# PCI with On-Site Surgical Services is most Cost-Effective Strategy (Primary or Elective PCI)

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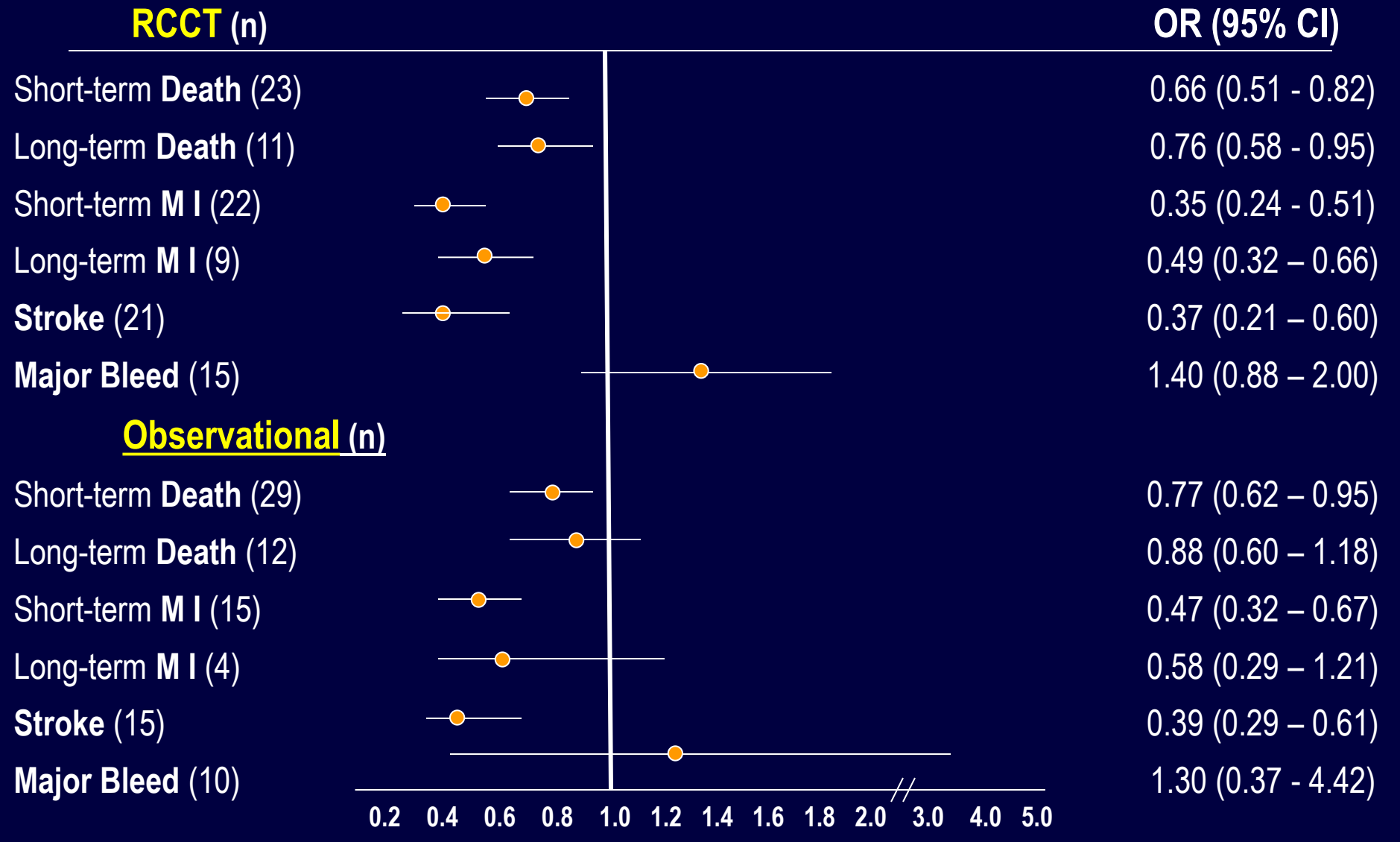
# Dean J. Kereiakes, MD – Disclosure Information

***Consulting fees:***

- **Modest**: Medpace, HCRI, Ablative Solutions, Inc.
- **Significant**: Boston Scientific, Abbott Vascular, REVA Medical Inc.

# Primary PCI vs. Fibrinolytic Therapy: Bayesian Hierarchical Meta-analysis of All Trials




* >*frequent, complete, durable reperfusion*

Huynh, Theroux et al. Circ 2009;119:3101

# Options for Catheter-Based Therapy of STEMI*

- Take the patient to PCI at a regional facility ("heart-attack center")

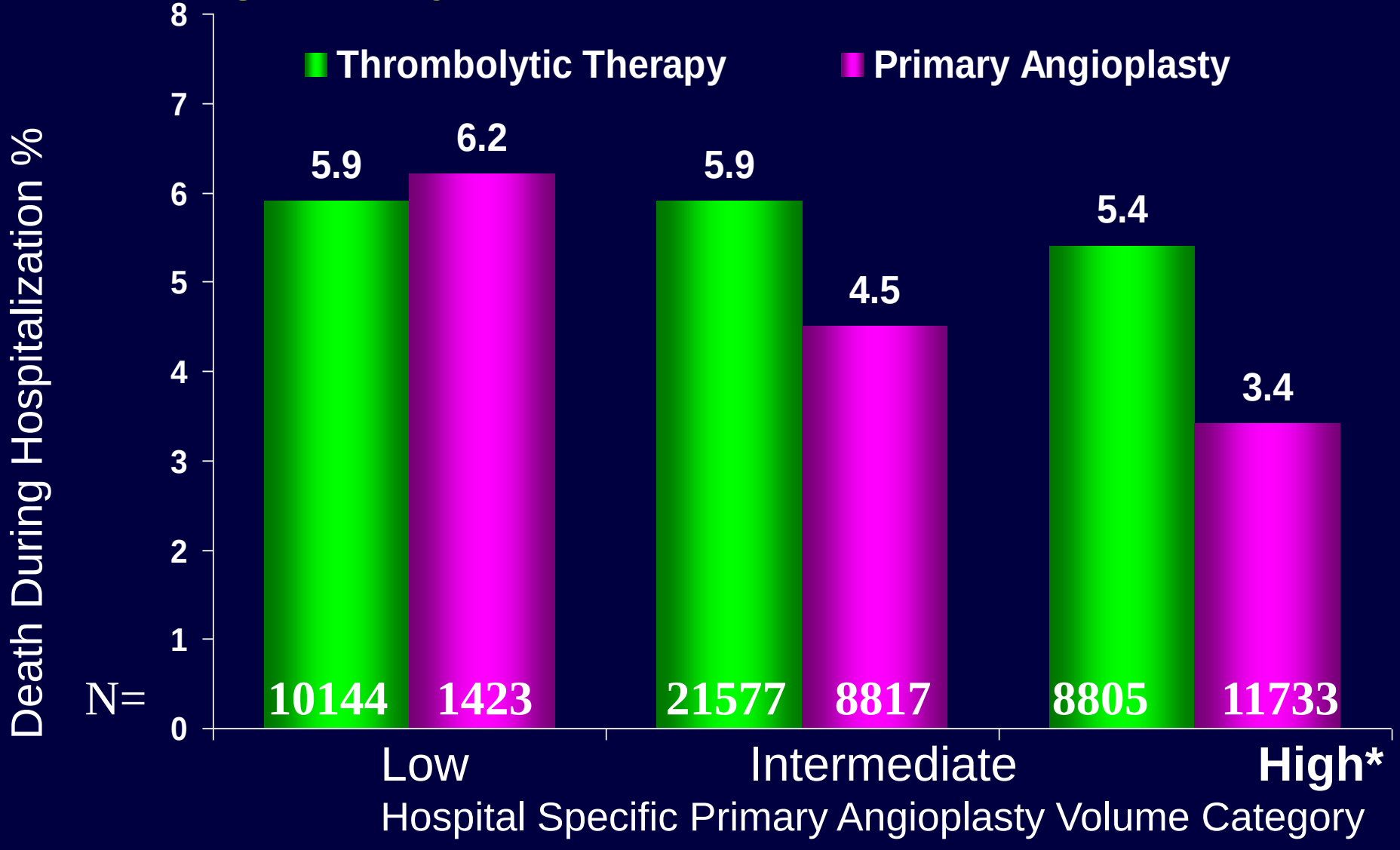
- Take PCI to the patient at a smaller community hospital

***PPCI preferred Rx ACC/AHA/SCAI Guidelines; Ohio 67/157(43%) acute care/critical access hospitals with ER's report D2B to CMS (~39% nationally)**

# "Truths" in Medicine Which Apply to PPCI for STEMI and Elective PCI

- Volume drives proficiency and efficiency: " practice makes perfect"
- Resources in medicine are limited (specialized nurses, doctors, equipment, etc.)
- Regionalization facilitates guideline adherence ,QI monitoring and access to advanced technologies / expertise (M.D. and staff)
- C-PORT PPCI was not definitive (prematurely terminated,underpowered pilot trial with ?outcomes and statistical methods) ;C-PORT E and MASS COMM have not fulfilled the promise of increased access to cost-efficient, quality PCI

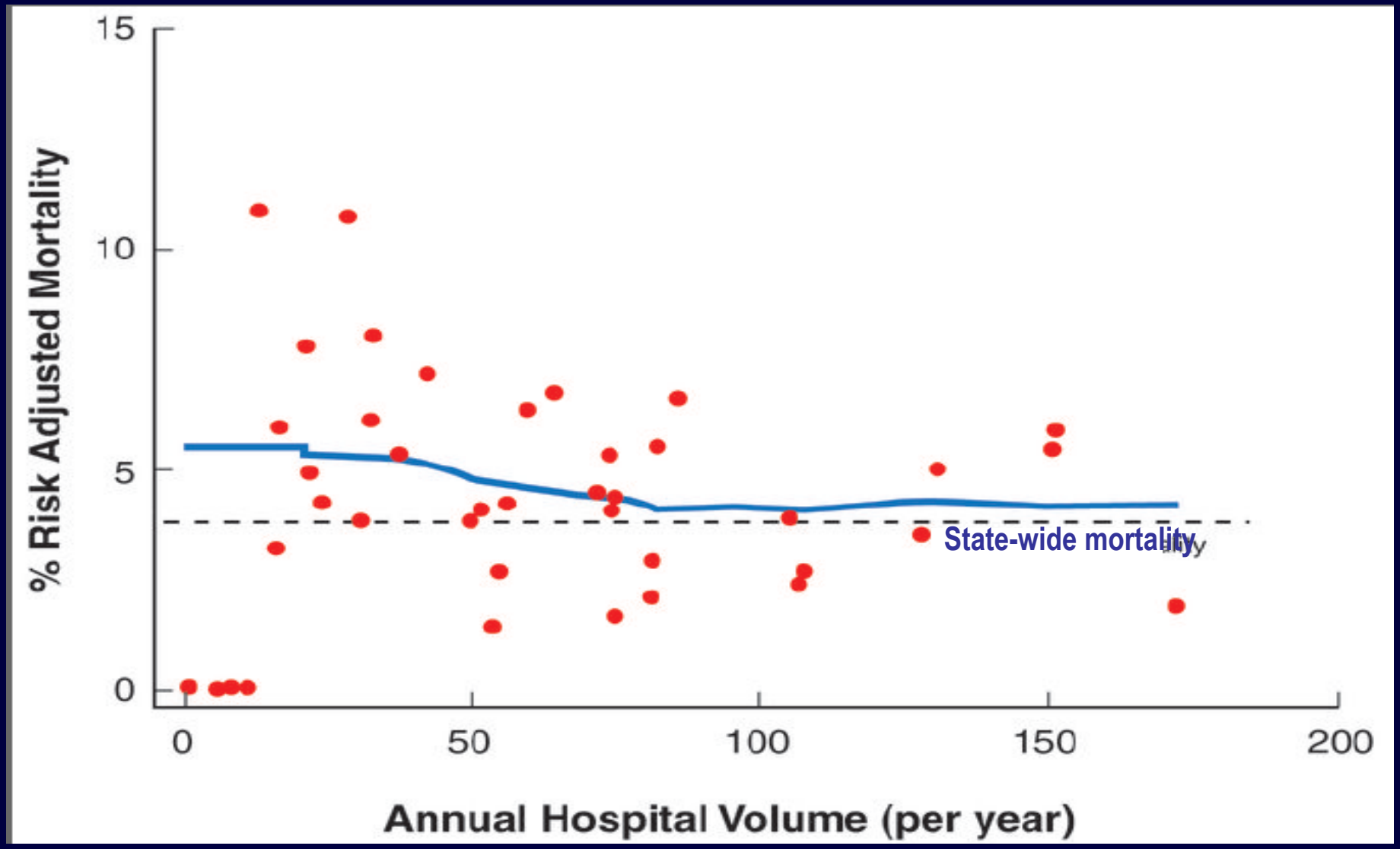
# Hospital Mortality Stratified by Hospital Primary Angioplasty Volumes[1]: NRMI Database




*Low ≤16, Intermediate 17-48, High ≥49/PCI/yr

[1]Magid, Barron et al. JAMA 2000;284:3131

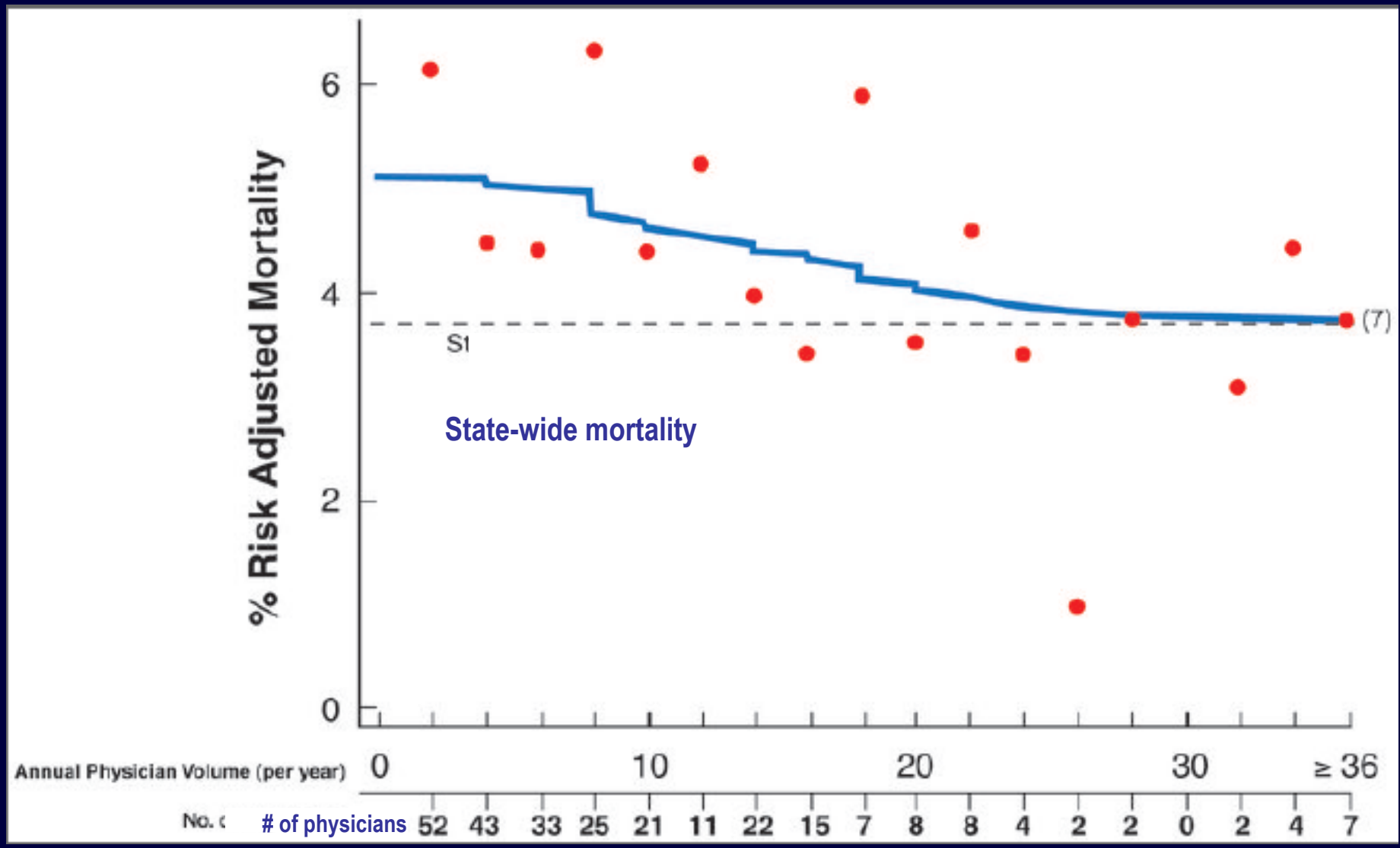
# Relationship of Hospital Primary PCI Volume and Hospital Mortality: New York State Database*




** 7,321 patients 2000-2002*

Srinivas et al. JACC 2009 ;53:574

# Relationship of Operator Primary PCI Volume and Hospital Mortality: New York State Database*

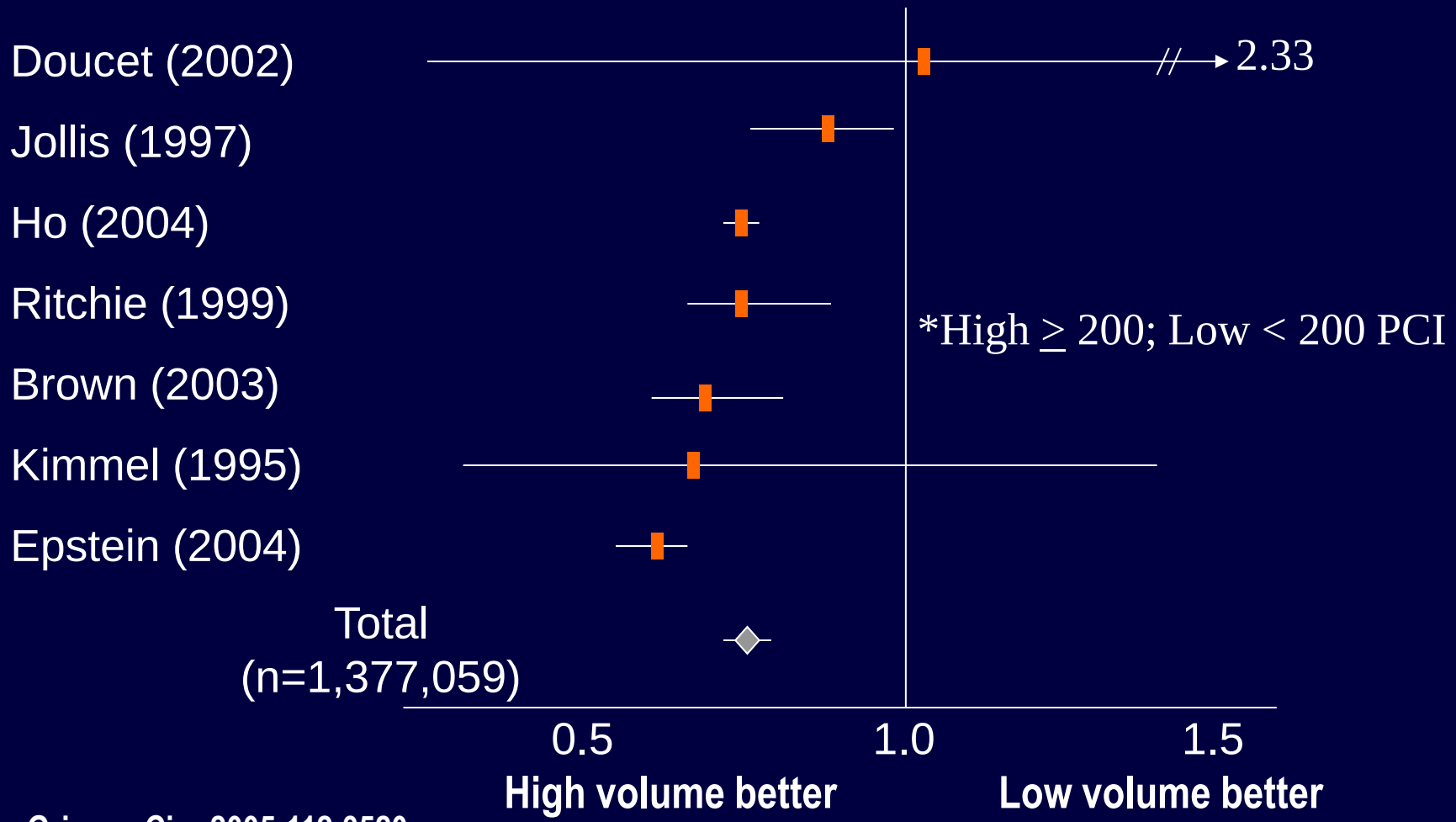



** 7,321 patients 2000-2002*

Srinivas et al. JACC 2009 ;53:574

# PCI Outcomes by Institutional Volume* of PCI

In Hospital Death:




Keeley, Grines Circ 2005;112:3520

MINI-REVIEW:
EXPERT OPINIONS

# Cardiovascular Manpower

## The Looming Crisis

Robert O. Bonow, MD; Sidney C. Smith, Jr, MD

USA WEEKEND

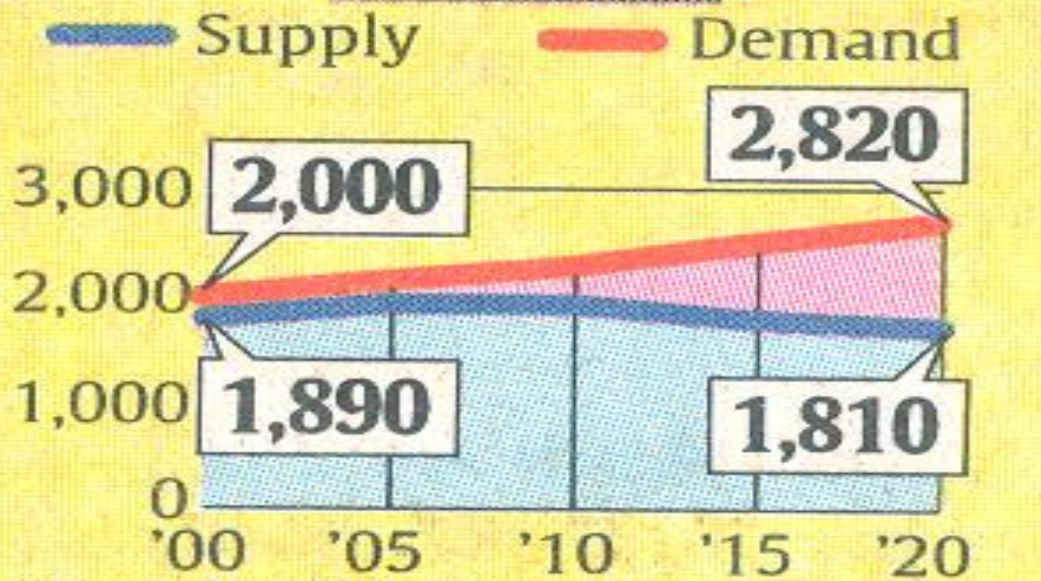
ALSO INSIDE:
DICK VITALE ON MAKING A DIFFERENCE
JEAN CARPER'S SUPER SALAD
JAZZ UP YOUR BACK YARD

# CRISIS in WHITE

A nursing shortage is quickly transforming round-the-clock hospital care into a fantasy of the past. Here's what you need to know to protect your loved ones.

