Helping Cardiovascular Professionals Learn. Advance. Heal.

Comparing Effectively: The Role of Registries in Comparative Effectiveness Research

National Comparative Effectiveness Summit
Washington DC
September 16, 2009

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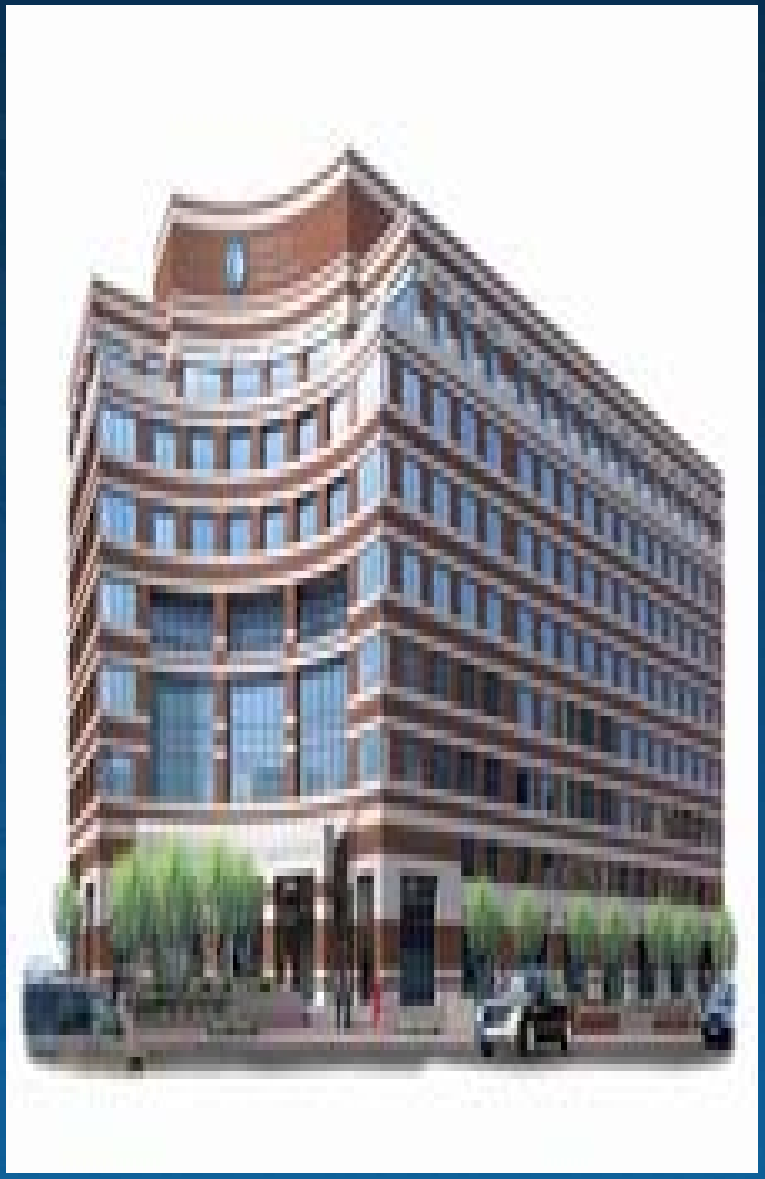
Vice President for Science and Quality, ACC

ACC

Chartered as a teaching institution in 1949

Now serves more than 37,000 cardiologists, nurses,
physicians' assistants, and pharmacists



American College of Cardiology

Science and Quality

- Science and Clinical Policy
  - Clinical Practice Guidelines
  - Data Standards
  - Performance Measures
  - Appropriate Use Criteria
- Quality Programs and Projects
- Partners in Quality
- National CV Data Registry

ACC and CER

- Enhanced decision-making
- Wise stewardship of resources
- Stimulus for evidence development
- Targeted approach to improve care
- Driver of implementation science

"Science tells us what we can do;

Guidelines what we should do;

Registries what we are actually doing."

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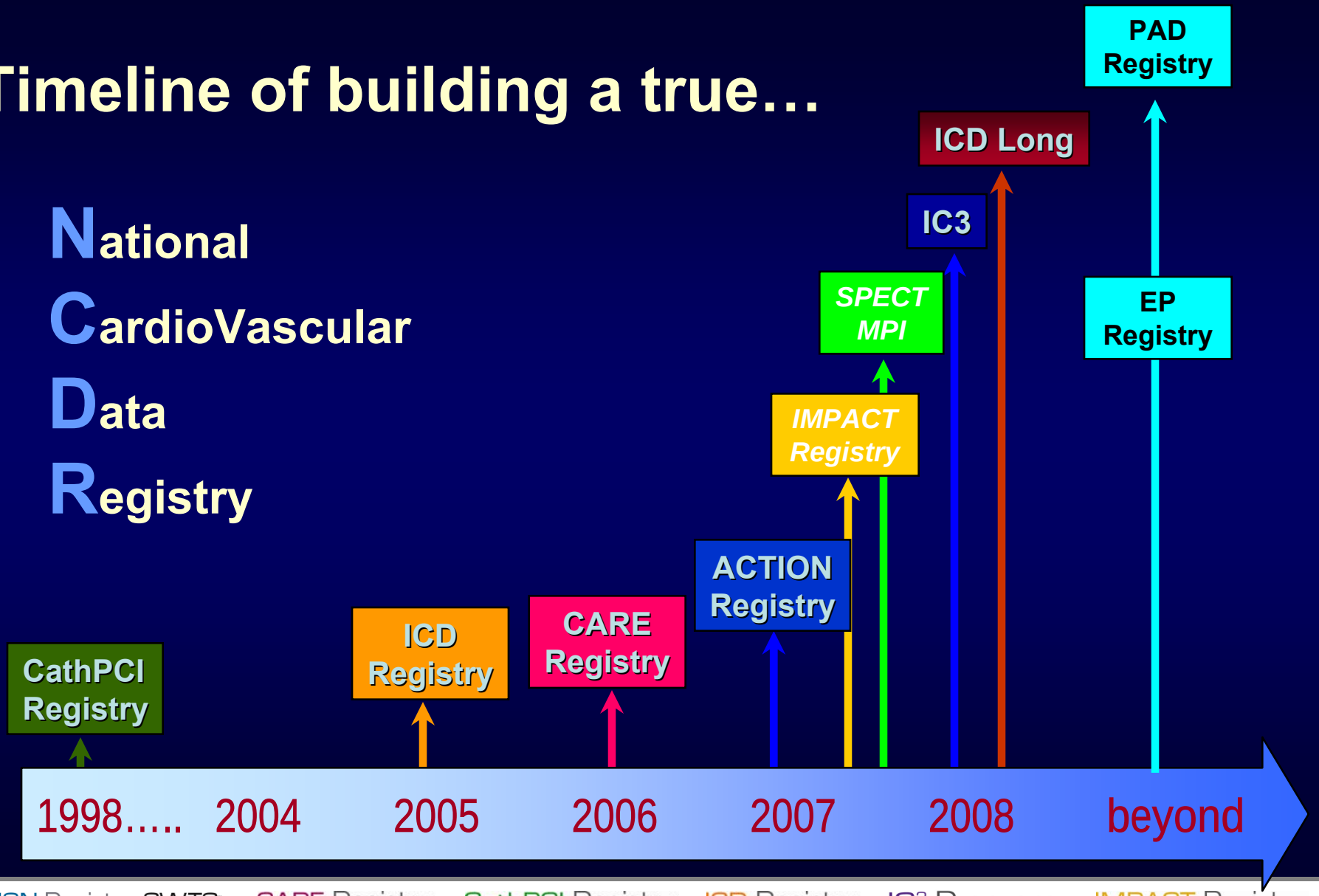
National Cardiovascular Data Registry

Timeline of building a true…

National
CardioVascular
Data
Registry



Participants and Patient Records

	Name	# of Participants	# of Patient Records
Hospital	CathPCI	1200	10 million
	ICD	1500	400,000
	ACTION-GWTG	425	150,000
	CARE	160	15,000
	IMPACT	Under Development	--
Practice	IC3	600	160,000

What is the National Cardiovascular Data Registry?

NCDR™
National Cardiovascular Data Registry

Registries

- CathPCI
- IMPACT
- ICD
- IC3
- CARE
- ACTION-GWTG

Registry Studies

- SPECT MPI
- ICD Long.

