Presenter Disclosure Information

Jan Kornder MD, FRCPC, FACC

The following relationships exist related to this presentation:

Over the last 2 years:

Advisory Boards: MODEST (Less than $5000 total):

BMS, Lilly, Servier, Sanofi Aventis, and Astra Zeneca

Speaker Honoraria: MODEST (Less than $10000 total)

Boehringer-Ingelheim, Astra Zeneca, Lilly, Pfizer, Sanofi Aventis, BMS

Research: Roche, Astra Zeneca, Merck-Schering, BMS, Sanofi

All Honoraria and consulting fees donated to charity

What is a Registry?

- A registry is a systematic recording of data on patients with a specific condition or device
- Registries do NOT test the benefits of one drug or device compared to another or placebo, they record real life data of what happens to pts with conditions or devices
- Registries can identify CARE GAPS or provide hypothesis generating questions, but do NOT answer specific treatment questions

What is a clinical trial?

- Biomedical or health-related research studies in human beings that follow a pre-defined protocol.
- Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured.
- Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.

What is GRACE?

- Launched in 1999, The Global Registry of Acute Coronary Events is an international database designed to track outcomes of patients presenting with acute coronary syndromes, including myocardial infarction or unstable angina.
- GRACE includes hospitals in North America, South America, Europe, Asia, Australia and New Zealand.

Multinational Site Network

	Argentina	7 sites	
	Australia	5 sites	
	Austria	5 sites	
	Belgium	6 sites	
	Brazil	7 sites	
	Canada	5 sites	
	France	7 sites	
	Germany	5 sites	
	Italy	5 sites	
	New Zealand	2 sites	
	Poland	6 sites	
	Spain	3 sites	
	UK	4 sites	
	USA	19 sites	

Adapted from The GRACE Investigators *Am Heart J* 2001;141:190-9

What is GRACE?

- Multinational, prospective registry of the entire spectrum of acute coronary syndromes (ACS)
- Observational database of clinical management practices and patient outcomes in ACS
- 14 countries in Europe, North and South America, Australia/New Zealand
- First 10 consecutive cases per centre/month with qualifying symptoms *plus* evidence of coronary artery disease

The GRACE Investigators *Am Heart J* 2001;141:190-9

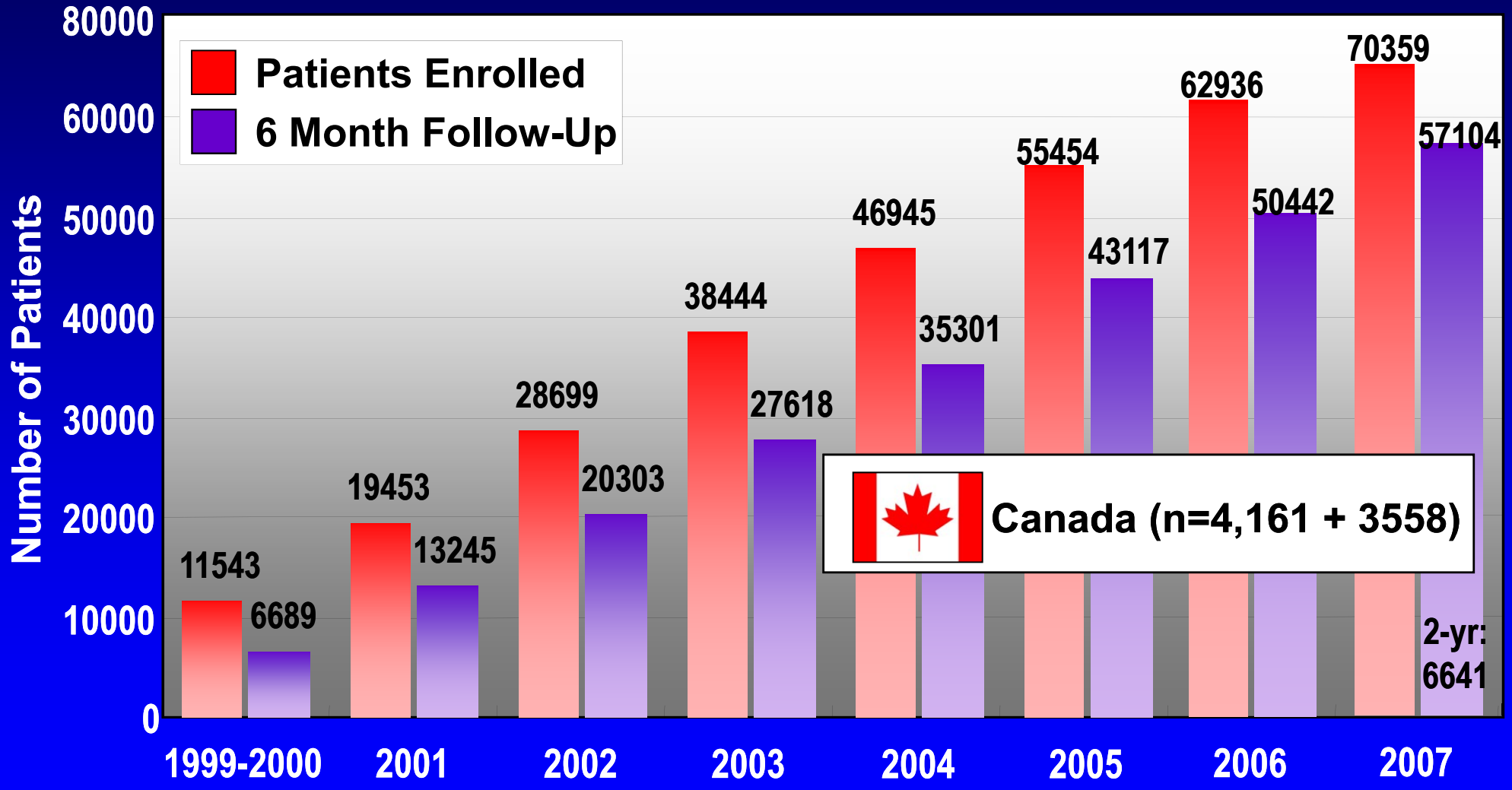
GRACE™
GLOBAL REGISTRY OF ACUTE CORONARY EVENTS

Objectives

- Identify opportunities to improve the quality of care for patients with ACS
- Describe diagnostic and treatment strategies and hospital and 6-month associated outcomes
- Develop hypotheses for future clinical research

GRACE™
GLOBAL REGISTRY OF ACUTE CORONARY EVENTS

Patient Enrolment + Follow-Up*



* As of Aug 26/08

What is Expanded Grace (GRACE 2)

- From 2001 to 2007, 31,982 patients with a suspected ACS were enrolled in expanded GRACE at 184 hospitals in 25 countries
- The distribution of patients was as follows: Asia 16.7%, Australia 3.8%, Europe 28.5%, North America 39.8%, and South America 11.2%.