# Nurses wanted

The supply and demand for full-time registered nurses (in thousands):




Note: 2010, 2015, 2020 numbers projected
Source: American Hospital Association

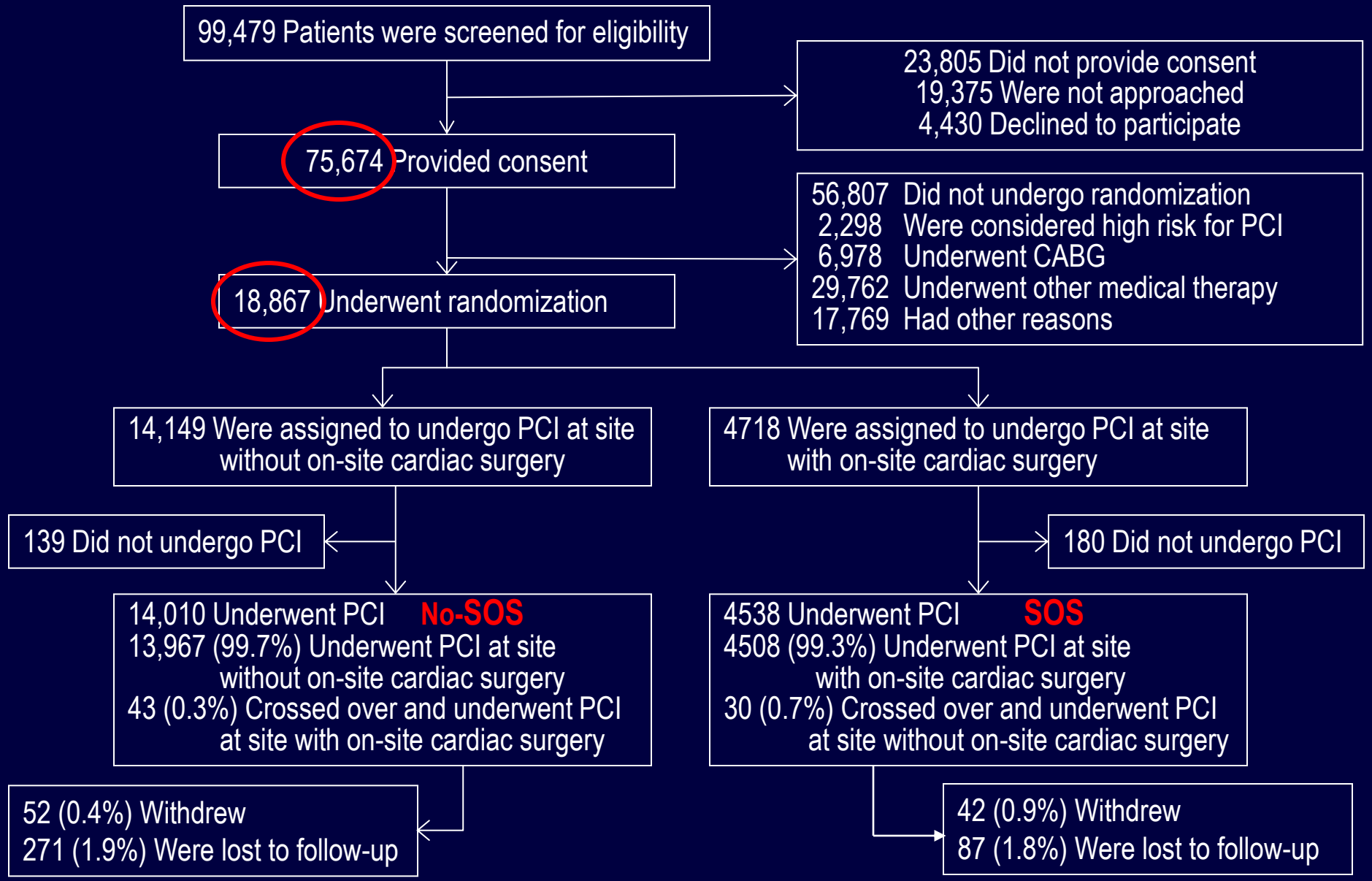
# THE CINCINNATI ENQUIRER

SATURDAY, MARCH 24, 2007

## Nursing shortage: Local hospitals recruit overseas

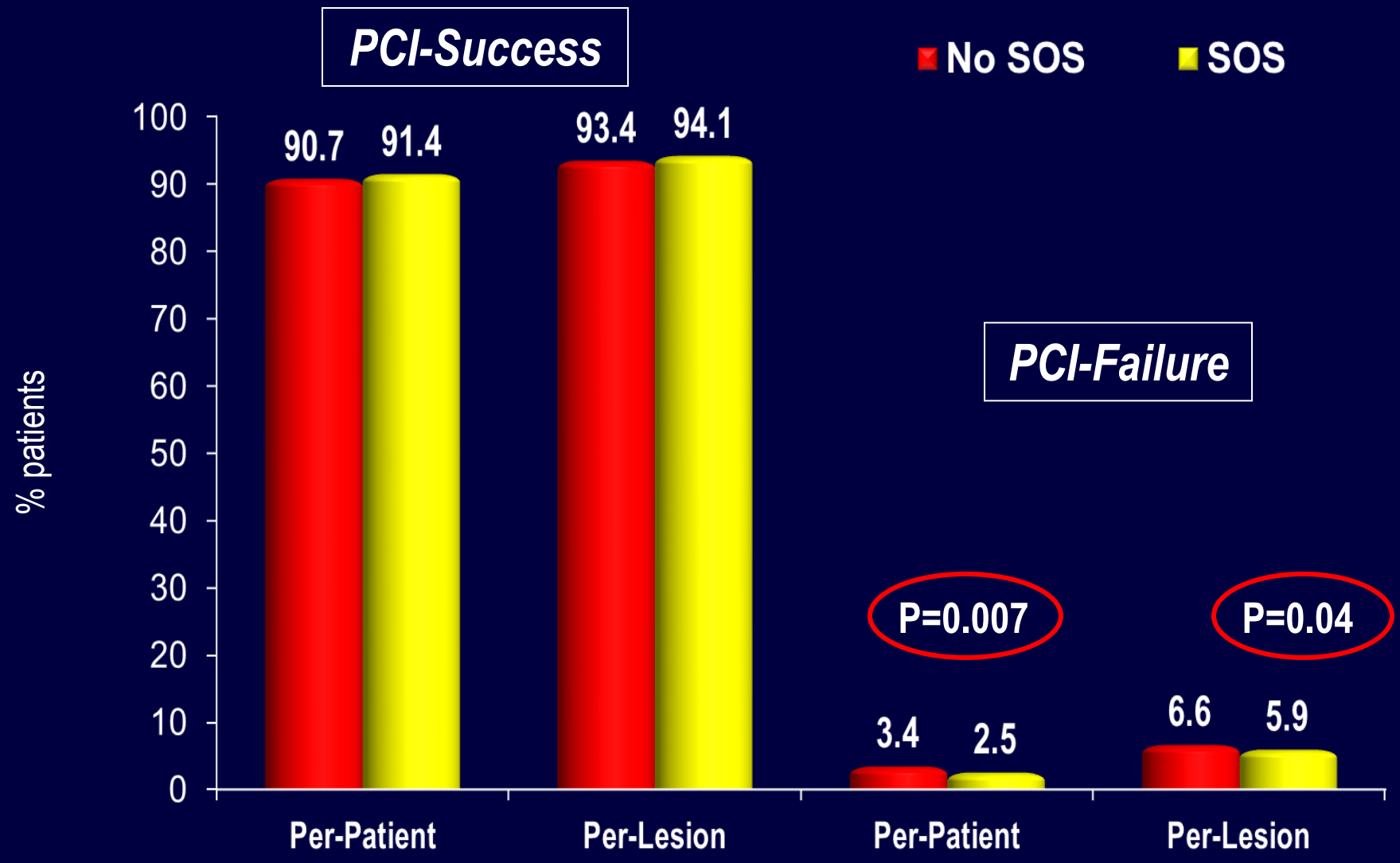
**“Monthly pay here can top a year’s in Philippines”**

# C-PORT E: Enrollment And Randomization



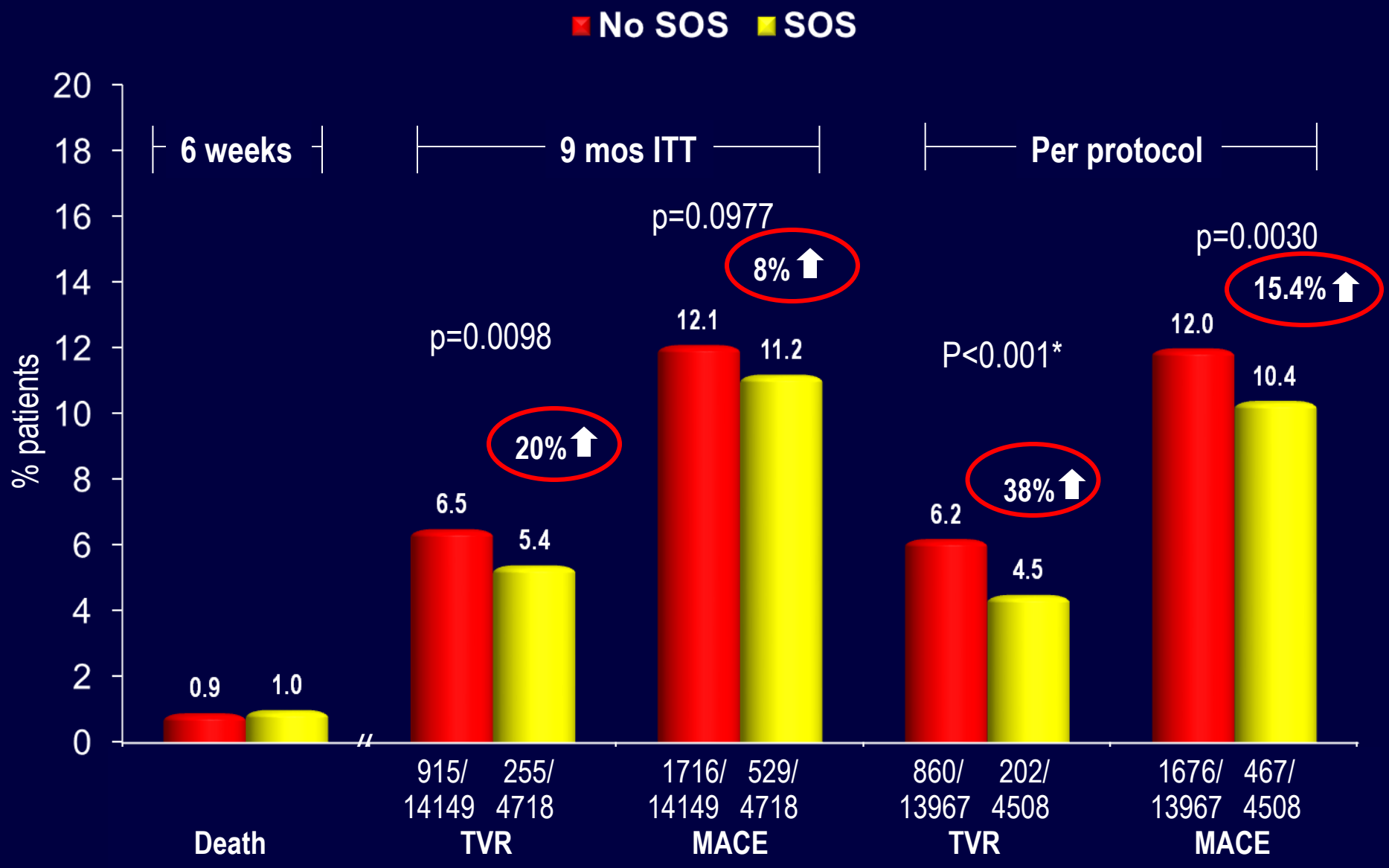

Aversano et al. N Engl J Med 2012;366:1792-1802

# C-PORT E: Procedural Success




Adapted from Aversano et al. N Engl J Med 2012;366:1792-1802

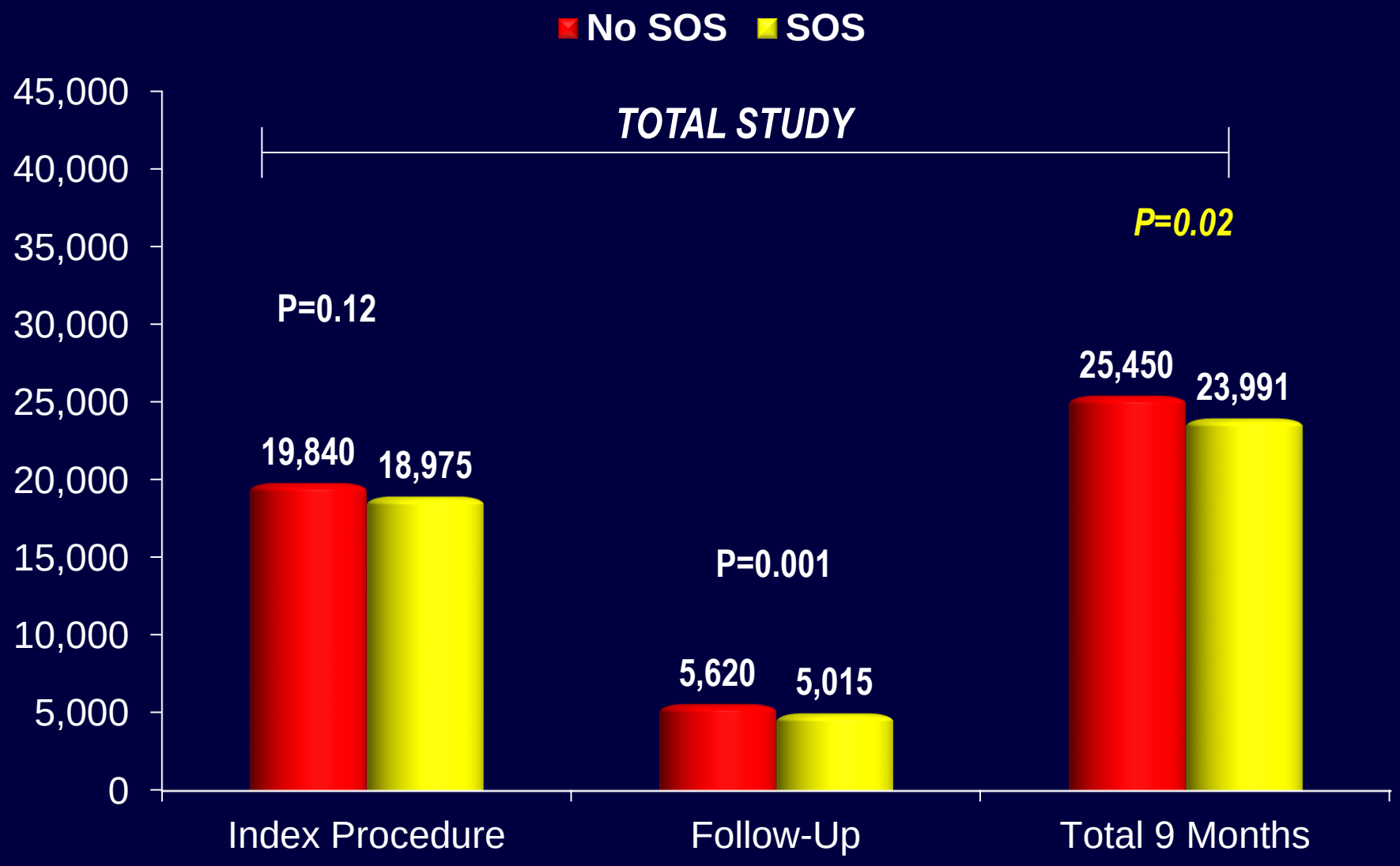
# C-PORT E: Clinical Outcomes




*Chi-squared analysis

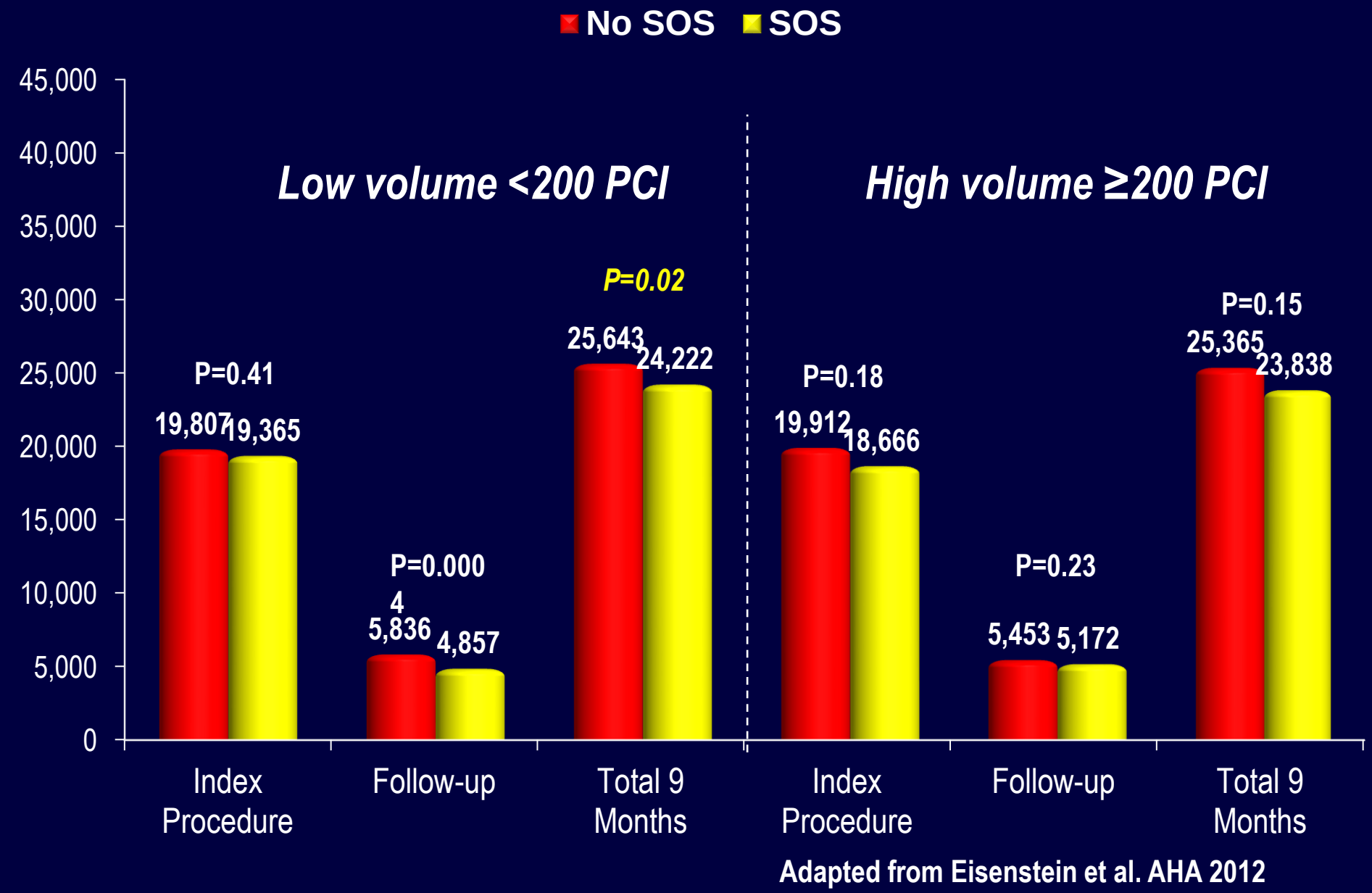
Adapted from Aversano et al. N Engl J Med 2012;366:1792-1802