Analytic Reporting Services

WellPoint CMS BCBS/
WVMI United ACC
BMC2 Aetna
HCA

- Guidelines Develop.
- Educational Needs Assess.
- Market Intelligence

Research & Publication Services

FDA Yale ACC
Industry DCRI Ad hoc
MAHI

Quality Improvement

Care Plans

Standard Order Sets

ACTION Registry-GWTG™ CARE Registry™ CathPCI Registry™ ICD Registry™ IC³ Program™ IMPACT Registry™

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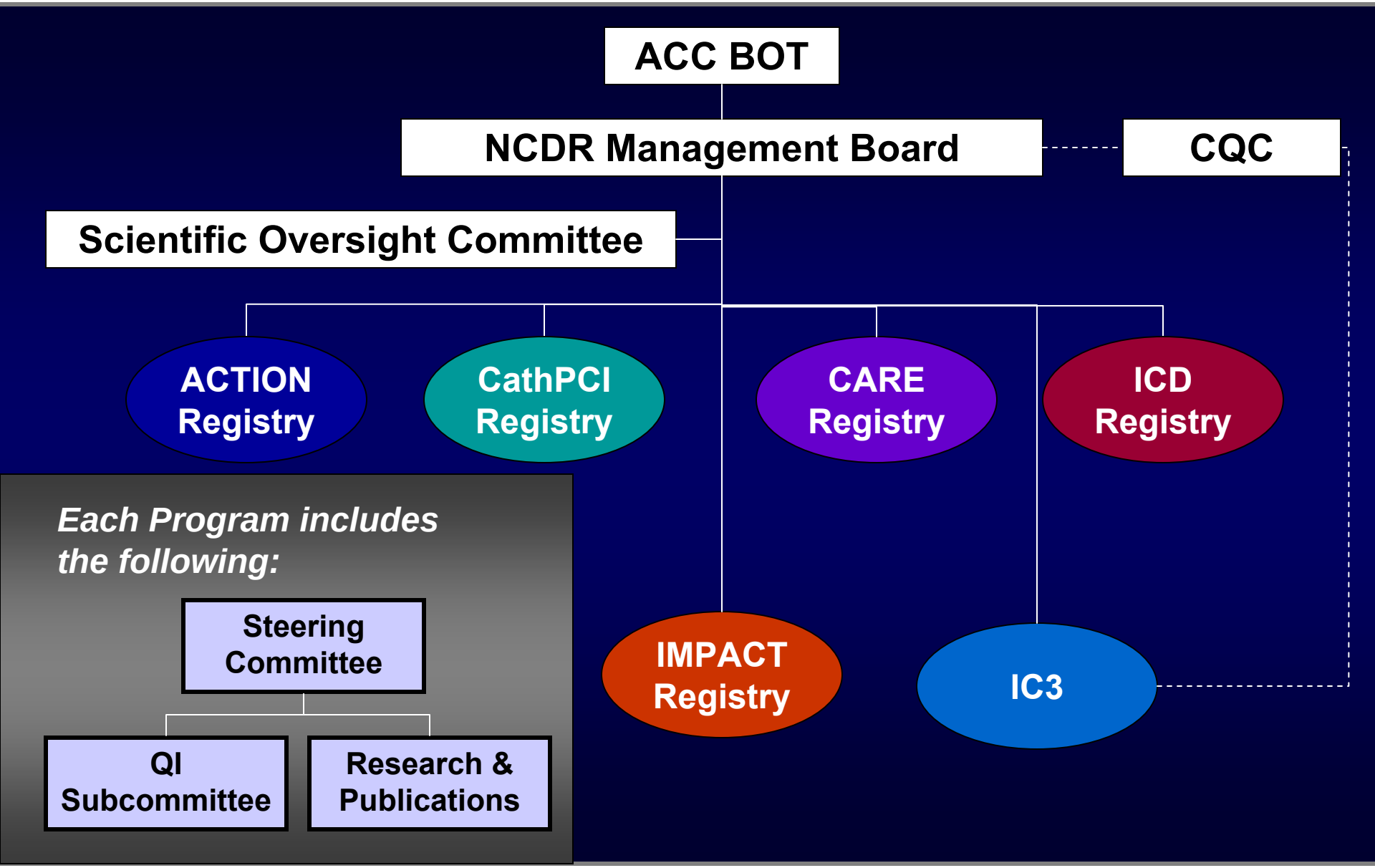
National Cardiovascular Data Registry



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Multispecialty Representation

CathPCI

- Society for Cardiovascular Angiography and Intervention

ICD

- Heart Rhythm Society

CARE

- Society for Cardiovascular Angiography and Intervention
- Society for Interventional Radiology
- American Academy of Neurology
- American Academy of Neurosurgery
- Society of Vascular Medicine and Biology

ACTION

- American Heart Association
- Chest Pain Centers Society

IMPACT

- American Academy of Pediatrics

Influence of NCDR Research

- Public Policy
- Quality Improvement: Guideline Adherence
  - Reducing D2B Times
  - Clinical Indications & Outcomes
  - Quality Improvement: Translational Research
- Post Market Surveillance
  - Adverse Events in Closure Devices
- **New technologies and effectiveness**
  - **Diffusion of new technology**

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Infrastructure tool for CER

Registries can:

- capture high quality clinical data efficiently
- be used for scientific discovery
  - track patients' longitudinal care
  - track drugs/devises
  - be linked to biological/imaging data
- complement/support RCTs
  - and perhaps be backbone for these
- helps drive new evidence into routine practice

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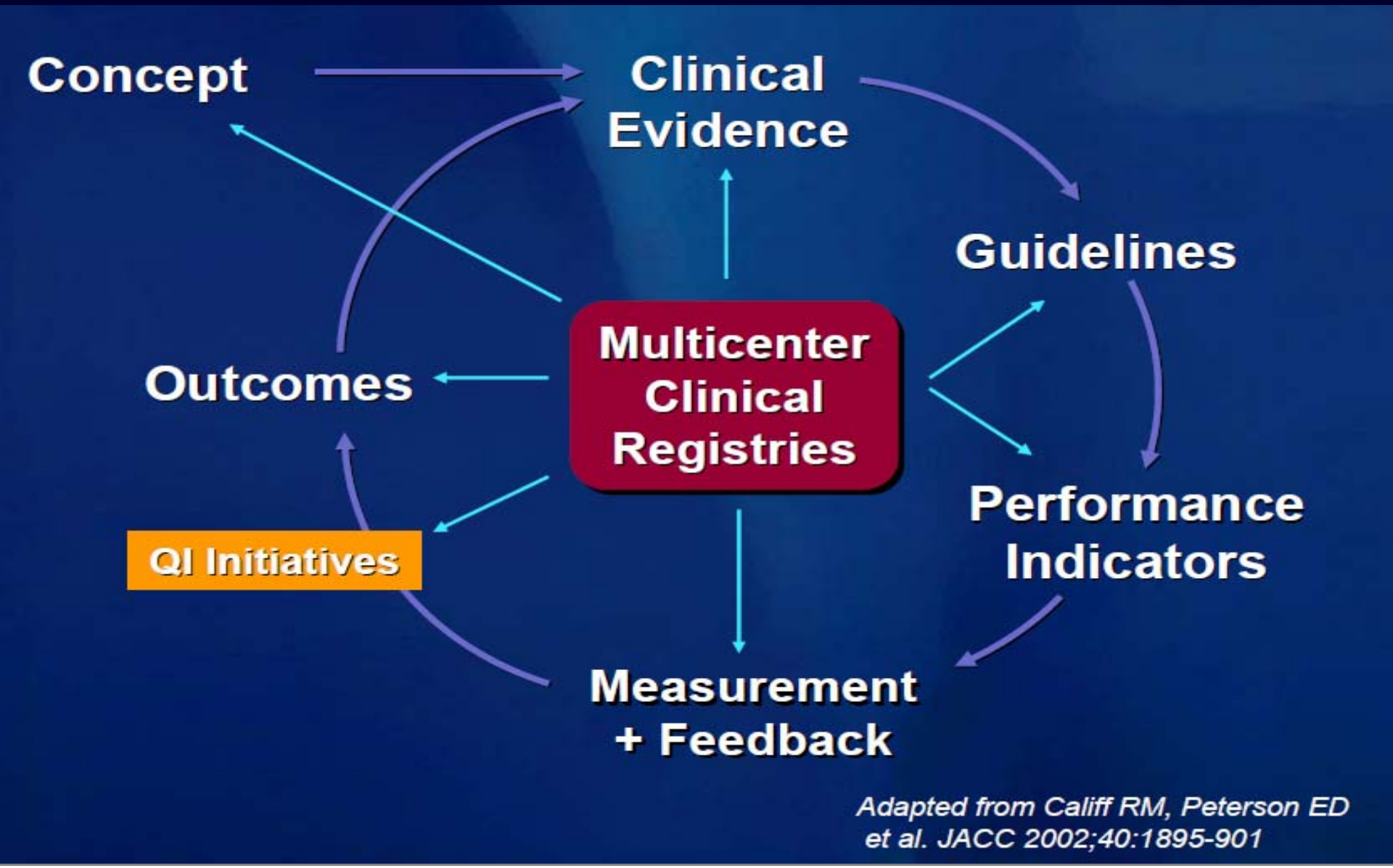
Registries for Evidence Development and Dissemination



Adapted from Califf RM, Peterson ED et al. JACC 2002;40:1895-901

CER "Definition"

- CER is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions.
- The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.
- CER research must assess a comprehensive array of health-related outcomes for diverse patient populations.
- This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.

Clinical Registries !

