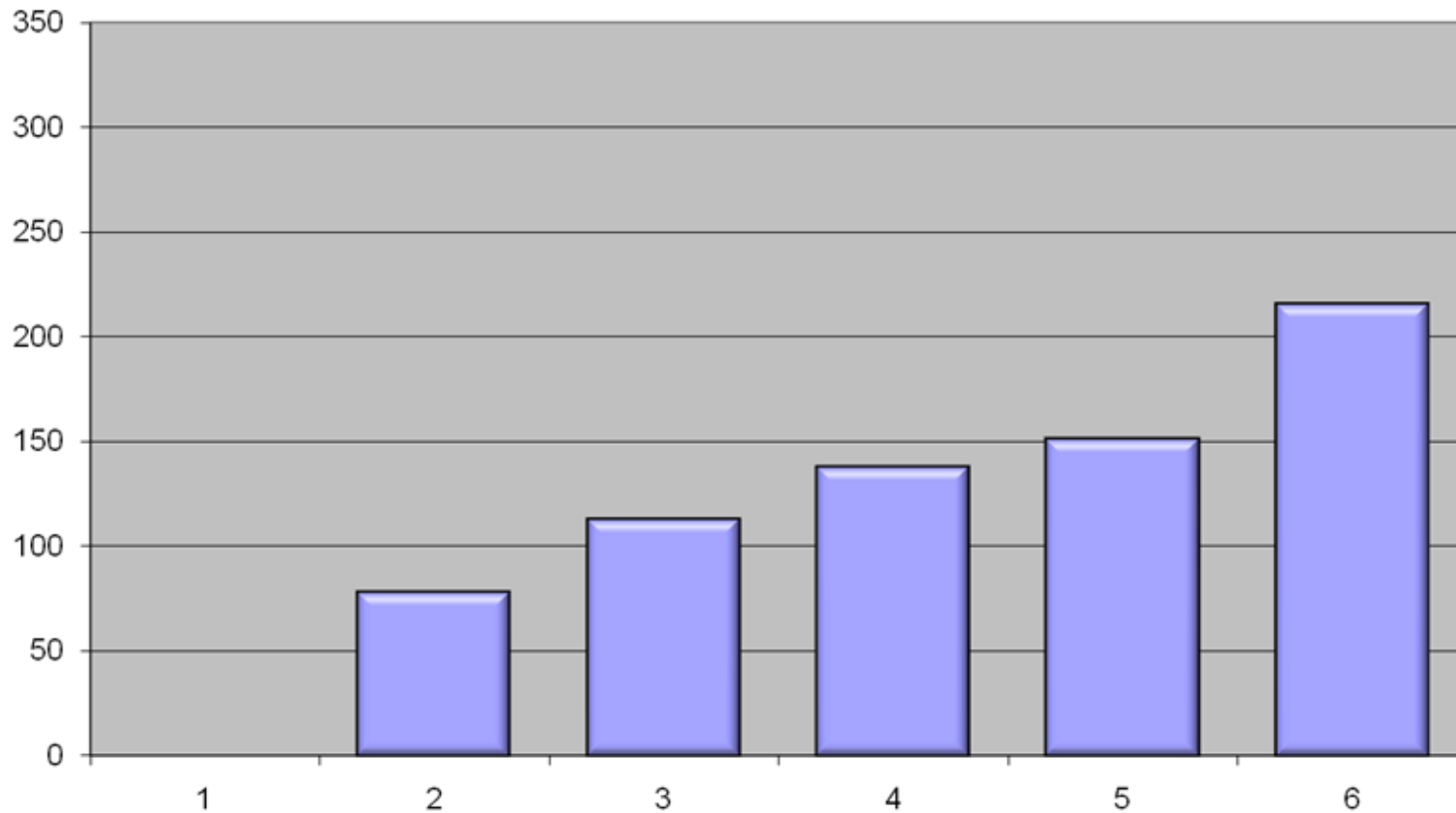


Number of Procedures performed in 2009⁷ by an individual Physician at this institution

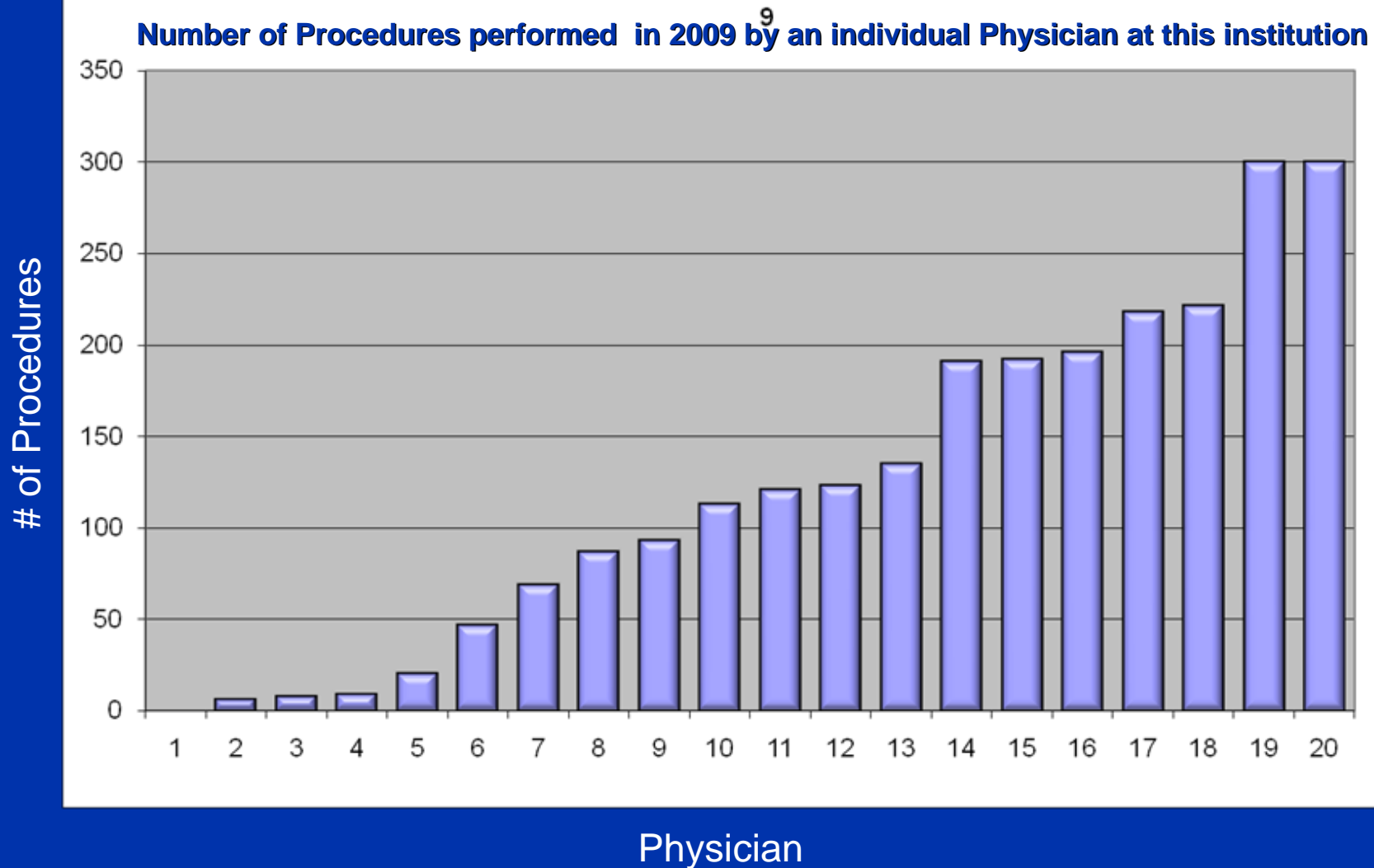


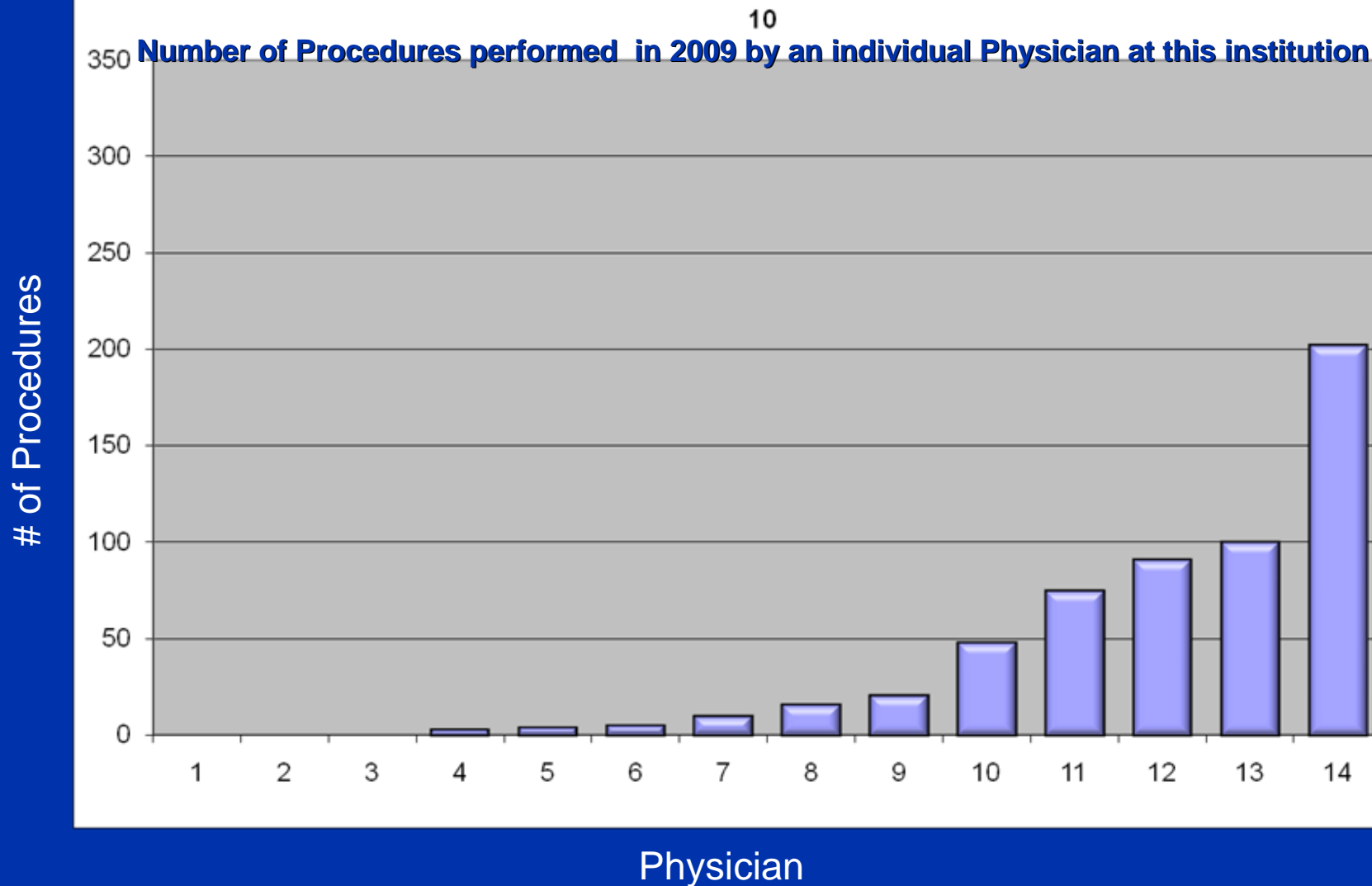
of Procedures

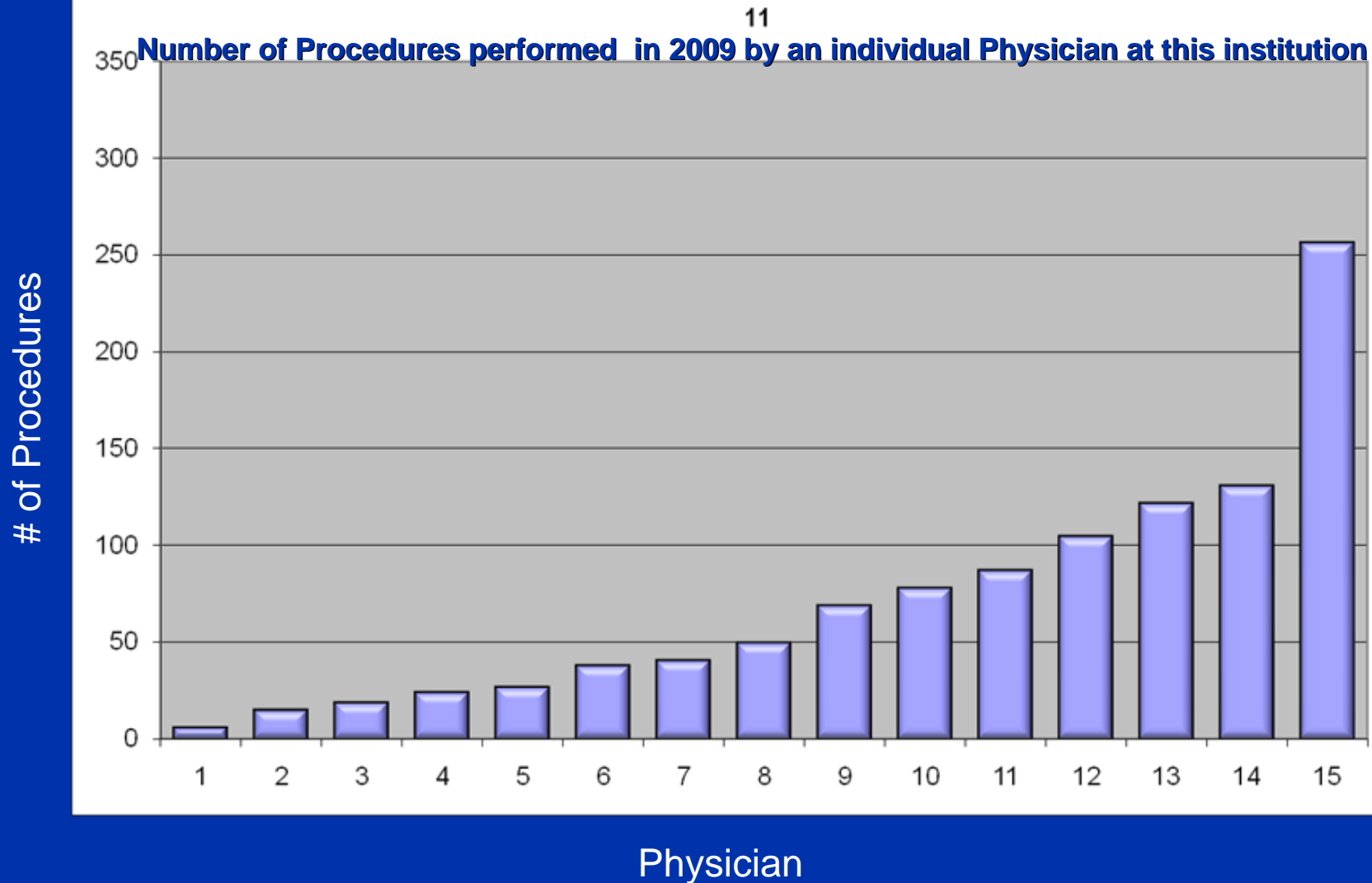
Number of Procedures performed in 2009⁸ by an individual Physician at this institution