# C-PORT E: Cost-Effectiveness



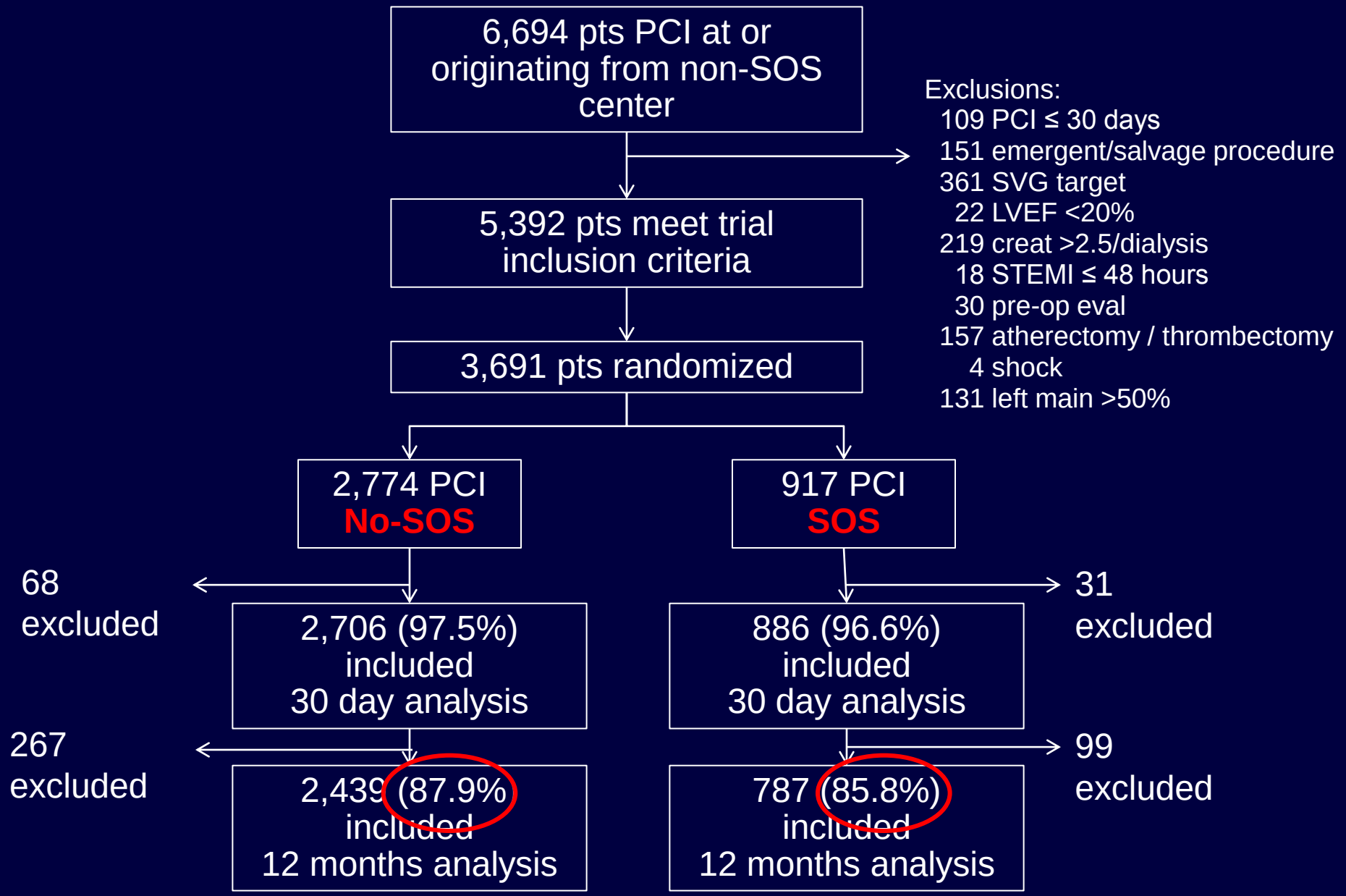

Adapted from Eisenstein et al. AHA 2012

# C-PORT E: Cost-Effectiveness



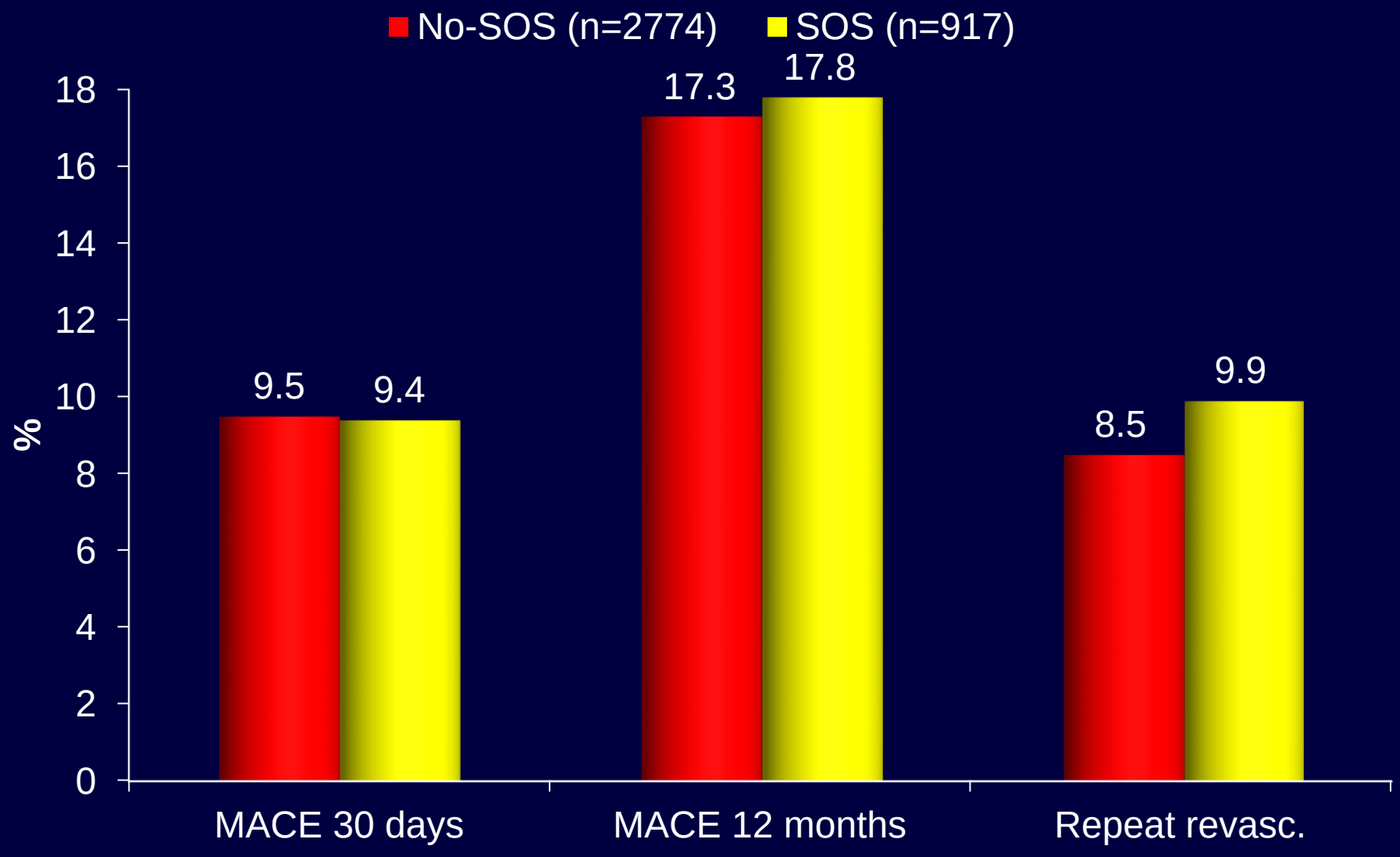

Adapted from Eisenstein et al. AHA 2012

# MASS COMM Patient Flow




Adapted from Jacobs et al. N Engl J Med 2013; Mar 11 [E-pub ahead of print]

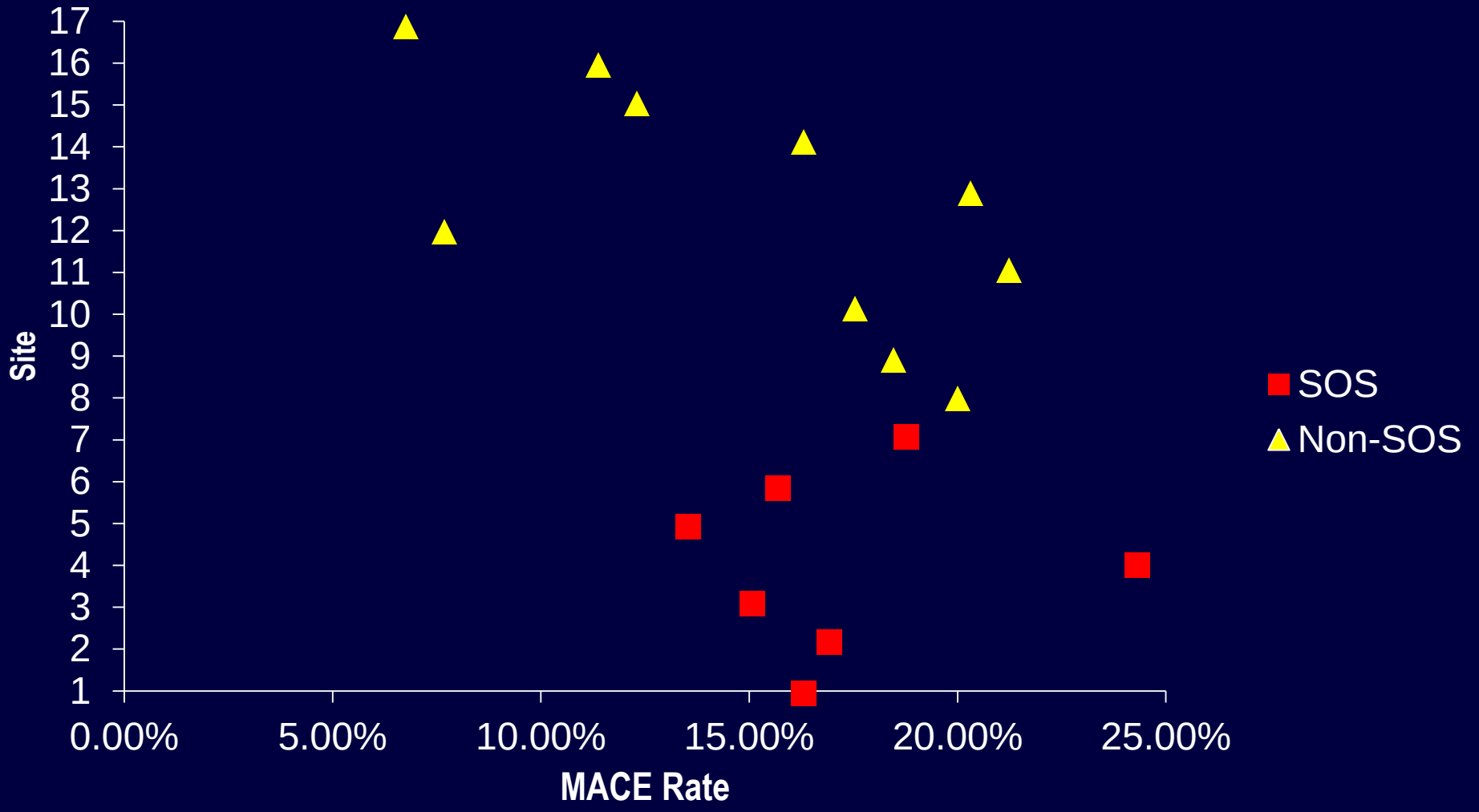
# Primary Endpoint Events: MASS COMM




Jacobs et al. New Engl J Med 2013;Mar 11 [E-pub ahead of print]

# Non-Emergency PCI At Hospitals With And Without On-Site Cardiac Surgery: MASS COMM

## 12-month MACE by Site




*Absolute between site variance of 17%

Jacobs et al. NEJM 2013 (pre-pub)

# Average Annual Operator Total PCI Procedural Volume 2006-2011: MASS-COMM Operators

| Operator category | 2006 Mean (min,max) | 2007 Mean (min,max) | 2008 Mean (min,max) | 2009 Mean (min,max) | 2010 Mean (min,max) | 2011* Mean (min,max) | *Average annual volume* |
|---|---|---|---|---|---|---|---|
| **SOS Only** (n=34 all yrs) | 143.5 (51, 269) | 122.6 (11, 274) | 118.0 (5, 212) | 105.4 (28,185) | 102.3 (18,181) | 103.9 (11, 176) | ***116.0*** |
| ***# by yr*** | ***29*** | ***32*** | ***33*** | ***33*** | ***32*** | ***32*** | |
| **SOS plus Non-SOS** (n=34) | 130.2 (11, 256) | 116.0 (10, 235) | 105.0 (6, 217) | 109.4 (1, 257) | 105.1 (5, 305) | 118.8 (48, 359) | ***112.9*** |
| ***# by yr*** | ***24*** | ***27*** | ***30*** | ***30*** | ***31*** | ***30*** | |

****~40% reduction in SOS annual operator volumes during course of study (vs. 9% no-SOS plus SOS)***

**Jacobs et al. NEJM 2013 (pre-pub; Supplemental Appendix Table S2)**

# Adjudicated Procedural Characteristics In The Angiographic Review Cohort: MASS COMM

| Characteristic | PCI at no-SOS hospitals without on-site cardiac surgery (n=289 pts and 392 lesions) | PCI at SOS hospitals with on-site cardiac surgery (n=87 pts and 106 lesions) | Relative Risk (95% CI) | P Value |
|---|---|---|---|---|
| Successful treatment of lesion – # of lesions (%) (per lesion) | 366 / 383 (95.6) | 102 / 105 (97.1) | 0.98 (0.95-1.02) | 0.59 |
| Procedural success – # of pts (%) (per pt) | 235 / 289 (81.3) | 65 / 87 (74.7) | 1.09 (0.95-1.24) | 0.22 |
| Complete revascularization – no. of pts (%) | 174 / 289 (60.2) | 52 / 87 (59.8) | 1.01 (0.83-1.23) | 1.00 |
| Met indication criteria for PCI – no. of lesions (%) | 369 / 392 (94.1) | 97 / 106 (91.5) | 1.03 (0.97-1.10) | 0.37 |

Jacobs et al. N Engl J Med 2013; Mar 11 [E-pub ahead of print]

# Procedural Success Percentages

**MASS-COMM**
**SOS hospitals**

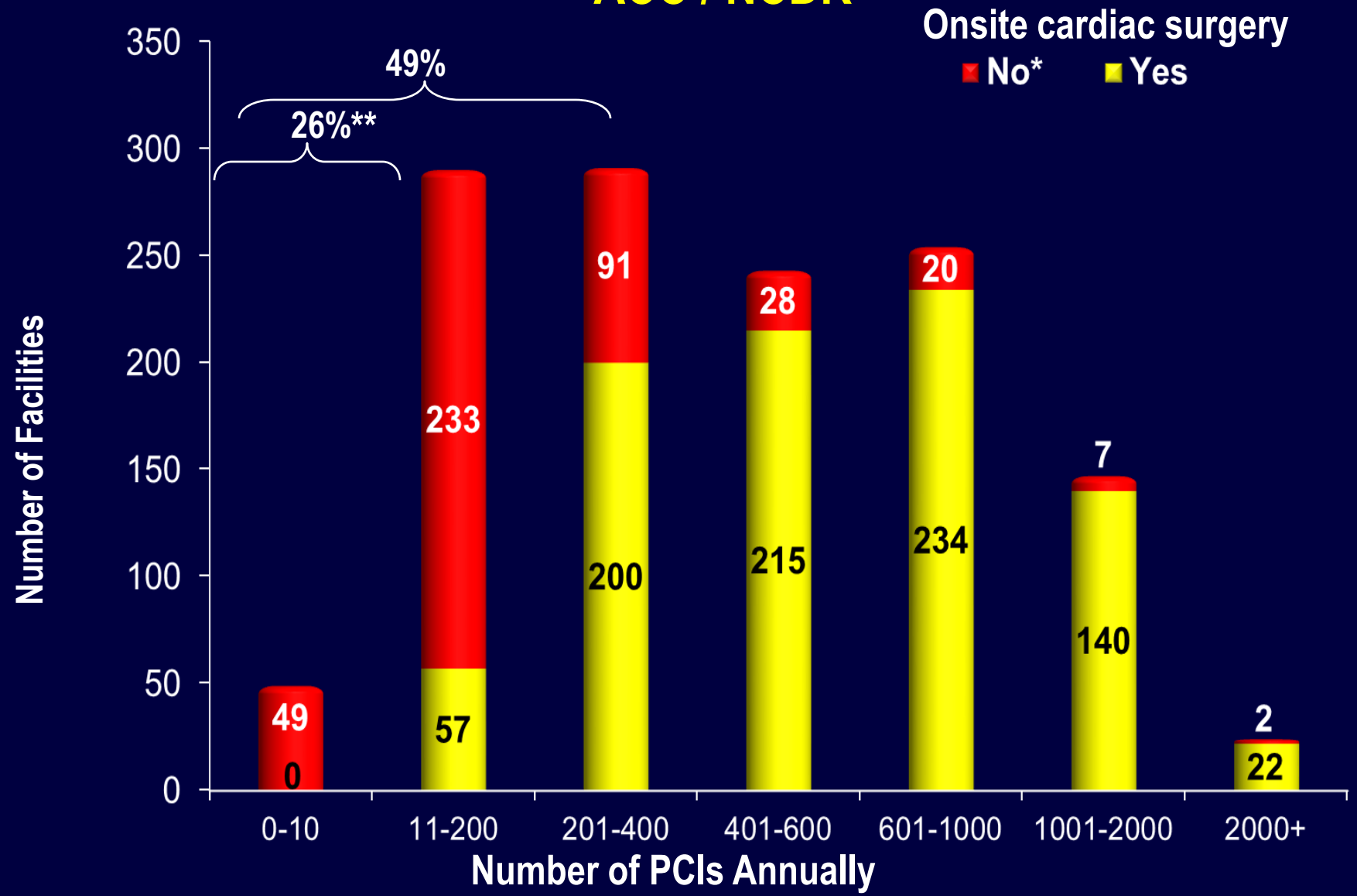
ACC-NCDR®

CathPCI Registry™

**Percentile Rankings**

| **75** | **97** | **98.3** | **98.9** | **99.4** | **99.7** | **100** |
|---|---|---|---|---|---|---|
| Per patient | Per lesion success | 10th | 25th | 50th | 75th | 90t |

# PCI Volume at Facilities With and Without On-Site Cardiac Surgery
## ACC / NCDR




*89% of no SOS centers ≤ 400 cases/year

** 83% of centers < 200 cases/year are no SOS

Dehmer et al. JACC 2012 (epub)