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Example of Research Using NCDR Data

NCDR™ National Cardiovascular Data Registry — Executive Summary Performance Metrics

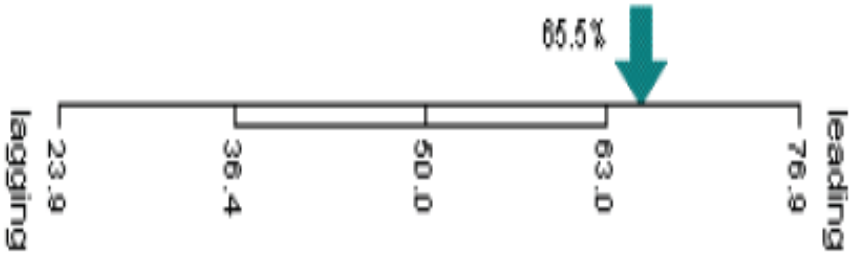
PCI Quality Measures

Worse — Better

1. Proportion of STEMI Pts with DBT <= 90"

My Hospital: 65.5% (Rank: 87 of 389, Rank Percentile: 78)

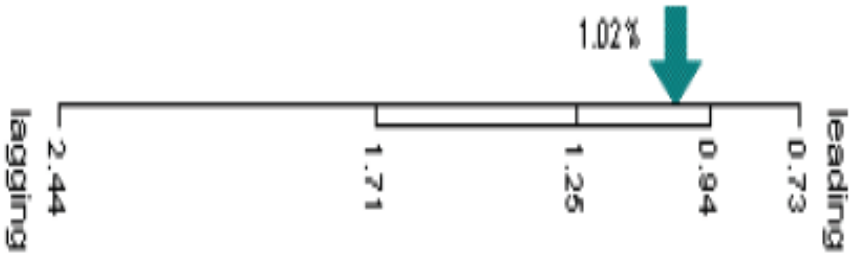
The proportion of primary PCI patients with DBT (door to balloon time) <= 90 minutes. The goal is to have a DBT of <= 90 minutes for all non-transferred patients pts having an ST elevated MI and having primary PCI. [Detail Line: 1767]



2. Risk Adjusted Mortality

My Hospital: 1.02% (Rank: 118 of 366, Rank Percentile: 68)

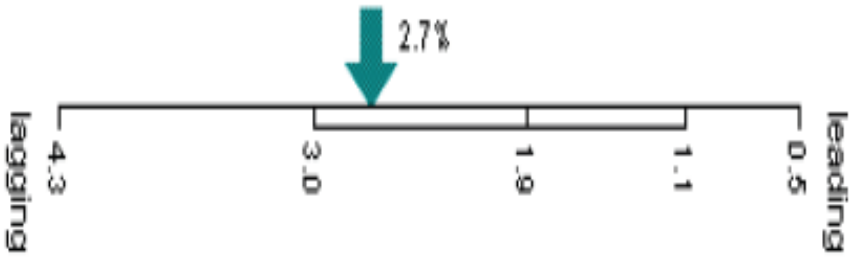
Your hospital's PCI mortality rate adjusted using the ACC-NCDR® risk adjustment model [Detail Line: 1732]



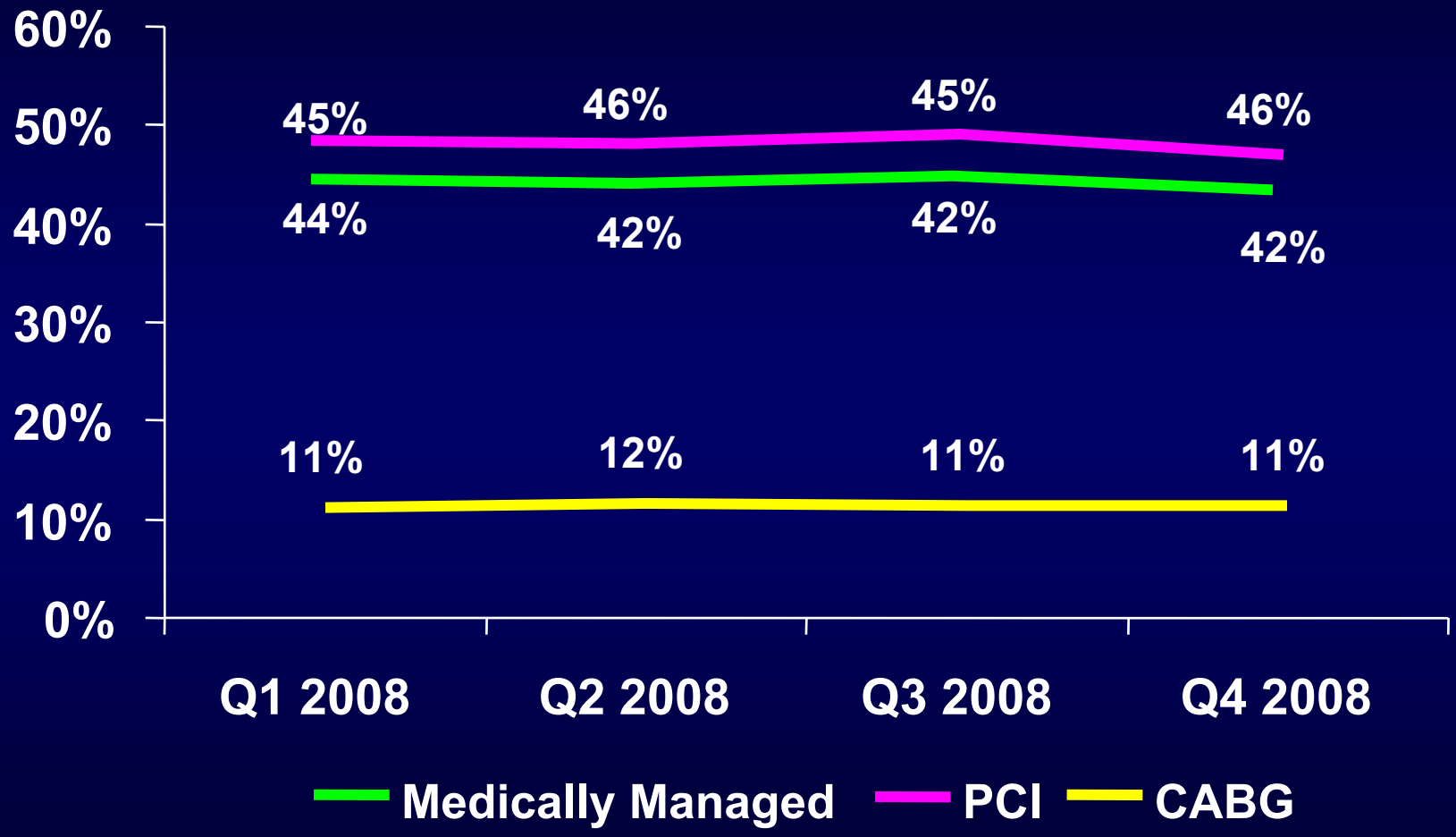
3. Incidence of Vascular Complications

My Hospital: 2.7% (Rank: 286 of 401, Rank Percentile: 30)

Includes procedures with at least one vascular complication. [Detail Line: 2029]



NSTEMI Revascularization Strategy Trends



ACTION Registry-GWTG DATA: January 1 – December 31, 2008

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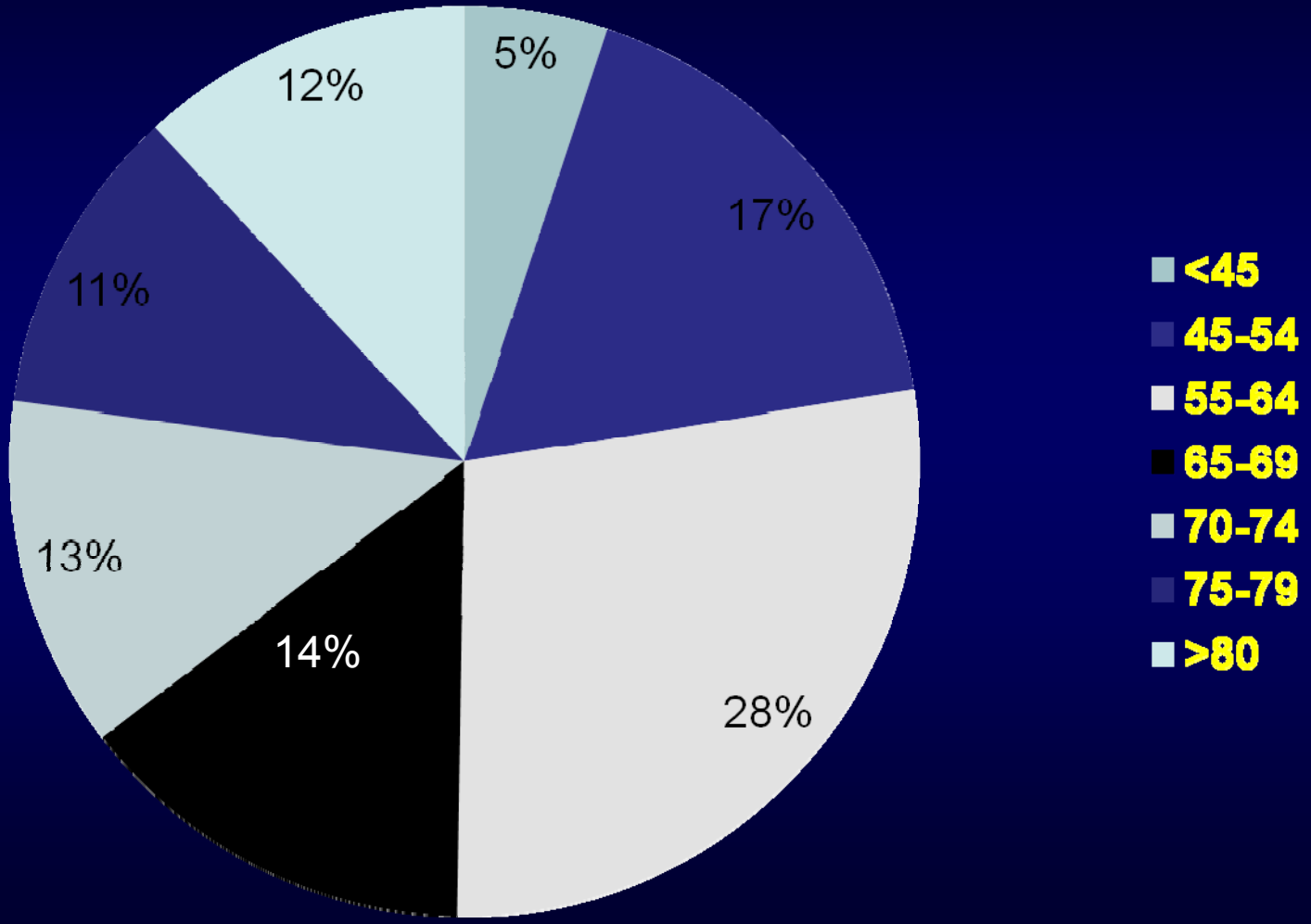
CathPCI 2007-2008