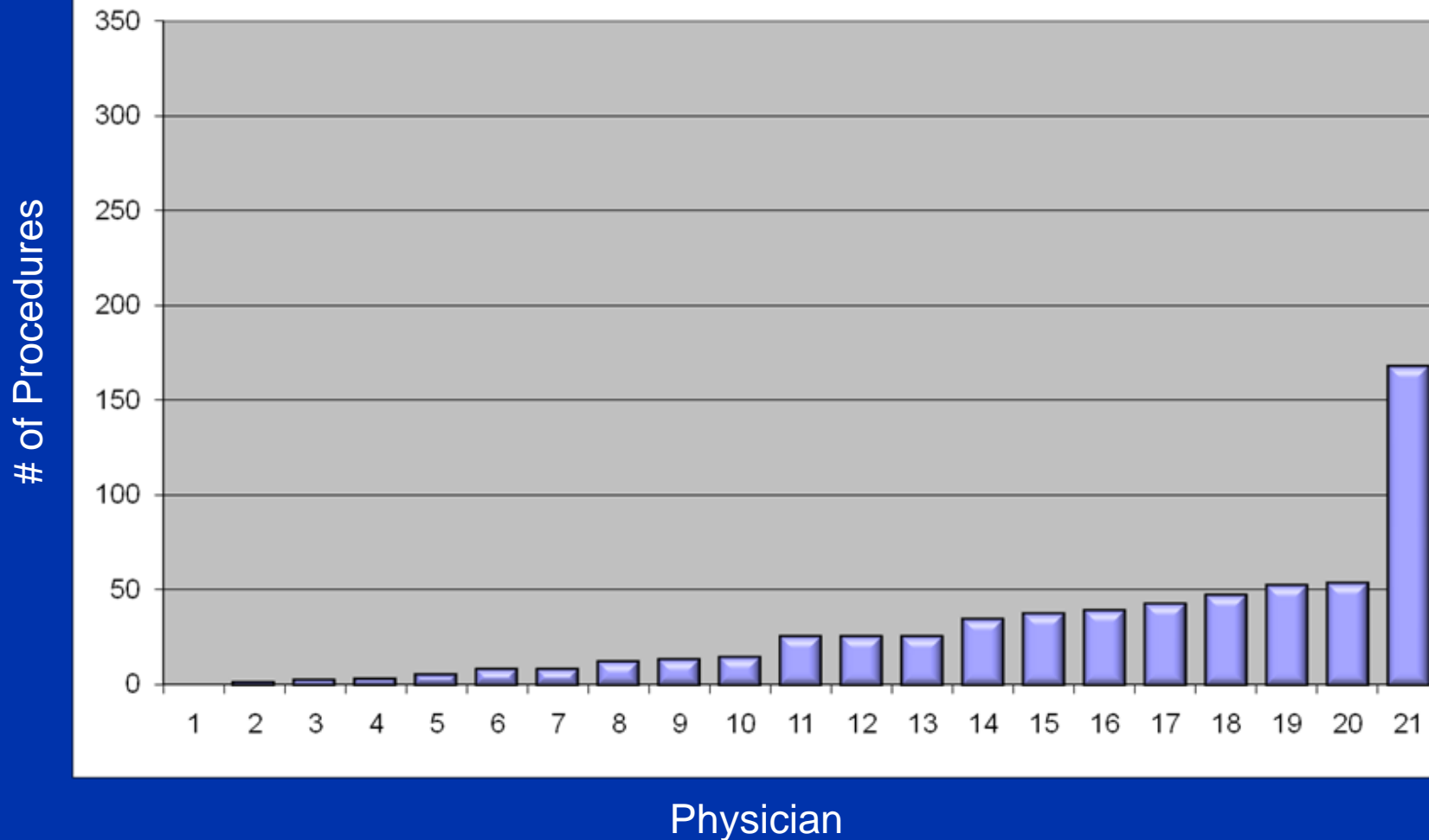
Physician

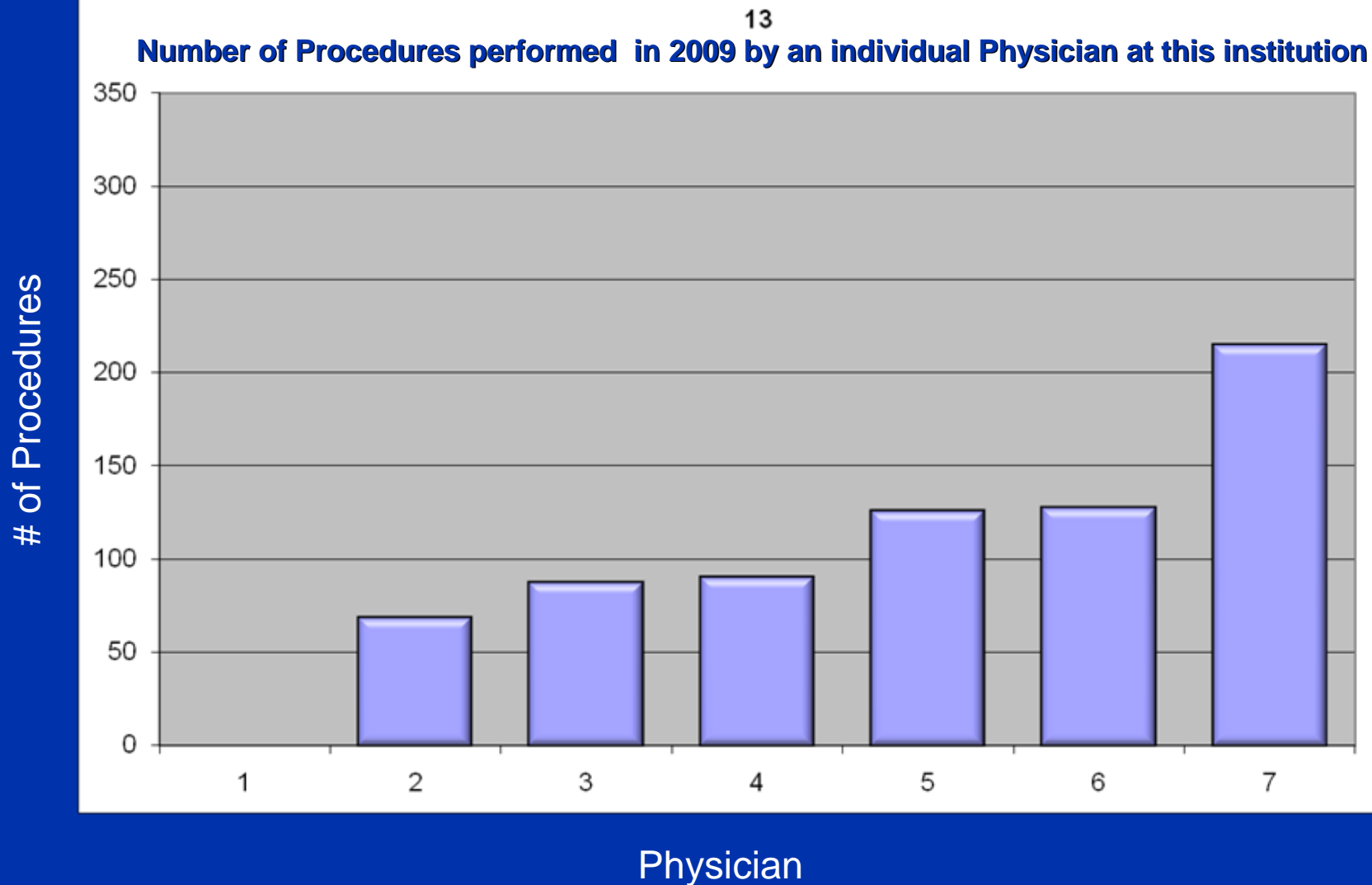




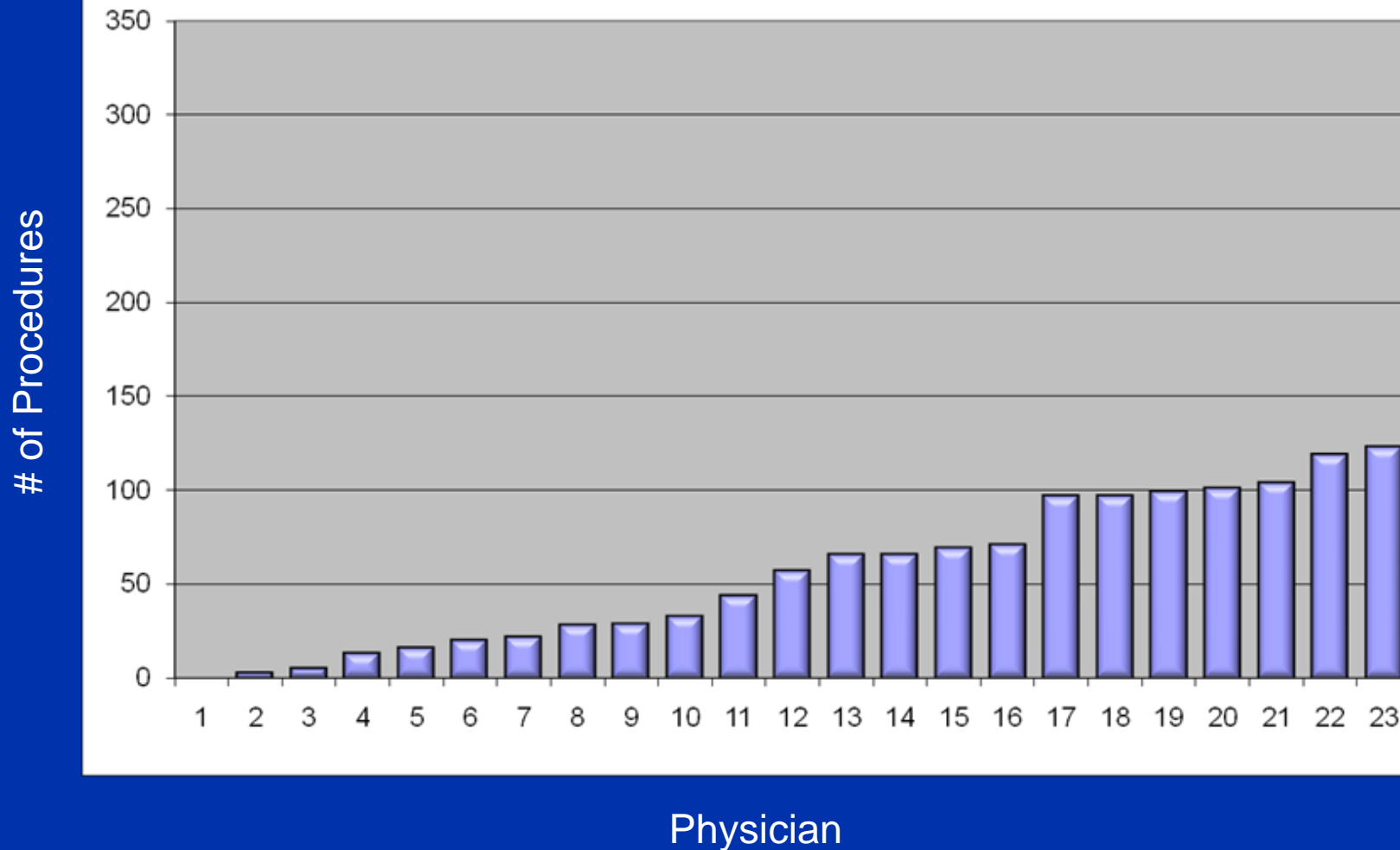


Number of Procedures performed in 2009¹² by an individual Physician at this institution

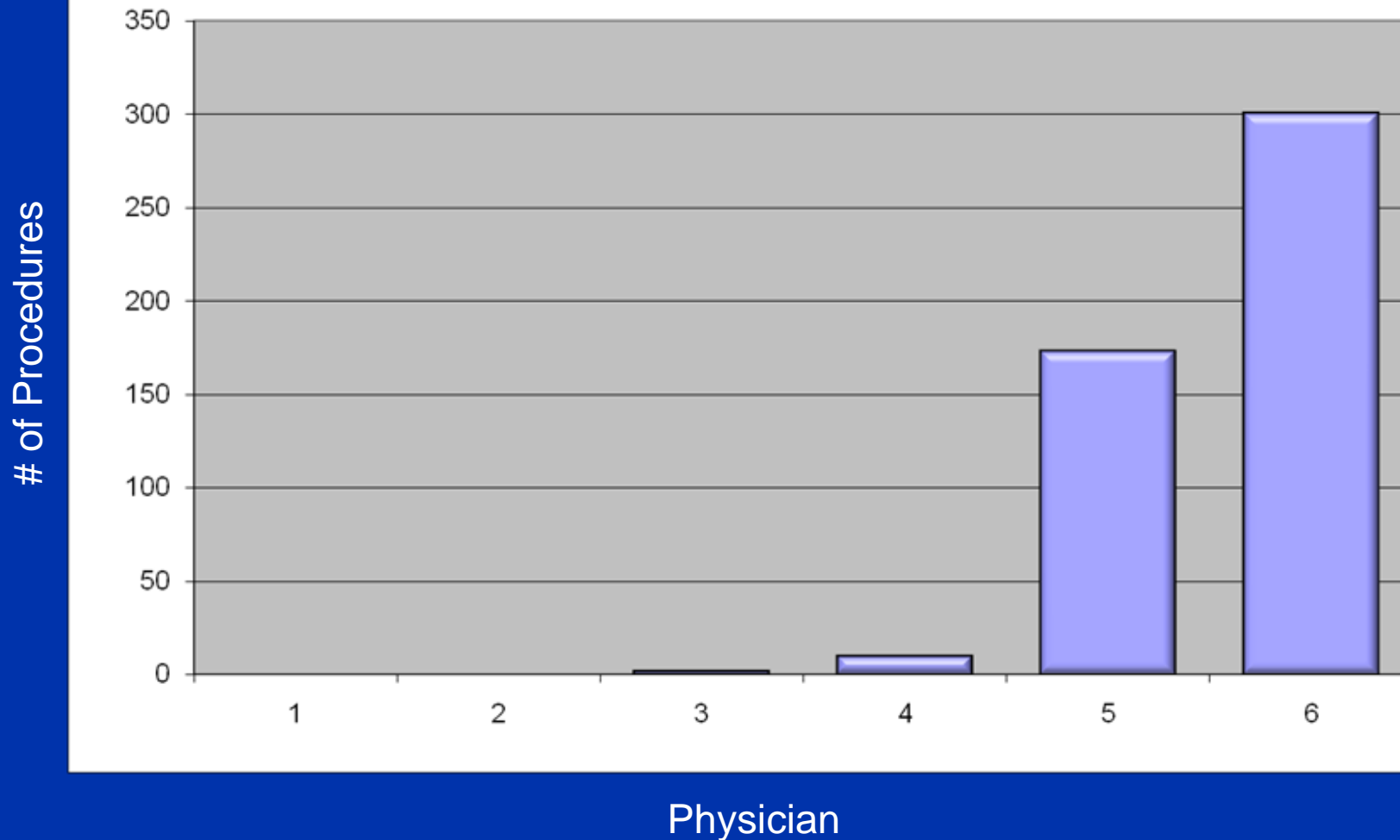


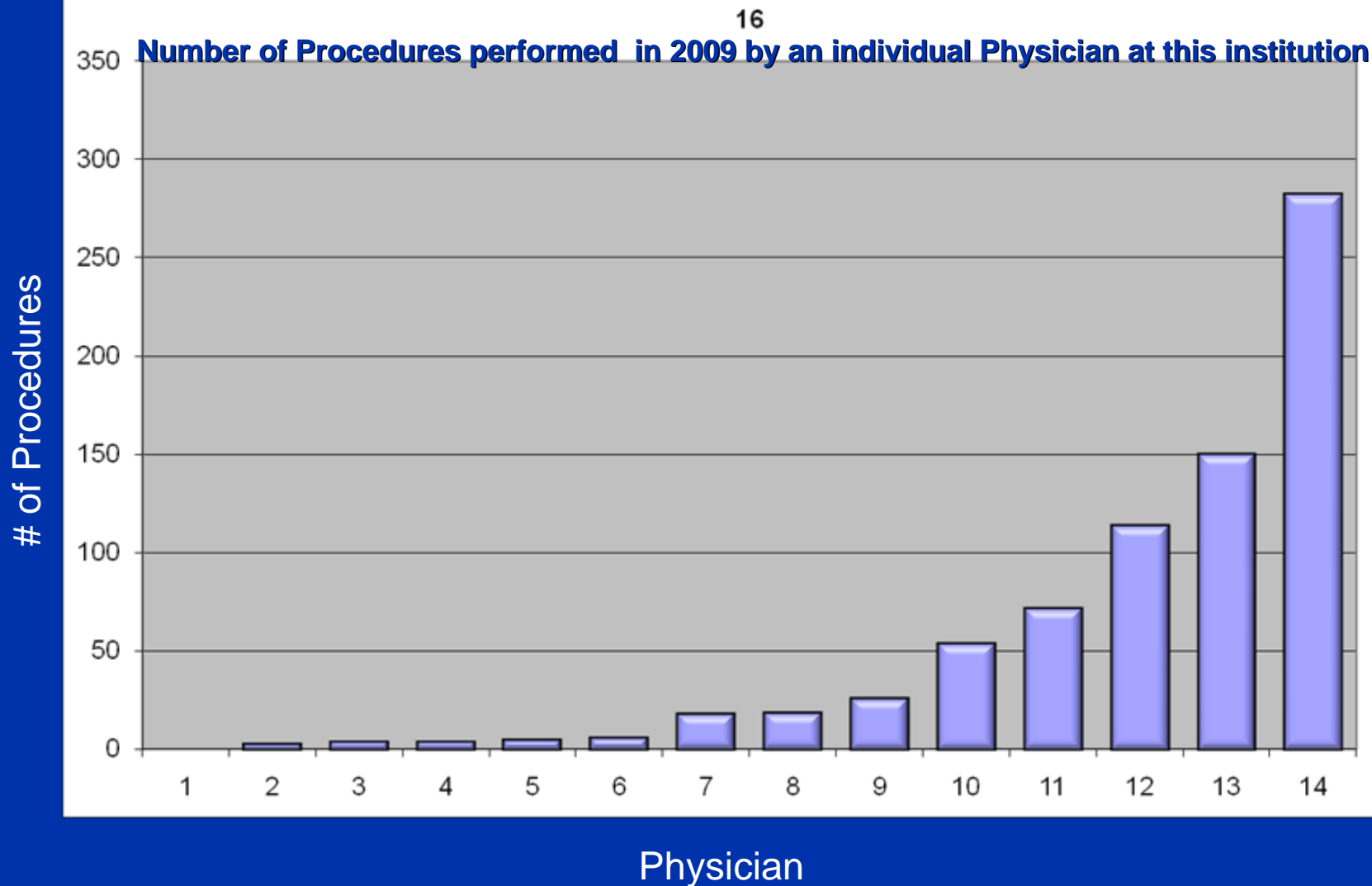


Number of Procedures performed in 2009 by an individual Physician at this institution¹⁴

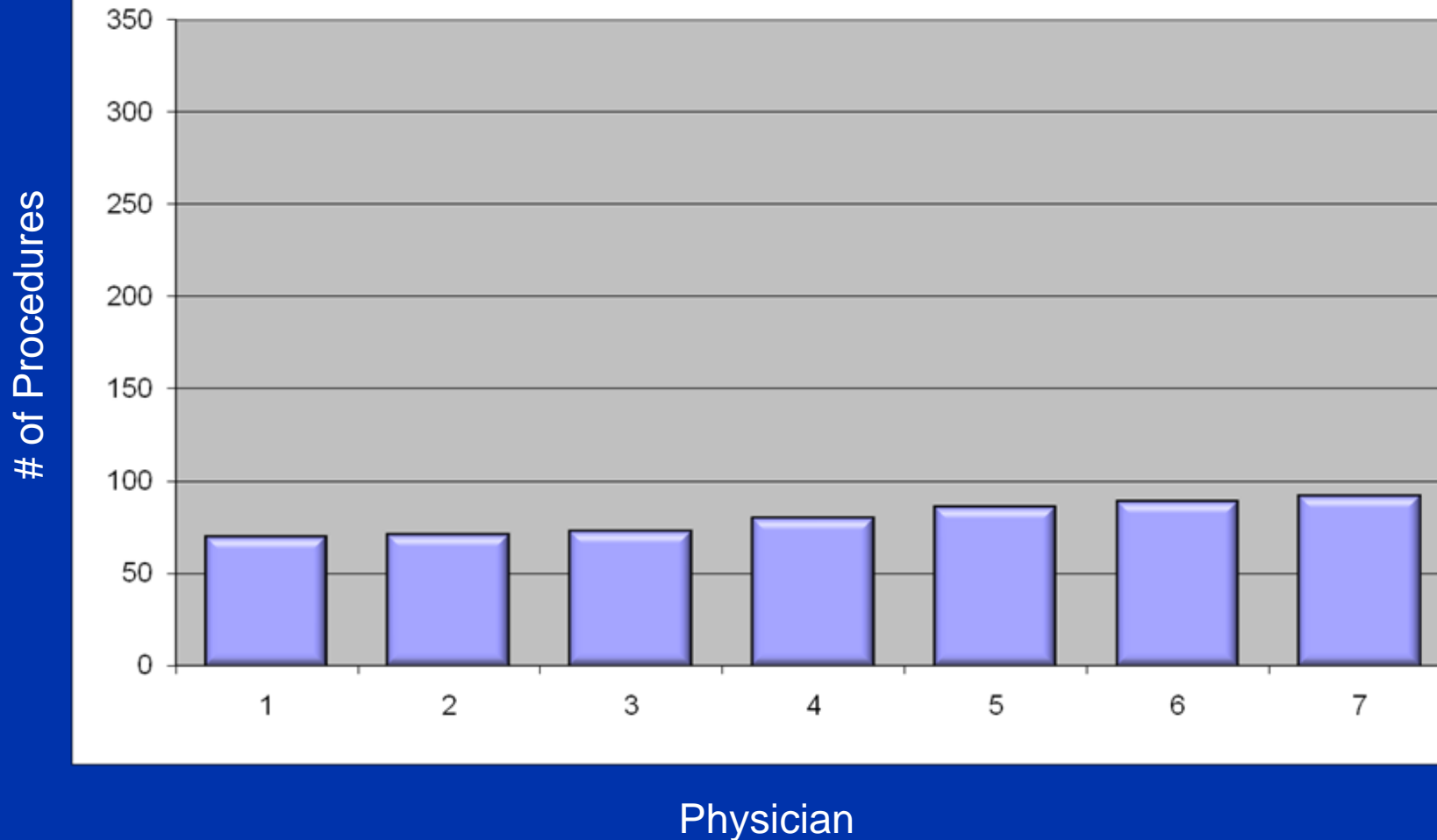


Number of Procedures performed in 2009¹⁵ by an individual Physician at this institution