EDITORIAL COMMENT

# Public Reporting in Interventional Cardiology

## The Challenges Ahead*

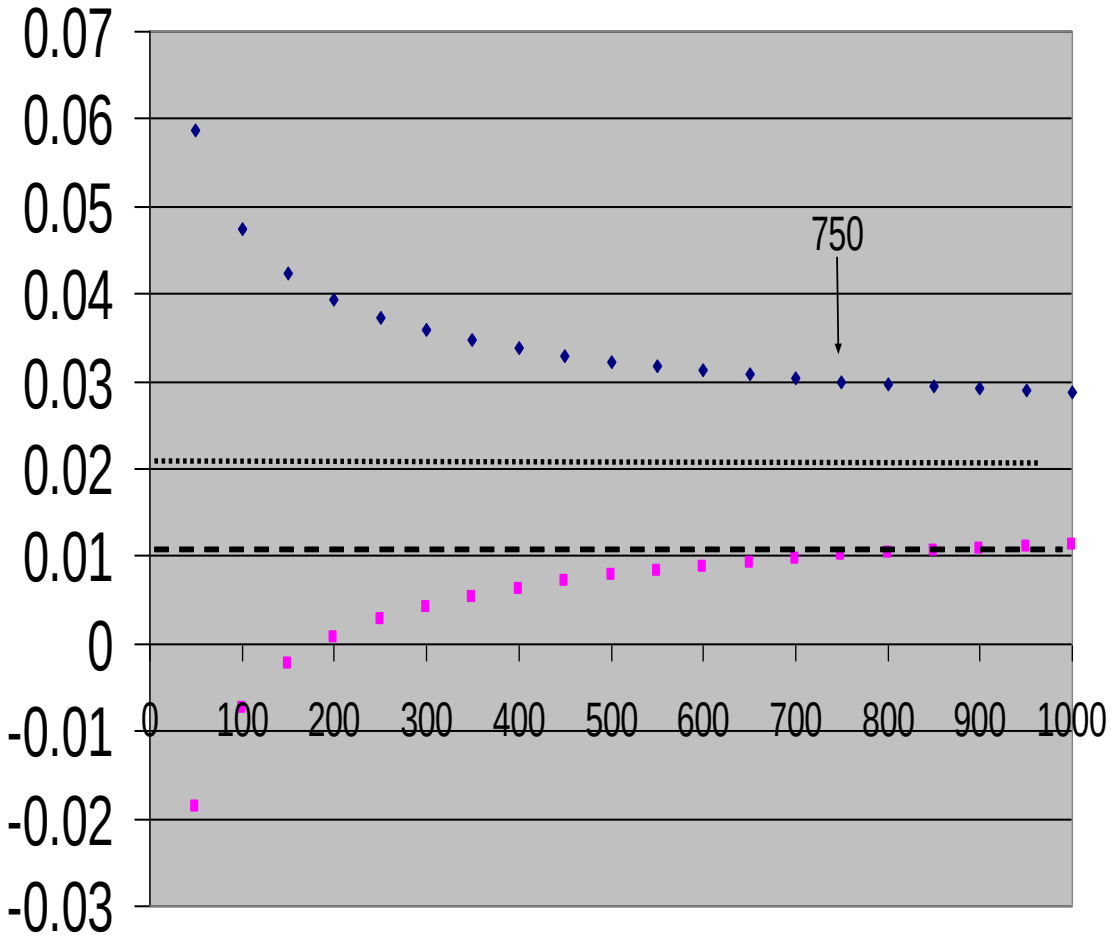
Gregory J. Dehmer, MD

*Temple, Texas*

"Assume the average state PCI mortality is 1%, but in a given year, an individual hospital has a mortality of 2%. At a facility volume of 400 cases annually and using a 95% confidence interval, it would take just about 2 years of data at 2% mortality to be certain the increase was significant rather than variation; at a facility volume of 200 PCIs annually, it would take almost 4 years to be certain. Therefore, as PCI volumes decrease, using a hospital's risk-adjusted mortality as the sole measure of quality is problematic."

Dehmer GJ. JACC Card Int 2013;6:631-633

# Another Volume Outcome Relationship




| Annual Volume | Years |
|---|---|
| 50 | 15.00 |
| 100 | 7.50 |
| 150 | 5.00 |
| 200 | 3.75 |
| 250 | 3.00 |
| 300 | 2.50 |
| 350 | 2.14 |
| 400 | 1.88 |
| 450 | 1.67 |
| 500 | 1.50 |
| 550 | 1.36 |
| 600 | 1.25 |
| 650 | 1.15 |
| 700 | 1.07 |
| 750 | 1.00 |

Statewide Mortality = 1%

Site Mortality = 2%

Aversano, T. ODH meeting, 12/12/12

# Total PCI Volumes by Year: Ohio Waiver Hospitals*

| | 2011 | 2012 |
|---|---|---|
| Knox CH | 338 | 361 |
| CH Williams County | 137 | 136 |
| Fort Hamilton Hughes | 117 | 130 |
| Marietta Memorial | 214 | 235 |
| Licking Memorial | 181 | 240 |
| OSU East | 14 | 67 |
| West Chester | 120 | 115 |
| UH Geauga | 53 | 135 |
| Southview M.C. | 80 | 120 |
| Mt. Carmel St. Ann's | 279 | 254 |

*Data provided by Ohio Department of Health 2/7/13

Catheterization and Cardiovascular Interventions 82:E69–E111 (2013)

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

**WRITING COMMITTEE MEMBERS**

**John G. Harold**, MD, MACC, FAHA, Chair, **Theodore A. Bass**, MD, FACC, FSCAI, Vice Chair, **Thomas M. Bashore**, MD, FACC, FAHA, FSCAI, **Ralph G. Brindis**, MD, MPH, MACC, FSCAI, **John E. Brush Jr**, MD, FACC, **James A. Burke**, MD, PhD, FACC, **Gregory J. Dehmer**, MD, FACC, FAHA, FSCAI, **Yuri A, Deychak**, MD, FACC, **Hani Jneid**, MD, FACC, FAHA, FSCAI, **James G. Jolliss**, MD, FACC, **Joel S. Landzberg**, MD, FACC, **Glenn N. Levine**, MD, FACC, FAHA, **James B. McClurken**, MD, FACC, **John C. Messenger**, MD, FACC, FSCAI, **Issam D. Moussa**, MD, FACC, FAHA, FSCAI, **J. Brent Muhlestein**, MD, FACC, **Richard M. Pomerantz**, MD, FACC, FSCAI, **Timothy A. Sanborn**, MD, FACC, FAHA, **Chittur A. Sivaram**, MBBS, FACC, **Christopher J. White**, MD, FACC, FAHA, FSCAI, **Eric S. Williams**, MD, FACC

- *"It is important to note that a signal exists suggesting that an institutional volume threshold <200 PCI/year appears to be consistently associated with worse outcomes across various studies."*
- *"Accordingly, the writing committee recommends that an institution without on-site surgery with a volume fewer than 200 PCI annually, unless in a region underserved because of geography, should strongly consider whether or not it should continue to offer this service."*

Catheterization and Cardiovascular Interventions 82:E69–E111 (2013)

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

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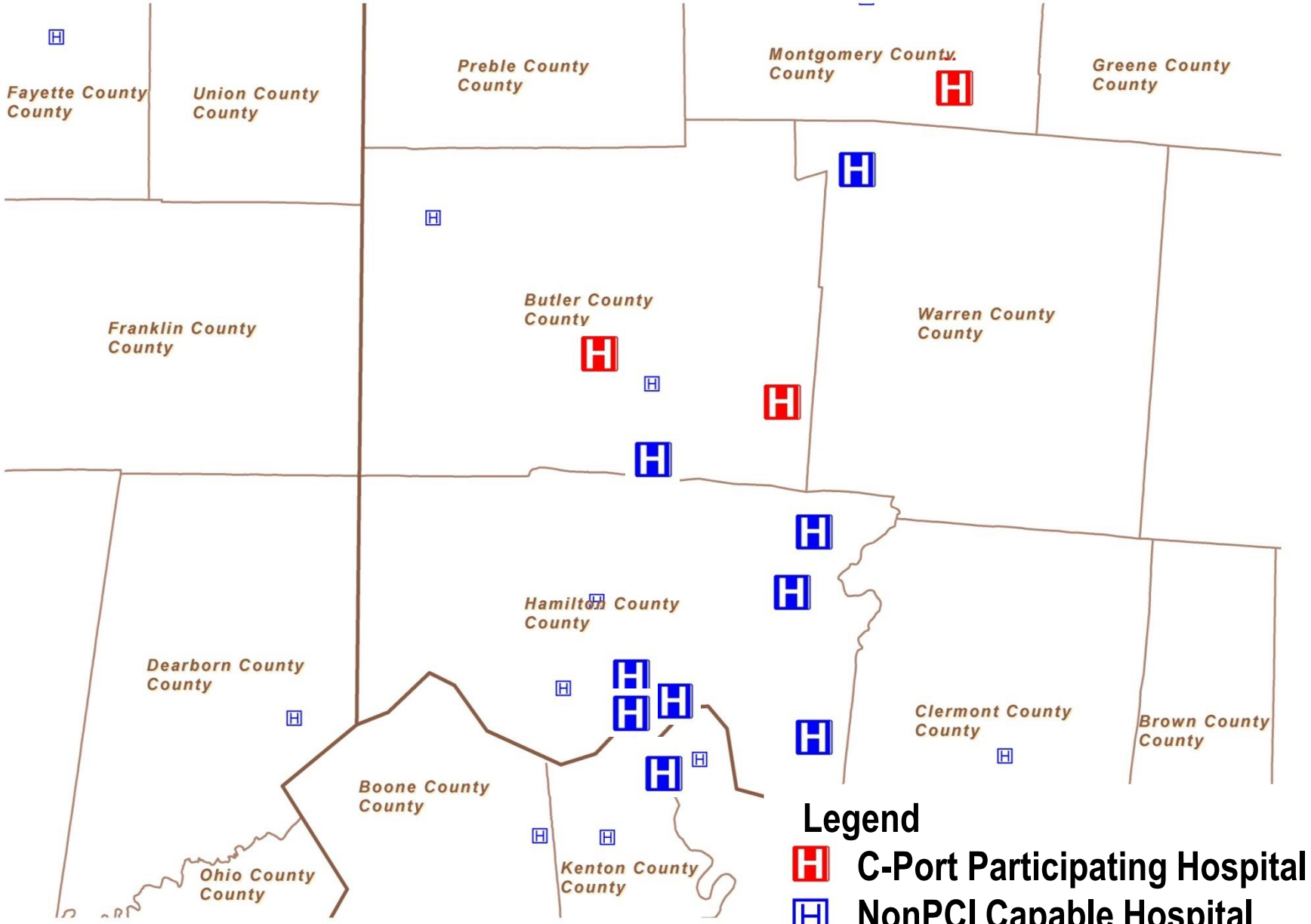
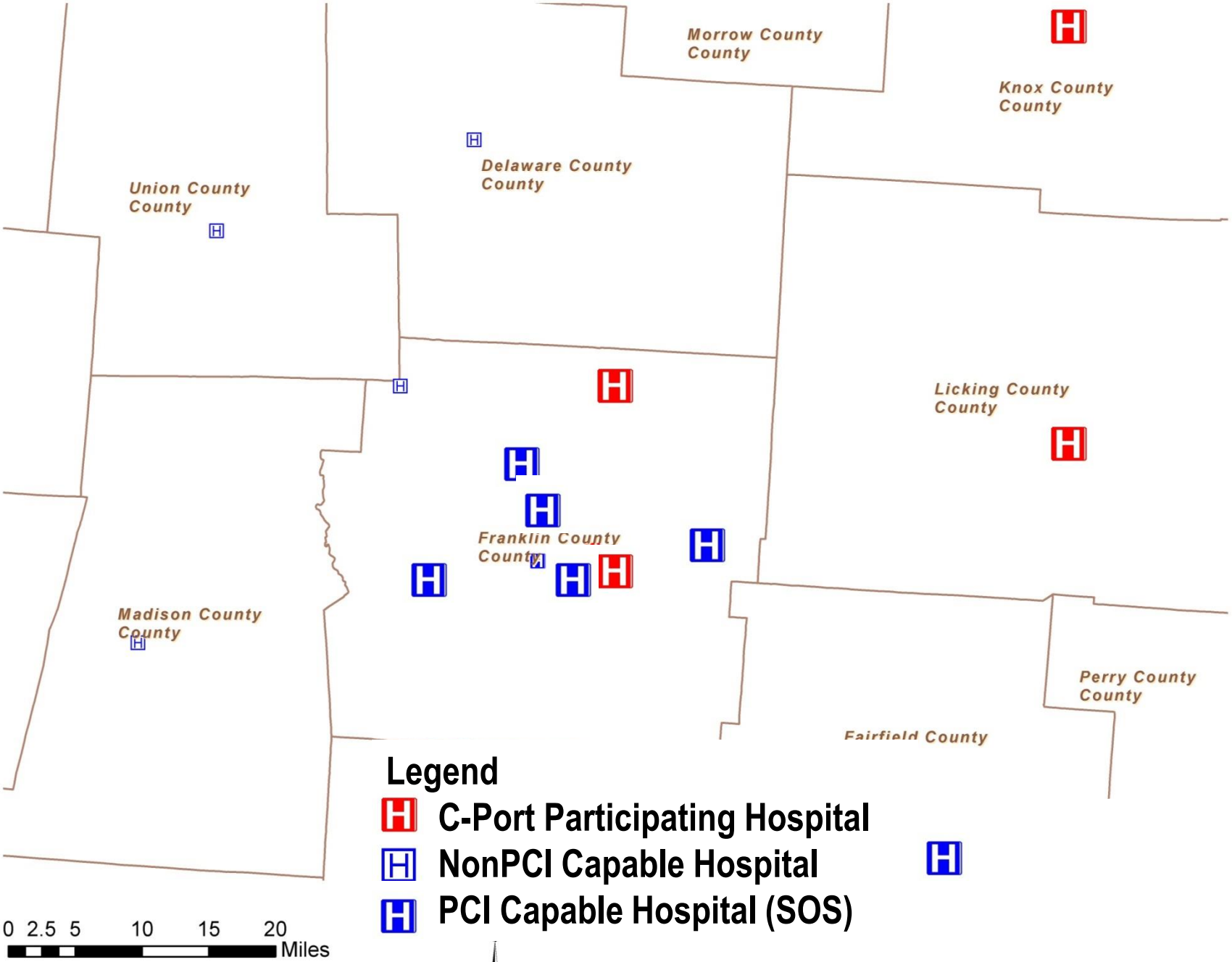
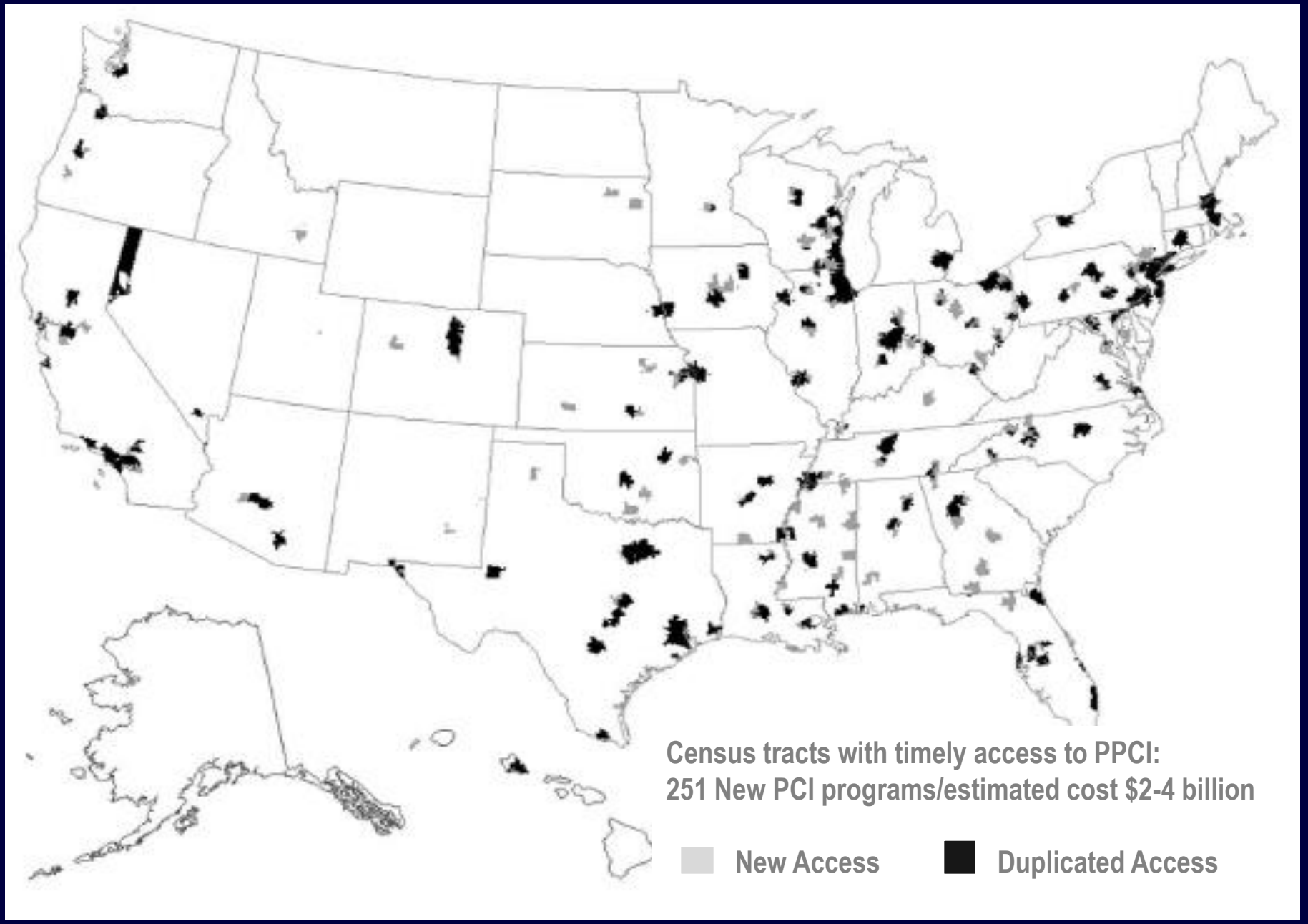
# Access to PPCI in Cincinnati



# Access to PPCI in Columbus



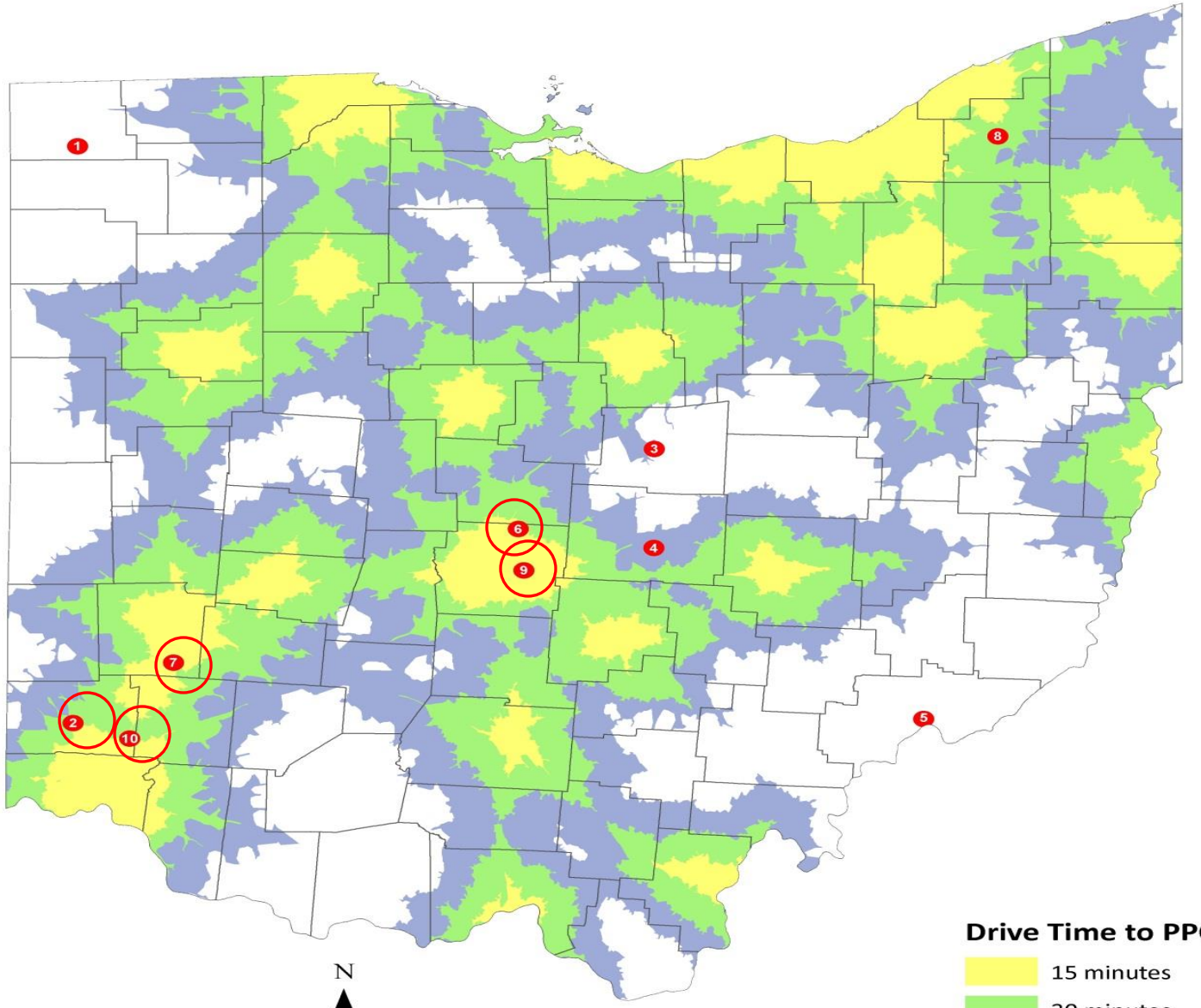
# Systematic Duplication of PCI Services by new PCI Programs : 2004-2008