Expanded GRACE = GRACE 2

* In Canada

Goodman et al *Am Heart J* 2009;158:193-201

GRACE Expansion

As of December 31, 2007

Country	Number of Sites*	Number of Patients
Australia	9	1,225
Austria	5	533
Bangladesh	1	100
Brazil	6	671
Bulgaria	23	398
Canada	44	11,265
China	14	3,809
Columbia	3	1,157
Ecuador	1	271
El Salvador	1	18
Germany	20	2,234
Guatemala	2	99
Italy	14	732
Latvia	1	371
Mexico	2	255
Panama	1	30
Peru	1	100
Poland	10	4,159
Portugal	1	153
Romania	3	319
Ukraine	3	215
United Arab Emirates	1	1,420
United States	11	1,456
Uruguay	2	81
Venezuela	5	911

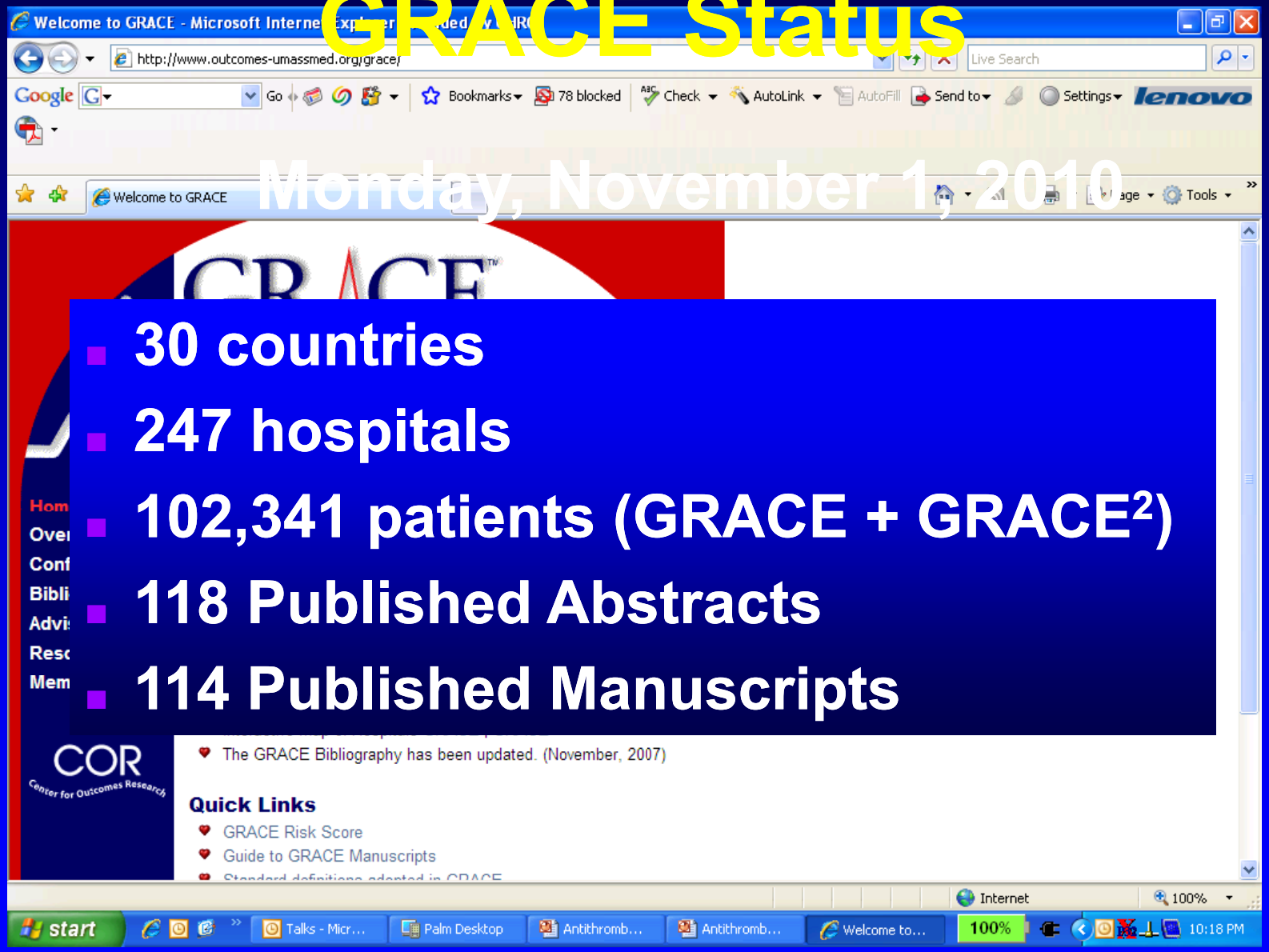
184 Hospitals

31,982 Patients

*Enrolled ≥1 non-transfer-in pt

GRACE Status

Monday, November 1, 2010

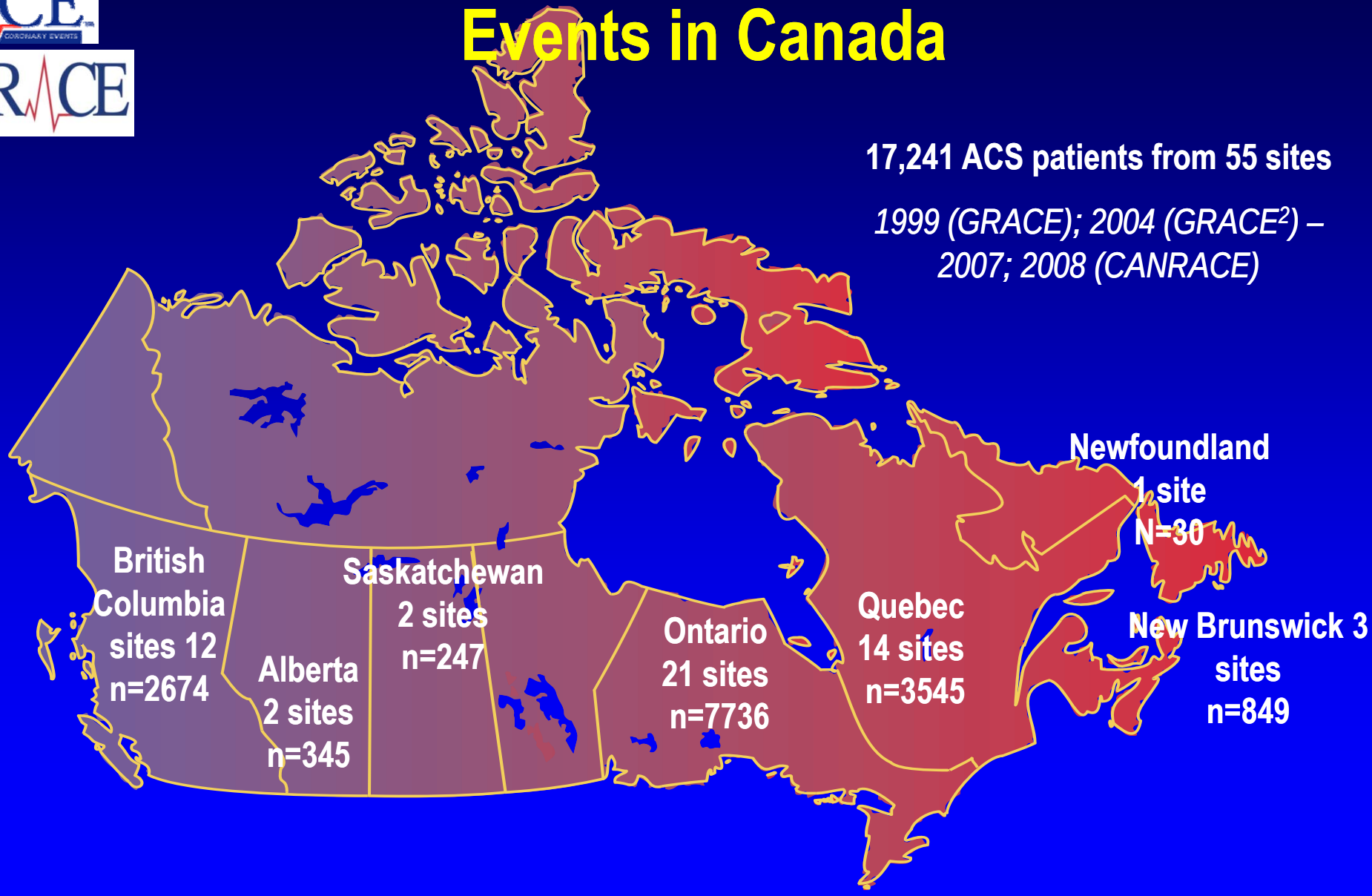


- 30 countries
- 247 hospitals
- 102,341 patients (GRACE + GRACE²)
- 118 Published Abstracts
- 114 Published Manuscripts