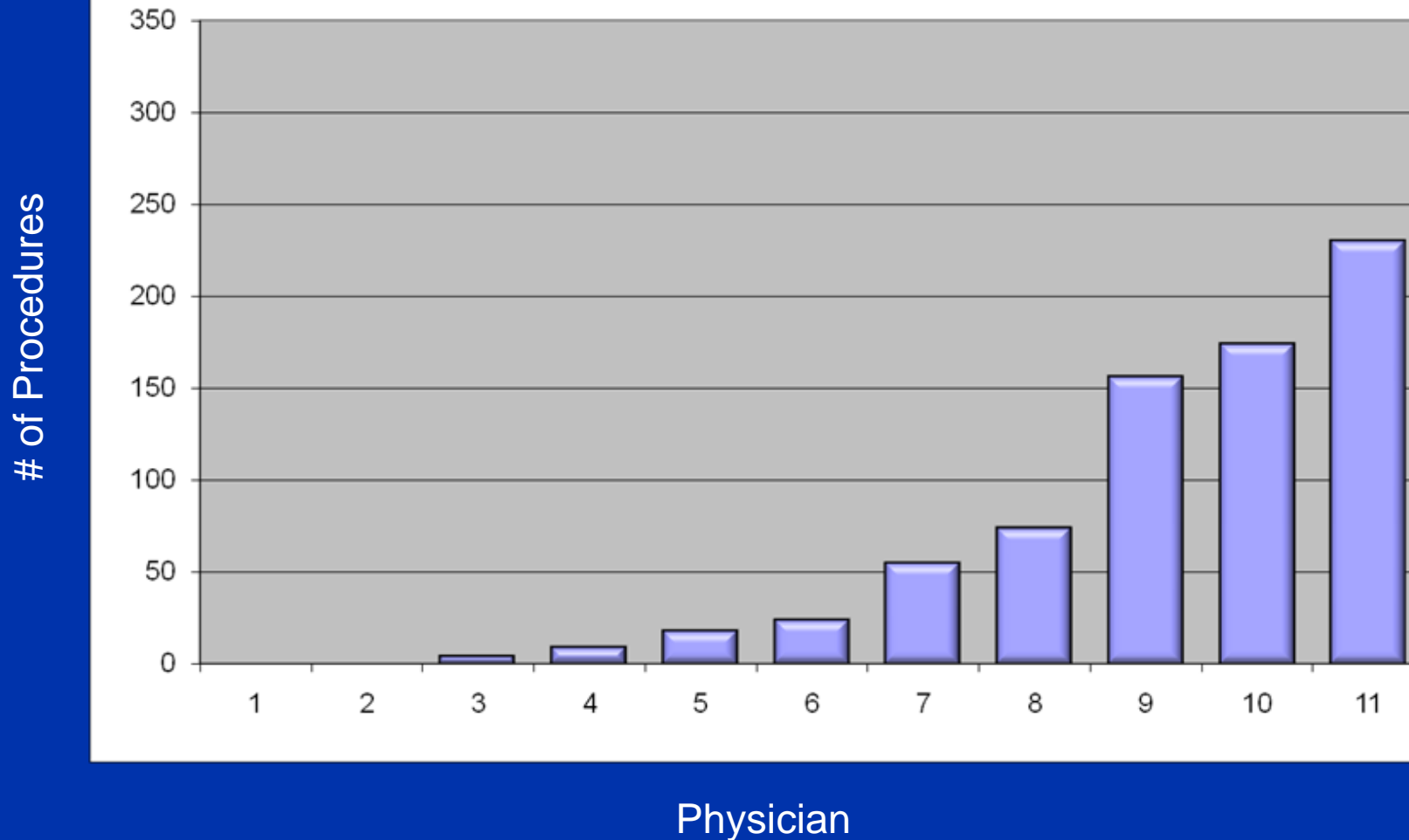


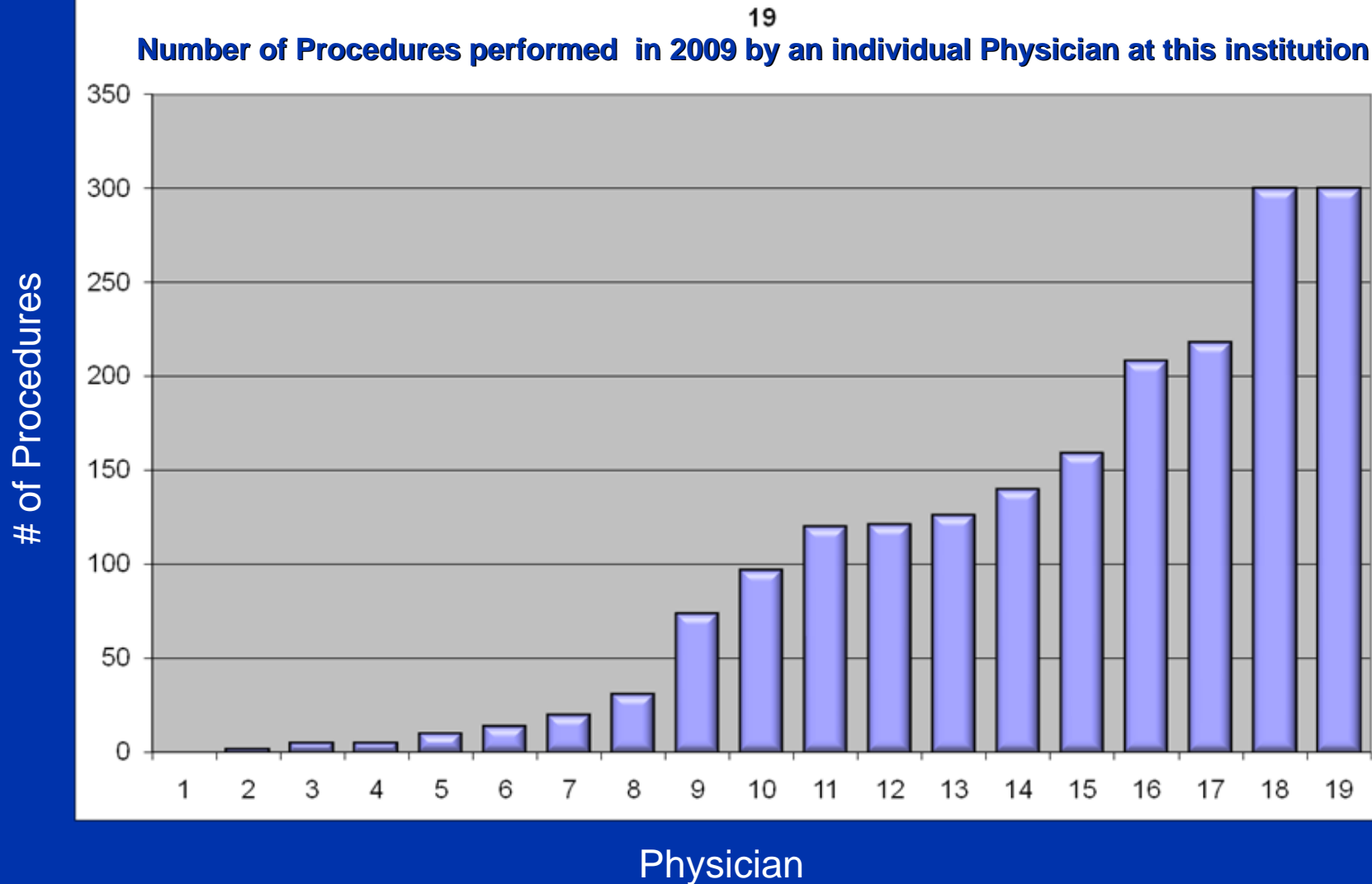


Number of Procedures performed in 2009¹⁷ by an individual Physician at this institution

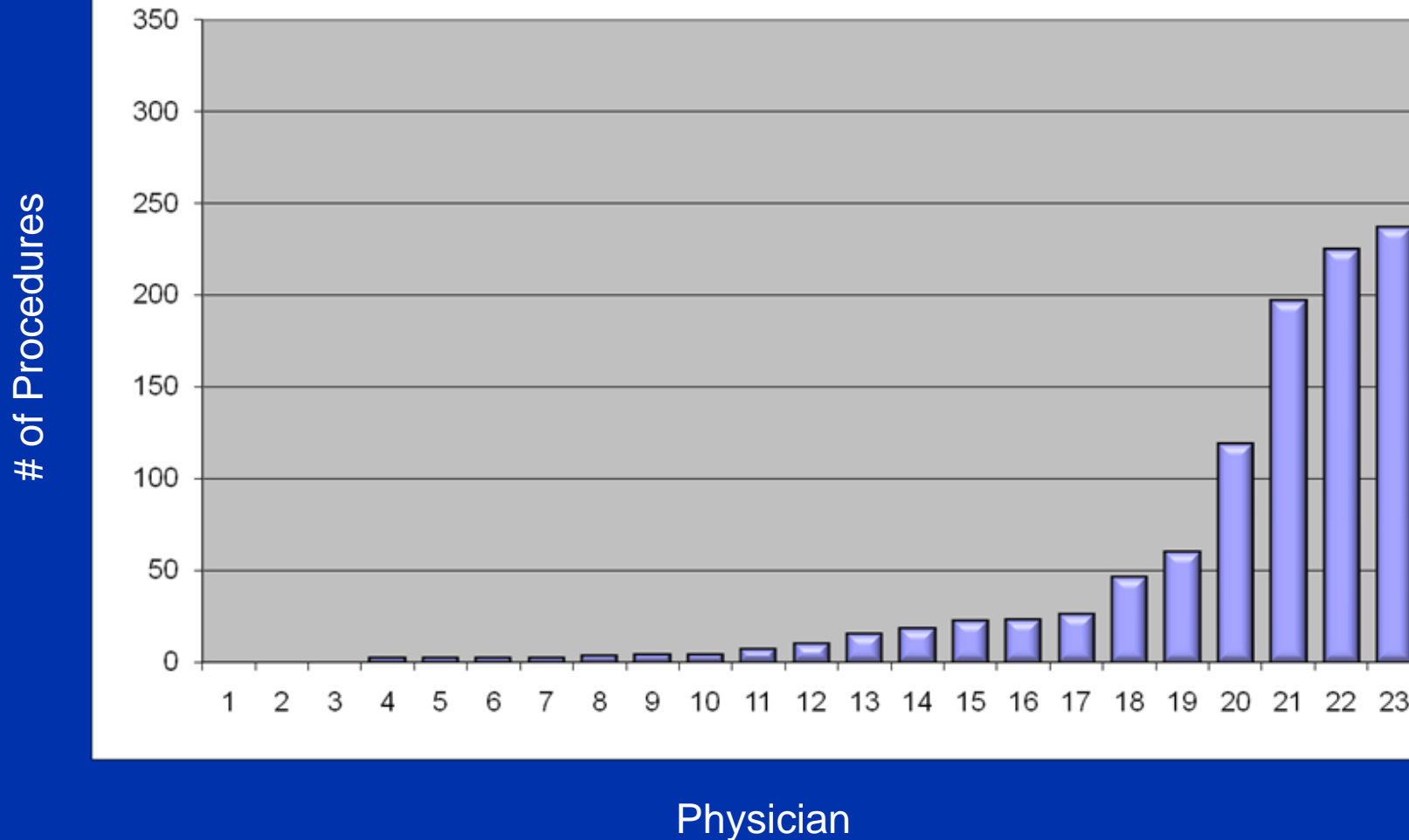


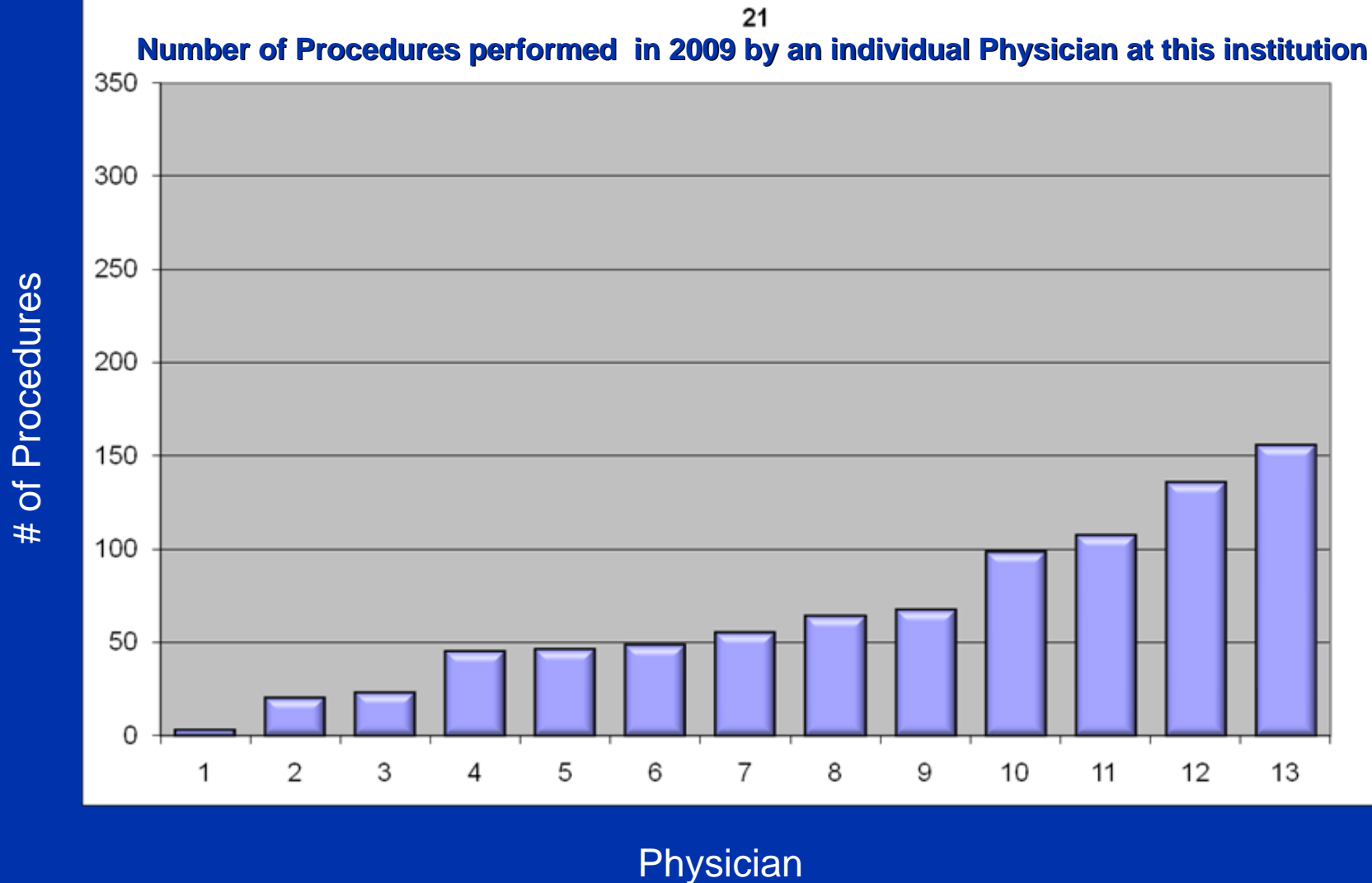
Number of Procedures performed in 2009¹⁸ by an individual Physician at this institution