Age Distribution



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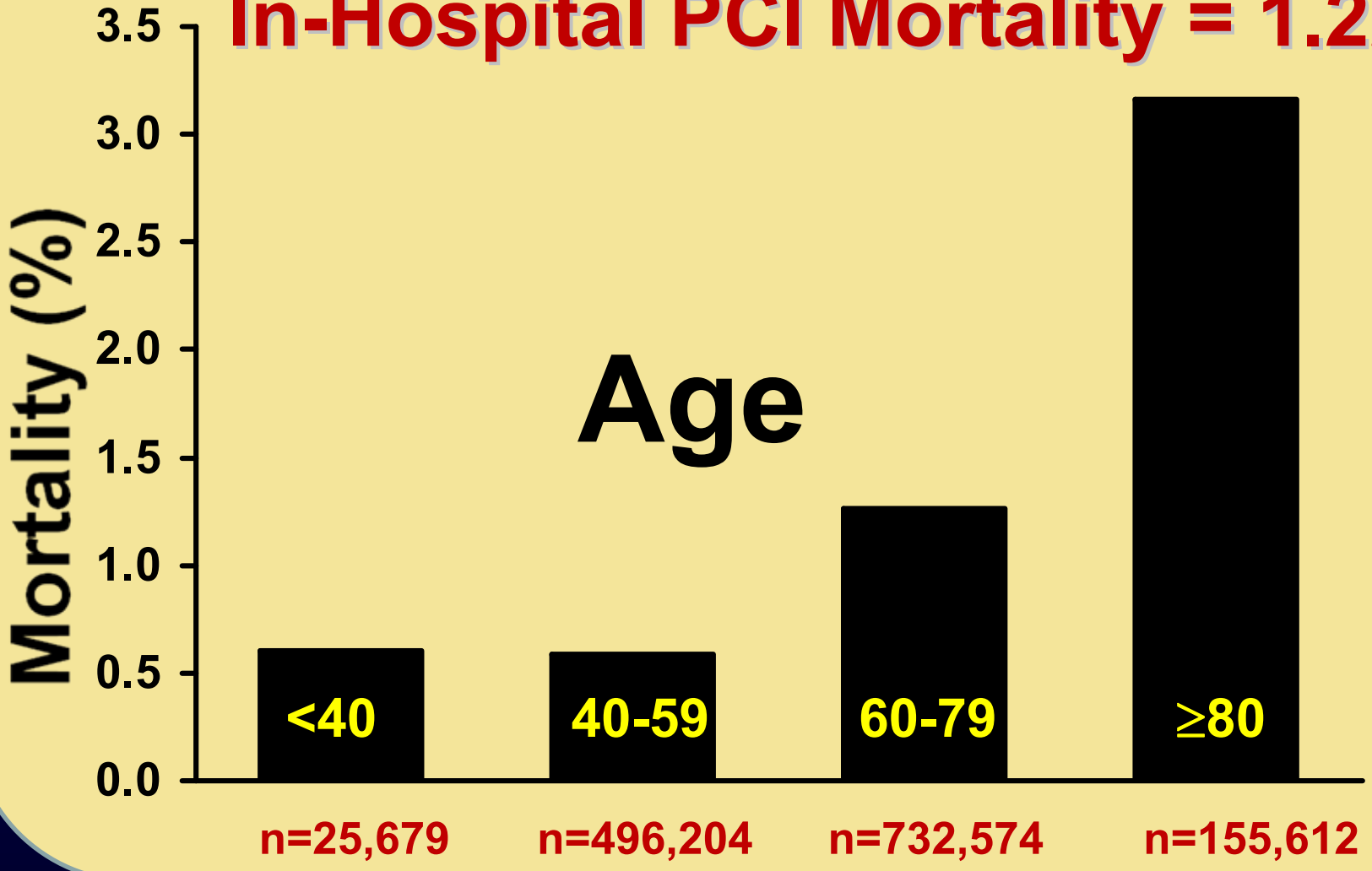
Age & PCI Mortality 2001-2006

In-Hospital PCI Mortality = 1.22%



Singh M et al Circ Cardiovasc Intervent 2009;2:20-26

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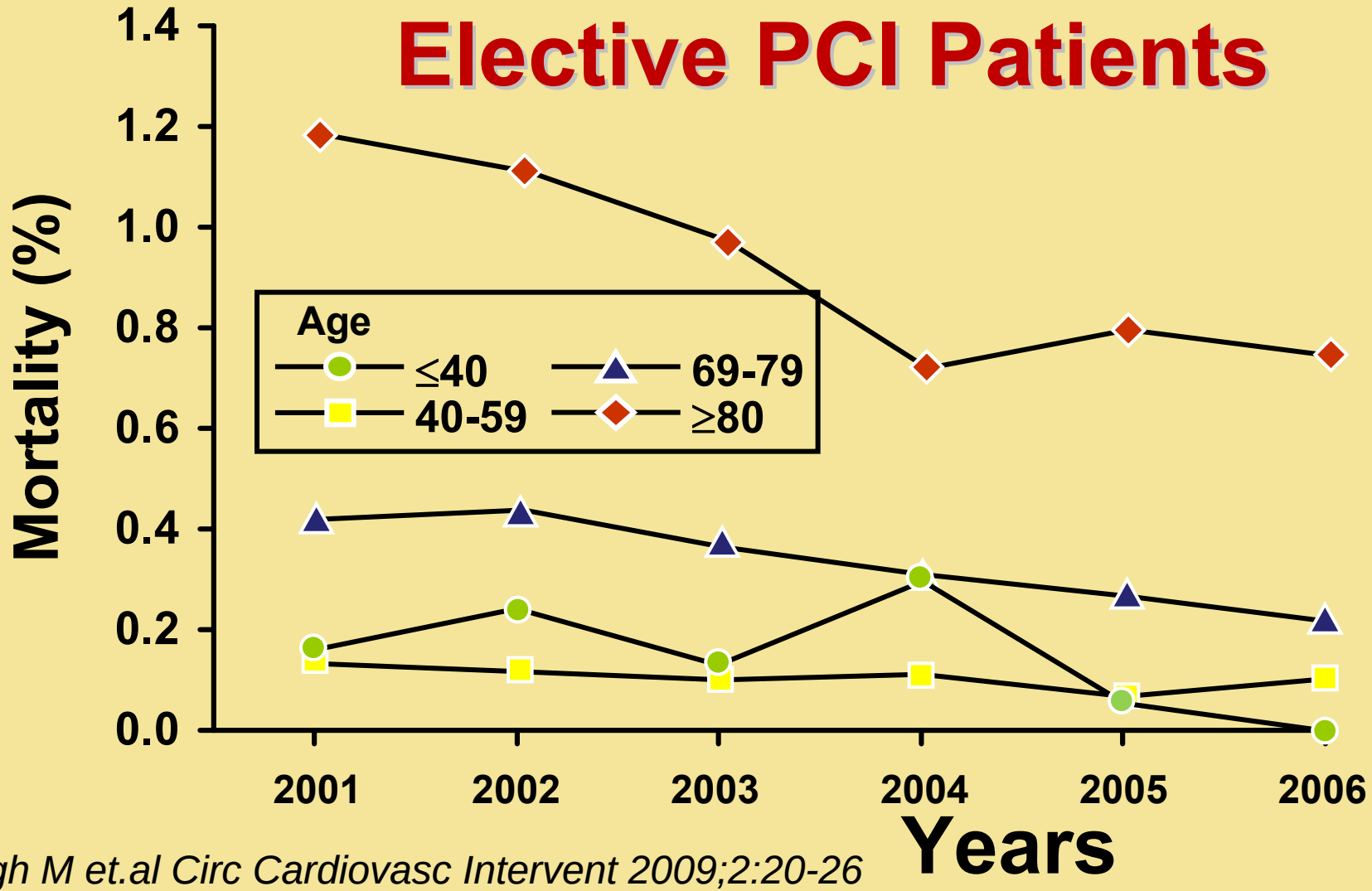
Trends : Age & PCI Mortality