Global Registry of Acute Coronary Events in Canada

17,241 ACS patients from 55 sites

1999 (GRACE); 2004 (GRACE^2) – 2007; 2008 (CANRACE)



247 Core GRACE & GRACE^2 Study Sites in 30 Countries*

*30 countries = 16 GRACE^2 + 7 core GRACE + 7 both

Registry Management and Funding

- Expanded GRACE is sponsored by an educational grant from sanofi-aventis to the COR. The COR serves as the International Scientific Coordinating Center for GRACE and expanded GRACE.

- GRACE is supported by an unrestricted educational grant from sanofi-aventis to the Center for Outcomes Research, University of Massachusetts Medical School.

Data Management

- Data were collected at each site by a trained coordinator using a standardized CRF.
- Demographic characteristics, medical history, presenting symptoms, duration of prehospital delay, biochemical and ECG findings, treatment practices, and a variety of hospital outcome data were collected.
- Standardized definitions of all patient-related variables and clinical diagnoses were used.
- Completed CRFs were faxed to the data coordinating center (Center for Outcomes Research [COR], University of Massachusetts Medical School, Worcester, MA);
- alternatively, data were entered into an electronic, Web-based CRF.

DATA Reporting to Sites

- Each hospital received a profile of its own center's data as well as a summary of its country's and overall world data on a quarterly basis.
- The goal of expanded GRACE was to expand to additional hospitals within participating main GRACE countries as well as to increase the number of participating countries in the GRACE project and enroll approximately 5,000 patients per year

CANRACE

Quarterly Report to Investigators

Quarter 4, 2008

Site ID: 94013

Province: BC

Confidential

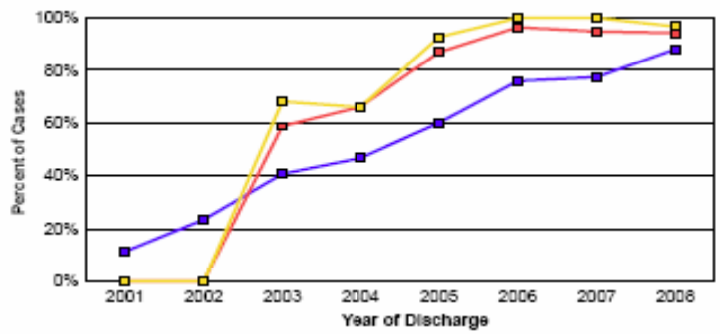
UMass Medical School
Center for
Outcomes Research

www.outcomes.org

Ticlopidine/Clopidogrel at Admission

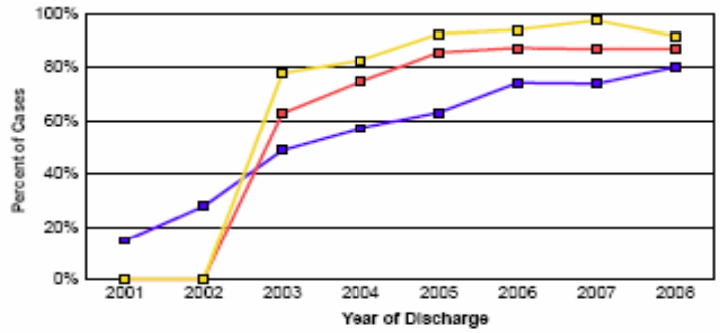
Site Province Canada

STE MI



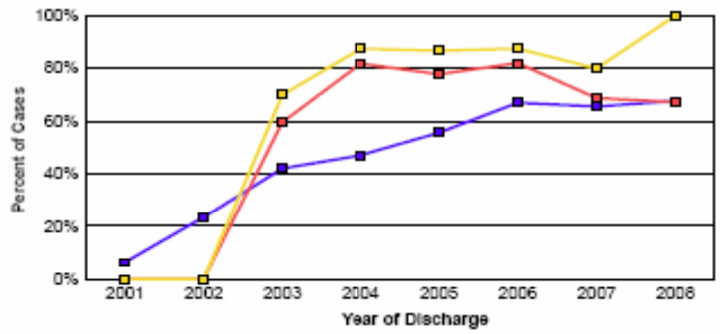
Denominator	2001	2002	2003	2004	2005	2006	2007	2008
Site	0	0	22	47	55	54	54	31

Non-STE MI



Denominator	2001	2002	2003	2004	2005	2006	2007	2008
Site	0	0	59	87	110	86	81	37

UA



Denominator	2001	2002	2003	2004	2005	2006	2007	2008
Site	0	0	20	16	15	8	5	1

GRACE™
GLOBAL REGISTRY OF ACUTE CORONARY EVENTS

Population-Based Sites

- Defined Community
- Includes all hospitals where community residents may seek care
- Ideally, socio-demographic and hospital characteristics match country or region as a whole

GRACE™
GLOBAL REGISTRY OF ACUTE CORONARY EVENTS

Representative Sites

- Convenience sample of hospitals considered representative of the hospitals in the region/country
- Balance characteristics such as size, academic vs. community hospital type, public vs. private status, facilities, etc.