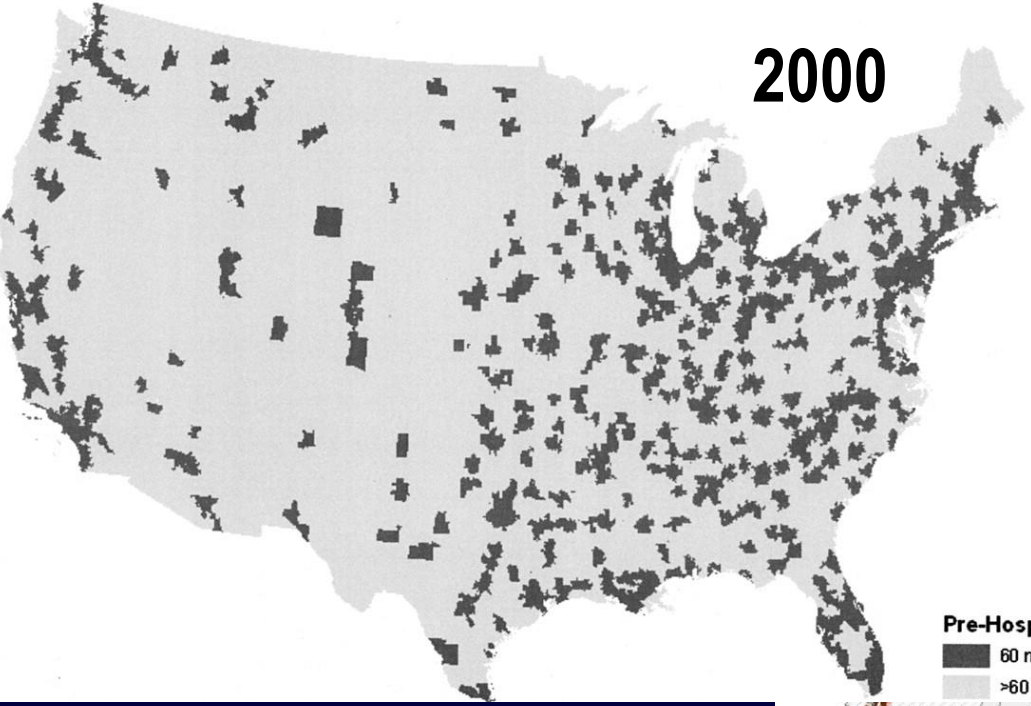

Concannon et al. Circ Card Qual Outcomes 2013;6: E-pub

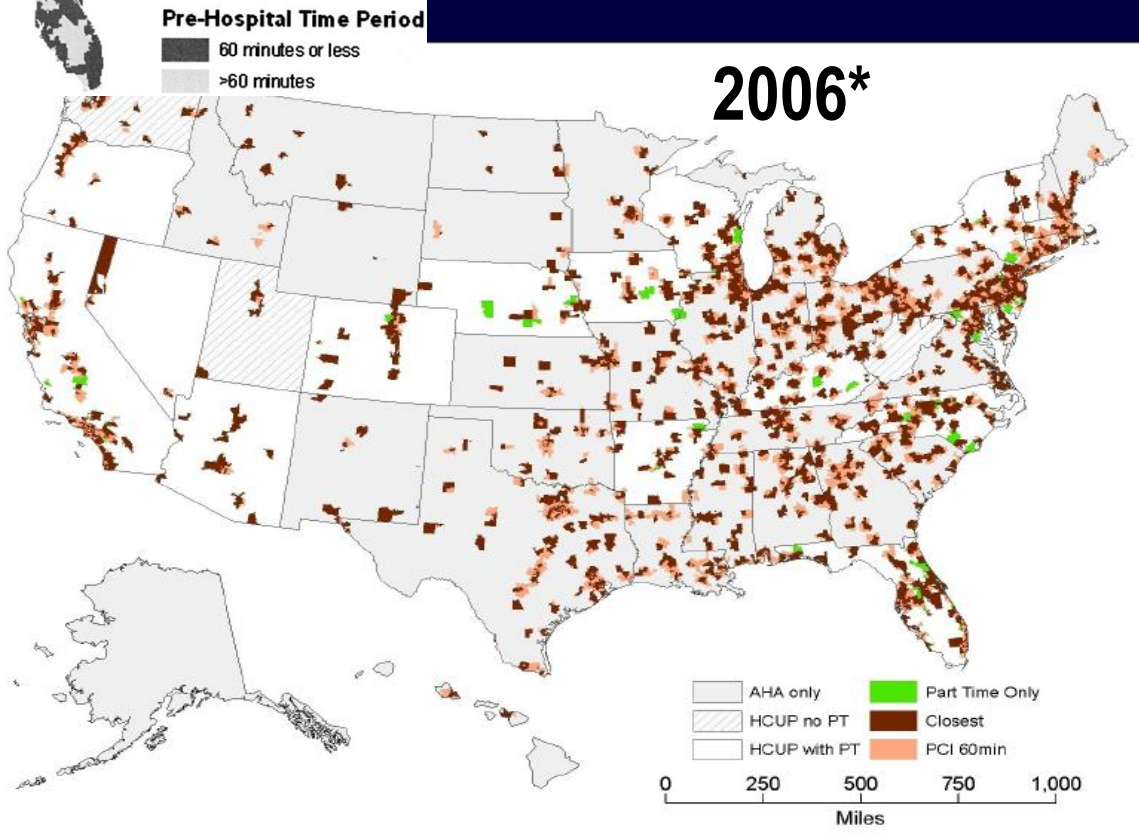
# Ohio CPORT Hospitals
# Drive Time Analysis for PPCI/SOS Hospitals

American Heart Association



# Driving Times and Distances to Hospitals with PCI in the U.S.: Implications for Pre-Hospital STEMI Triage: 2000-2006

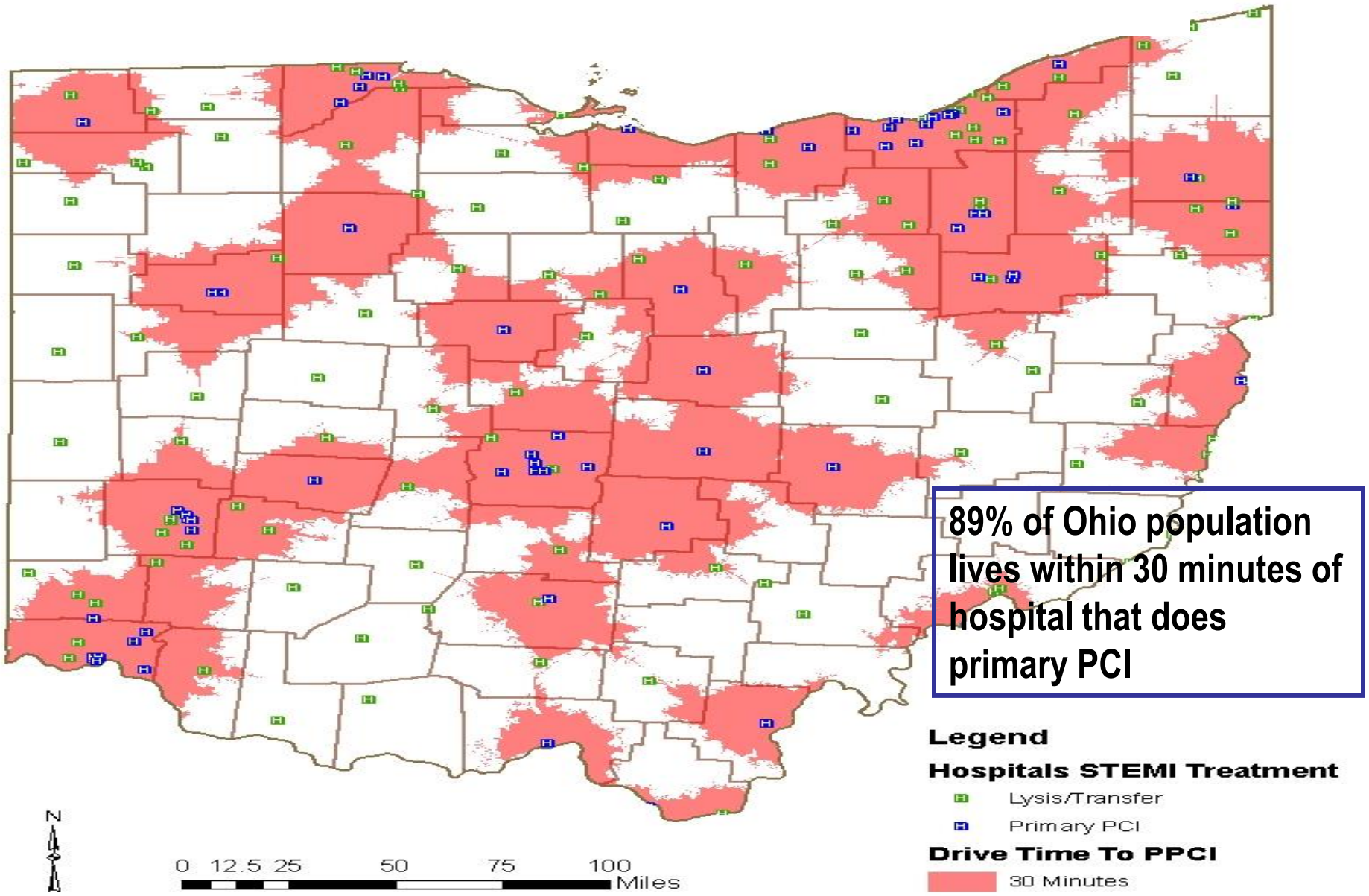



"Nearly 80% of the adult population in the United States lived within 60 minutes of a PCI hospital in 2000"

*44% increase PCI capacity (521 new programs) with 1% increase in access *(79 vs 80% ≤ 60min ground transport)*

Nallamothu et al. Circ 2006;113:1189
Conconnan et al. Circ Cardiovasc Qual Outcomes 2012;5:14-20


89% of Ohio population lives within 30 minutes of hospital that does primary PCI
Legend
Hospitals STEMI Treatment
Lysis/Transfer
Primary PCI
Drive Time To PPCI
30 Minutes
N
0 12.5 25 50 75 100
Miles

# Transportation and Reperfusion Options for STEMI


Call 911, call fast

**Patient sympto m onset of STEMI**

**911 EMS dispatch**

**EMS on-scene**

***Encourage 12-lead ECGs at FMC****

**Consider pre-hospital fibrinolytic if capable and EMS-needle ≤ 30 min**

**EMS Triage plan**

Hospital fibrinolysis: Door-needle ≤ 30 min

**Not PCI capable**

Interhospital transfer

**PCI capable**

**Goals‡**

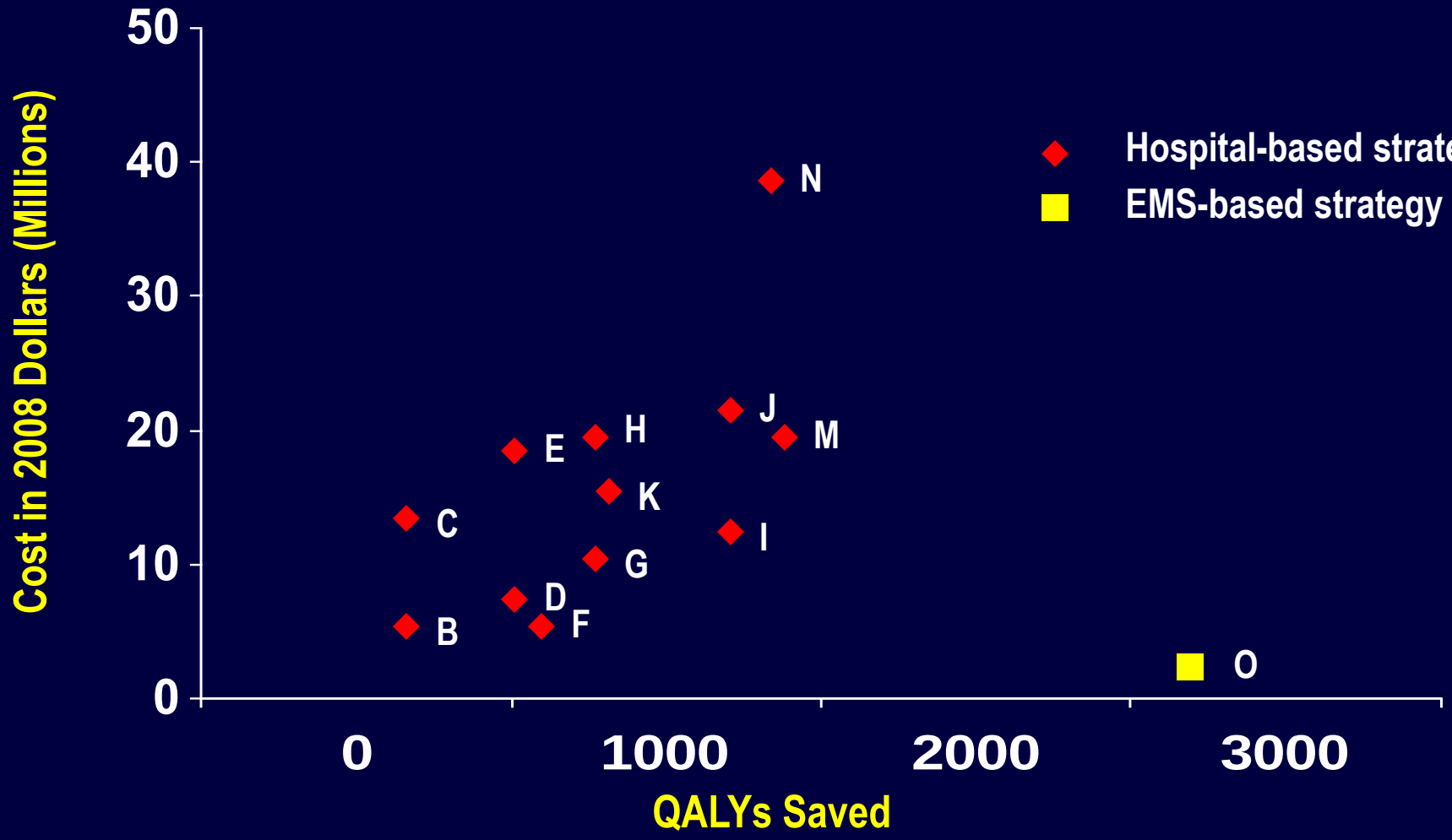
Patient | Dispatch | EMS on scene | EMS transport | **EMS transport: EMS-balloon ≤90 min**

5 min after symptom onset | 1 min | ≤ 8 min | **Pre-hospital fibrinolysis: EMS-needle ≤ 30 min** | Patient self-transport: hospital door-balloon ≤ 90 min

**pre-hospital ECG transmit / NHLBI Consensus document*

*Antman E, in Braunwald, Heart Disease 2005*

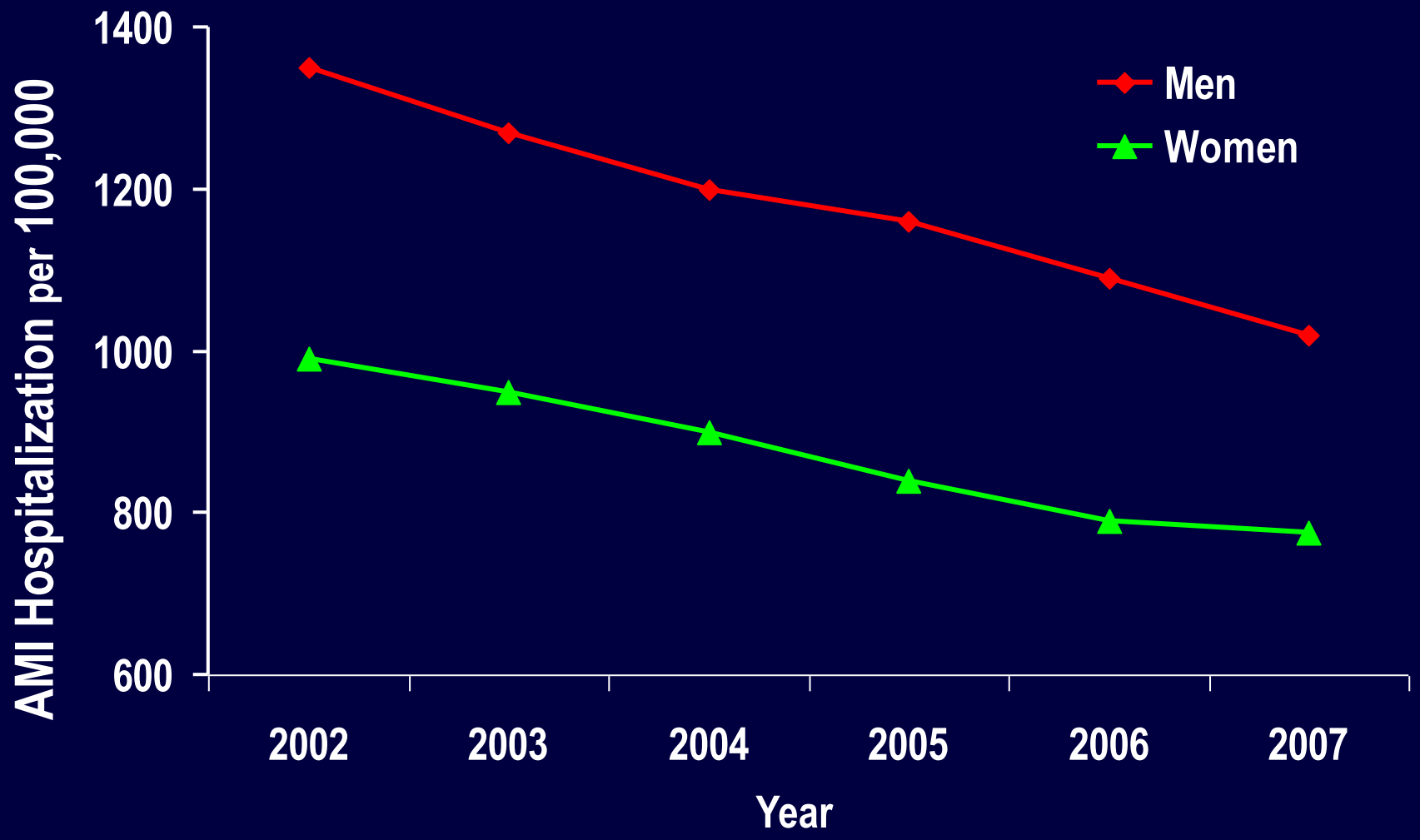
# Comparative Effectiveness of STEMI Regionalization Strategies *




*"build more" vs "use more effectively"
EMS-based= less costly and more effective