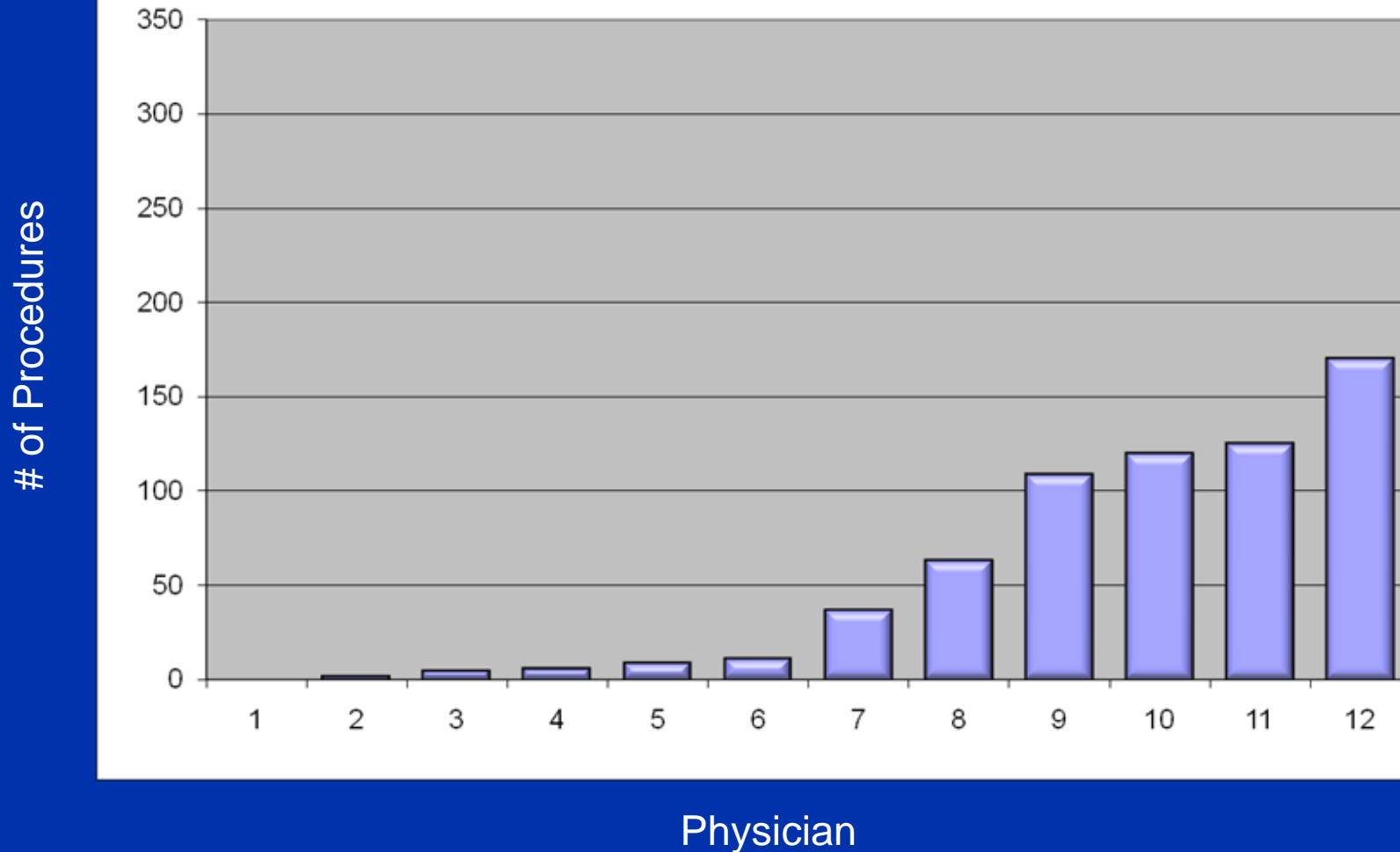


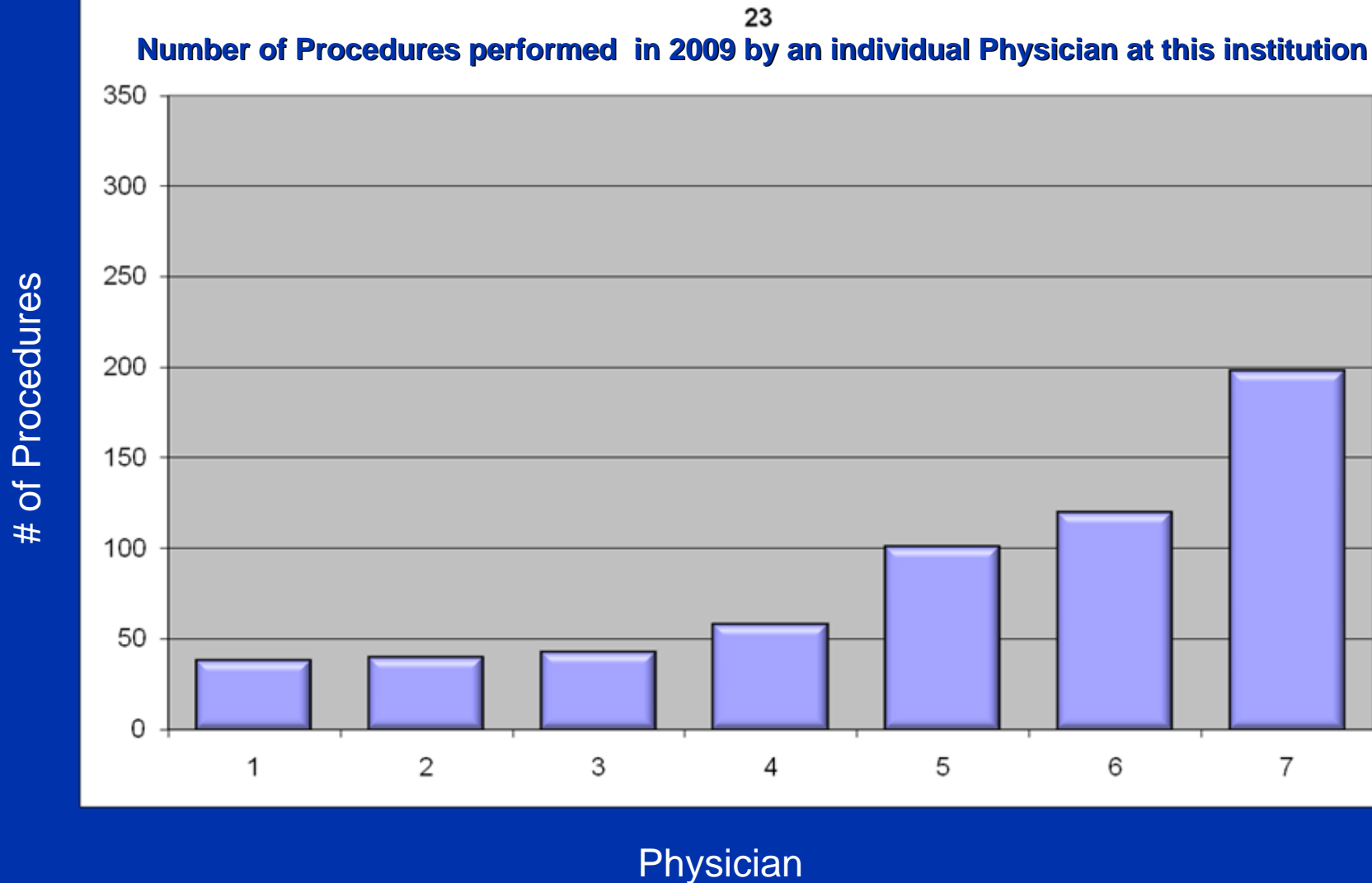
Number of Procedures performed in 2009²⁰ by an individual Physician at this institution

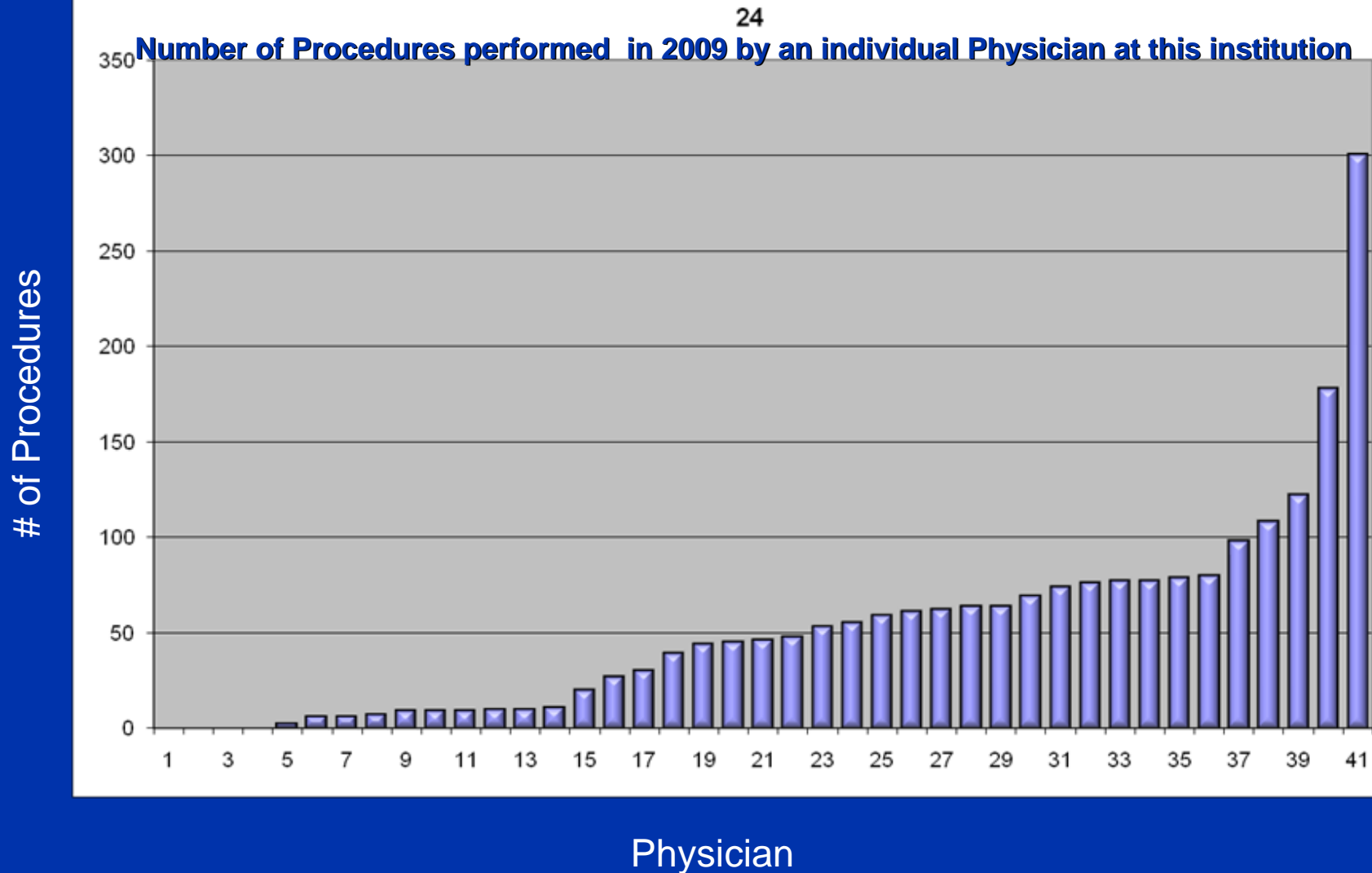




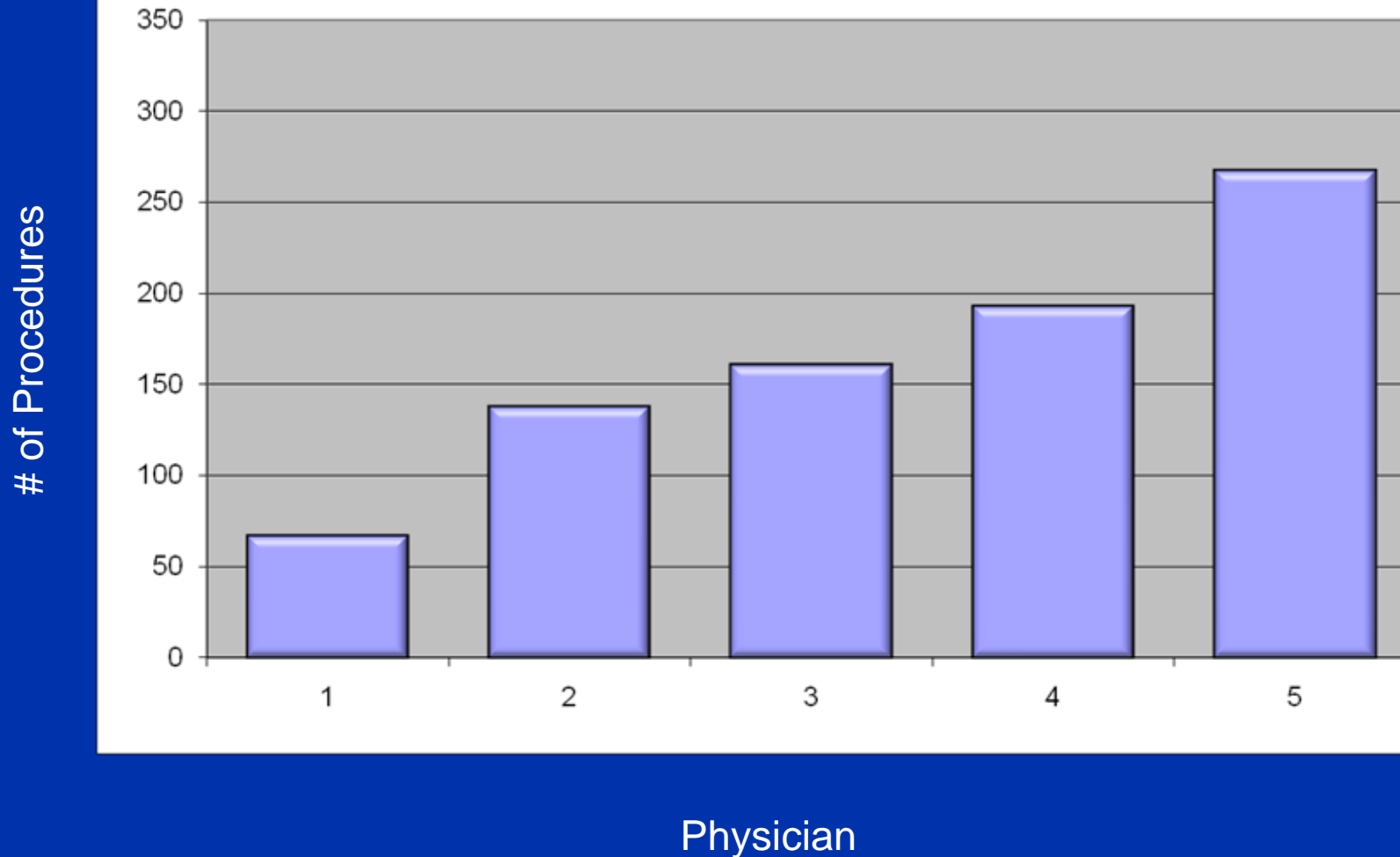
Number of Procedures performed in 2009²² by an individual Physician at this institution





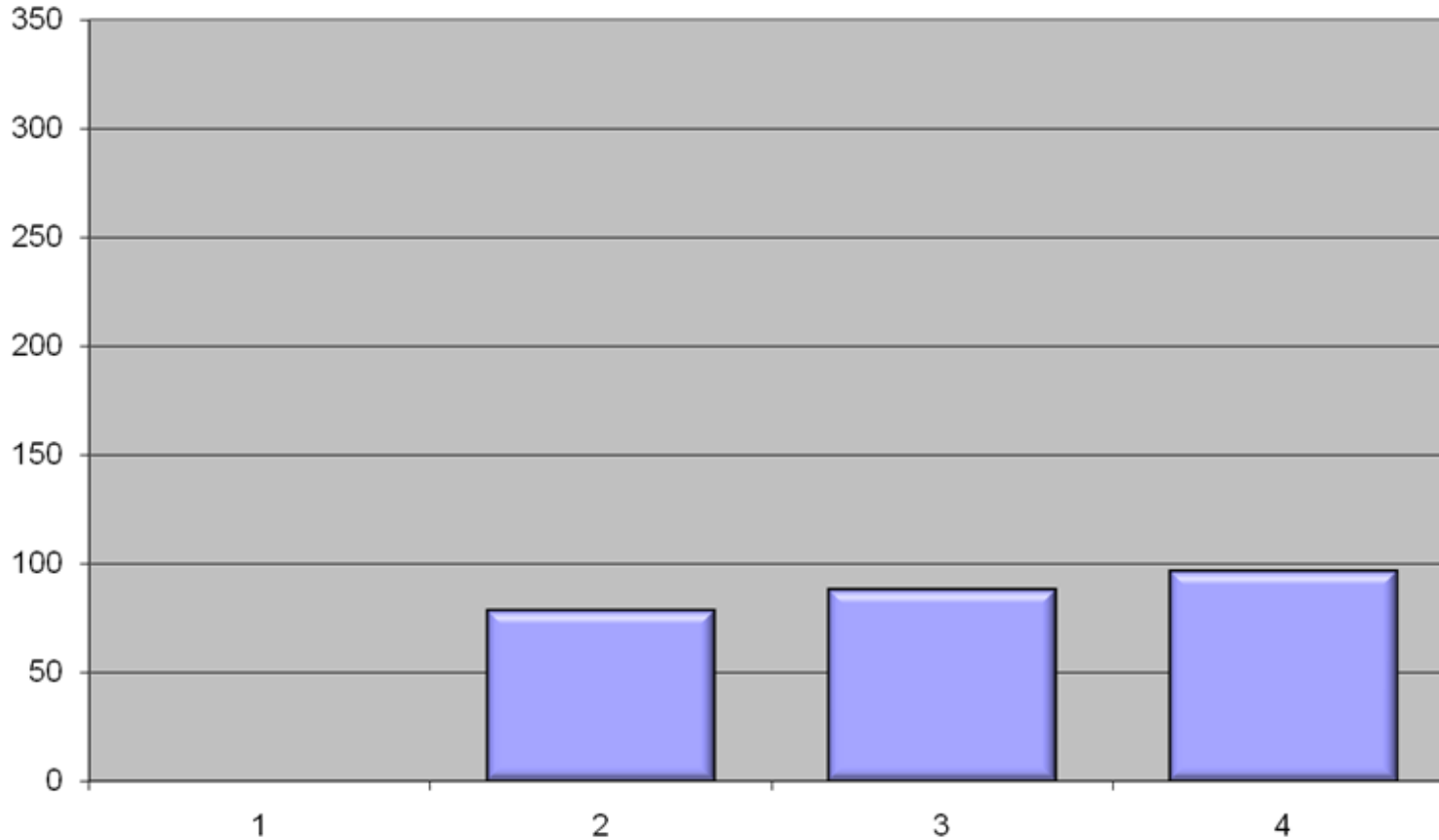


Number of Procedures performed in 2009²⁵ by an individual Physician at this institution



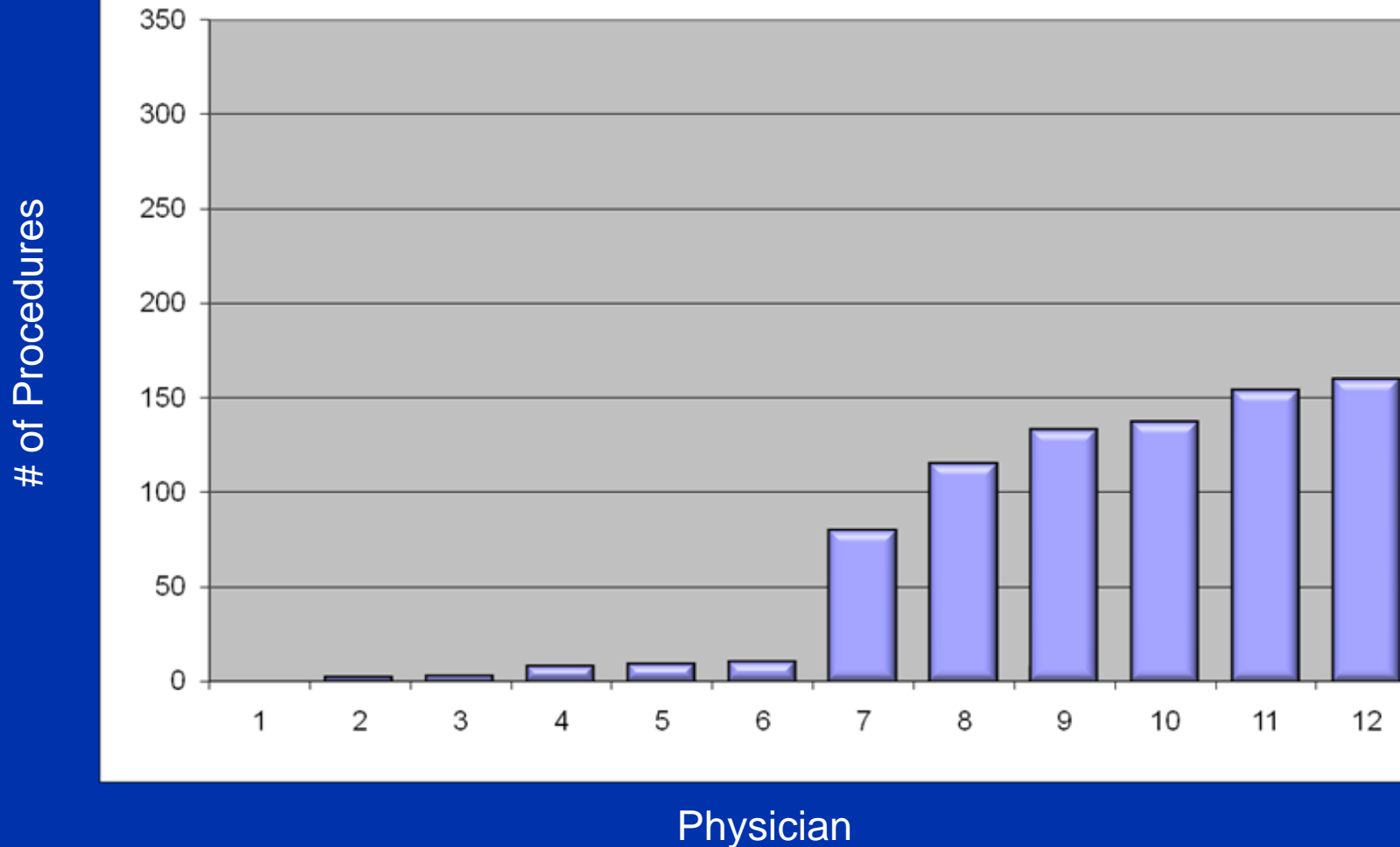
of Procedures

Number of Procedures performed in 2009²⁶ by an individual Physician at this institution