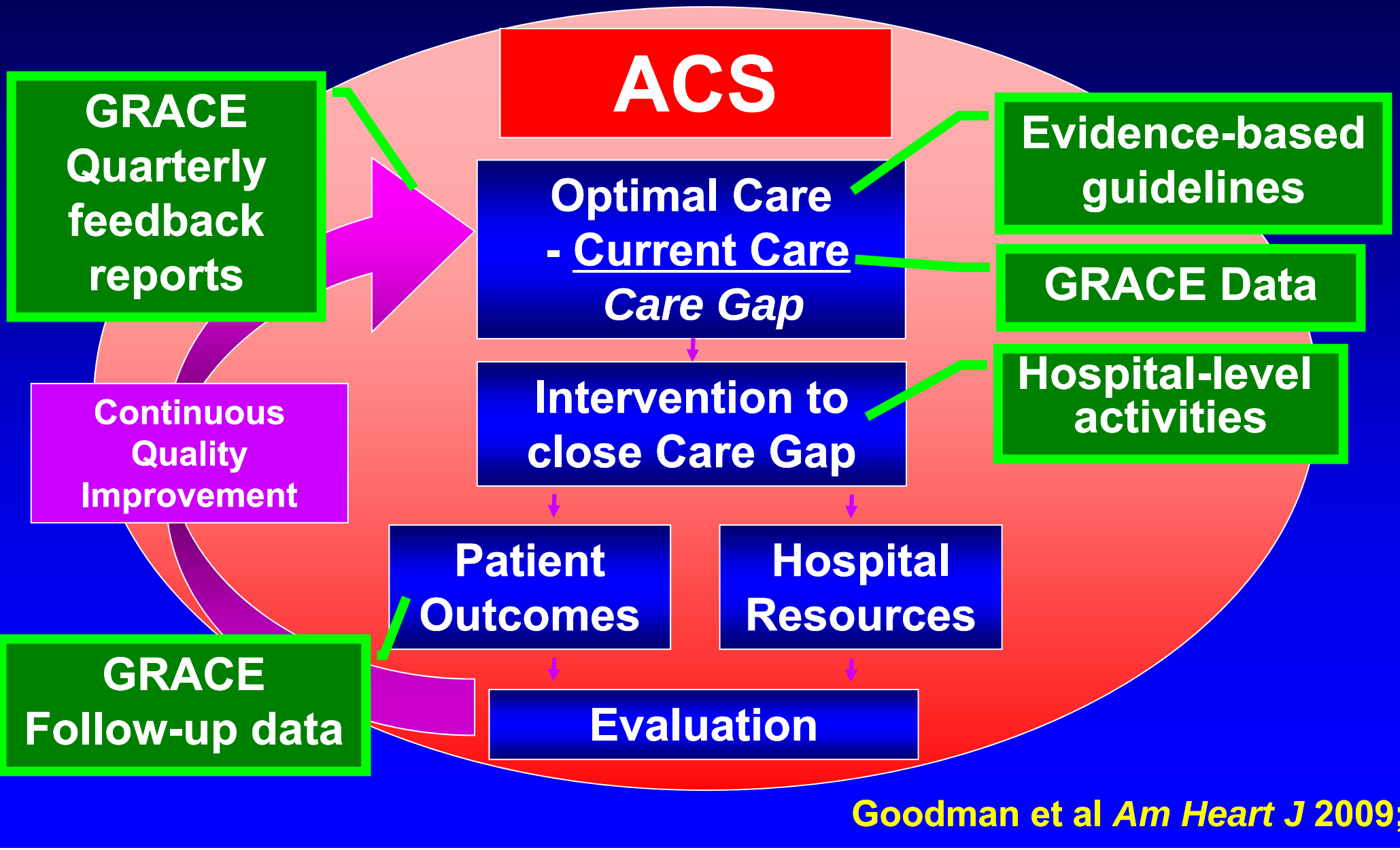
Case Selection Strategy

- Select first ~10 qualifying cases in each month
- Confirm inclusion/exclusion criteria
- Patient consent for follow-up
- Enroll patient
- Complete initial CRF
- Complete 6-month follow-up CRF

What is a CARE GAP?

- A CARE GAP is the difference between optimal therapy as suggested by clinical trials and the actual care given at YOUR Hospital

Optimal ACS Management: Closing the Care Gap



Goodman et al *Am Heart J* 2009;

Decline in Rates of Death and Heart Failure in Acute Coronary Syndromes, 1999-2006

Keith A. A. Fox, MB, ChB, FRCP
Philippe Gabriel Steg, MD
Kim A. Eagle, MD
Shaun G. Goodman, MD, MSc
Frederick A. Anderson, Jr, PhD
Christopher B. Granger, MD
Marcus D. Flather, MBBS, FRCP
Andrzej Budaj, MD, PhD
Ann Quill, MA
Joel M. Gore, MD
for the GRACE Investigators

Context Randomized trials provide robust evidence for the impact of pharmacological and interventional treatments in patients with ST-segment elevation and non–ST-segment elevation acute coronary syndromes (NSTE ACS), but whether this translates to changes in clinical practice is unknown.

Objective To determine whether changes in hospital management of patients with ST-segment elevation myocardial infarction (STEMI) and NSTE ACS are associated with improvements in clinical outcome.

Design, Setting, and Patients In the Global Registry of Acute Coronary Events (GRACE), a multinational cohort study, 44 372 patients with an ACS were enrolled and followed up in 113 hospitals in 14 countries between July 1, 1999, and December 31, 2006.

Main Outcome Measures Temporal trends in the use of evidence-based pharmacological and interventional therapies; patient outcomes (death, congestive heart failure, pulmonary edema, cardiogenic shock, stroke, myocardial infarction).

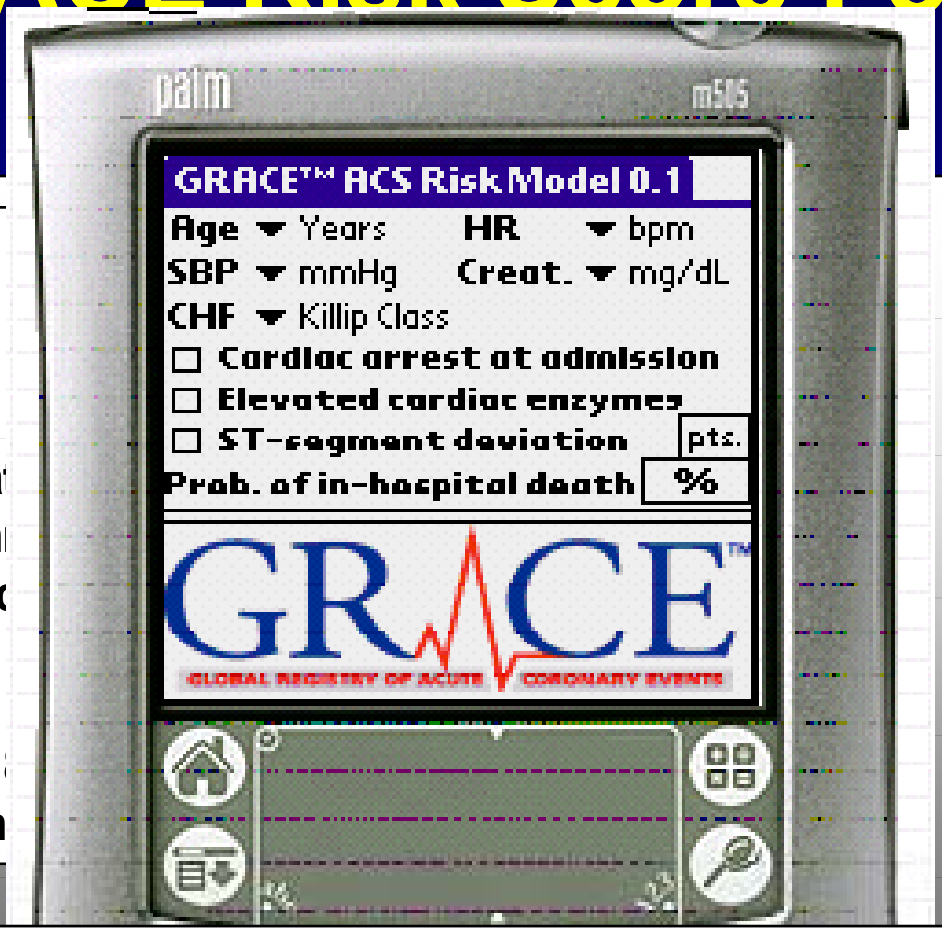
JAMA 2007;297:1892-1900

GRACE
GLOBAL REGISTRY OF ACUTE CORONARY EVENTS

SMH
ST. MICHAEL'S HOSPITAL

Wednesday, May 2nd, 2007 Edition of USA TODAY

GRACE Risk Score For All ACS



% of Patients

Risk Factor
Age
Diabetes
Hypertension
Heart rate (per 30 bea
Systolic BP (per 20 m
Killip Class (per ↑ in
Cardiac Arrest
Initial Cardiac Marker
Initial Creatinine (per
ST-segment deviation