Singh M et.al Circ Cardiovasc Intervent 2009;2:20-26

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Pre-CathPCI Risk Models

Label	Full Model †				Precath Simple Model			
	O.R.	95% CI		Wald Chi-Square	O.R.	95% CI		Wald Chi-Sq
Age (for age<=70) ‡	1.55	1.44	1.69	115.33	1.52	1.40	1.64	107.92
Age (for age>70) ‡	1.71	1.57	1.88	125.80	1.76	1.60	1.91	150.93
Previous History - CHF	1.29	1.13	1.47	13.85	1.75	1.54	1.98	77.25
Peripheral Vascular	1.53	1.35	1.74	42.39	1.67	1.48	1.89	67.78
Chronic Lung Disease	1.48	1.31	1.66	43.04	1.52	1.36	1.71	52.87
GFR for stemi ‡	0.77	0.74	0.80	181.90	0.77	0.75	0.78	377.55
Cardiogenic Shock at Admission	8.35	7.40	9.44	1168.28	12.19	10.86	13.68	1804.73
NYHA Class IV for STEMI	1.21	1.05	1.39	6.74	1.61	1.46	1.79	81.71
Urgent PCI Status- STEMI §	1.09	0.64	1.83	0.09	1.25	0.748	2.07	0.71
Emergency PCI Status-STEMI §	2.07	1.30	3.31	9.24	2.65	1.68	4.18	17.58
Salvage PCI Status-STEMI §	14.55	8.39	25.21	91.08	21.45	12.57	36.61	126.36

† Full model also includes Previous PCI, PreOp IABP, Ejection Fraction, Coronary Lesion >= 50%: Subacute Thrombosis (Y/N), Highest Risk Pre-Procedure TIMIFlow = none, Diabetes/Control, Highest Risk Lesion: SCAI Lesion Class 2 or 3, BMI for STEMI/non STEMI, Previous Dialysis for STEMI/non STEMI, Highest Risk Lesion Segment Category for STEMI/non STEMI. ‡ Per 10 unit increase. § Versus Elective

Registries Can Define QI Targets

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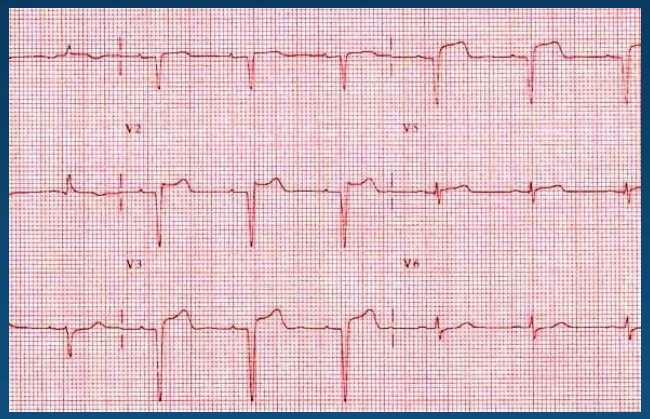
J Am Coll Cardiol, 2009; 53:161-166



27%

Pre-hospital ECG

↓ Door to reperfusion times

↓ Risk-adjusted mortality

Why does it matter? Mortality falls even with decreases in already low times!

CathPCI Registry 2005-06 (N=43,801) Rathore et al, Circulation, AHA08 abstract #6174)

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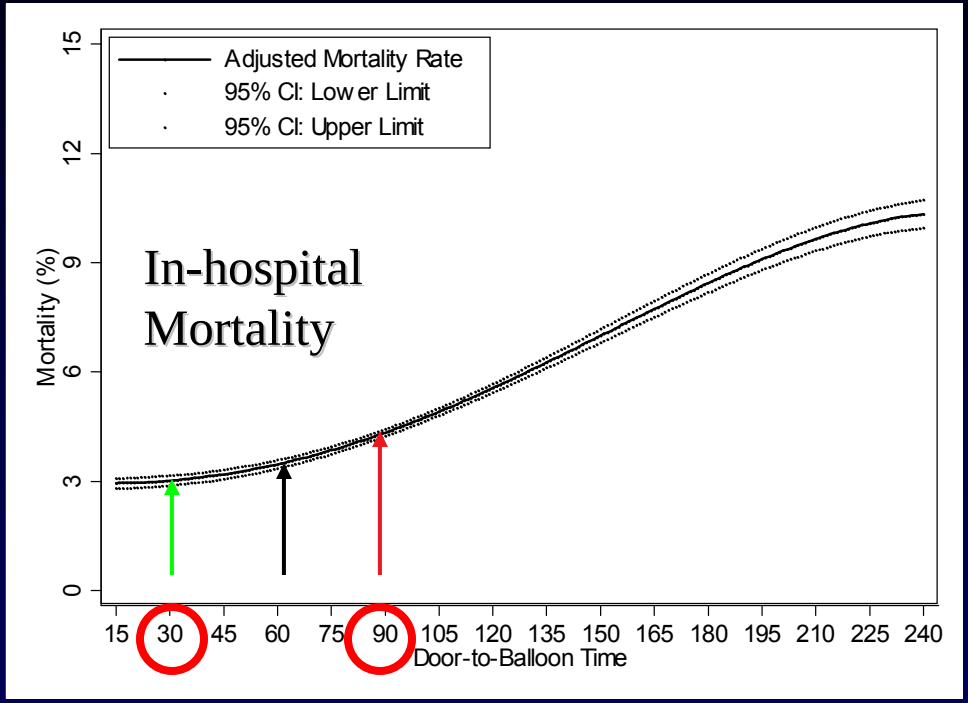
Fractional Polynomial - Adjusted



Overall mortality 4.6%

Best fit from 3rd degree polynomial

P<0.001 for comparison with linear term

⇓D2B from 90 to 60 minutes associated with ⇓0.8% Mortality

⇓D2B from 60 to 30 minutes associated with ⇓0.5% Mortality

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Quality can save Money

U. M. Khot et. Al., Emergency Department Activation of the Catheterization Laboratory and Immediate Transfer to an Immediately Available Catheterization Laboratory to Reduce Door to Balloon Time in ST Elevation Myocardial Infarction. *Circulation. 2007; 116*

ED Activation of Cath Lab &
Immediate Transfer by Care Team

- D2B decreased 113 min to 75 minutes
- Transfer in 147 minutes to 85 minutes
- Infarct size reduced (creatinine kinase)
- LOS 5 +/- 7 days to 3 +/- 2 days
- Cost $26K (+/- $29k) to $18K (+/- $9K)

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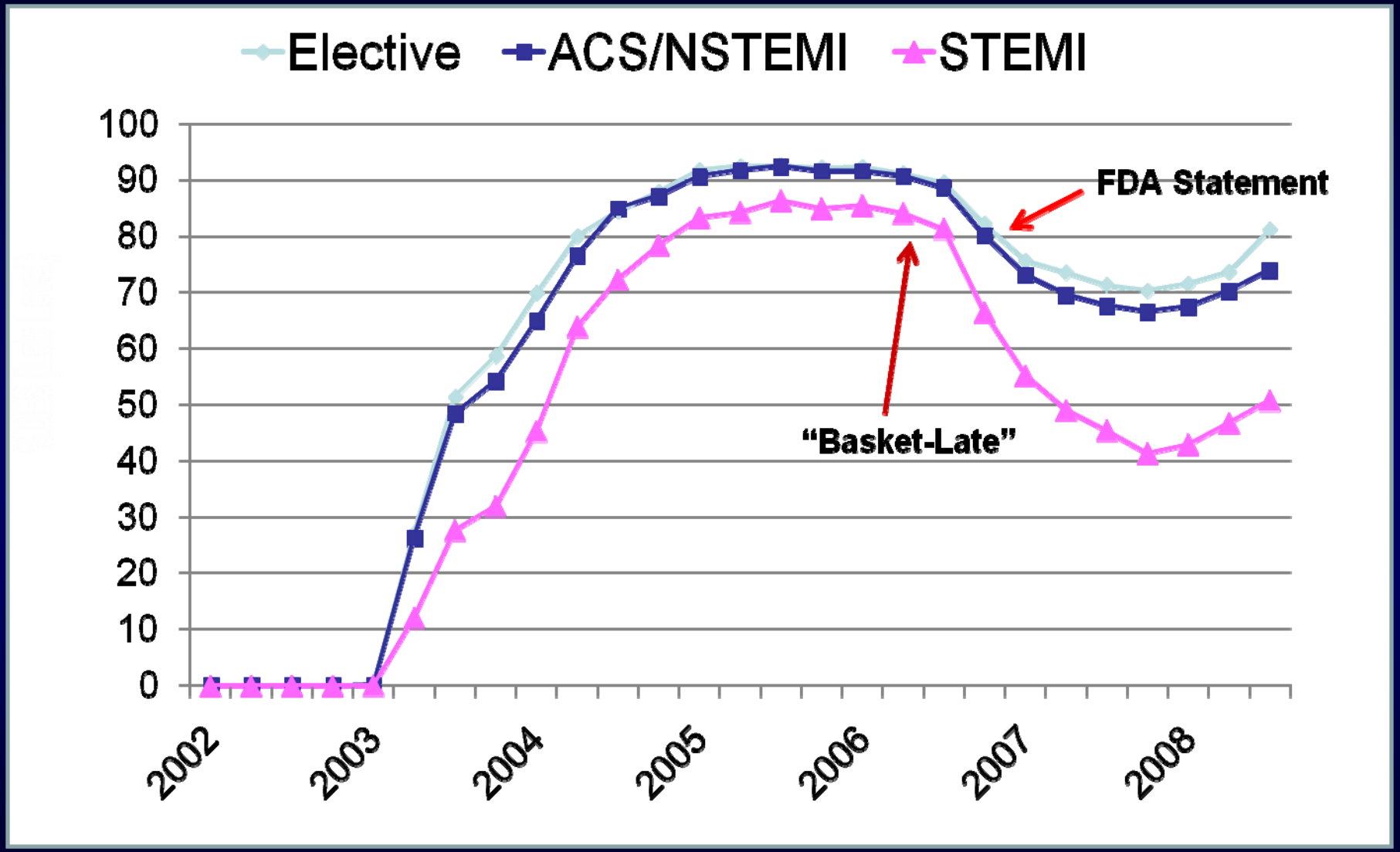
%Drug Eluting Stents



NCDR - Elective PCI
PCI Volume with Mortality

NCDR Centers (n= 403) 2001 - 2004

Annual PCI Volume	# of Sites	Number of Patients (%)	Mortality (%)	Odds Ratio (95% CI) (vs. volume ≥801)
0-200	43	6,305 (1.3)	0.49	1.17 (0.81 - 1.71)
201-400	85	42,039 (8.7)	0.49	1.12 (0.96 - 1.31)
401-800	132	116,116 (24.0)	0.45	1.10 (0.99 - 1.22)
≥801	139	318,500 (65.9)	0.39	ref.