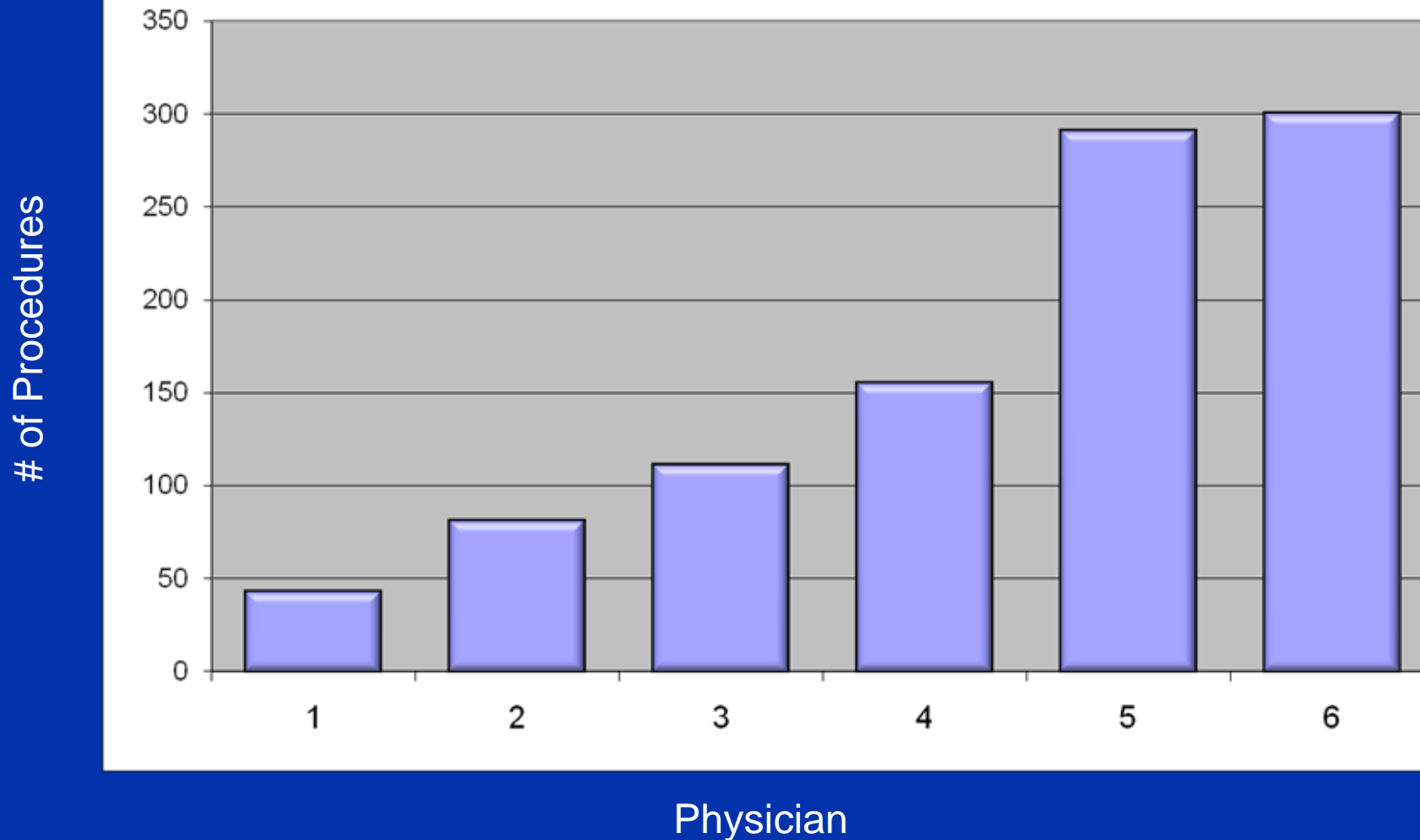


Physician

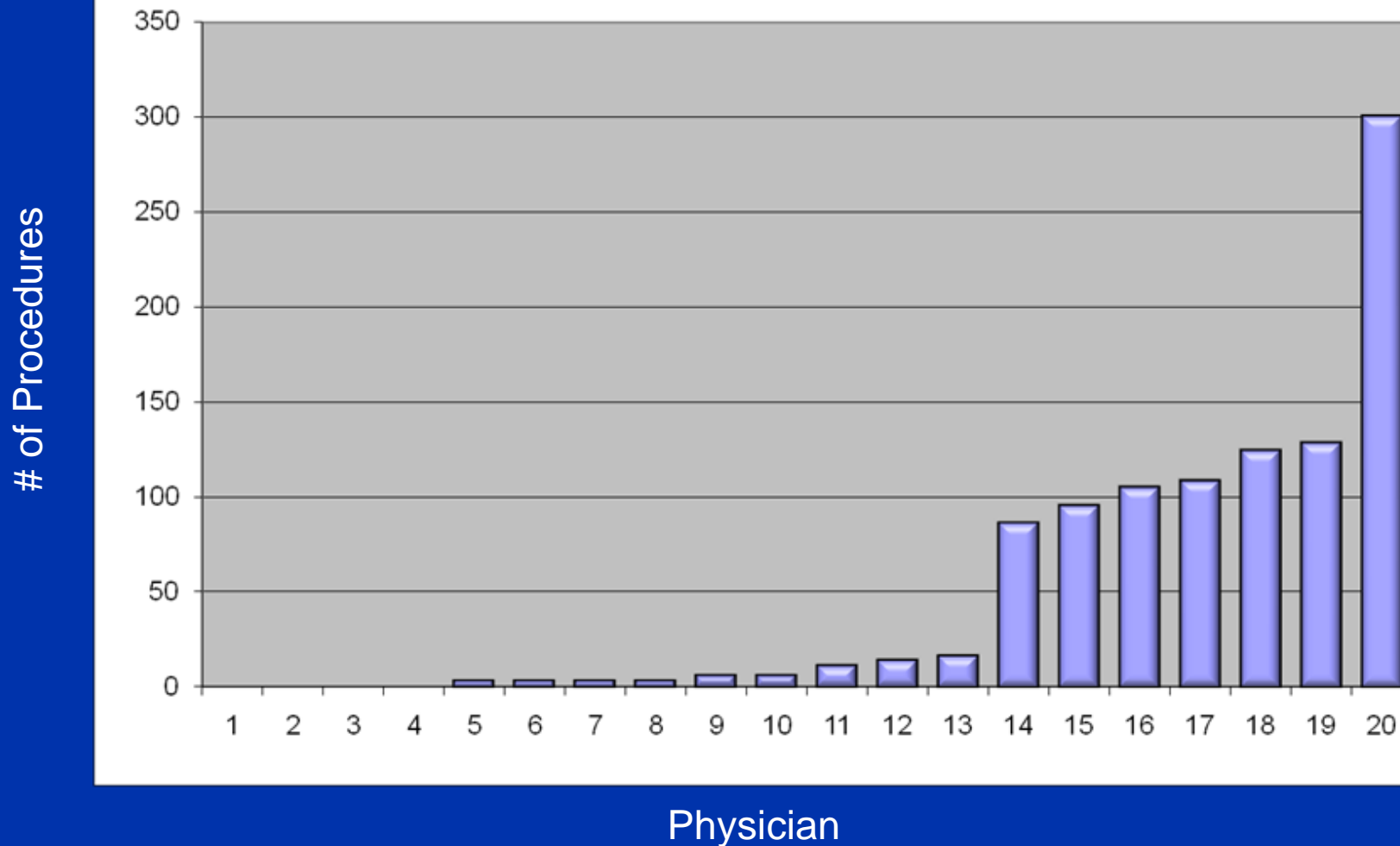
Number of Procedures performed in 2009²⁷ by an individual Physician at this institution



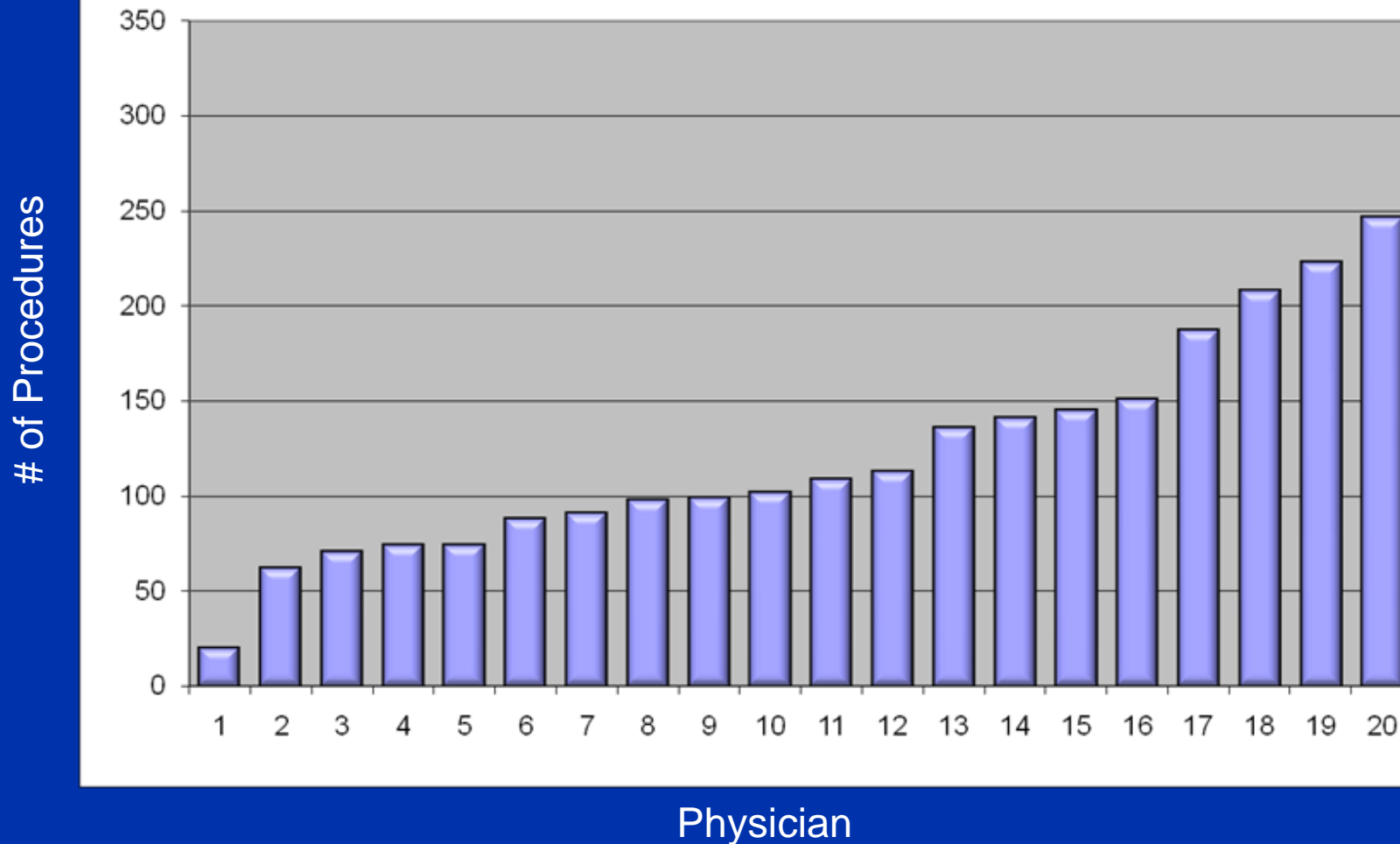
Number of Procedures performed in 2009²⁸ by an individual Physician at this institution



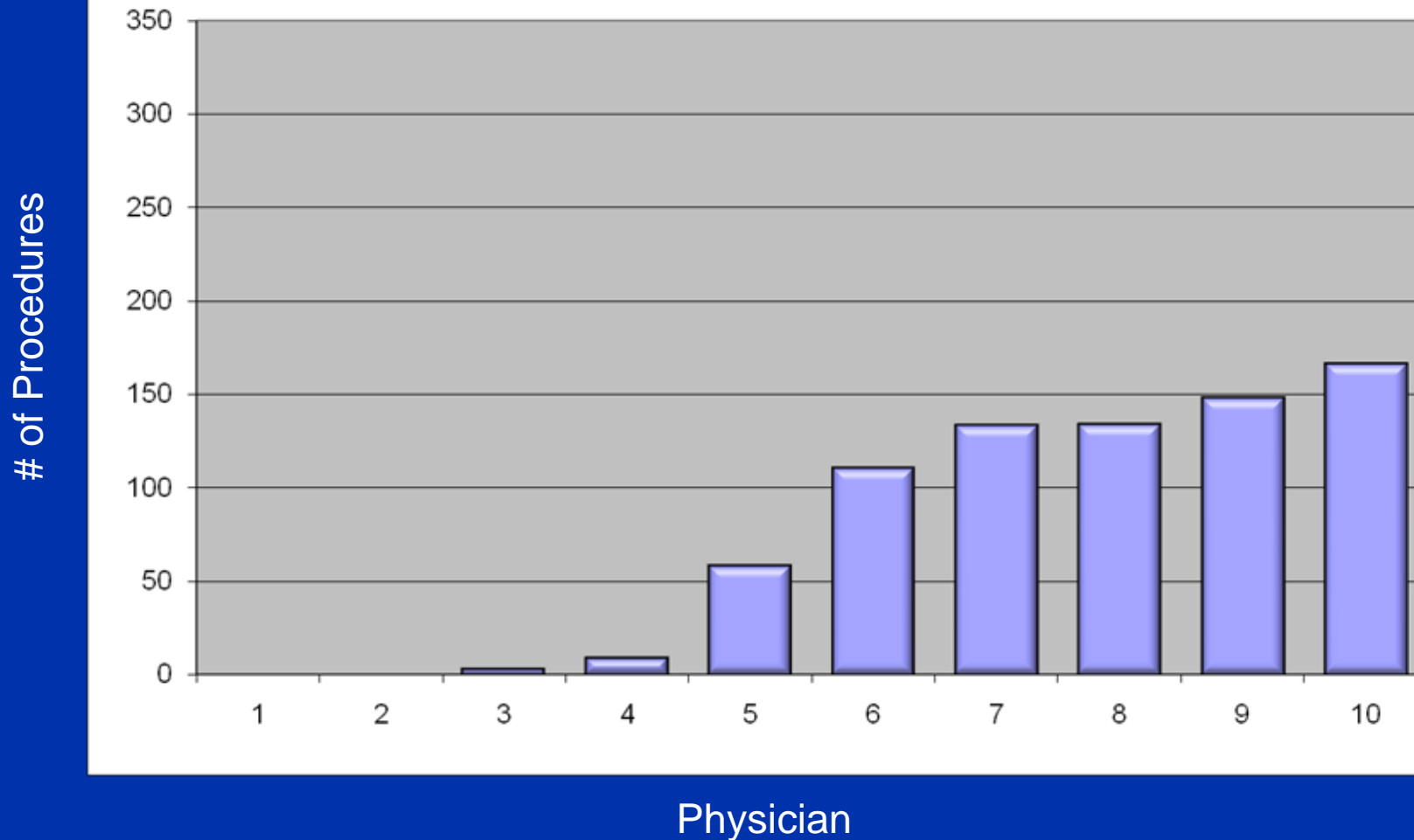
Number of Procedures performed in 2009²⁹ by an individual Physician at this institution



Number of Procedures performed in 2009³⁰ by an individual Physician at this institution

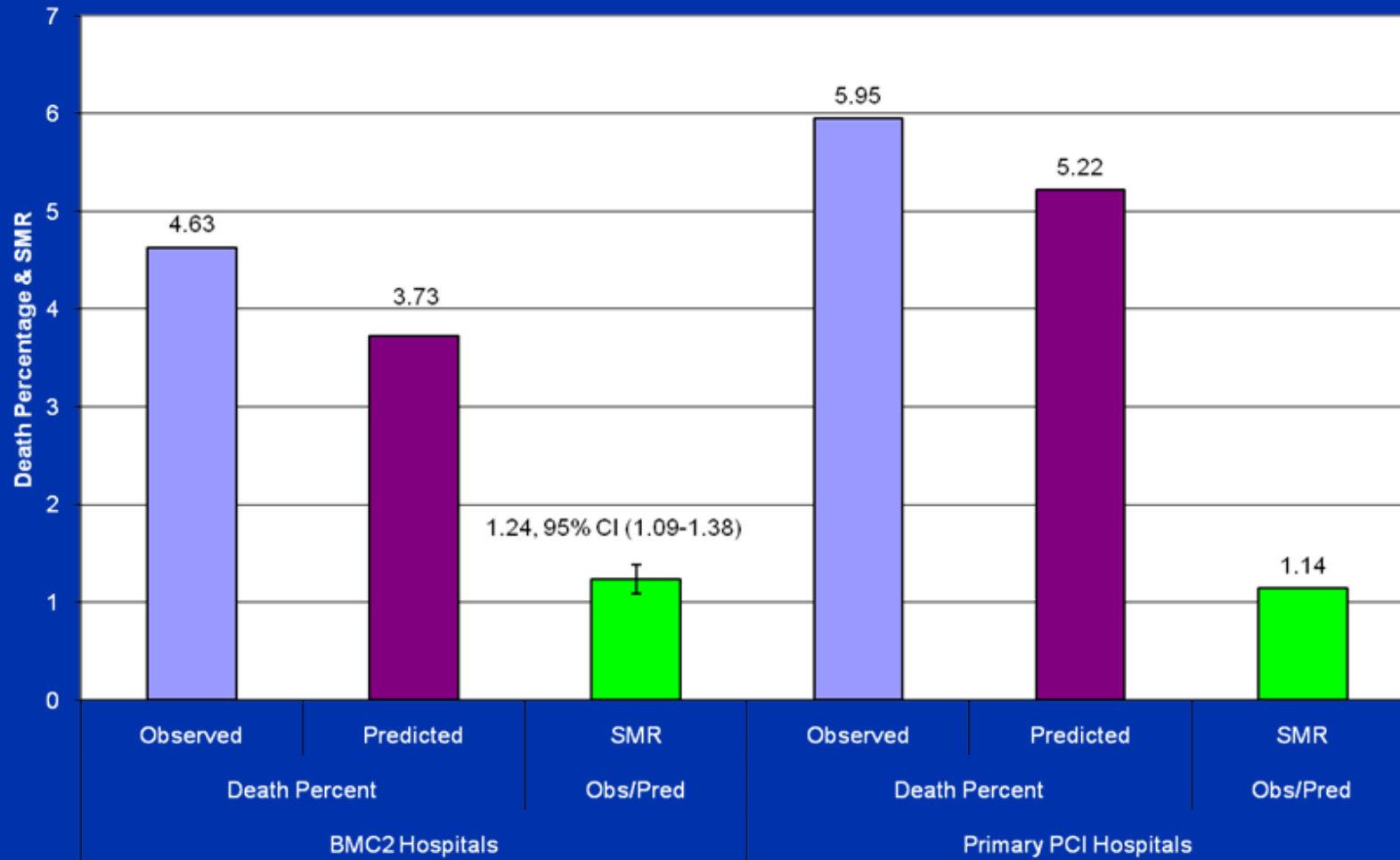


Number of Procedures performed in 2009³¹ by an individual Physician at this institution