n=11,389

60
50
40
30
20
10
0

0.2 0.3 23 29 36 44 52

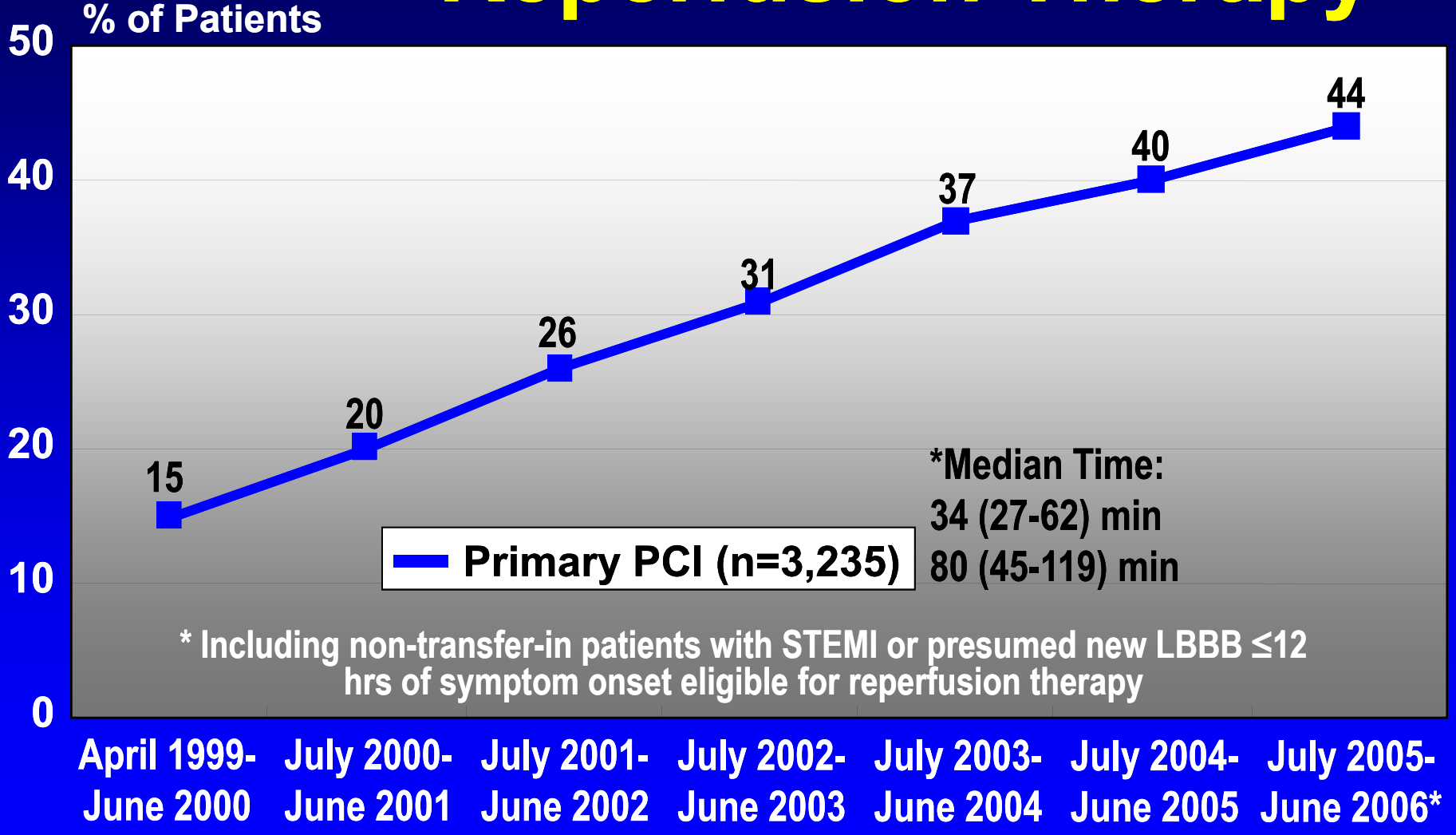
≤60 70 240 ≥250

Risk Score (Points)

Download PDA version at www.outcomes-umassmed.org/grace/acs_risk.cfm

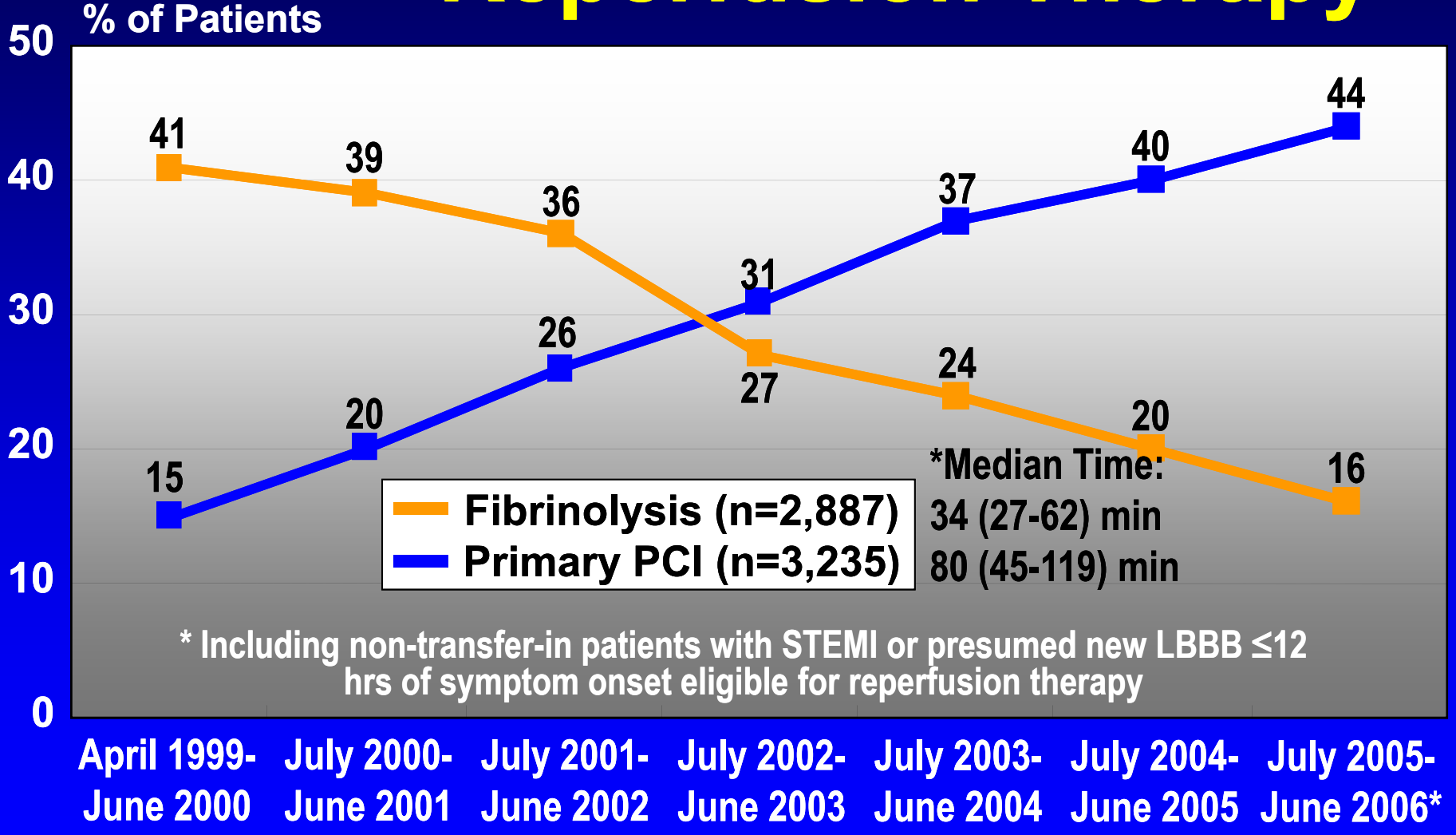
Granger et al *Arch Int Med* 2003;163:2345-53