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Percutaneous Coronary Interventions in Facilities without On-Site Cardiac Surgery: A Report from the National Cardiovascular Data Registry (NCDR)

ACC/SCAI – i2 Summit

Late Breaking Clinical Trials

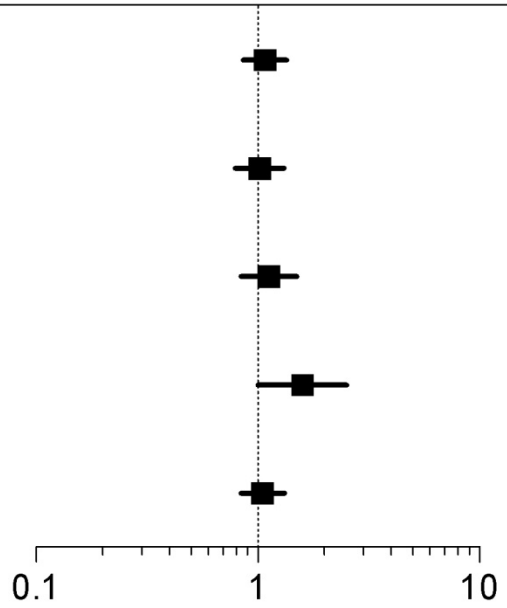
March 29, 2008

NCDR™ National Cardiovascular Data Registry

Percutaneous Coronary Interventions in Facilities without On-Site Cardiac Surgery

Safety and Efficacy of PCI Without On-site Surgical Back-up

Outcome	Total N	Odds Ratio (95% CI)	p-value
Mortality - overall	308,105	1.08 (0.86 - 1.35)	0.507
Mortality - primary PCI pts	33,002	1.02 (0.79 - 1.31)	0.881
Mortality - non-primary PCI pts	275,089	1.12 (0.84 - 1.50)	0.444
Emergency CABG	308,124	1.59 (1.00 - 2.52)	0.049
Mortality - pts not requiring emergency CABG	306,961	1.05 (0.84 - 1.32)	0.671



Risk Adjusted Outcomes

Odds Ratio (OR): outcomes for patients at On-Site (vs. Off-Site) facilities adjusting for site correlations and potential confounding variables

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Risk of Local Adverse Effects Following Cardiac Catheterization by Hemostasis Device and Gender

A Report from the NCDR in
Partnership with the FDA

Dale Tavris, Syamal Dey, Albrecht Gallauresi, Richard Shaw,
William Weintraub, Kristi Mitchell, Ralph Brindis

Grant from Office of Women's Health, Food and Drug Administration

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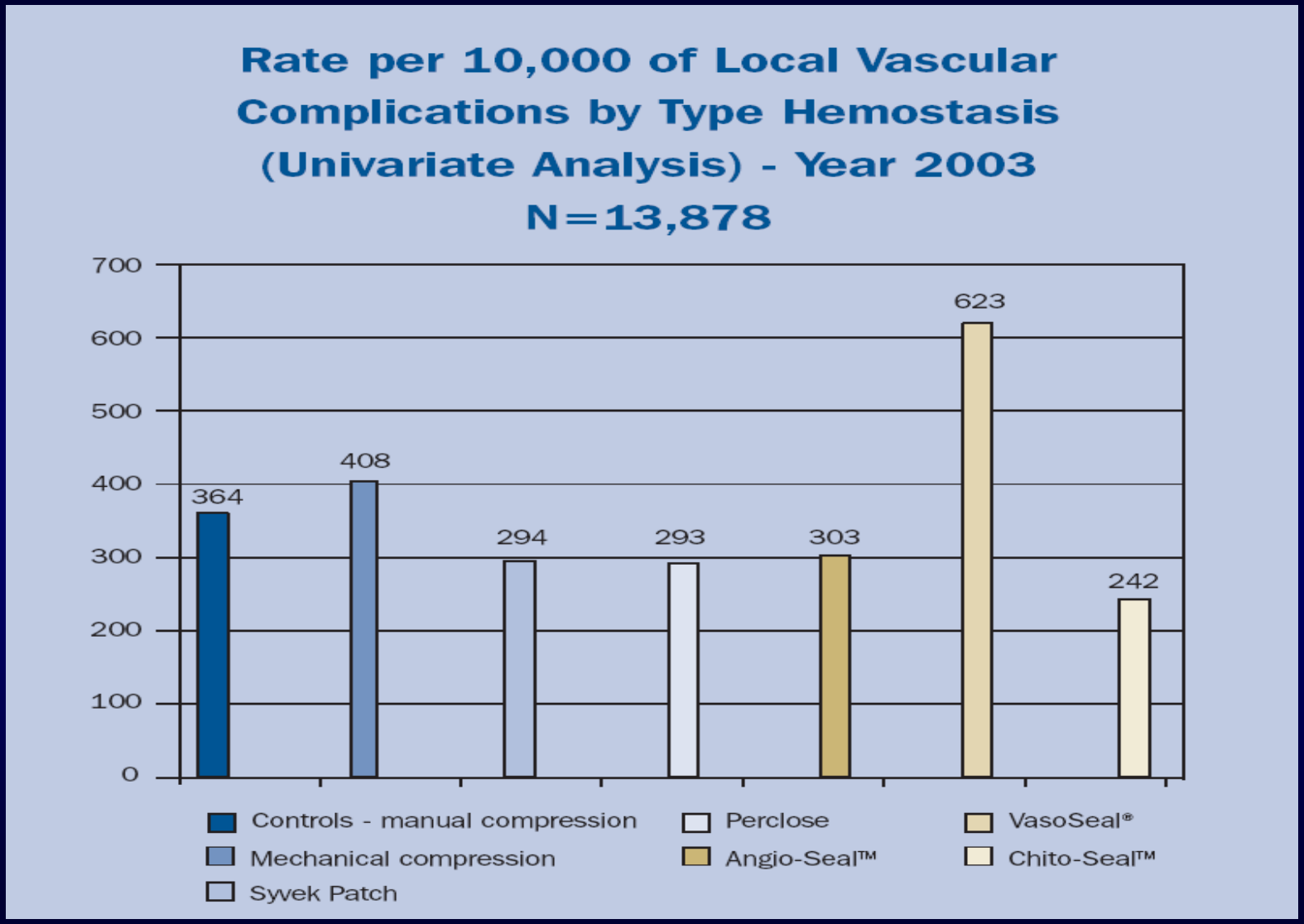
Risk of Local Adverse Effects Following Cardiac Catheterization by Hemostasis Device and Gender



A Report from the NCDR in Partnership with the FDA

Certification and Outcomes with ICDs

Higher risks of adverse events and complications for patients treated by non-electrophysiologists

Complications Stratified by Physician Certification

	Total, No.	Physician Certification			
		EP	CVD	TS	Other
	n=111,293	n=78,857	n=24,399	n=1,862	n=6,175
Adverse events (%)					
Any complication	3.5	3.3	3.8	5.5	3.8
Major Complication	1.3	1.2	1.5	2.2	1.5
Minor Complication	2.3	2.3	2.4	3.6	2.4

EP: Electrophysiologist, CVD: nonelectrophysiologist Cardiologist, TS; Thoracic Surgeon

Curtis et al. , JAMA 2009; 301 (16) 1661:1670

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Outcomes Following Coronary Stenting: A National Study of Long Term, Real-World Outcomes of Bare-Metal and Drug-Eluting Stents

Pamela S. Douglas, J. Matthew Brennan, Kevin J. Anstrom, Eric L. Eisenstein, David Dai, Ghazala Haque, David F. Kong, Ralph Brindis, Art Sedrakyan, David Matchar, Eric D. Peterson