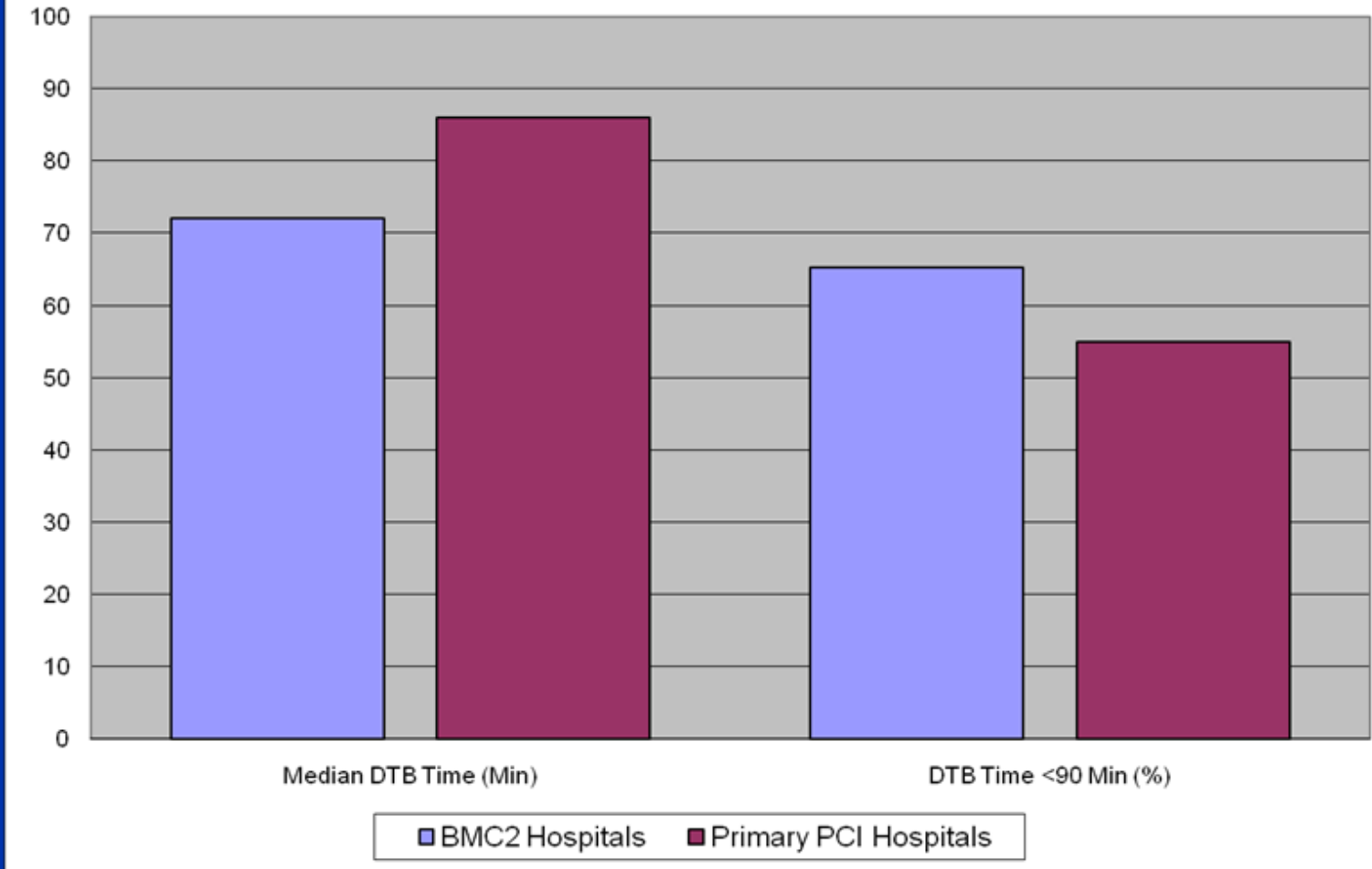


- 2007 comparisons of standardized mortality ratios for the PCI and PPCI sites reveal that the PPCI sites have a lower ratio of observed over predicted deaths (statistically not different).
- The 2007 comparison of median D2B times and % < 90 minutes for PCI and PPCI sites reveal that (in 2007) PPCI sites had slightly longer D2B times than PCI sites.

Death in 2007 in BMC2 STEMI Patients vs. Primary PCI Hospital Patients



2007 Comparison of PCI STEMI and PPCI Door to Balloon Times



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

MONITORING & COMPLIANCE

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.

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 [MCL333.22253]
- 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 BMC² 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

The screenshot shows the Michigan Department of Community Health website. The main heading is "Annual Survey" under the "Certificate of Need Annual Survey" section. The page contains the following text:

Annual Survey
Certificate of Need Annual Survey

The CON Annual Survey is an online survey tool designed to improve and expedite the data reporting process to the Department as required by Part 227 of the Public Health Code. The information collected is used by the Department in conducting its review of future CON applications as well as determining compliance with the terms and conditions of already approved projects. The survey is hosted at www.mi.data.org.

Questions: If you have any questions regarding password access or completing the online survey, please contact the survey vendor, Southeastern Michigan Health Association (SEMA) Center for Population Health, at 313.873.3344 or by email at jagustin@sema.org.

If you have specific data related questions, please contact Andrea Moore at 517.241.3346 or by e-mail at amoore@mi.chhs.gov.

Compliance: Michigan statute, including MCL 333.22237 and 333.2225, requires completion of this survey, and the failure to complete the survey in a timely manner may result in enforcement action. Please note facilities that are delinquent may be subject to Department compliance action pursuant to MCL 333.22247, including but not limited to civil fines for noncompliance.

2009 Survey Reports: The Department has released the following 2009 Annual Status Reports. These reports include a wealth of information on Michigan's health care system. This page will be updated routinely as additional reports become available or existing reports are revised.

Data Release: In addition, the Department will release periodically data briefs summarizing some of the annual survey data. Data briefs will be listed below as they are released. We hope you find these data releases helpful.

October 2010 - 2009 Beds & Covered Clinical Services Summary

State of Michigan
 Department of Community Health - Certificate of Need Program
 Levelt Case Building, 325 S. Walnut Street
 Lansing, MI 48913

Your questions and comments regarding our website are welcome.
 Site last updated on 11/30/2010 (11/30/2010)
 Updated November 30, 2010

Michigan.gov Home | Michigan.gov | Contact Us | State Link | Site
 Privacy Policy | List Sites | Accessibility Policy | Security Policy | Site Map | About Us | Survey

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ANNUAL SURVEY REPORTS

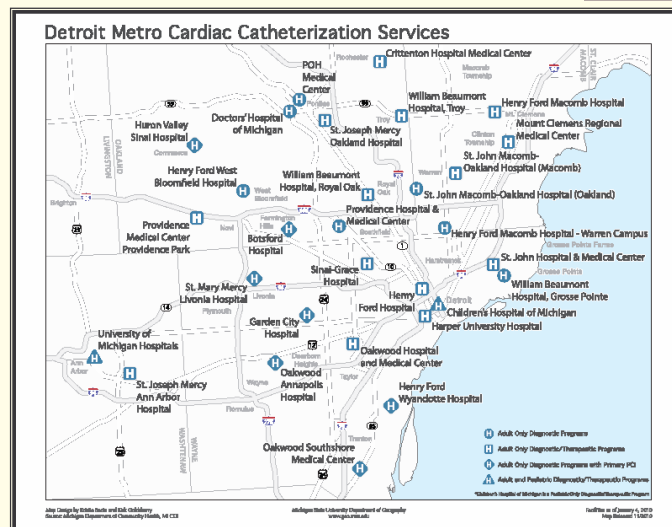
Report 060 contains aggregate data by service type (diagnostic, therapeutic) and by sessions, but not equivalencies.

2009 Michigan Certificate of Need Annual Survey
Adult Cardiac Catheterization Services
Report 060

Facility Number	Facility Name	Type	Number of Late	Total Studies				Left Heart Cath	Number of Sessions		
				Diagnostic CC & EP	Therapeutic CC & EP	Therapeutic Other	Diagnostic (inc. EP)		Therapeutic (inc. EP)	Total w/ Paralysis	
56 0020	HENRY FORD MACOMB HOSPITAL - WARREN CA	H	1	91	51	2	91	91	91	144	144
56 0060	MOUNT CLEMENS REGIONAL MEDICAL CENTER	H	3	1,066	915	608	0	1,066	65	2,088	2,221
56 0070	ST. JOHN MACOMB-OKLAND HOSP (MACOMB)	H	3	6,609	2,551	2,408	0	2,277	1,464	2,471	3,813
56 0120	HENRY FORD MACOMB HOSPITAL	H	3	1,066	1,075	120	0	1,066	1,075	2,030	2,030
63 0014	HURON VALLEY-SINAI HOSPITAL	H	1	444	97	241	0	437	97	541	782
63 0030	WILLIAM BEAUMONT HOSPITAL, ROYAL OAK	H	11	3,925	7,467	2,891	0	3,750	3,772	7,527	9,069
63 0050	OUTSPOUR HOSPITAL	H	1	441	292	240	1	441	292	742	993
63 0070	CRITTENTON HOSPITAL MEDICAL CENTER	H	3	1,448	954	380	0	1,448	954	2,405	2,785
63 0080	ST. JOHN MACOMB-OKLAND HOSP (OKLAND)	H	1	866	0	325	574	292	0	292	334
63 0120	DOCKRUM HOSPITAL OF MICHIGAN	H	1	0	0	53	0	0	0	0	53
63 0128	FORH MEDICAL CENTER	H	1	438	0	0	0	438	0	0	0
63 0130	PROVIDENCE HOSPITAL AND MEDICAL CENTER	H	5	3,342	2,899	995	0	3,342	2,899	5,441	6,346
63 0140	ST. JOSEPH MERCY OKLAND HOSPITAL	H	4	7,207	2,136	2,747	0	2,476	2,139	4,615	6,613
63 0160	WILLIAM BEAUMONT HOSPITAL, TROY	H	2	1,375	1,139	92	0	1,375	1,139	2,514	2,514
63 0176	HENRY FORD WEST BLOOMFIELD HOSPITAL	H	2	234	193	140	197	234	193	427	567
63 0177	PROVIDENCE MEDICAL CENTER-PROVIDENCE	H	2	322	343	85	316	322	343	665	759
74 0020	ST. JOSEPH MERCY PORT HURON HOSPITAL	H	1	133	25	1,059	125	133	0	133	1,219
74 0020	PORT HURON HOSPITAL	H	3	2,859	1,219	228	0	1,163	736	1,916	2,599
81 0020	ST. JOSEPH MERCY ANN ARBOR HOSPITAL	H	5	3,337	2,744	331	0	3,337	2,744	6,101	6,411
81 0060	UNIVERSITY OF MICHIGAN HOSPITAL	H	8	6,765	5,698	730	0	6,327	2,584	5,937	8,247
82 0018	OKAUCHO ANNAPOLIS HOSPITAL	H	1	1,085	198	688	0	175	111	441	455
82 0030	WILLIAM BEAUMONT HOSPITAL, GROSSE POINTE	H	1	46	128	80	46	46	0	46	134
82 0070	GARDEN CITY HOSPITAL	H	1	575	248	480	575	175	248	843	1,252
82 0120	OKAUCHO HOSPITAL AND MEDICAL CENTER	H	4	17,208	5,945	8,800	0	5,886	3,159	6,478	7,185
82 0170	OKAUCHO SOUTHSIDE MEDICAL CENTER	H	1	1,451	200	1,318	0	156	120	613	672
82 0200	ST. MARY MERCY LIVONIA HOSPITAL	H	2	1,197	475	3,090	0	104	134	136	441
82 0230	HENRY FORD WYANDOTTE HOSPITAL	H	2	1,413	513	901	0	519	251	519	2,529
83 0080	CHILDREN'S HOSPITAL OF MICHIGAN	H	2	240	111	44	111	83	73	130	332
83 0100	HENRY FORD HOSPITAL	H	6	5,408	2,520	2,429	0	2,983	1,463	4,384	6,367
83 0120	HARPER UNIVERSITY HOSPITAL	H	5	6,865	2,282	6,334	0	2,266	1,289	2,799	4,088

*diagnostic programs only. The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section E of the survey.

Maps by Service Category



METHODOLOGY & VOLUME REQUIREMENTS

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

CON-716 Worksheet (3-10)

- Total number of laboratories where cardiac catheterization procedures are performed.
- Flagship and diagnostic cardiac catheterization program only - Number of adult diagnostic cardiac catheterization procedures performed in at least Codes 00.26, 07.20(7), 08.03(8), 09. The number reported here is used in item 7 only for primary PCI.
- Number of sessions where at least one adult diagnostic cardiac catheterization procedure was performed, including diagnostic EP studies (Codes A and B below).
- Number of sessions where at least one adult therapeutic cardiac catheterization procedure was performed, including therapeutic EP studies (Codes C through H below).

Adult Cardiac Catheterization and Specialty Procedures

Must Report to CCRS: None Report to CCRS: Primary or Secondary PCI

Table - Count each procedure performed in laboratories identified in item 1, regardless of session.

Adult Procedure Category (Procedure Codes)	Primary PCI		Secondary PCI		Total Procedure Sessions	Annual Change
	No. of Procedures	Procedures Equivalent to	No. of Procedures	Procedures Equivalent to		
A Diagnostic Cardiac Catheterization (00.26, 07.20(7), 08.03(8), 09.00)	1.0	0.0	0.0	0.0	1.0	NA
B Diagnostic Cardiac Catheterization - Primary PCI (00.26, 07.20)	2.0	0.0	0.0	0.0	2.0	NA
C Diagnostic Cardiac Catheterization (00.26, 07.20, 08.03, 09.00)	1.0	0.0	0.0	0.0	1.0	NA
D Therapeutic Cardiac Catheterization (00.26, 07.20, 08.03, 09.00)	2.0	0.0	0.0	0.0	2.0	NA
E Therapeutic Cardiac Catheterization - Primary PCI (00.26, 07.20, 08.03, 09.00)	2.0	0.0	0.0	0.0	2.0	NA
F Therapeutic Cardiac Catheterization - Secondary PCI (00.26, 07.20, 08.03, 09.00)	0.0	0.0	0.0	0.0	0.0	NA
G Therapeutic Cardiac Catheterization - Other (00.26, 07.20, 08.03, 09.00)	0.0	0.0	0.0	0.0	0.0	NA
H Other Therapeutic Cardiac Catheterization (00.26, 07.20, 08.03, 09.00)	0.0	0.0	0.0	0.0	0.0	NA
I Diagnostic Cardiac Catheterization - Pericardial (00.26, 07.20, 08.03, 09.00)	1.0	0.0	0.0	0.0	1.0	NA
J Diagnostic Cardiac Catheterization - Pericardial - Coronary (00.26, 07.20, 08.03, 09.00)	1.0	0.0	0.0	0.0	1.0	NA
K Diagnostic Cardiac Catheterization - Pericardial - Superior Vena Cava (00.26, 07.20, 08.03, 09.00)	2.0	0.0	0.0	0.0	2.0	NA
L Therapeutic Cardiac Catheterization - Pericardial (00.26, 07.20, 08.03, 09.00)	0.0	0.0	0.0	0.0	0.0	NA
M Therapeutic Cardiac Catheterization - Atrial (00.26, 07.20, 08.03, 09.00)	0.0	0.0	0.0	0.0	0.0	NA
N Other Therapeutic Cardiac Catheterization (00.26, 07.20, 08.03, 09.00)	0.0	0.0	0.0	0.0	0.0	NA
O Total Procedures/Procedures Equivalent	6	0	0	0	6	NA

* Adult procedure means services in a patient 18 and older. An adult interventional study is 18 and older.
 ** Excludes selective coronary lesion angiography when performed as part of a diagnostic or therapeutic cardiac catheterization for a possible disease device.
 6 Number of sessions where at least one adult cardiac catheterization procedure was performed in labs identified in item 1 (Codes A through H). Do not include other imaging rooms that are not designated or used for cardiac catheterization services. Item 6 must be equal to or less than the total of items 2 and 4 combined.
 7 Number of all sessions performed in labs identified in item 1, including percutaneous (Codes A through H). Do not include other imaging rooms that are not designated or used for cardiac catheterization services. Item 7 must be equal to or greater than item 6.

No. of Sessions
 Item 6
 Item 7

Questions

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

Jeremy W. Buckley, MD,^a Eric R. Bates, MD,^a and Brahmajee K. Nallamothu, MD, MPH^{a,b} *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 PPCI
- “Access”: % of Michigan population in census tract whose population-based centers were located within the HSA