Trends in Acute Reperfusion Therapy



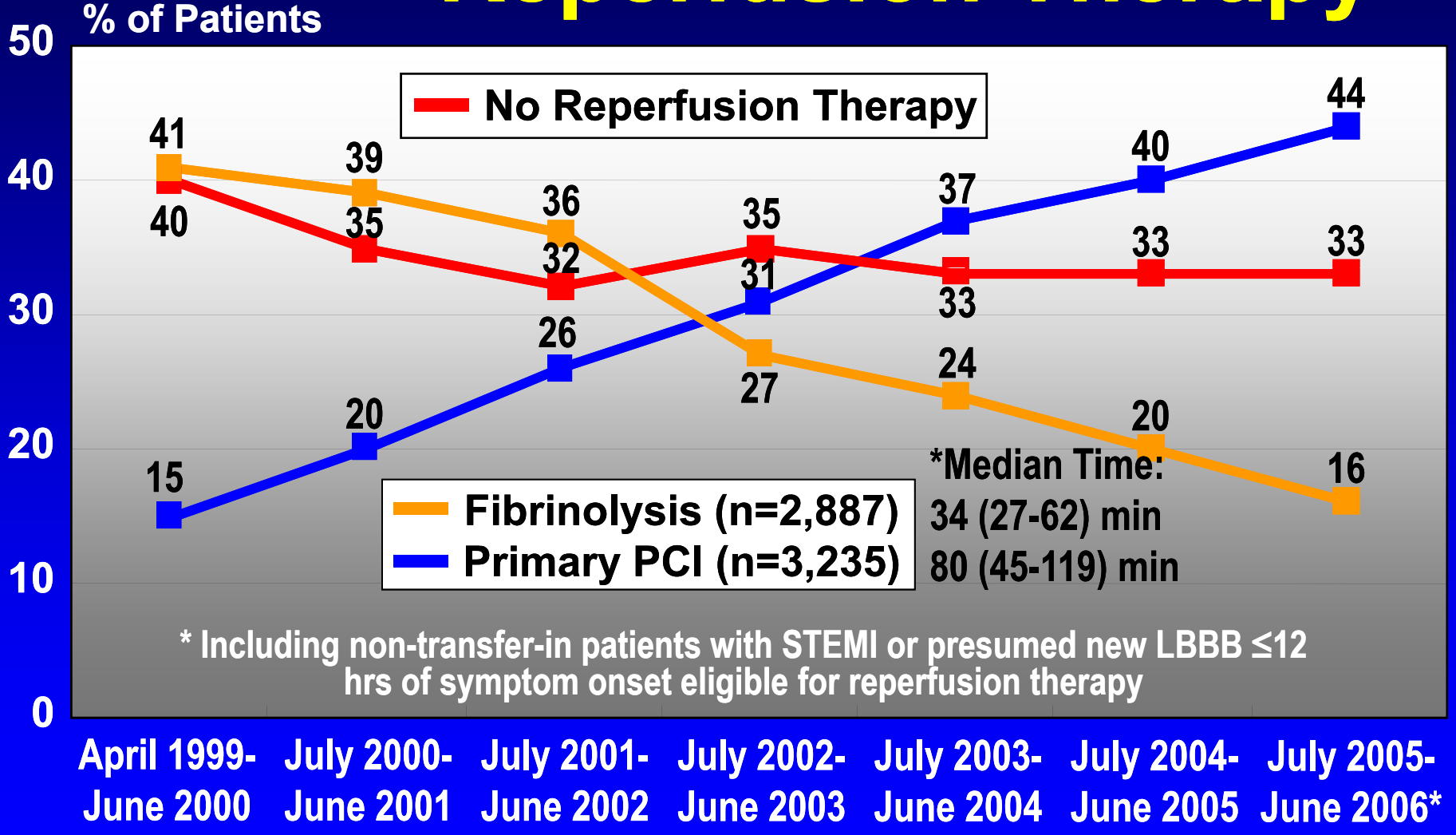
Eagle et al *Eur Heart J* 2008;29:609-17

Trends in Acute Reperfusion Therapy



Eagle et al *Eur Heart J* 2008;29:609-17

Trends in Acute Reperfusion Therapy

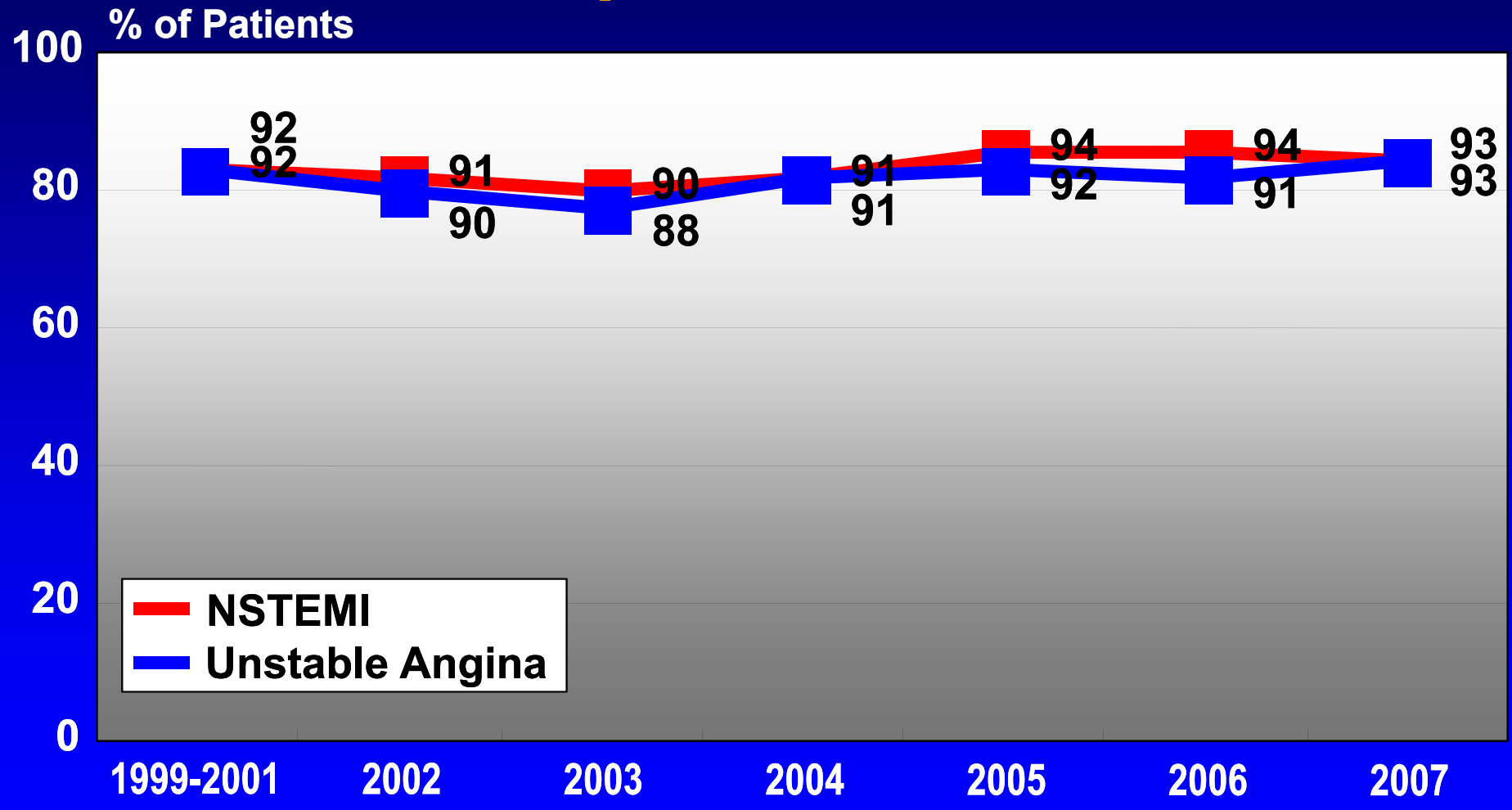


Eagle et al *Eur Heart J* 2008;29:609-17

Non-ST Elevation ACS

NSTEMI (n=28,431) + Unstable Angina (n=26,134)