Concannon, Aversano et al.
Circ Cardiovasc Qual Outcomes 2010; 3:506-13

# AMI Hospitalization Rate (per 100,000 Beneficiary-Years*) For Men and Women 2002-2007

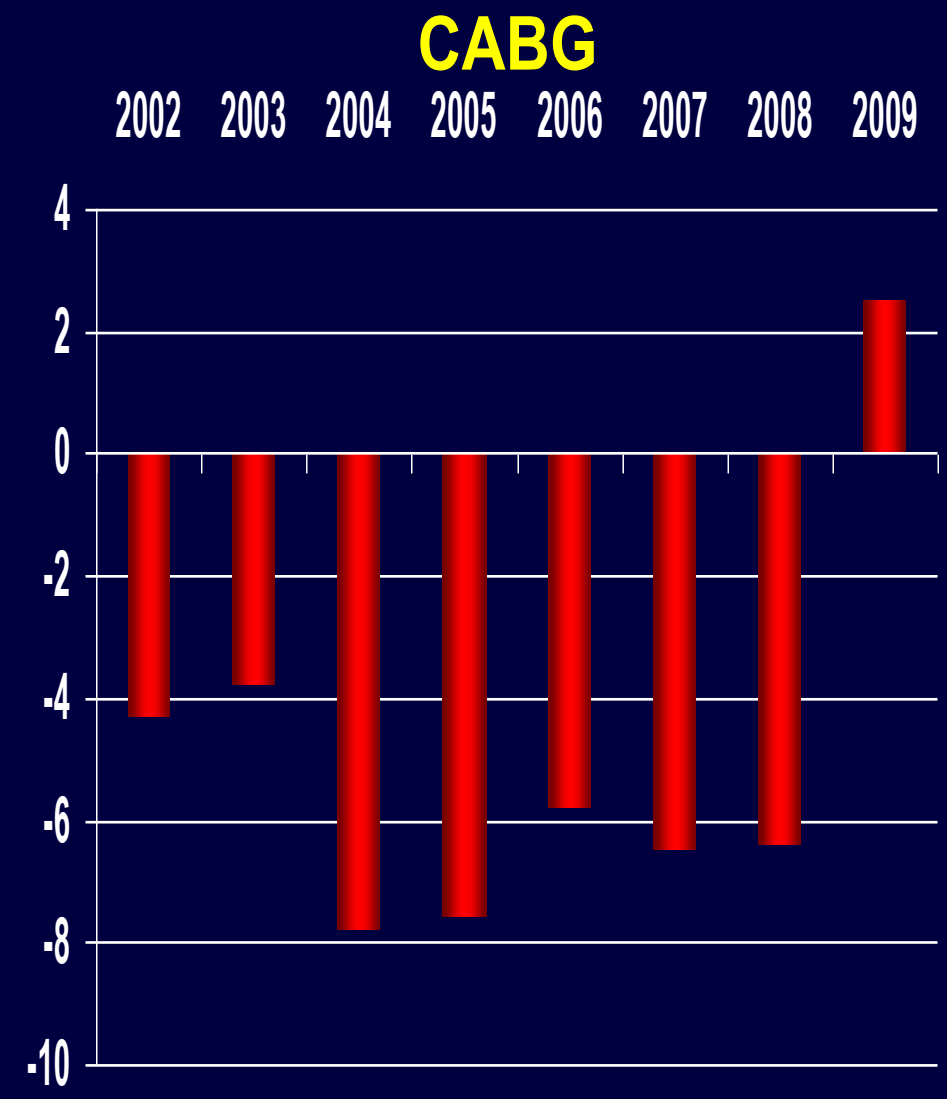


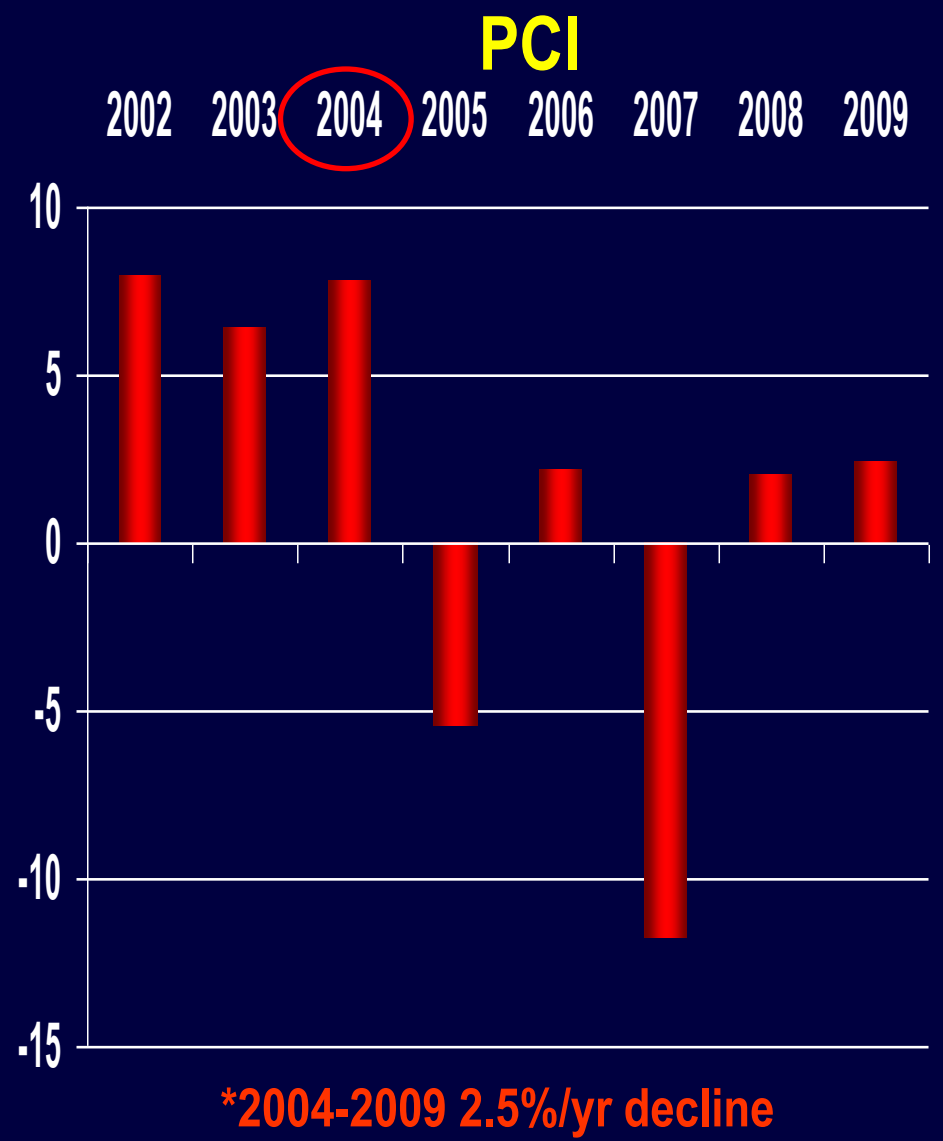

* Medicare Fee-For-Service

Chen et al. Circ 2010;121:1322

# U.S. Coronary Revascularization Trends 2001-2009:

## Year / Year % Change




*2004-2009 2.5%/yr decline

Riley et al. Circ Cardiovasc Qual Outcomes 2011;4:193-7

# Unintended (?) Consequences of no-SOS center proliferation:

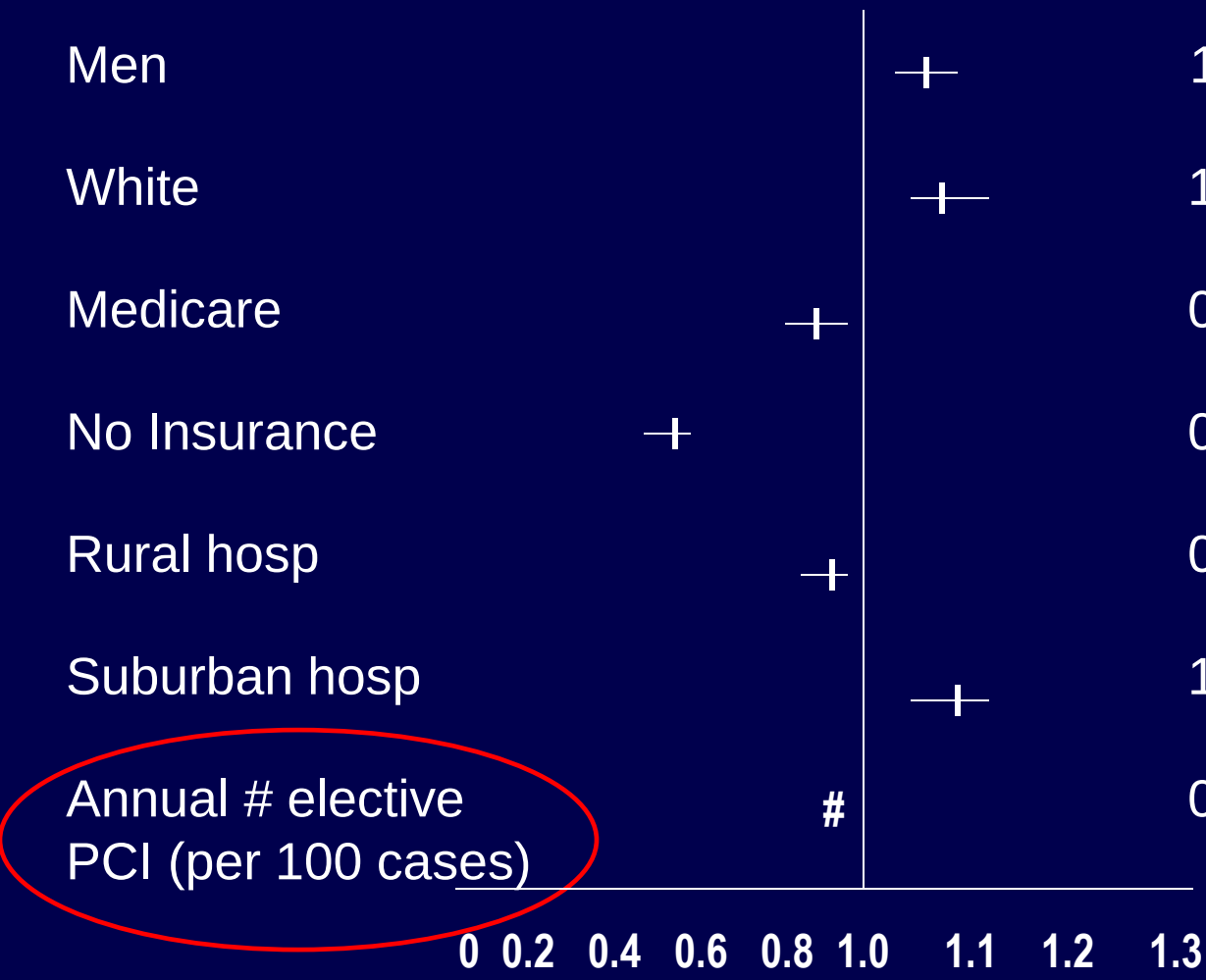
- Promote the performance of unnecessary PCI procedures to justify their existence (Chan et al. JACC 2013)
- Less likely to document objective measures of ischemia and /or lesion severity (FFR,IVUS)
- Geographic disparity in location exaggerates decline in annual per center procedural volumes (MASS-COMM) with consequent adverse clinical outcomes and confounds quality analyses.
- PCI results are no better (CPORT-E and MASS-COMM "not inferior" hypothesis: PCI success less / repeat revascularization more) and cost appears to be greater!

- Who benefits from this?

# Conclusions

- **Volume drives proficiency and efficiency/resources in medicine are limited**. Regionalized STEMI care with EMS integration is the most cost-effective approach to STEMI
- **Fragmentation and reduplication of CV services is costly in both dollars and outcomes**. CPORT PPCI/E and MASS COMM have increased PCI capacity with no change in access and the "covert" objective has been market share
- **Focus** should now be **placed on developing regional centers of excellence in care for STEMI with global EMS integration** to facilitate pre-hospital identification and triage of STEMI patients.
- **Elective PCI** is **most cost-effectively provided** by higher volume centers with on-site CV surgery **(SOS) facilities**.

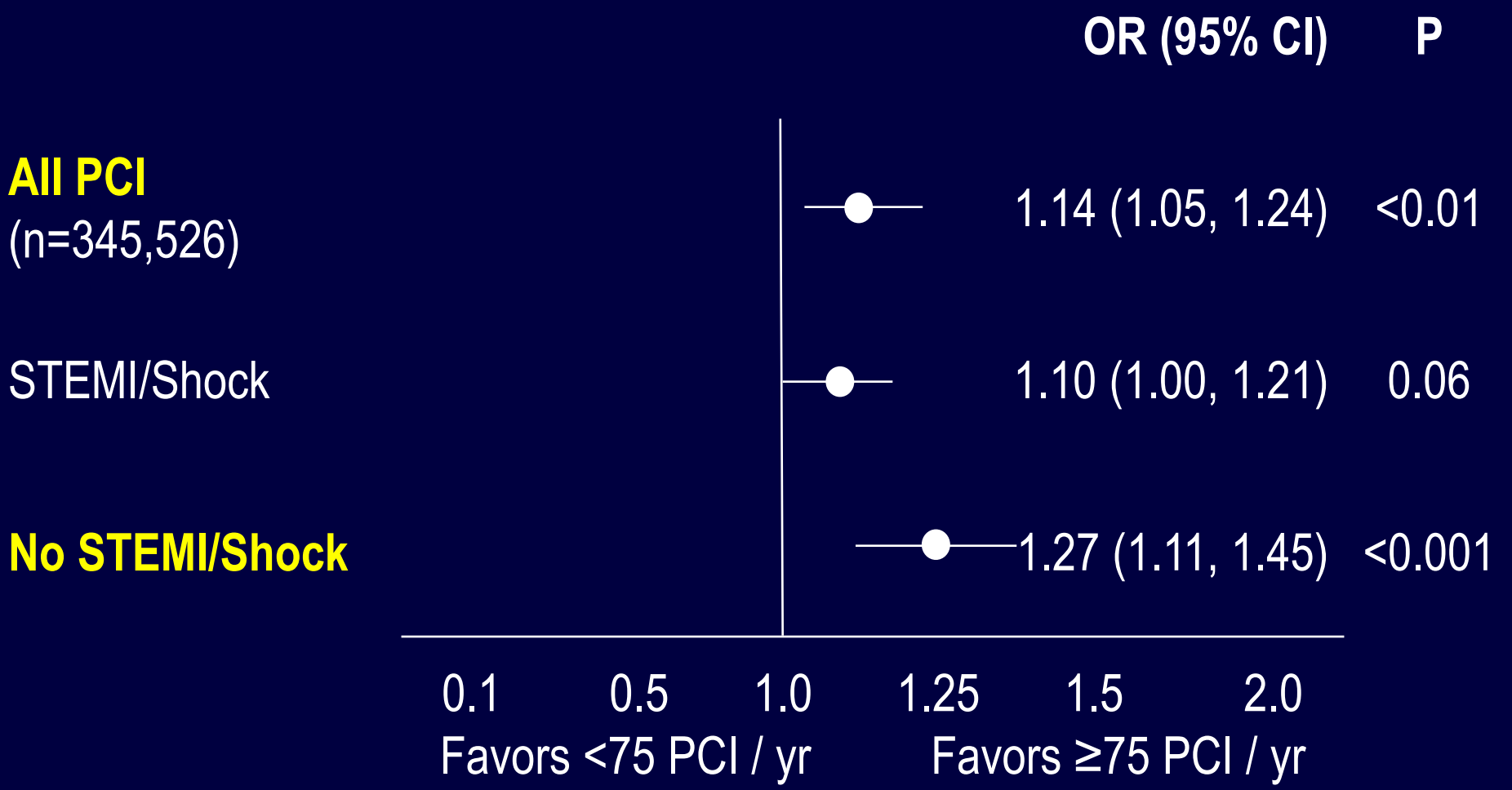
# Predictors of Inappropriate PCI




| | OR (95% CI) | P value |
|---|---|---|
| Men | 1.08 (1.05-1.11) | <0.001 |
| White | 1.09 (1.05-1.14) | <0.001 |
| Medicare | 0.85 (0.83-0.88) | <0.001 |
| No Insurance | 0.56 (0.50-0.61) | <0.001 |
| Rural hosp | 0.92 (0.88-0.96) | <0.001 |
| Suburban hosp | 1.10 (1.07-1.13) | <0.001 |
| Annual # elective PCI (per 100 cases) | 0.99 (0.99-0.99) | <0.001 |

Adapted from Chan et al. JACC 2013 (prepub-Sept)

# Physician Annual PCI Volume And In-Hospital Mortality ACC/NCDR*
# July 2008-July 2009

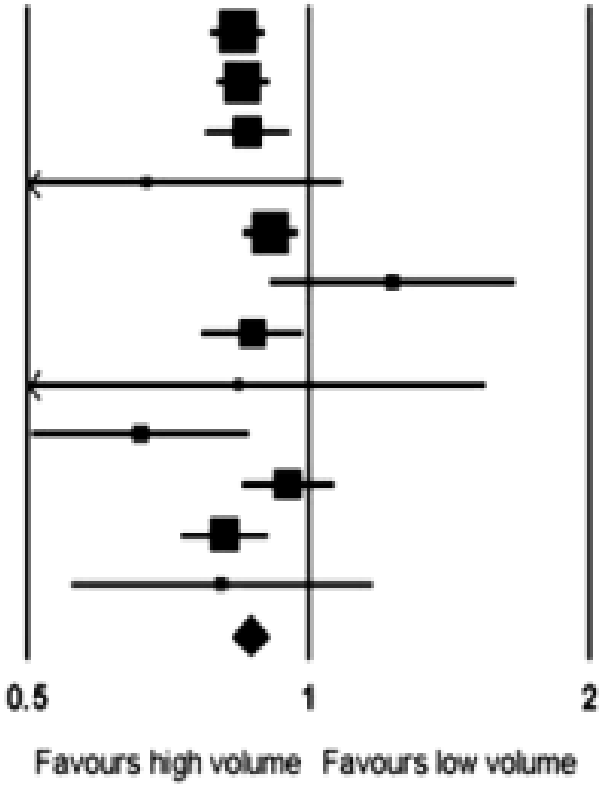



*3649 physicians; 345,526 PCI; 543 Cath PCI hospitals*

Minges et al. Circulation 2011;124:A16550 (abstract)

# PCI Center Volume* And In-Hospital Mortality: Meta-Analysis Of 10 Studies Involving 1,322,342 Patients

| Model | Study name | Mean study year | Odds ratio | Lower limit | Upper limit |
|---|---|---|---|---|---|
| | Ho[4] | 1986 | 0.840 | 0.787 | 0.897 |
| | Ho[4] | 1990 | 0.850 | 0.797 | 0.907 |
| | Hannan *et al.*[23] | 1993 | 0.860 | 0.775 | 0.954 |
| | Vakili *et al.*[15] | 1995 | 0.670 | 0.414 | 1.084 |
| | Ho[4] | 1995 | 0.910 | 0.852 | 0.972 |
| | Kimmel *et al.*[13] | 1995 | 1.230 | 0.910 | 1.662 |
| | Canto *et al.*[12a] | 1996 | 0.870 | 0.767 | 0.986 |
| | Tsuchihashi *et al.*[10] | 1997 | 0.840 | 0.456 | 1.547 |
| | Hannan *et al.*[24] | 1999 | 0.660 | 0.505 | 0.862 |
| | Carey *et al.*[14a] | 2000 | 0.950 | 0.849 | 1.063 |
| | Allareddy *et al.*[22] | 2002 | 0.813 | 0.731 | 0.904 |
| | Shirashi *et al.*[11] | 2003 | 0.807 | 0.557 | 1.169 |
| Random | | | 0.865 | 0.827 | 0.905 |