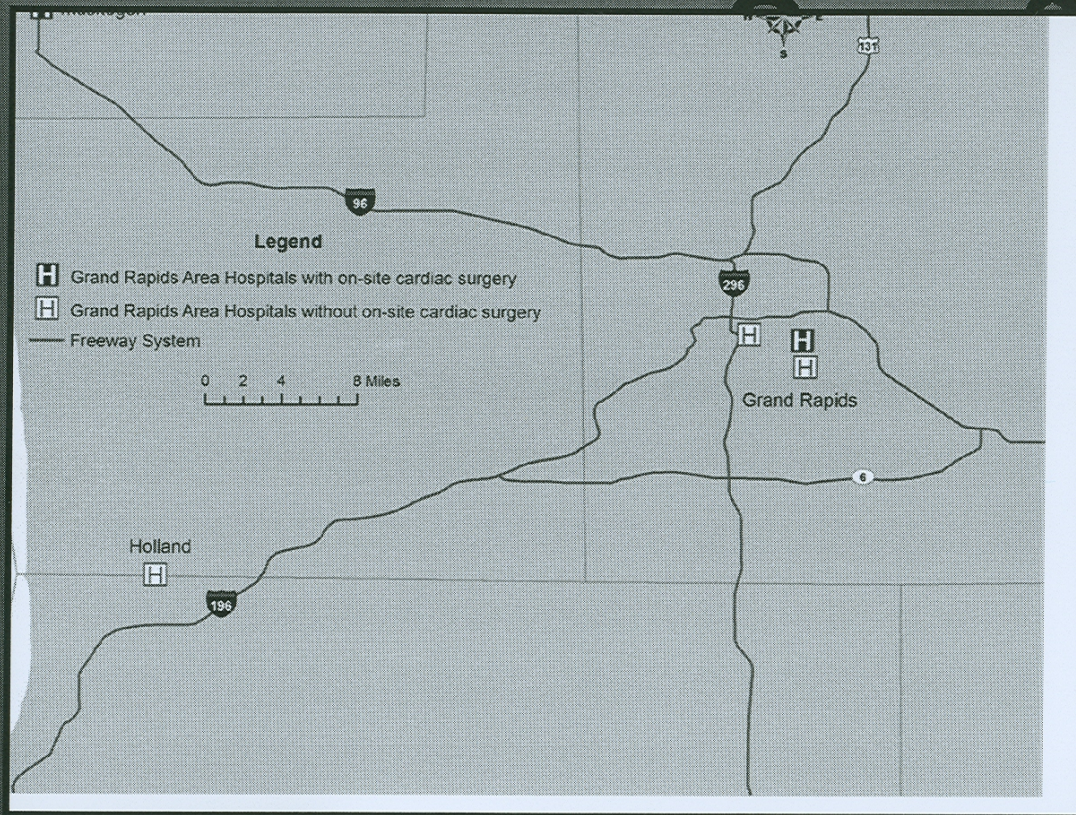
Results

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

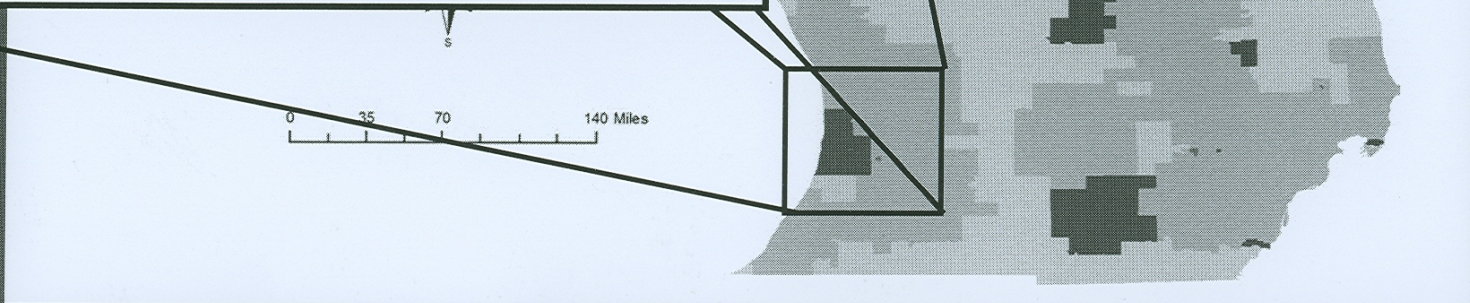
Conclusions/Implications

- 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



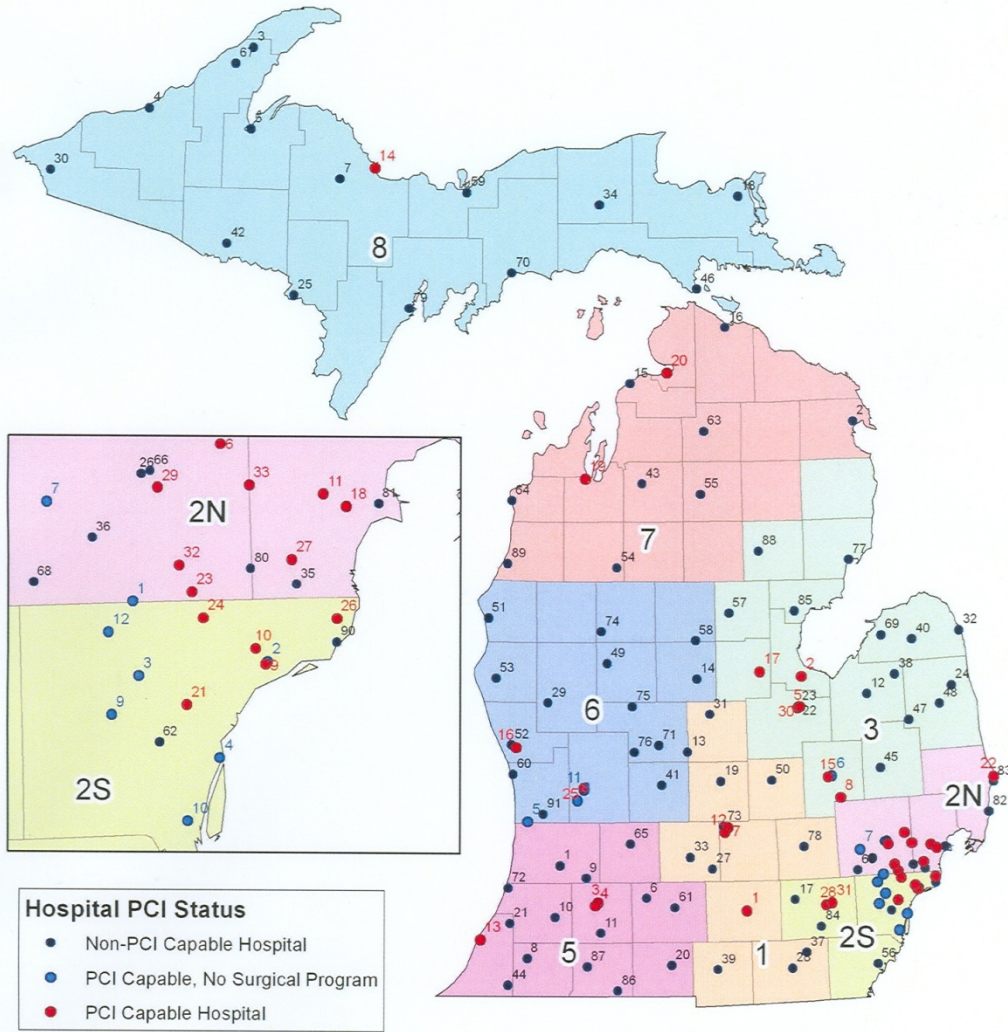
**Net Effect of
Improving Access
to P-PCI within 20
miles of 4.8%**



Michigan Primary Percutaneous Coronary Intervention (PCI) Hospitals (1/20/10)

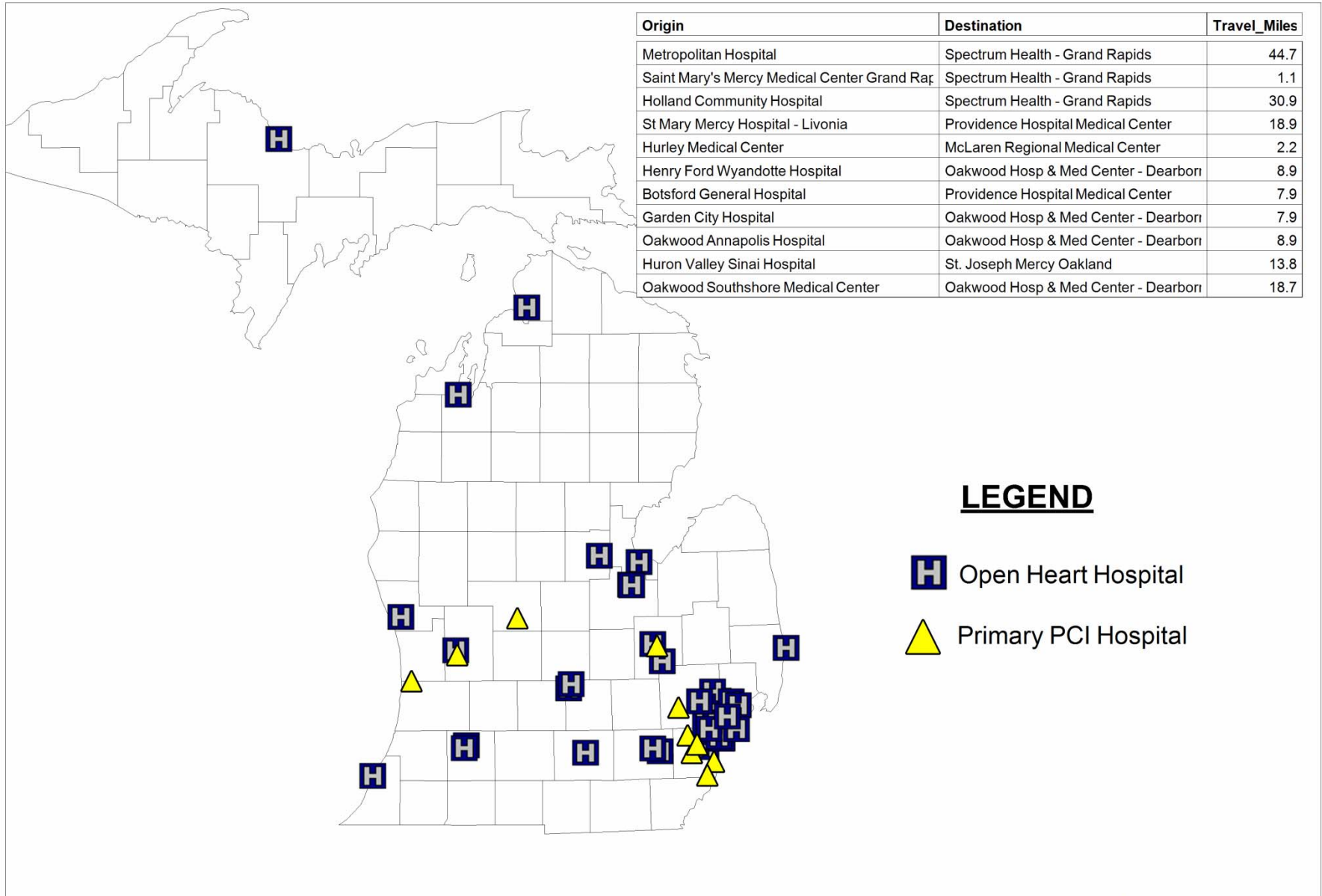
Emergency Preparedness / Trauma Regions

DRAFT (rev 4/8/10)



MICHIGAN PRIMARY PCI HOSPITALS WITHOUT SURGICAL BACKUP AND OPEN HEART HOSPITAL LOCATIONS

Attachment G



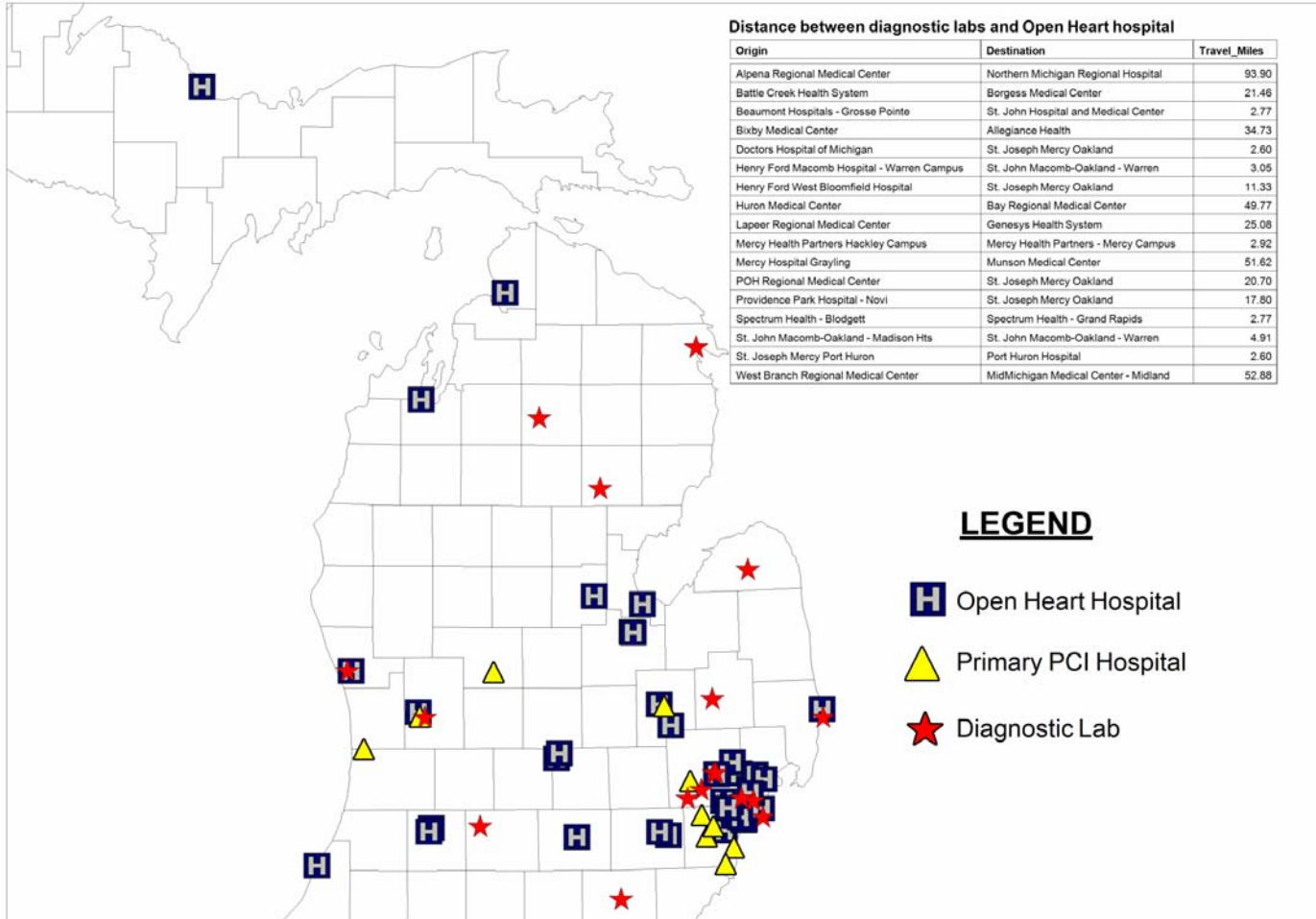
LEGEND

 Open Heart Hospital




 Primary PCI Hospital

Geographical Access Implications - Elective PCI

MICHIGAN CARDIAC CATH LOCATIONS



LEGEND

-  Open Heart Hospital
-  Primary PCI Hospital
-  Diagnostic Lab

Thank you

Outcomes of Nonemergent Percutaneous Coronary Intervention With and Without On-site Surgical Backup: A Meta-Analysis

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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.¹ 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

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without on-site cardiac surgery.⁸ 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.⁹

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

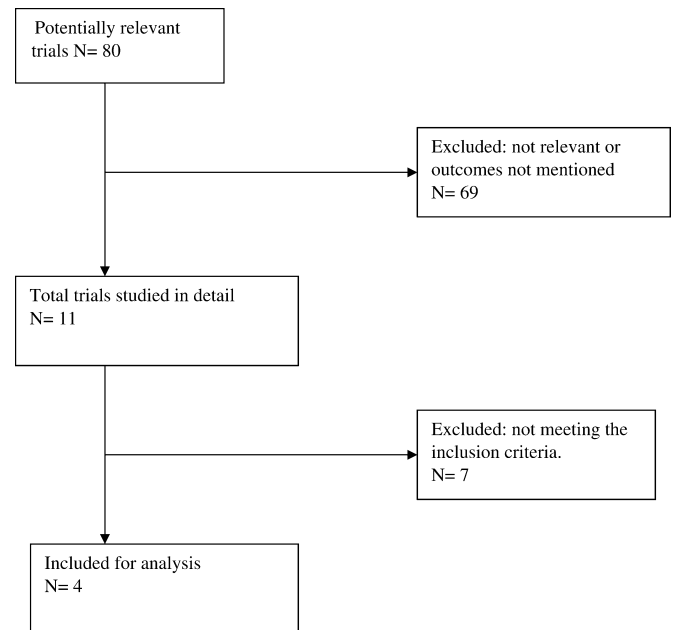


FIGURE 1. Trial selection and inclusion flow diagram.

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

Table 1. Results of heterogeneity analysis.

End Point	Q-value	df (Q)	P Value	I-squared	Result
In-hospital death	3.4	1	0.067	70.2	Homogenous
Nonfatal myocardial infarction	1.4	3	0.707	0.0	Homogenous
Emergency coronary artery bypass graft	2.0	1	0.155	50.7	Homogenous

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).

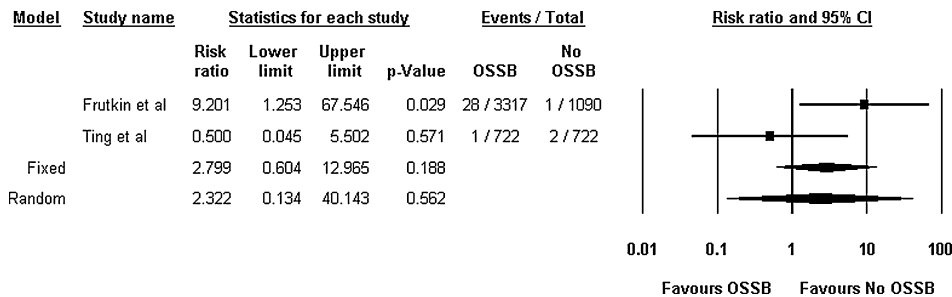


FIGURE 2. Risk of in-hospital death with on-site surgical backup versus no backup.

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

Characteristics		Dellavalle, 1995	Melberg, 2006	Frutkin, 2008	Ting, 2006
N	SB	154	304	3317	722
	NSB	174	305	1090	722
Age	SB	55 ± 12	58 ± 10	66 ± 13	64.9 ± 12.5
	NSB	64 ± 18	59 ± 10	66 ± 12	64.9 ± 12.7
Females	SB	37 (24%)	61 (20%)	1129 (34%)	246 (34%)
	NSB	33 (19%)	64 (21%)	300 (27.5%)	218 (30%)
Prior MI	SB	72 (47%)	39	1320 (40%)	273 (39%)
	NSB	108 (62%)	39	319 (29%)	248 (34%)
Prior PCI	SB	15 (9.1%)	9	1583 (48%)	245 (34%)
	NSB	30 (17.2%)	6	477 (44%)	244 (34%)
Prior stroke/TIA	SB	—	—	603 (18%)	80 (11%)
	NSB	—	—	163 (15%)	69 (10%)
Prior CABG	SB	1 (0.6%)	6	728 (22%)	84 (12%)
	NSB	5 (2.7%)	5	220 (20%)	74 (10%)
PVD	SB	—	—	421 (13%)	72 (10%)
	NSB	—	—	125 (11%)	86 (12%)
DM	SB	—	5	110 (34%)	170 (24%)
	NSB	—	9	310 (28%)	176 (24%)
HTN	SB	—	25	2527 (76%)	480 (69%)
	NSB	—	24	820 (75%)	496 (69%)
CKD	SB	—	—	193 (6%)	18 (2%)
	NSB	—	—	29 (3%)	18 (3%)
CHF	SB	—	—	346 (10%)	38 (5%)
	NSB	—	—	65 (6%)	39 (5%)
LVEF less than 40%	SB	—	—	374 (19%)	92 (13%)
	NSB	—	—	59 (9%)	74 (10%)

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.

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

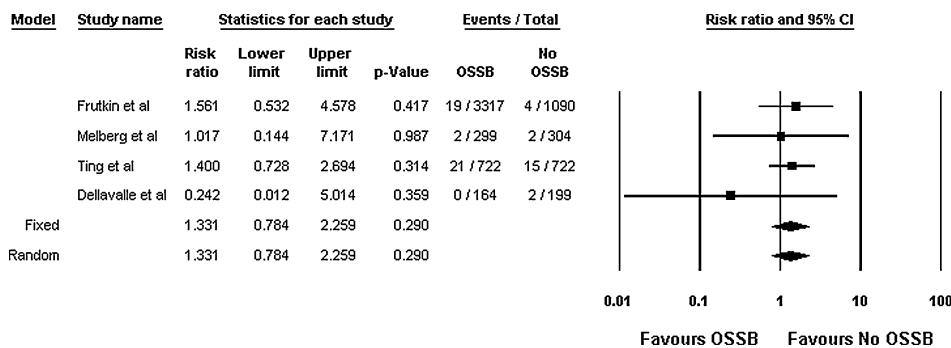


FIGURE 3. Risk of nonfatal myocardial infarction with on-site surgical backup versus no backup.

Table 3. Angiographic characteristics of patients in studies included in the meta-analysis.

Characteristics	Dellavalle		Melberg, 2006		Frutkin		Ting, 2006	
	SB	NSB	SB	NSB	SB	NSB	SB	NSB
Extent of disease								
SVD	98 (60%)	139 (70%)	39	39	999 (30%)	299 (27%)	—	—
DVD	56 (34%)	44 (22%)	35	37	1079 (33%)	356 (33%)	423 (62%)	429 (61%)
TVD	10 (6%)	16 (8%)	26	24	1231 (37%)	434 (40%)		
Type of PCI								
SV	131 (80%)	179 (90%)	—	—	2244 (68%)	773 (71%)	646 (90%)	636 (88%)
MV	33 (20%)	20 (10%)	—	—	852	282 (26%)	75 (10%)	86 (12%)
LM	3 (2%)	0	—	—	27 (0.8%)	4 (0.4%)	—	—
VG	1 (0.5%)	4 (2%)	—	—	263 (8%)	60 (6%)	22 (3%)	24 (3%)
No. of stents placed	—	—	—	—	1.7 ± 1.3	1.8 ± 1.1	1.3 ± 0.9	1.5 ± 1.0

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.