Duke Clinical Research Institute
Duke University Medical Center

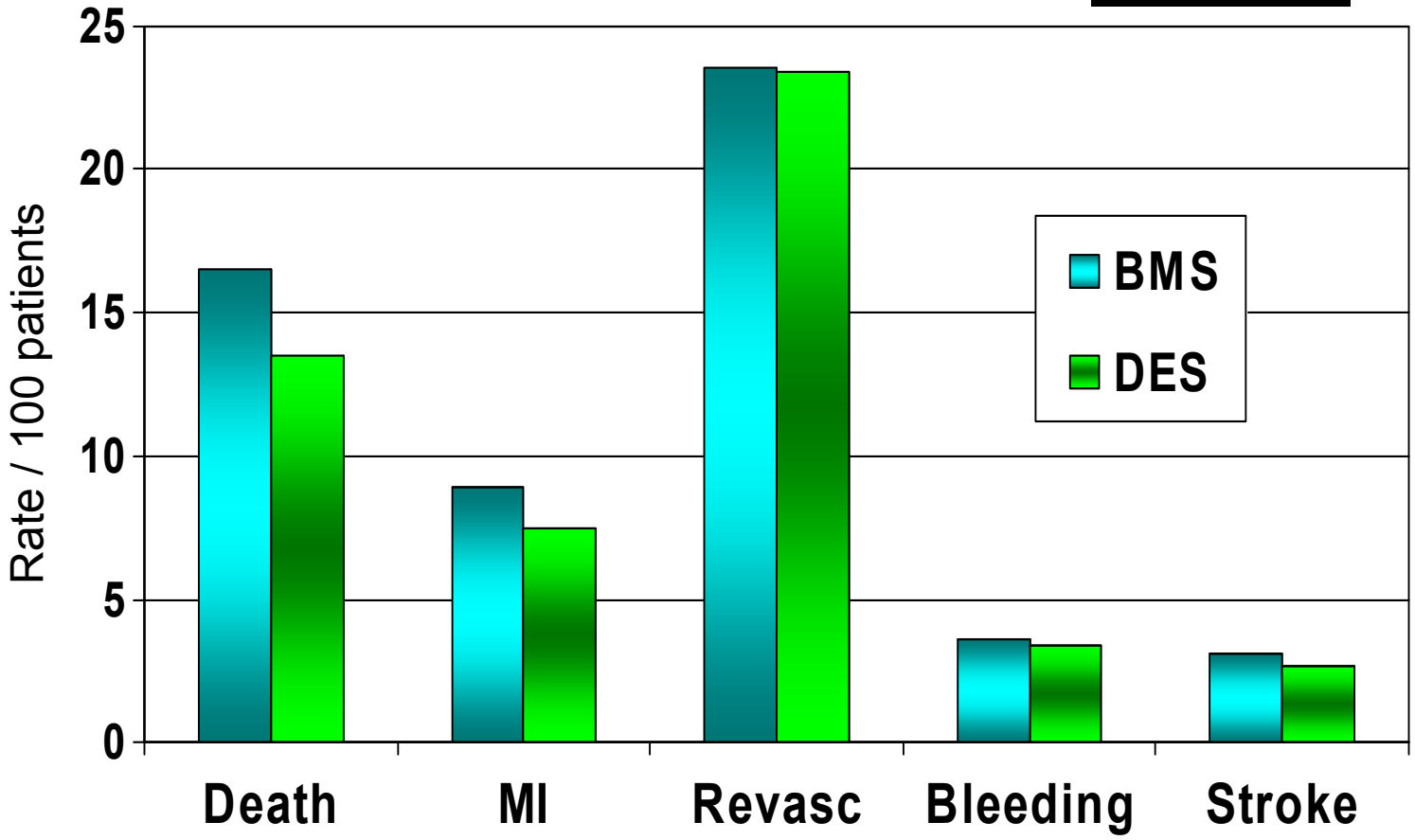
Goal and Population

- **Goal**
  - To examine comparative effectiveness and safety of DES vs BMS in a national PCI cohort
- **Study population**
  - All PCI pts ≥ 65 yo in NCDR CathPCI 1/04-12/06
  - Follow up obtained through linkage to CMS inpatient claims data using indirect identifiers; 76% matched
- **Final cohort**
  - 262,700 pts
  - 83% DES; 46% Cypher, 55% Taxus

Analysis

- **30 month outcomes**
  - Death, MI, Stroke, Revascularization, Major bleeding
  - Overall and in important subgroups
- **Outcomes adjustments**
  - Inverse propensity weighted model (102 covariates)
  - Cox proportional hazards model (60 covariates)
- **Sensitivity analyses**
  - Results in ‘RCT-like’ population
  - Non-CV ‘cause’ of death

DES & BMS Event Rates:30-month Adjusted



Conclusions

- NCDR data can be linked to claims data
- Data analysis allows a robust, longitudinal assessment of clinical effectiveness
- Comparing outcomes of DES to BMS at 30 months
  - No major DES safety concerns
  - Lower death and MI rates in DES patients
  - Slightly lower revascularization, bleeding rates
  - Similar stroke rates

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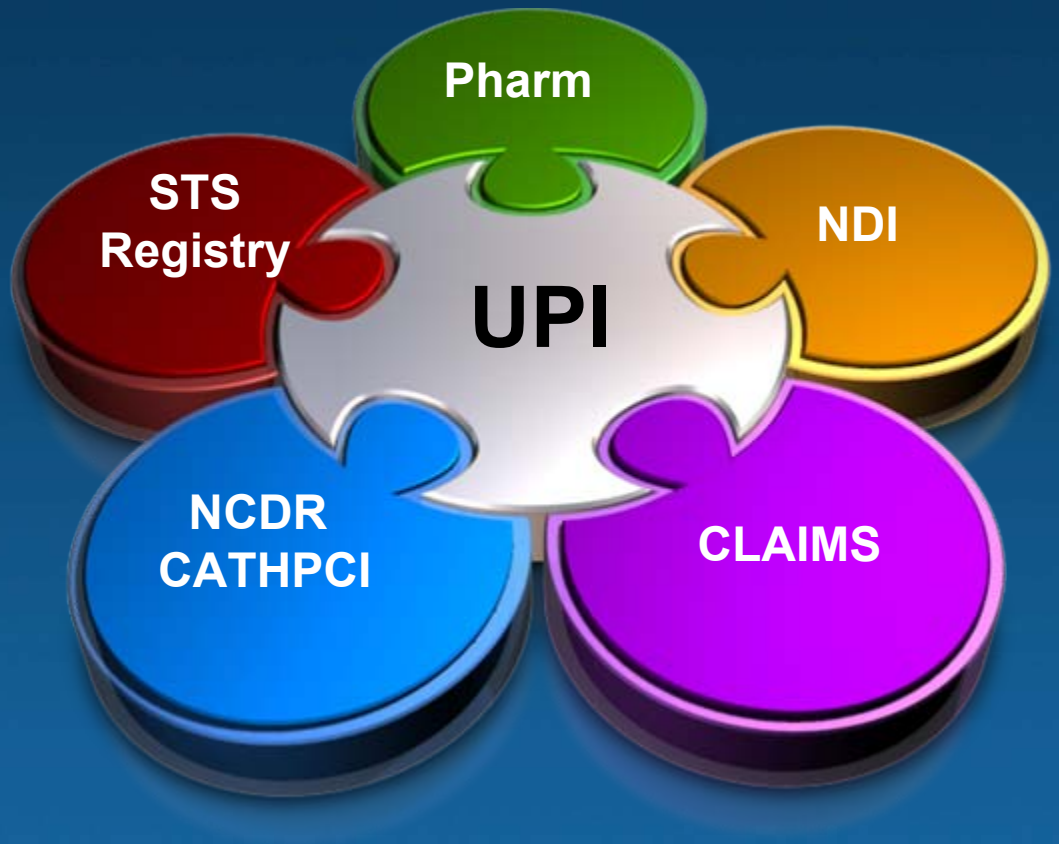
National Data Repository for Comparative Effectiveness Research