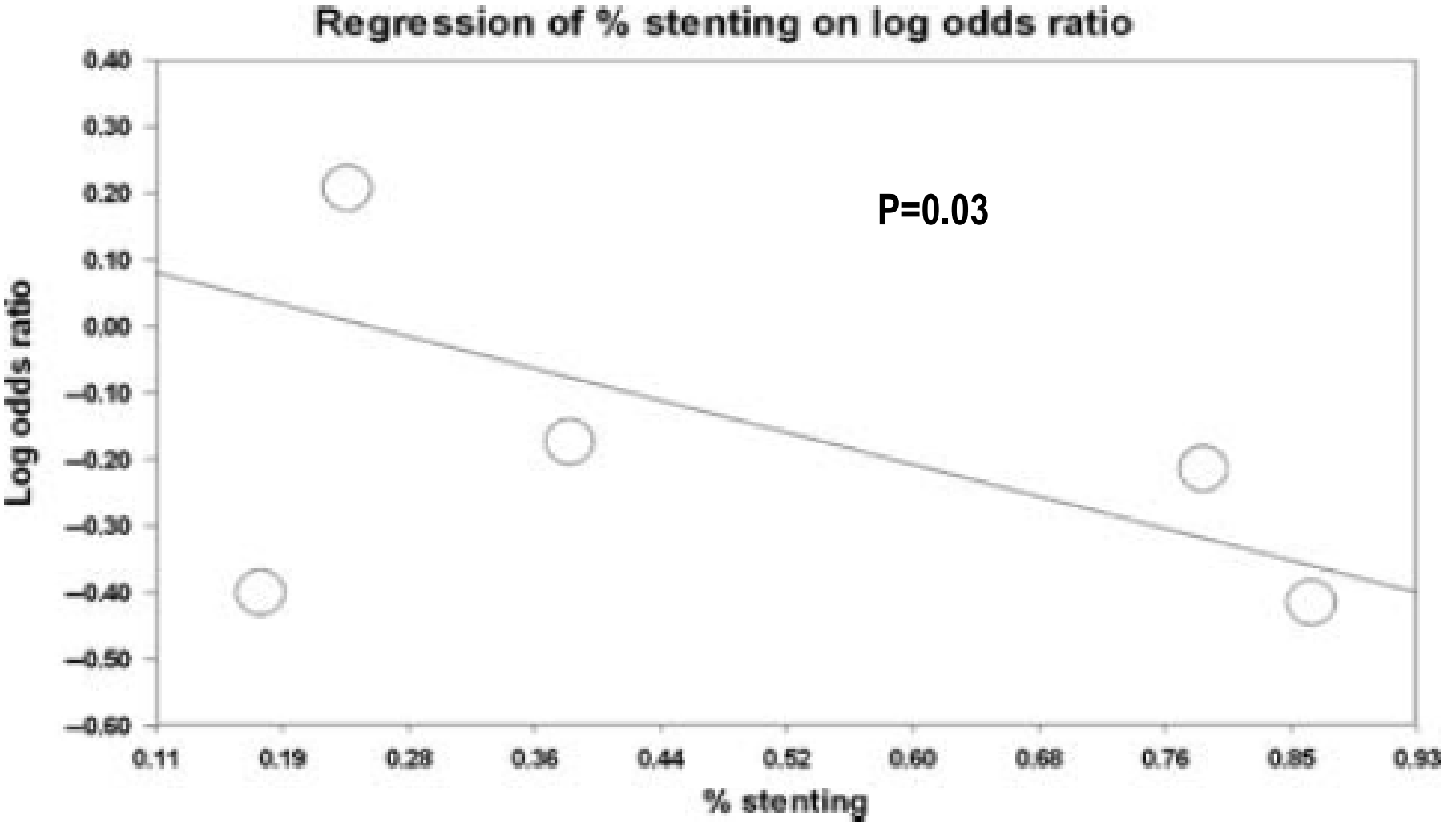

**High volume ≥600/yr; lower volume 400-600/yr*

Post et al. Eur Heart J 2010;31:1985-1992

Catheter Cardiovasc Interv. 2013;82:E69-E111

ACCF/AHA/SCAI 2013 Update Clinical Competence Statement

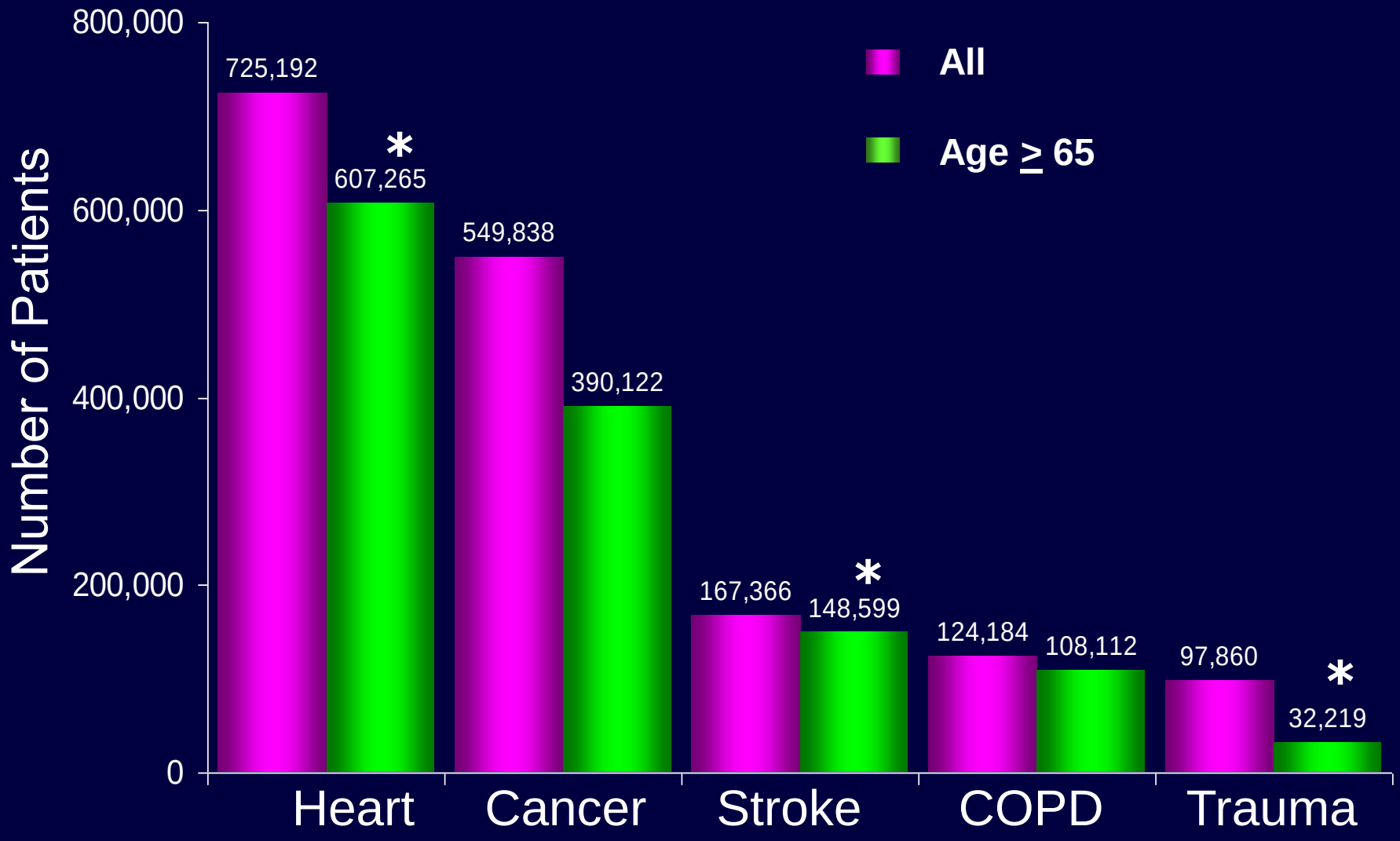
# Meta-Regression of % Stent PCI on PCI Volume In Hospital Mortality Effect Size*




** >negative log odds ratio = stronger effect size (greater volume-outcome relationship)*

Post et al. Eur Heart J 2010;31:1985-1992

# Deaths in the United States by Cause




***CHD=7x all-cause trauma; 3x stroke**

*Anderson RN. National Vital Statistics Report, Vol 49, 2001*

*The* NEW ENGLAND JOURNAL *of* MEDICINE

SPECIAL ARTICLE

# A National Evaluation of the Effect of Trauma-Center Care on Mortality

**Ellen J. MacKenzie, Ph.D., Frederick P. Rivara, M.D., M.P.H., Gregory J. Jurkovich, M.D., Avery B. Nathens, M.D., Ph.D. Katherine P. Frey, M.P.H., Brian L. Egleston, M.P.P., David S. Salkever, Ph.D., and Daneil O. Scharfstein, Sc.D.**

***CONCLUSIONS***

**Our findings show that the risk of death is significantly lower when care is provided in a trauma center than in a non-trauma center and argue for continued efforts at regionalization.**

**N Engl J Med 2006;354:366**

AHA/ASA Scientific Statement

# Metrics for Measuring Quality of Care in Comprehensive Stroke Centers: Detailed Follow-Up to Brain Attack Coalition Comprehensive Stroke Center Recommendations

## A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association *

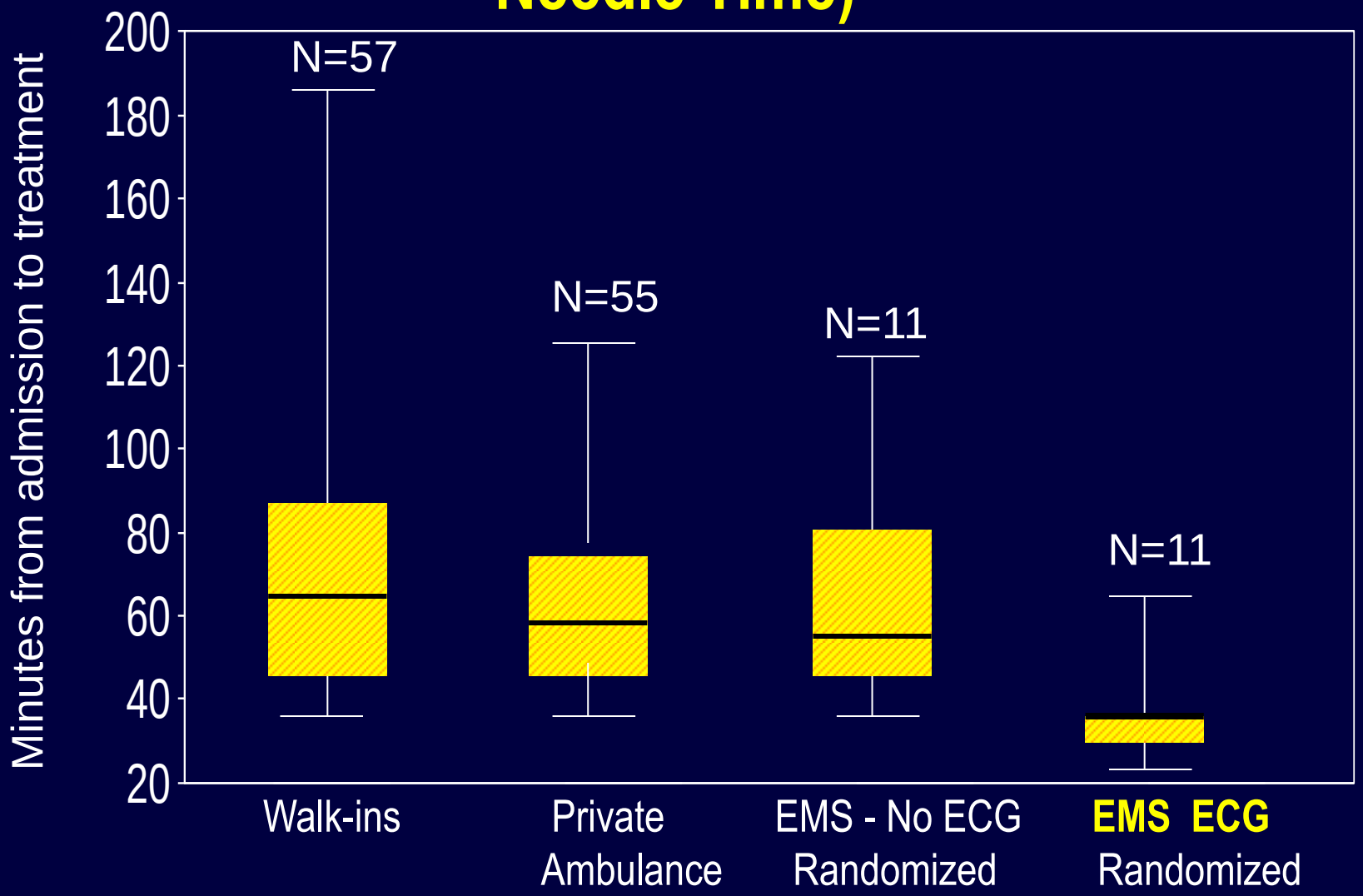
*Endorsed by the Society of Vascular and Interventional Neurology*

Dana Leifer, MD, FAHA, Chair; Dawn M. Bravata, MD; J.J. (Buddy) Connors III, MD; Judith A. Hinchey, MD, MS, FAHA; Edward C. Jauch, MD, MS, FAHA; S. Claiborne Johnston, MD, PhD; Richard Latchaw, MD; William Likosky, MD, FAHA; Christopher Ogilvy, MD; Adnan I. Qureshi, MD, FAHA; Debbie Summers, RN, MSN, FAHA; Gene Y. Sung, MD, MPH, FAHA; Linda S. Williams, MD; Richard Zorowitz, MD, FAHA; on behalf of the American Heart Association Special Writing Group of the Stroke Council, Atherosclerotic Peripheral Vascular Disease Working Group, Council on Cardiovascular Surgery and Anesthesia, and Council on Cardiovascular Nursing