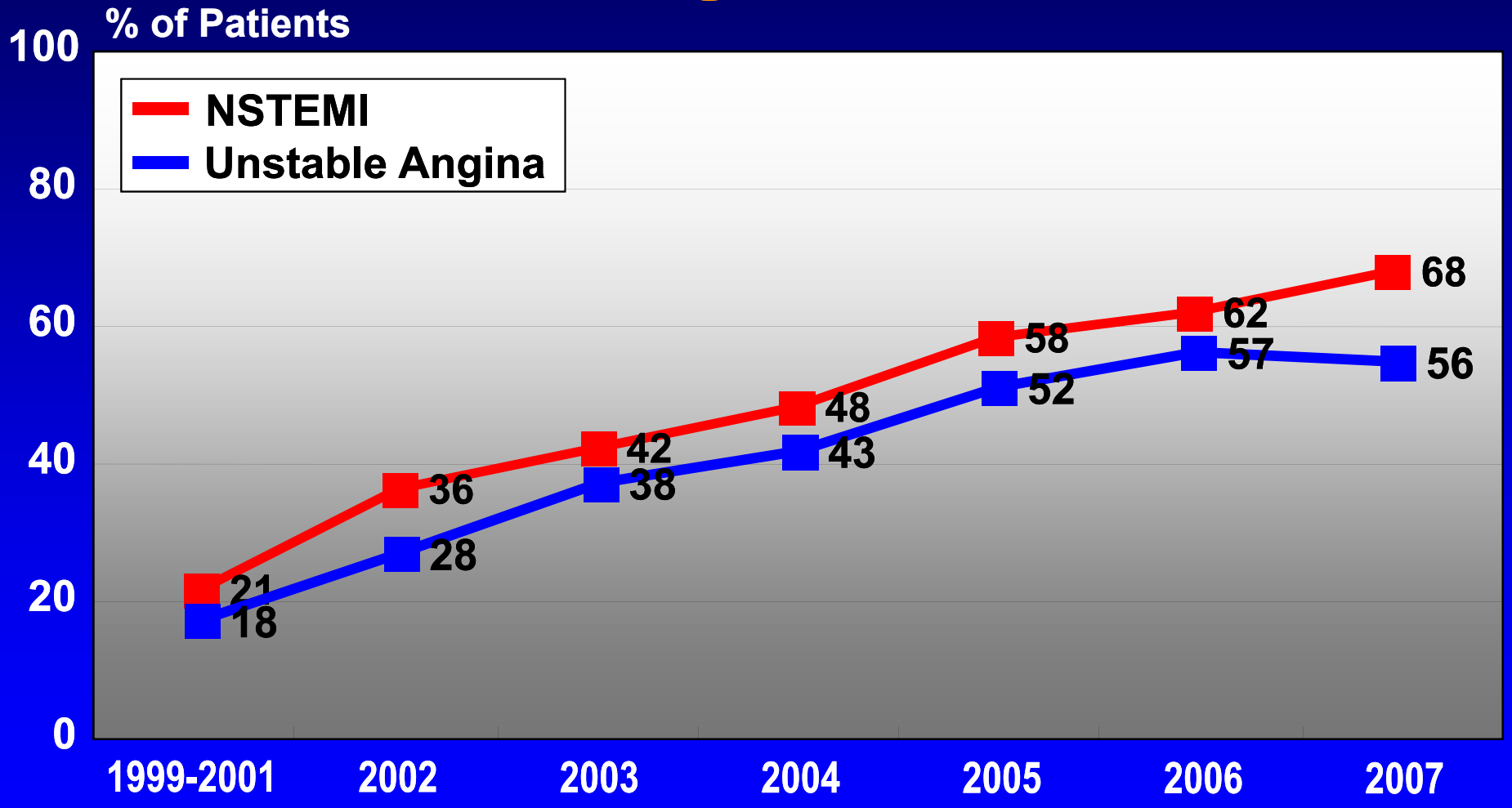
Trends in Aspirin Use at Admission



Non-ST Elevation ACS

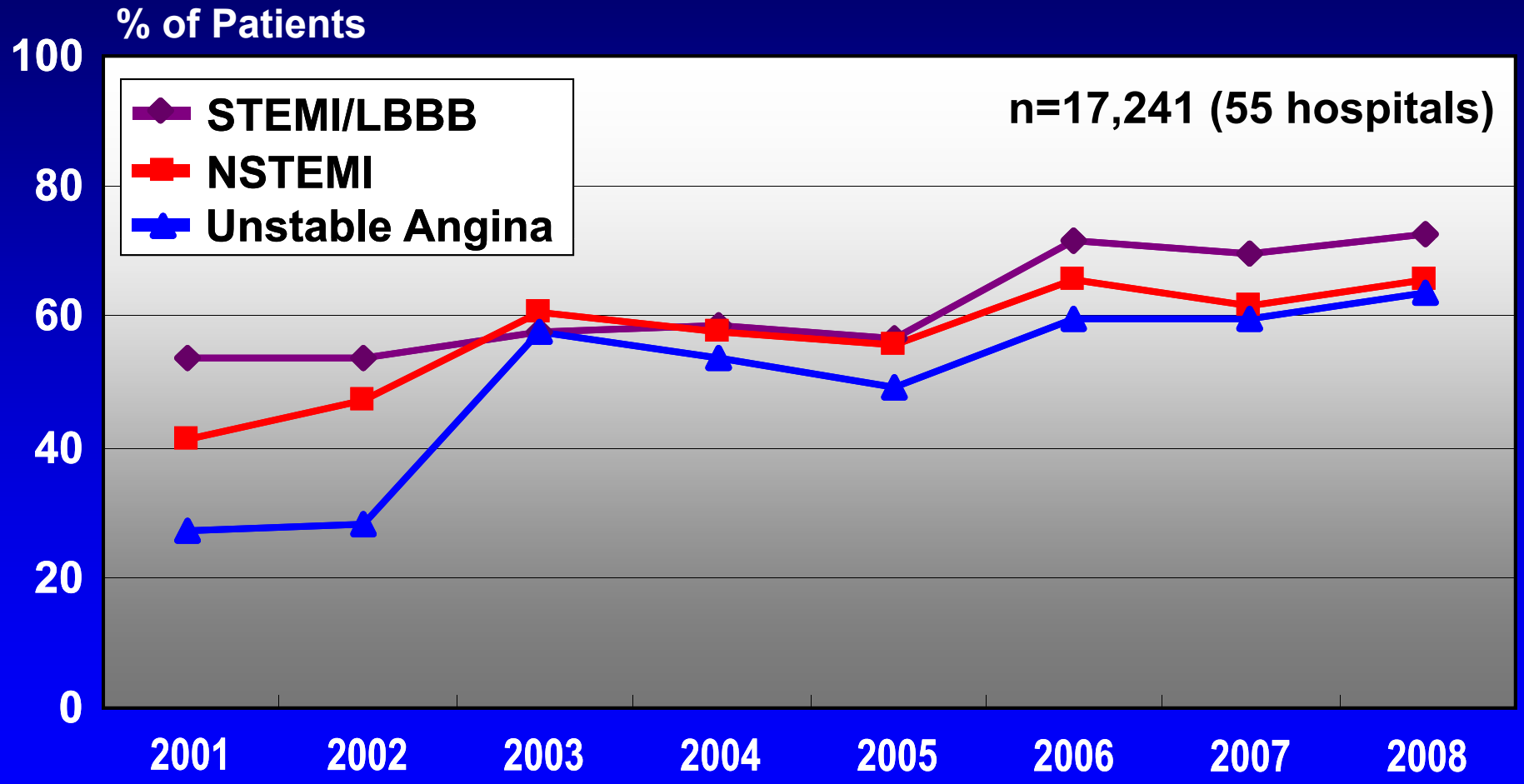
NSTEMI (n=28,431) + Unstable Angina (n=26,134)