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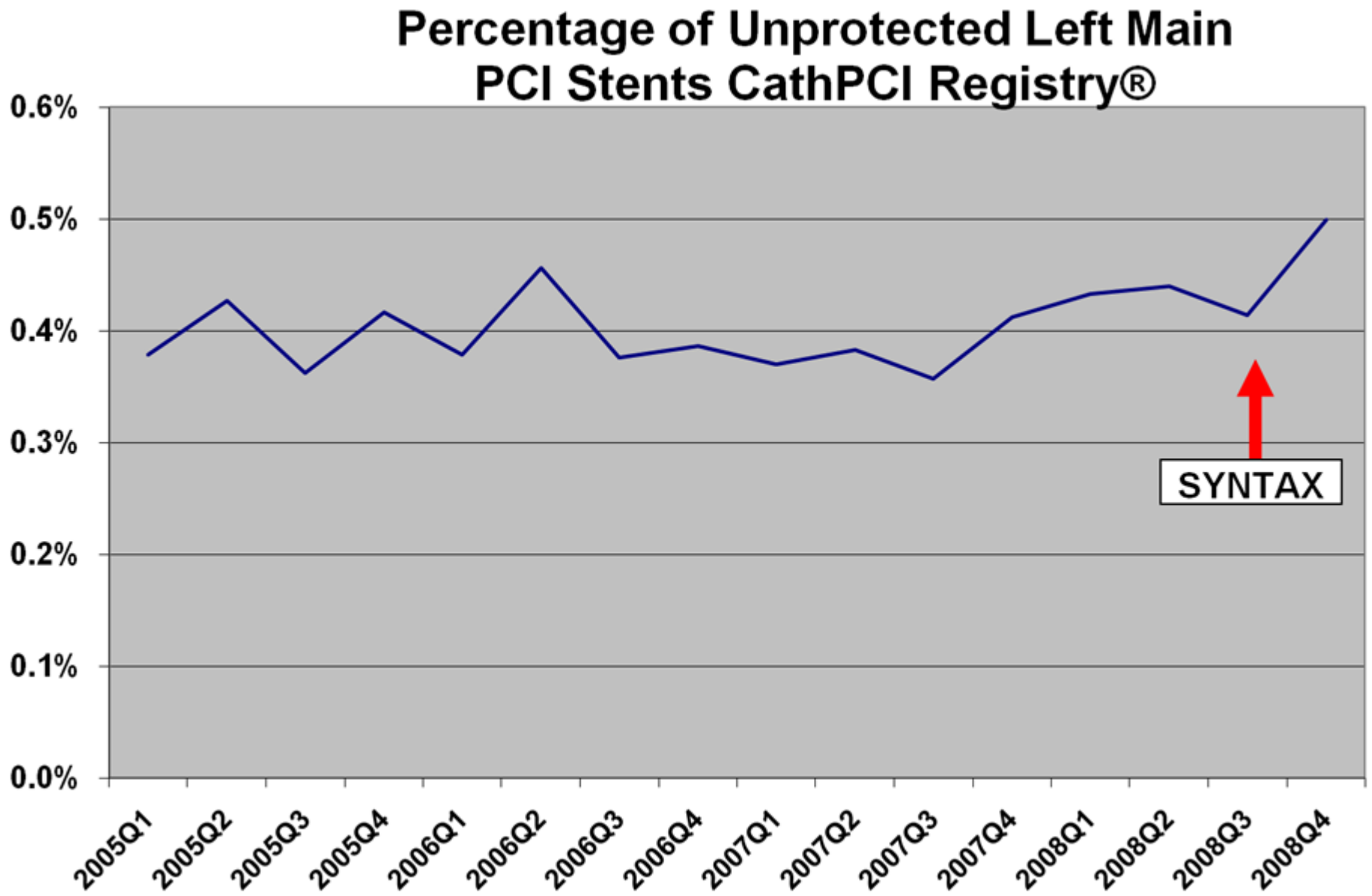
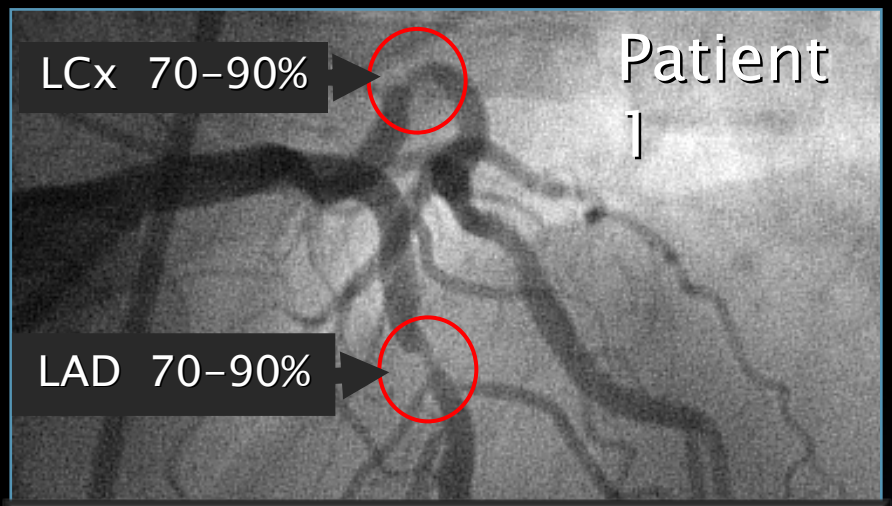
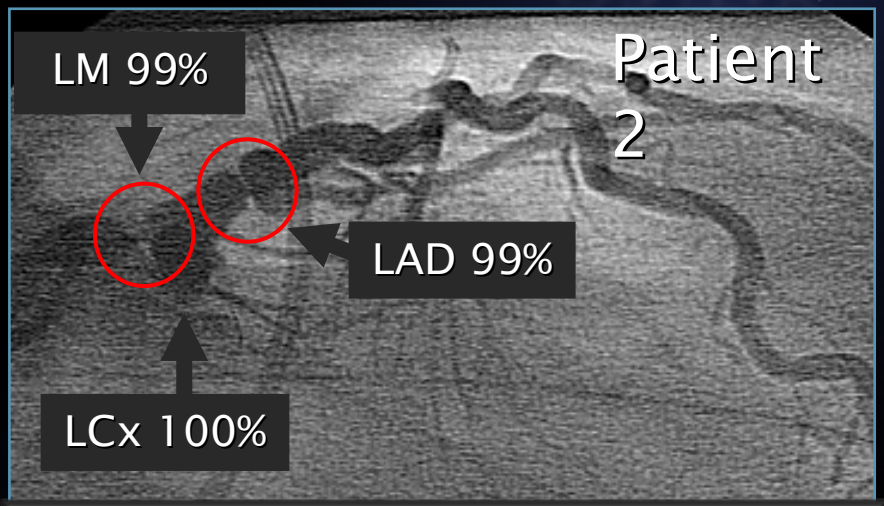


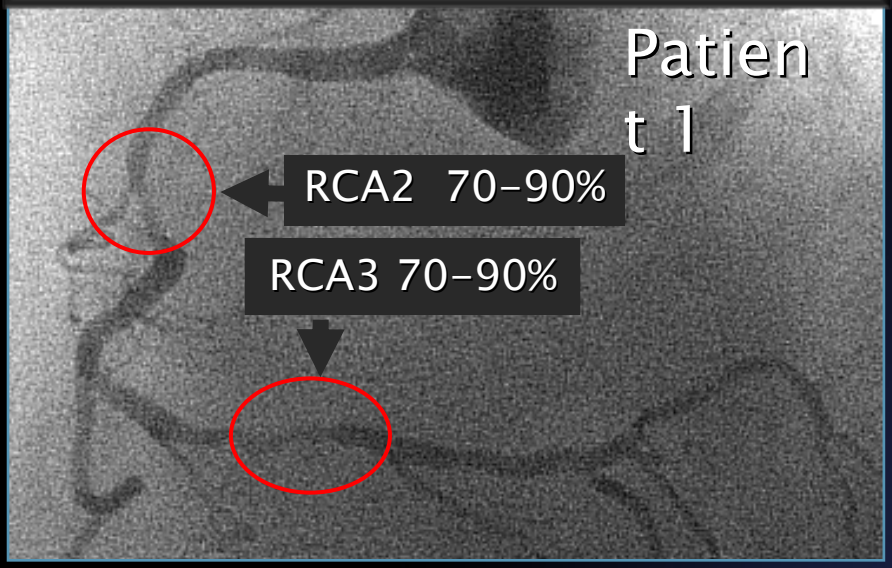
There is '3-vessel disease' and '3-vessel disease'

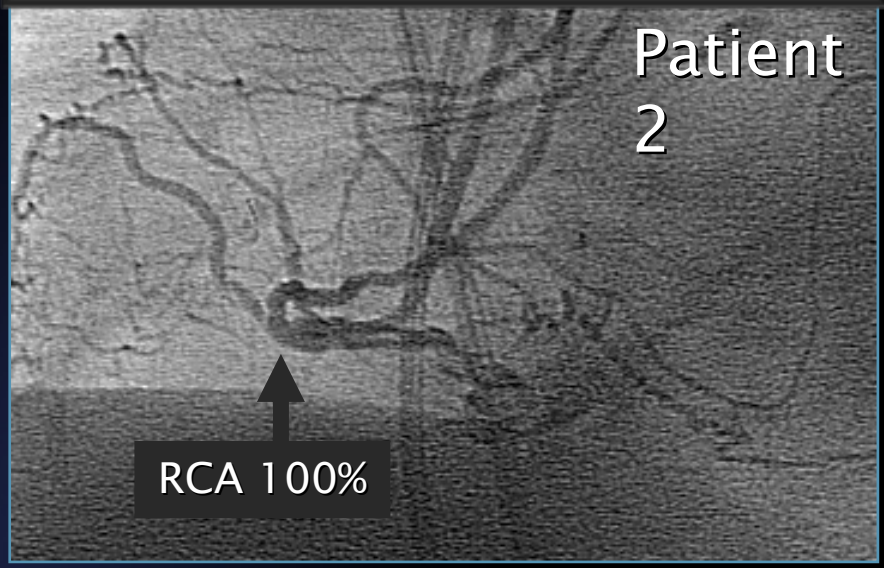


SYNTAX SCORE 21



SYNTAX SCORE 52





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NHLBI GO Grant Proposal: ACC/STS - CardioLINK

- **Purpose**
  - **Compare CABG and PCI using linked databases from the CathPCI and STS Registries for in-hospital outcomes**
- **Clinical data linked to MEDPAR data for long-term survival and economic outcomes**
- **Develop prediction models of death after initial revascularization in setting of chronic CAD**

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ACC/STS – CardioLINK

- Create propensity score for patients undergoing isolated CABG or PCI in stable CAD
- Create a model to predict the SYNTAX score based on co-variables available in STS and NCDR databases
- Compare long-term survival, hospitalization for MI, renal failure, stroke, and repeat revascularization using propensity scores from matched pairs and also by disease severity from derived SYNTAX scores

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ACC/STS – CardioLINK

- Cost and incremental cost-effectiveness of CABG vs PCI for matched subgroups
- Outcomes in cost per life year gained and cost per quality-adjusted life year gained

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CER and Registries

- **Perfect Opportunity for Coverage with Evidence Development (CED)**
  - Offers the "Carrots" and "Sticks" for Registry participation
  - Realizes opportunities to assess new technology in real world applications – non-RCT and off label uses
  - Percutaneous Aortic Valves
  - Atrial Fibrillation Ablation
  - New CV Imaging Technologies

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CER and Registries

- The integral role that Registries will play in CER needs to be financially supported at both the hospital/clinician level and at the Registry infrastructure level
- With a robust national data repository, the goal of CER will be ideally achieved

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"The right objective for health care is to increase value for patients, which is the quality of patient outcomes relative to the dollars expended."

- Michael Porter

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