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 provide a highly experienced and promptly available team 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

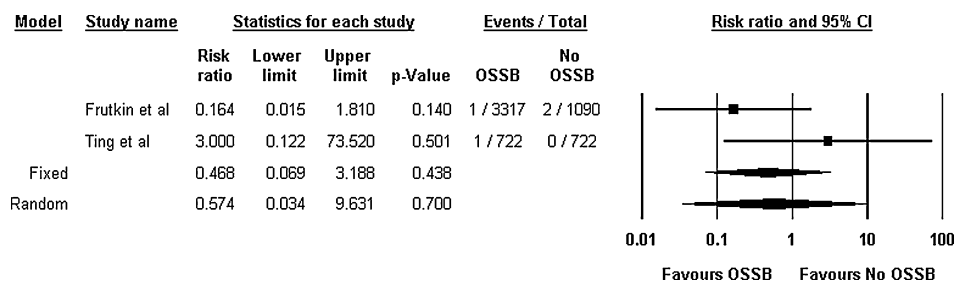


FIGURE 4. Risk of emergency coronary artery bypass graft with on-site surgical backup versus no backup.

Risks of PCI Without Onsite Surgical Backup

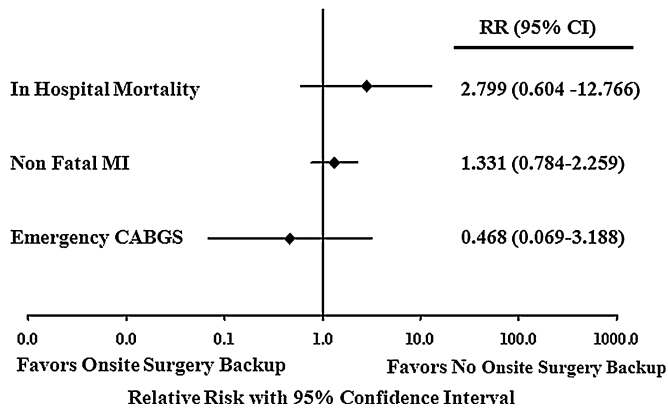


FIGURE 5. Summary figure.

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.

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Facility No	Type	Facility Name	Facility City
500080	H	HENRY FORD MACOMB HOSPITAL - MT. CLEMENS	MT. CLEMENS
400020	H	KALKASKA MEMORIAL HEALTH CENTER	KALKASKA
100020	H	PAUL OLIVER MEMORIAL HOSPITAL	FRANKFORT
020010	H	MUNISING MEMORIAL HOSPITAL	MUNISING
760010	H	DECKERVILLE COMMUNITY HOSPITAL	DECKERVILLE
490030	H	MACKINAC STRAITS HEALTH SYSTEM, INC.	ST. IGANCE
320040	H	HARBOR BEACH COMMUNITY HOSPITAL	HARBOR BEACH
090020	H	BAY REGIONAL MEDICAL CENTER (WEST CAMPUS)	BAY CITY
230021	H	EATON RAPIDS MEDICAL CENTER	EATON RAPIDS
500100	H	SOUTHEAST MICHIGAN SURGICAL HOSPITAL	WARREN
070020	H	BARAGA COUNTY MEMORIAL HOSPITAL	L'ANSE
640021	H	MERCY HEALTH PARTNERS, LAKESHORE CAMPUS	SHELBY
030032	H	ALLEGAN GENERAL HOSPITAL	ALLEGAN
310021	H	ASPIRUS KEWEENAW HOSPITAL	LAURIUM
660020	H	ASPIRUS ONTONAGON HOSPITAL	ONTONAGON
520051	H	BELL MEMORIAL HOSPITAL	ISHPEMING
140010	H	BORGESS-LEE MEMORIAL HOSPITAL	DOWAGIAC
800041	H	BRONSON LAKEVIEW HOSPITAL	PAW PAW
790032	H	CARO COMMUNITY HOSPITAL	CARO
150021	H	CHARLEVOIX AREA HOSPITAL	CHARLEVOIX
190011	H	CLINTON MEMORIAL HOSPITAL	ST JOHNS
270022	H	GRAND VIEW HEALTH SYSTEM	IRONWOOD
230022	H	HAYES GREEN BEACH MEMORIAL HOSPITAL	CHARLOTTE
480020	H	HELEN NEWBERRY JOY HOSPITAL	NEWBERRY
460052	H	HERRICK MEDICAL CENTER	TECUMSEH
790031	H	HILLS & DALES GENERAL HOSPITAL	CASS CITY
760041	H	MARLETTE REGIONAL HOSPITAL	MARLETTE
760030	H	MCKENZIE MEMORIAL HOSPITAL	SANDUSKY
260011	H	MIDMICHIGAN MEDICAL CENTER - GLADWIN	GLADWIN
360021	H	NORTHSTAR HEALTH SYSTEM	IRON RIVER
320030	H	SCHEURER HOSPITAL	PIGEON
770010	H	SCHOOLCRAFT MEMORIAL HOSPITAL	MANISTIQUE
590030	H	SHERIDAN COMMUNITY HOSPITAL	SHERIDAN
340021	H	SPARROW IONIA HOSPITAL	IONIA
670021	H	SPECTRUM HEALTH REED CITY HOSPITAL	REED CITY
590201	H	SPECTRUM HEALTH UNITED MEMORIAL - KELSEY	LAKEVIEW
060020	H	ST. MARY'S OF MICHIGAN STANDISH HOSPITAL	STANDISH
510020	H	WEST SHORE MEDICAL CENTER	MANISTEE
130100	H	SOUTHWEST REGIONAL REHABILITATION CENTER	BATTLE CREEK
330050	H	SPARROW HEALTH SYSTEM - ST. LAWRENCE CAM	LANSING
630150	H	STRAITH HOSPITAL FOR SPECIAL SURGERY	SOUTHFIELD
630060	H	DMC SURGERY HOSPITAL	MADISON HEIGHTS
310020	H	PORTAGE HOSPITAL	HANCOCK
710030	H	ROGERS CITY REHABILITATION HOSPITAL	ROGERS CITY
390030	H	BRONSON VICKSBURG HOSPITAL	VICKSBURG
470010	H	BRIGHTON HOSPITAL	BRIGHTON HOSPITAL
730060	H	HEALTHSOURCE SAGINAW, INC.	SAGINAW
630013	H	OAKLAND REGIONAL HOSPITAL	SOUTHFIELD
160020	H	CHEBOYGAN MEMORIAL HOSPITAL	CHEBOYGAN
690020	H	OTSEGO MEMORIAL HOSPITAL	GAYLORD

350010	H	ST. JOSEPH HEALTH SYSTEM - TAWAS	TAWAS CITY
330010	H	INGHAM REGIONAL MEDICAL CENTER - PENN	LANSING
610030	H	MERCY HEALTH PARTNERS - GENERAL CAMPUS	MUSKEGON
700030	H	ZEELAND COMMUNITY HOSPITAL	ZEELAND
110040	H	COMMUNITY HOSPITAL WATERVLIET	WATERVLIET
750020	H	THREE RIVERS HEALTH	THREE RIVERS
590010	H	CARSON CITY HOSPITAL	CARSON CITY
620010	H	GERBER MEMORIAL HOSPITAL	FREMONT
830240	H	HUTZEL WOMEN'S HOSPITAL	DETROIT
500030	H	ST. JOHN NORTH SHORES HOSPITAL	HARRISON TWP.
320020	H	HURON MEMORIAL HOSPITAL	BAD AXE
180010	H	MIDMICHIGAN MEDICAL CENTER CLARE	CLARE
300010	H	HILLSDALE COMMUNITY HEALTH CENTER	HILLSDALE
590060	H	SPECTRUM HEALTH UNITED MEMORIAL - UNITED	GREENVILLE
810010	H	FOREST HEALTH MEDICAL CENTER, LLC	YPSILANTI
740030	H	ST. JOHN RIVER DISTRICT HOSPITAL	EAST CHINA
730030	H	COVENANT MEDICAL CENTER - N MICHIGAN	SAGINAW
530010	H	MEMORIAL MEDICAL CENTER OF WEST MICHIGAN	LUDINGTON
540030	H	MECOSTA COUNTY MEDICAL CENTER	BIG RAPIDS
810040	H	ST. JOSEPH MERCY SALINE HOSPITAL	SALINE
130080	H	OAKLAWN HOSPITAL	MARSHALL
410070	H	MARY FREE BED REHABILITATION HOSPITAL	GRAND RAPIDS
700010	H	NORTH OTTAWA COMMUNITY HOSPITAL	GRAND HAVEN
170020	H	CHIPPEWA COUNTY WAR MEMORIAL HOSPITAL	SAULT STE MARIE
800020	H	SOUTH HAVEN COMMUNITY HOSPITAL	SOUTH HAVEN
810080	H	CHELSEA COMMUNITY HOSPITAL	CHELSEA
750010	H	STURGIS HOSPITAL	STURGIS
460020	H	EMMA L. BIXBY MEDICAL CENTER	ADRIAN
080010	H	PENNOCK HOSPITAL	HASTINGS
650010	H	WEST BRANCH REGIONAL MEDICAL CENTER	WEST BRANCH
820040	H	HENRY FORD COTTAGE HOSPITAL	GROSSE POINTE FARMS
110070	H	LAKELAND HOSPITAL, NILES	NILES
200020	H	MERCY HOSPITAL - GRAYLING	GRAYLING
830410	H	REHABILITATION INSTITUTE	DETROIT
220020	H	DICKINSON COUNTY HEALTHCARE SYSTEM	IRON MOUNTAIN
840010	H	MERCY HOSPITAL	CADILLAC
210010	H	ST. FRANCIS HOSPITAL	ESCANABA
120010	H	COMMUNITY HEALTH CENTER OF BRANCH COUNTY	COLDWATER
780010	H	MEMORIAL HEALTHCARE	OWOSSO
370010	H	CENTRAL MICHIGAN COMMUNITY HOSPITAL	MT. PLEASANT
740010	H	ST. JOSEPH MERCY PORT HURON HOSPITAL	PORT HURON
830520	H	KARMANOS CANCER CENTER	DETROIT
040010	H	ALPENA REGIONAL MEDICAL CENTER	ALPENA
820250	H	OAKWOOD HERITAGE HOSPITAL	TAYLOR
290010	H	GRATIOT MEDICAL CENTER	ALMA
630080	H	ST. JOHN MACOMB-OAKLAND HOSP (OAKLAND)	MADISON HEIGHTS
470020	H	ST. JOSEPH MERCY LIVINGSTON HOSPITAL	HOWELL
630014	H	HURON VALLEY-SINAI HOSPITAL	COMMERCE
610010	H	MERCY HEALTH PARTNERS - HACKLEY CAMPUS	MUSKEGON
740020	H	PORT HURON HOSPITAL	PORT HURON
440010	H	LAPEER REGIONAL MEDICAL CENTER	LAPEER
630176	H	HENRY FORD WEST BLOOMFIELD HOSPITAL	WEST BLOOMFIELD

700020	H	HOLLAND HOSPITAL	HOLLAND
820170	H	OAKWOOD SOUTHSORE MEDICAL CENTER	TRENTON
610020	H	MERCY HEALTH PARTNERS - MERCY CAMPUS	MUSKEGON
630177	H	PROVIDENCE MEDICAL CENTER-PROVIDENCE PAR	NOVI
500020	H	HENRY FORD MACOMB HOSPITAL - WARREN CAMP	WARREN
130031	H	BATTLE CREEK HEALTH SYSTEM	BATTLE CREEK
410060	H	METROPOLITAN HOSPITAL	GRAND RAPIDS
240030	H	NORTHERN MICHIGAN REGIONAL HOSPITAL	PETOSKEY
580030	H	MERCY MEMORIAL HOSPITAL	MONROE
110050	H	LAKELAND HOSPITAL, ST. JOSEPH	ST. JOSEPH
830080	H	CHILDREN'S HOSPITAL OF MICHIGAN	DETROIT
560020	H	MIDMICHIGAN MEDICAL CENTER-MIDLAND	MIDLAND
410080	H	SAINT MARY'S HEALTH CARE	GRAND RAPIDS
820010	H	OAKWOOD ANNAPOLIS HOSPITAL	WAYNE
520050	H	MARQUETTE GENERAL HEALTH SYSTEM	MARQUETTE
730050	H	ST. MARY'S OF MICHIGAN	SAGINAW
630070	H	CRITTENTON HOSPITAL MEDICAL CENTER	ROCHESTER
830500	H	DETROIT RECEIVING HOSPITAL	DETROIT
820190	H	ST. MARY MERCY LIVONIA HOSPITAL	LIVONIA
730020	H	COVENANT MEDICAL CENTER - COOPER	SAGINAW
730061	H	COVENANT MEDICAL CENTER - HARRISON	SAGINAW
500060	H	MOUNT CLEMENS REGIONAL MEDICAL CENTER	MOUNT CLEMENS
820030	H	WILLIAM BEAUMONT HOSPITAL, GROSSE POINTE	GROSSE POINTE
630050	H	BOTSFORD HOSPITAL	FARMINGTON HILLS
410010	H	SPECTRUM HEALTH BLODGETT HOSPITAL	GRAND RAPIDS
630120	H	POH MEDICAL CENTER	PONTIAC
330020	H	INGHAM REGIONAL MEDICAL CENTER	LANSING
630110	H	DOCTORS' HOSPITAL OF MICHIGAN	PONTIAC
820070	H	GARDEN CITY HOSPITAL	GARDEN CITY
820230	H	HENRY FORD WYANDOTTE HOSPITAL	WYANDOTTE
380010	H	ALLEGIANCE HEALTH	JACKSON
630130	H	PROVIDENCE HOSPITAL AND MEDICAL CENTER	SOUTHFIELD
250050	H	MCLAREN REGIONAL MEDICAL CENTER	FLINT
500070	H	ST. JOHN MACOMB-OAKLAND HOSP (MACOMB)	WARREN
500110	H	HENRY FORD MACOMB HOSPITAL	CLINTON TOWNSHIP
090050	H	BAY REGIONAL MEDICAL CENTER	BAY CITY
630160	H	WILLIAM BEAUMONT HOSPITAL, TROY	TROY
390010	H	BORGESS MEDICAL CENTER	KALAMAZOO
280010	H	MUNSON MEDICAL CENTER	TRAVERSE CITY
390020	H	BRONSON METHODIST HOSPITAL	KALAMAZOO
250040	H	HURLEY MEDICAL CENTER	FLINT
830450	H	SINAI-GRACE HOSPITAL	DETROIT
630140	H	ST. JOSEPH MERCY OAKLAND HOSPITAL	PONTIAC
250072	H	GENESYS REGIONAL MEDICAL CENTER	GRAND BLANC
830220	H	HARPER UNIVERSITY HOSPITAL	DETROIT
810030	H	ST. JOSEPH MERCY ANN ARBOR HOSPITAL	ANN ARBOR
330060	H	EDWARD W SPARROW HOSPITAL	LANSING
820120	H	OAKWOOD HOSPITAL AND MEDICAL CENTER	DEARBORN
410040	H	SPECTRUM HEALTH BUTTERWORTH HOSPITAL	GRAND RAPIDS
830190	H	HENRY FORD HOSPITAL	DETROIT
830420	H	ST. JOHN HOSPITAL & MEDICAL CENTER	DETROIT
810060	H	UNIVERSITY OF MICHIGAN HOSPITALS	ANN ARBOR

630030 H WILLIAM BEAUMONT HOSPITAL, ROYAL OAK

ROYAL OAK

Total

Beds Total Acute Care H25_L4E	AODP # diagnostic	AOD/TP #diag/thera	AOD/P-PCI #diag/thera	A/PD/T/P #diag/thera	bed #
	1				1
	8				8
	8				8
	11				11
	15				15
	15				15
	17				17
	20				20
	20				20
	20				20
	24				24
	24				24
	25				25
	25				25
	25				25
	25				25
	25				25
	25				25
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	25				25
	25				25
	26				26
	30				30
	34				34
	36				36
	36				36
	36				36
	36				36
	39				39
	41				41
	45				45
	45				45
	46				46
	46				46

49		49
53		53
57		57
57		57
58		58
60		60
61		61
61		61
61		61
63		63
64	?	64
64		64
65		65
65		65
68		68
68		68
71		71
73		73
74		74
74		74
77		77
80		80
81		81
82		82
82		82
83		83
84		84
88	140	88
88		88
88	53	88
89		89
89		89
90		90
94		94
96		96
97	385	97
98		98
102		102
111		111
118		118
119	135	119
123		123
124		124
125		125
130	848	130
133	866	133
136		136
153		153
154	3	154
163	2950	163
183	115	183
191	234	191

193			380/150	193
193			1651/200	193
196		1,230/964		196
200		3,342/2,099		200
203	91			203
204	499			204
208			944/347	208
214		5,595/2,608		214
217	385??			217
224		1,454/988		224
228			240/111	228
230		5,066/2,148		230
230			436/276	230
247			1085/198	247
264		1861/1336		264
268		4362/1093		268
270		1449/956		270
273				273
273			1197/473	273
275		10364/3256		275
277				277
288		1906/915		288
289	46			289
305			441/301	305
306	22			306
308	438			308
310		7420/1666		310
321	0			321
323			575/268	323
323			1413/515	323
325		6241/1766		325
340		322/343		340
342		8225/2816		342
348	6,609			348
349		1844/1075		349
356		10665/3011		356
361		1375/1139		361
372		12491/5637		372
377		11266/4205		377
380		1883/1359		380
383			763/304	383
383		2422/543		383
395		7279/3136		395
410		6567/2375		410
506		6605/2380		506
513		3357/2744		513
587		7674/2582		587
632		17280/5965		632
755			6143/4656	755
762		5450/2520		762
769		9377/3834		769
848			6765/5698	848

1,031
25,111

3925/7467

1,031

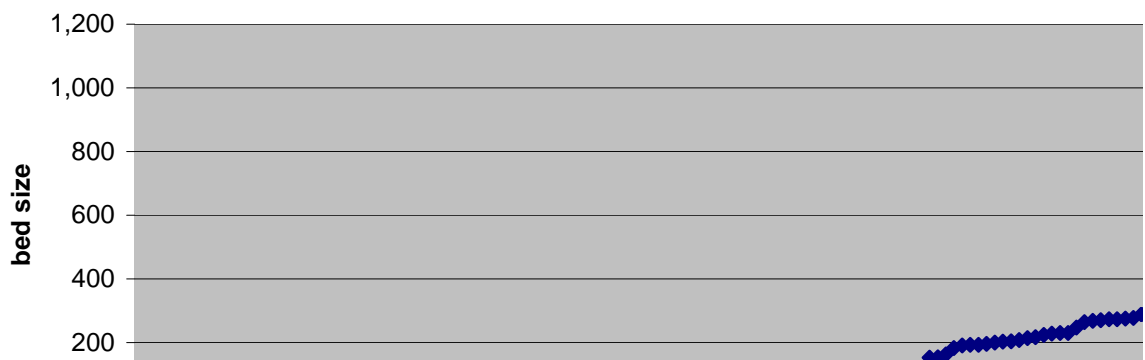
SOLE Provider County

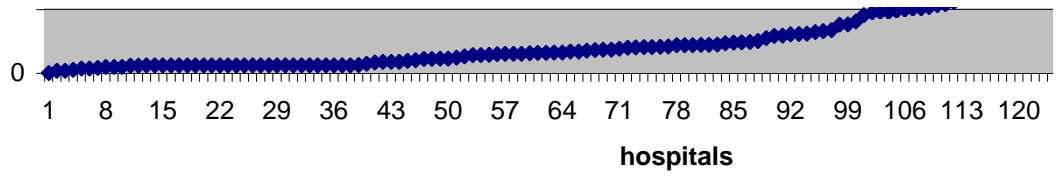
SOLE provider w/lab

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

Hospital Bed Range





labs
/ing and
57)