*certification process JCAHO

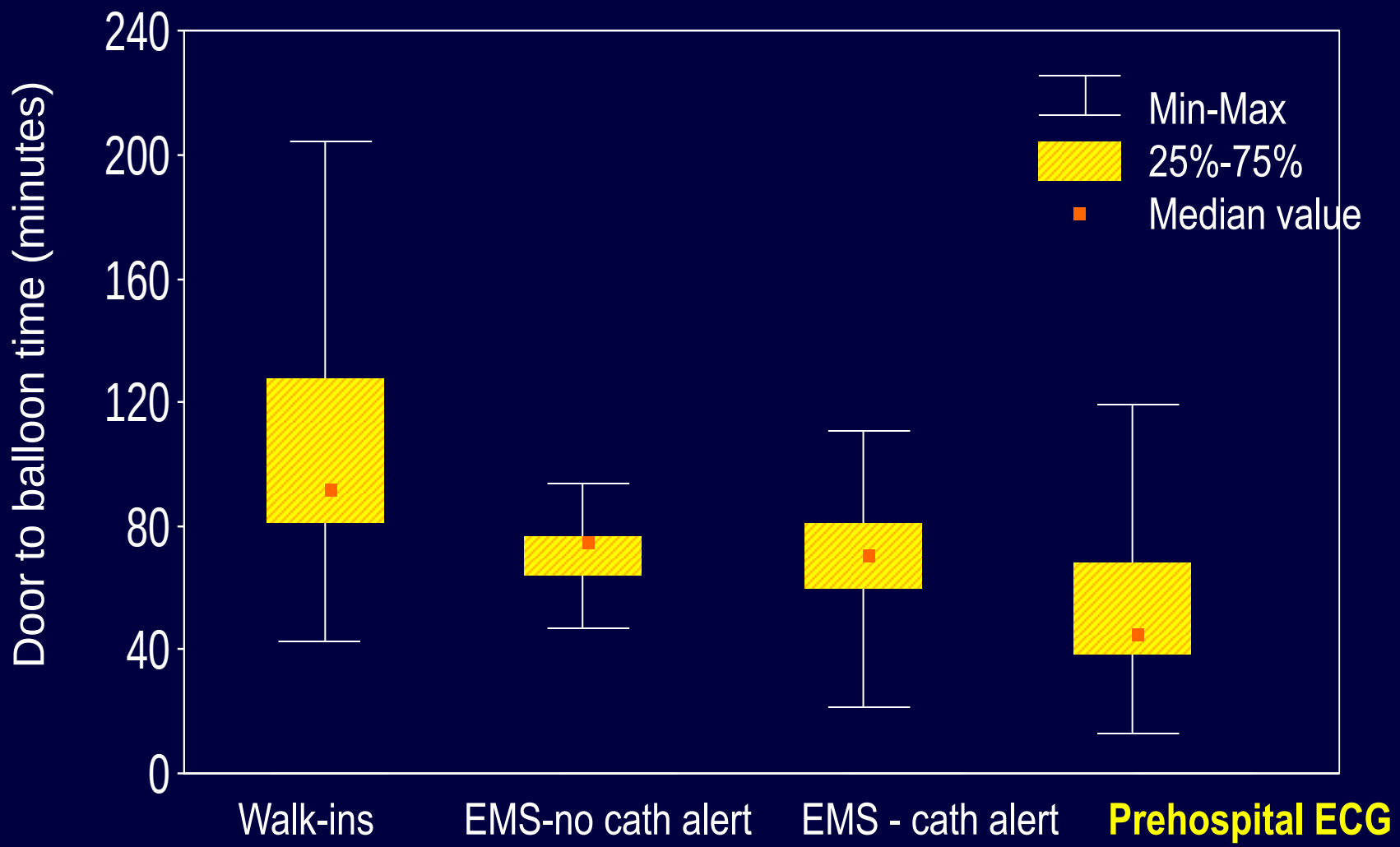
Stroke 2009;42:00-00

# EMS Transport and Prehospital ECG to Expedite Hospital Thrombolysis (Door to Needle Time)



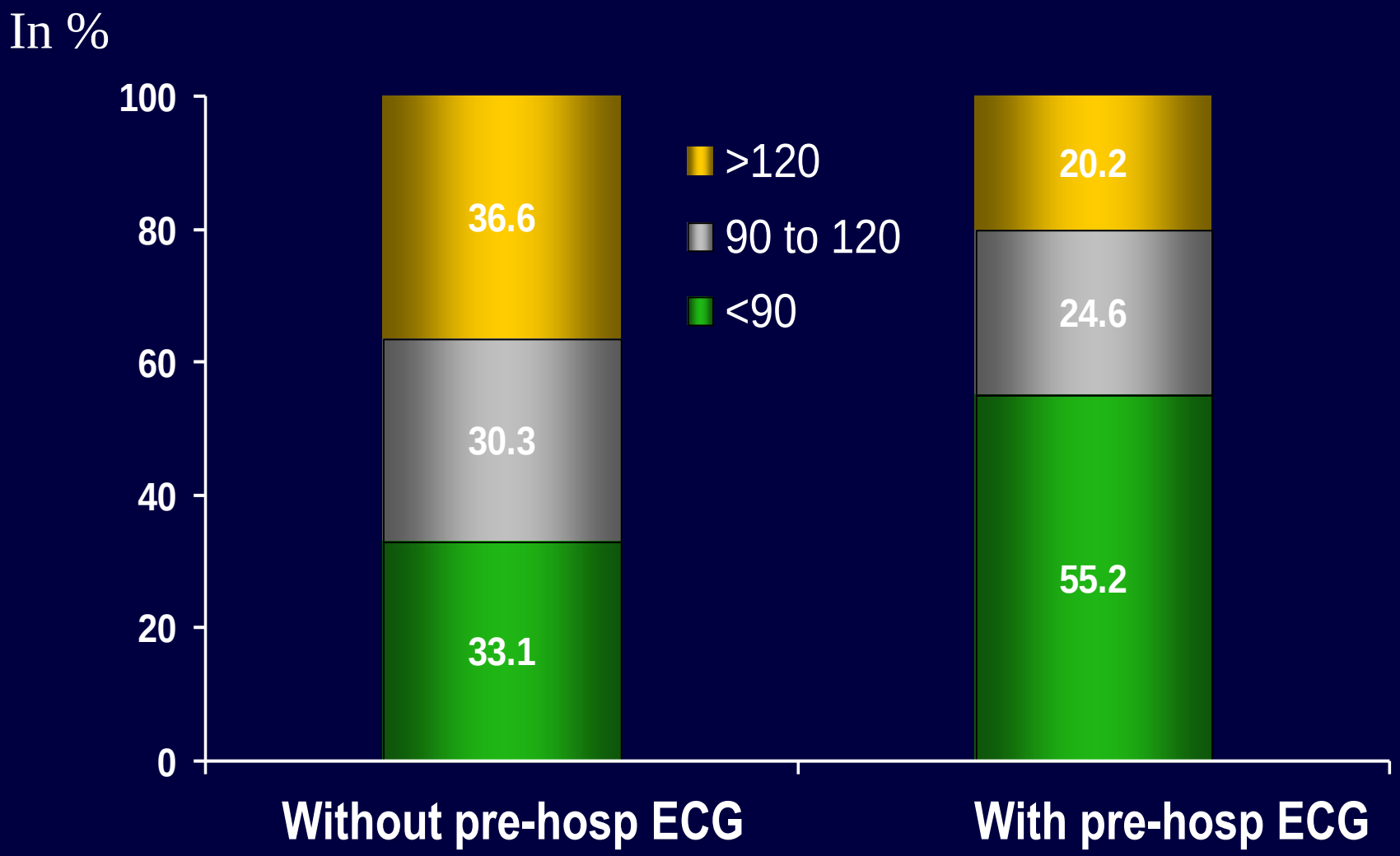

Kereiakes et al. Am Heart J 1992;123:835

# Prehospital ECG Facilitates In-hospital Primary Angioplasty



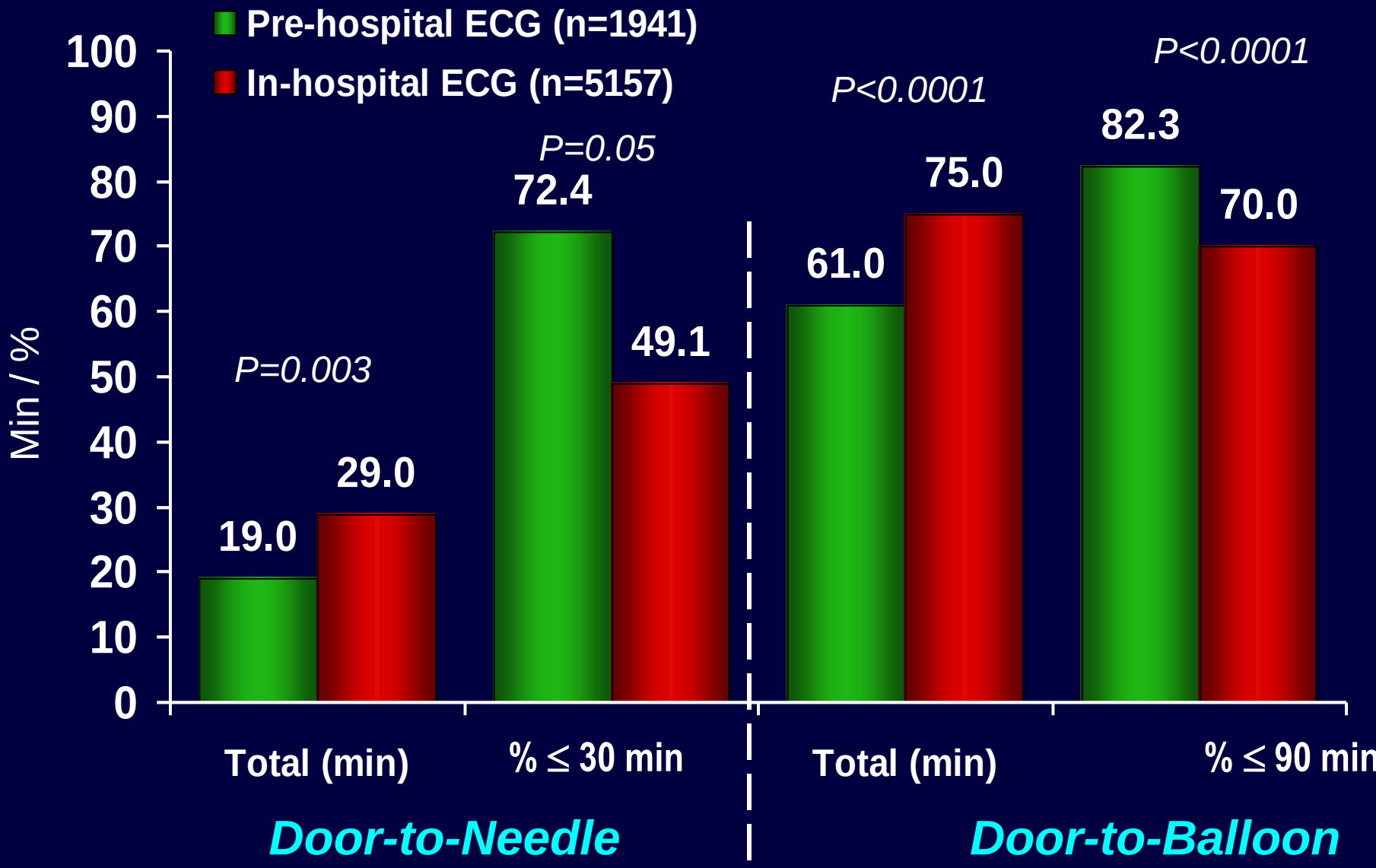

Bush et al. JACC 2005;45:222

# Pre-Hospital ECG and Door-To-Balloon Time: NRMI 4




Curtis et al. JACC 2006;47:1544-52

# Pre-Hospital ECG and Reperfusion: ACTION NCDR




Adapted from Diercks et al. JACC 2009;53:161-6

SPECIAL ARTICLE

# Pre-Hospital 12-Lead Electrocardiography Programs

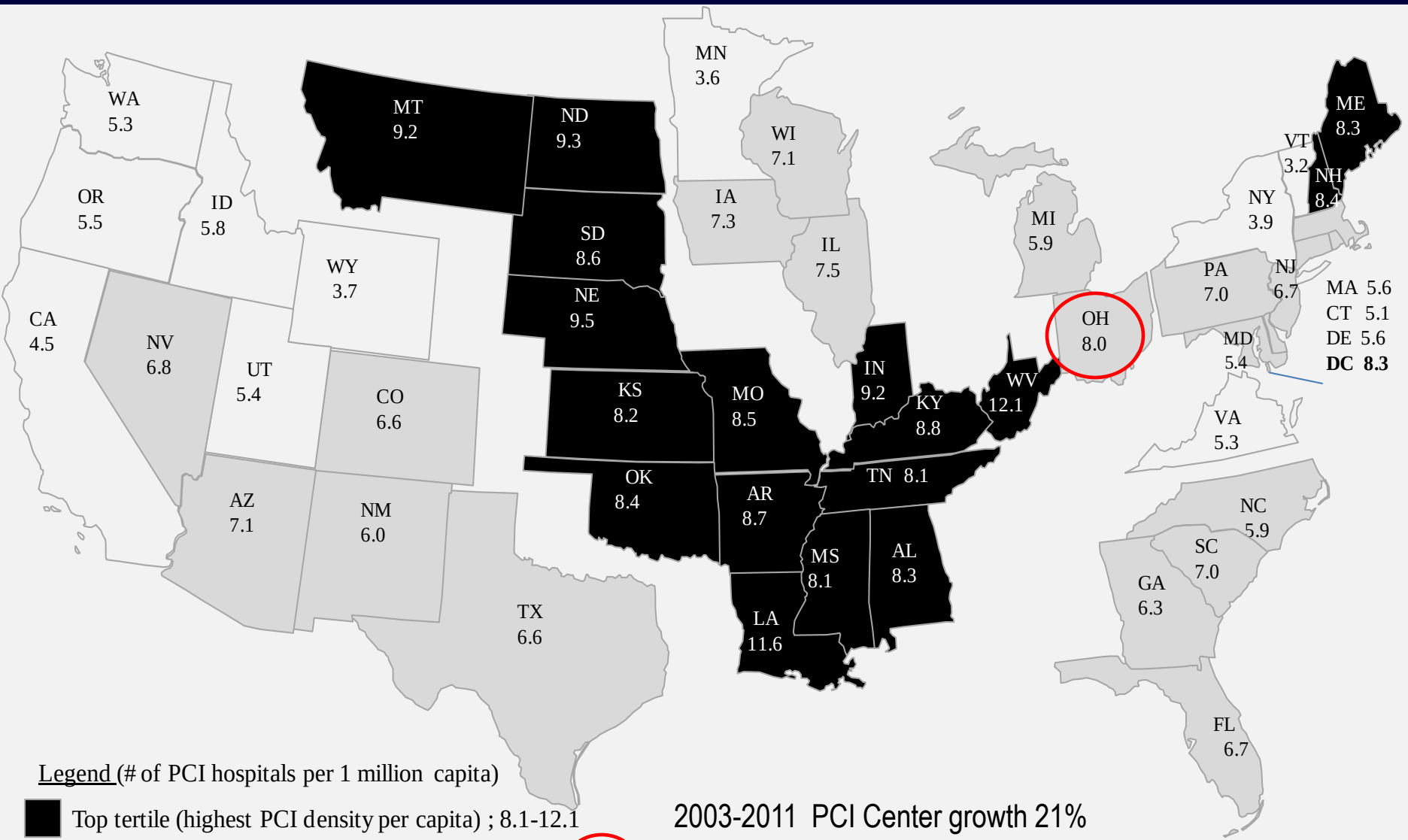
## A Call for Implementation by Emergency Medical Services Systems Providing Advanced Life Support—National Heart Attack Alert Program (NHAAP) Coordinating Committee; National Heart, Lung, and Blood Institute (NHLBI); National Institutes of Health

J. Lee Garvey, MD,* Bruce A. MacLeod, MD, FACEP,† George Sopko, MD,‡
Mary M. Hand, MSPH, RN,‡ on behalf of the National Heart Attack Alert Program (NHAAP) Coordinating Committee

*Charlotte, North Carolina; Pittsburgh, Pennsylvania; and Bethesda, Maryland*

JACC 2006;47:485-91

# PCI Facility Density Map: # PCI Centers / 1 MM Capita



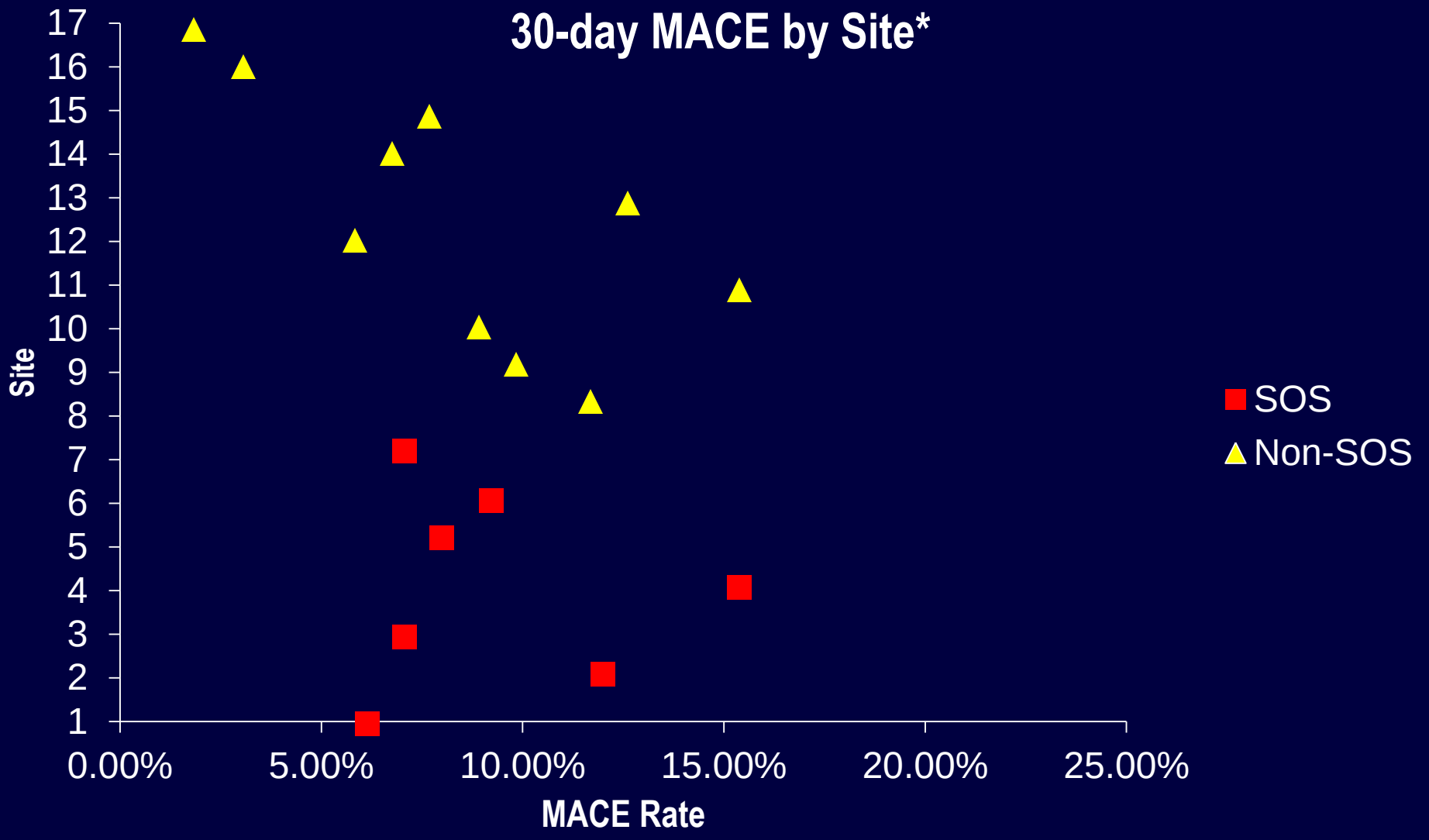

Legend (# of PCI hospitals per 1 million capita)

- Top tertile (highest PCI density per capita) ; 8.1-12.1
- 2nd tertile (near the median density per capita) ; 5.9 – 8.0
- 1st tertile (fewest PCI density per capita) ; 3.2-5.8

2003-2011 PCI Center growth 21%
Population growth 8.3%
Disease (CAD, AMI) prevalence ↓

Langabeer, Henry, Kereiakes et al. JAHA (in press)

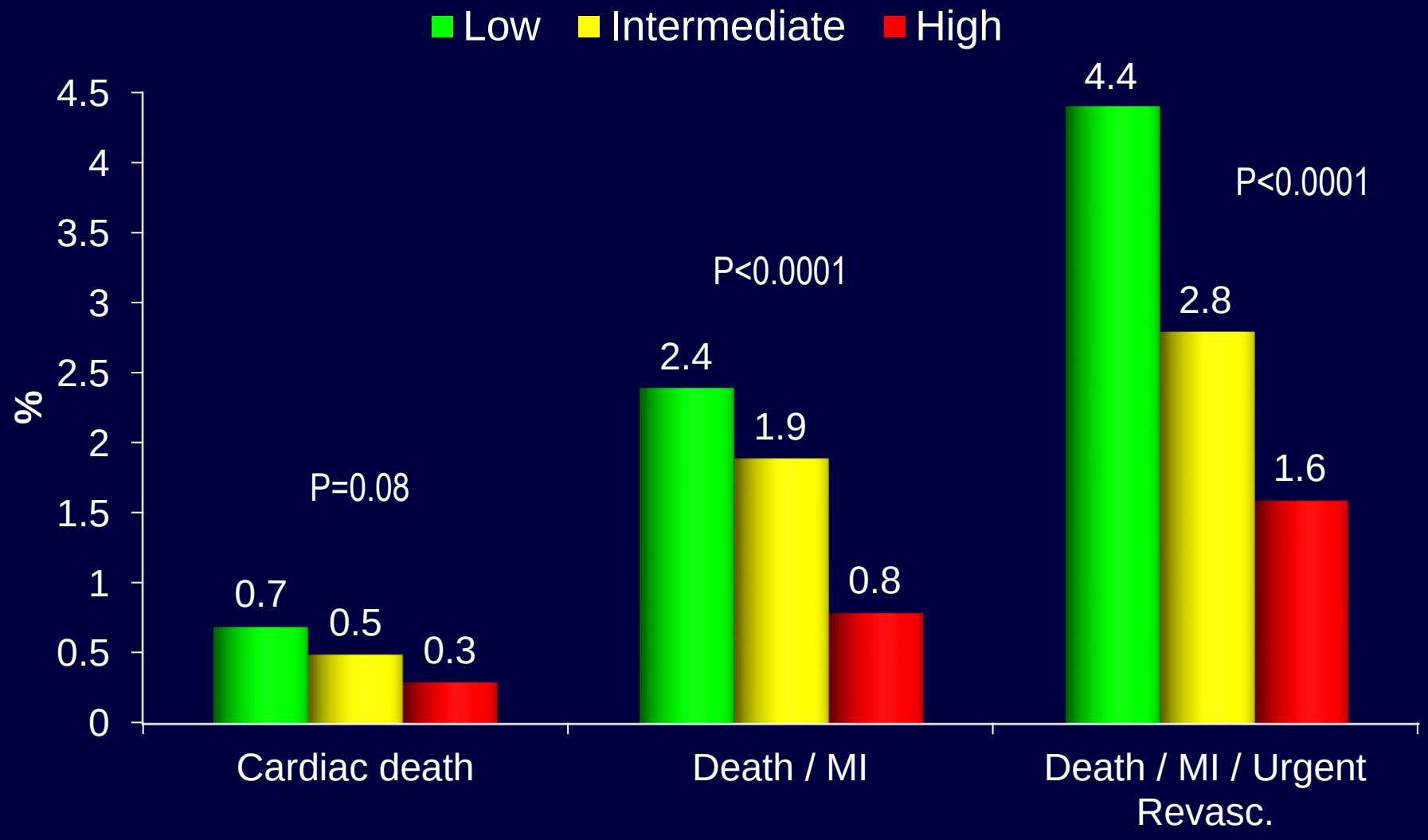
# Non-Emergency PCI At Hospitals With And Without On-Site Cardiac Surgery: MASS COMM




*Absolute between site variance of 14%

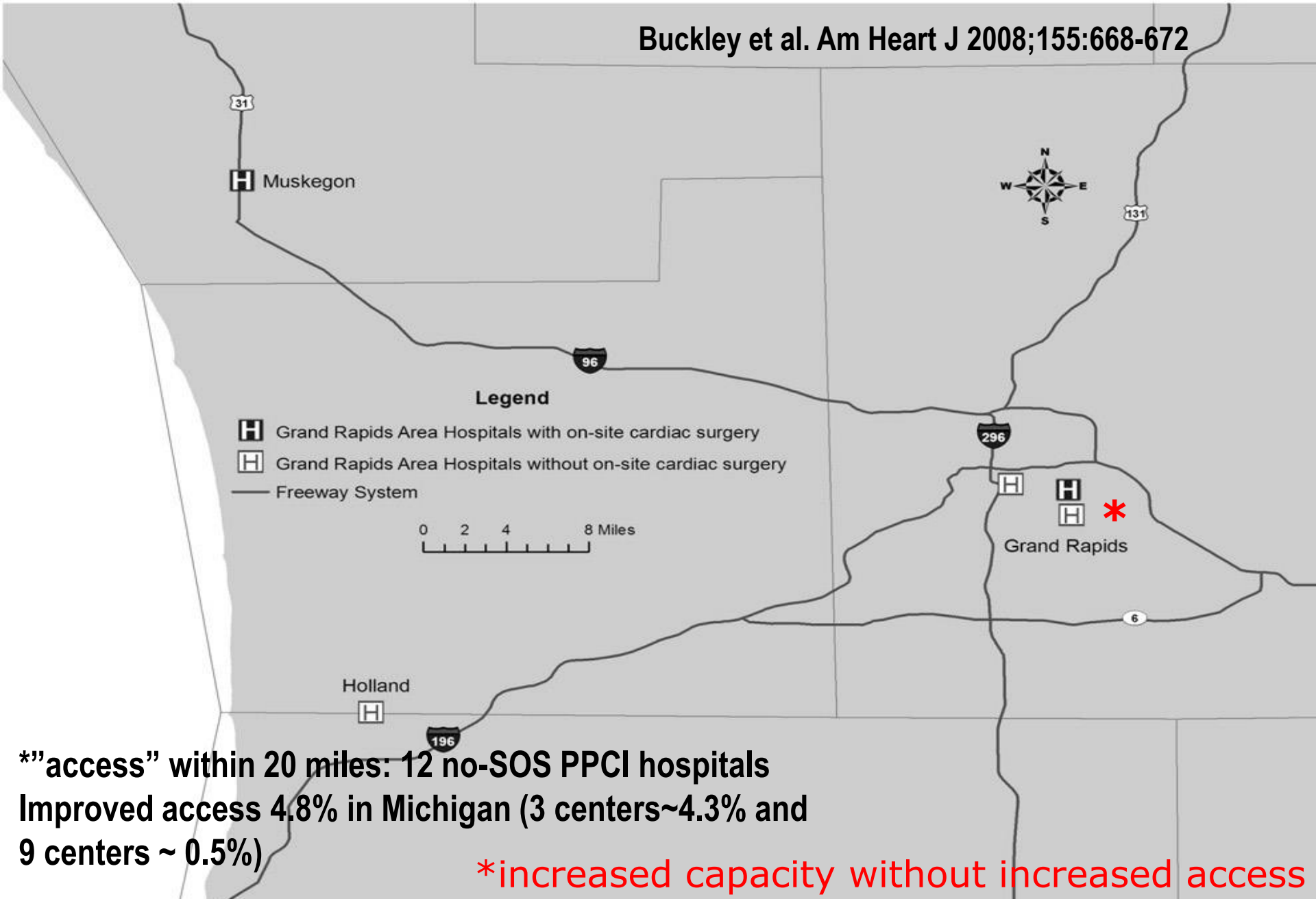
Jacobs et al. NEJM 2013 (pre-pub)

# Adverse Events In-Hospital Stratified By Hospital Volume Status: German CYPHER Registry




Khattab et al. Circulation 2009;120:600

# Primary PCI Hospitals With And Without SOS in Grand Rapids*




*"access" within 20 miles: 12 no-SOS PPCI hospitals

Improved access 4.8% in Michigan (3 centers~4.3% and 9 centers ~ 0.5%)

*increased capacity without increased access