Trends in Clopidogrel Use at Admission*

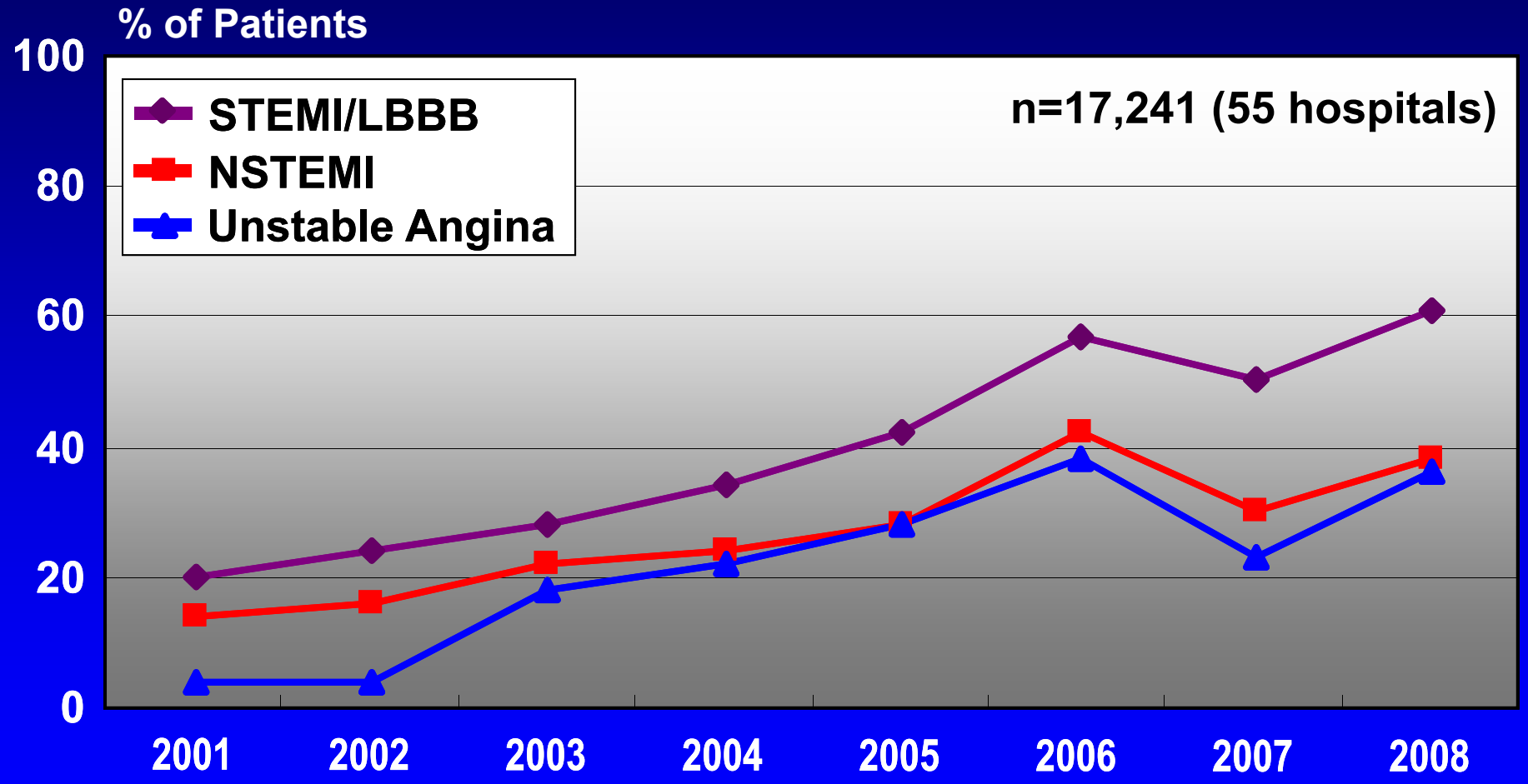


* 1st 24 hours

Trends in Cardiac Catheterization



Trends in PCI



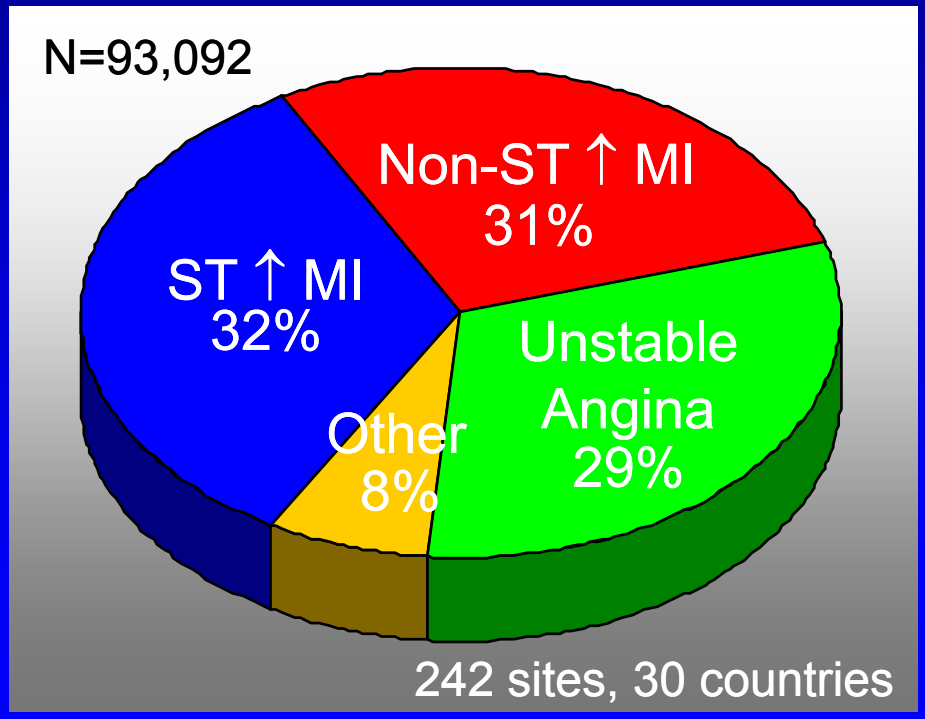
What are we doing at Surrey Memorial Hospital compared to British Columbia, Canada, and the Rest of the World?

GRACE GRACE 2 CANRACE

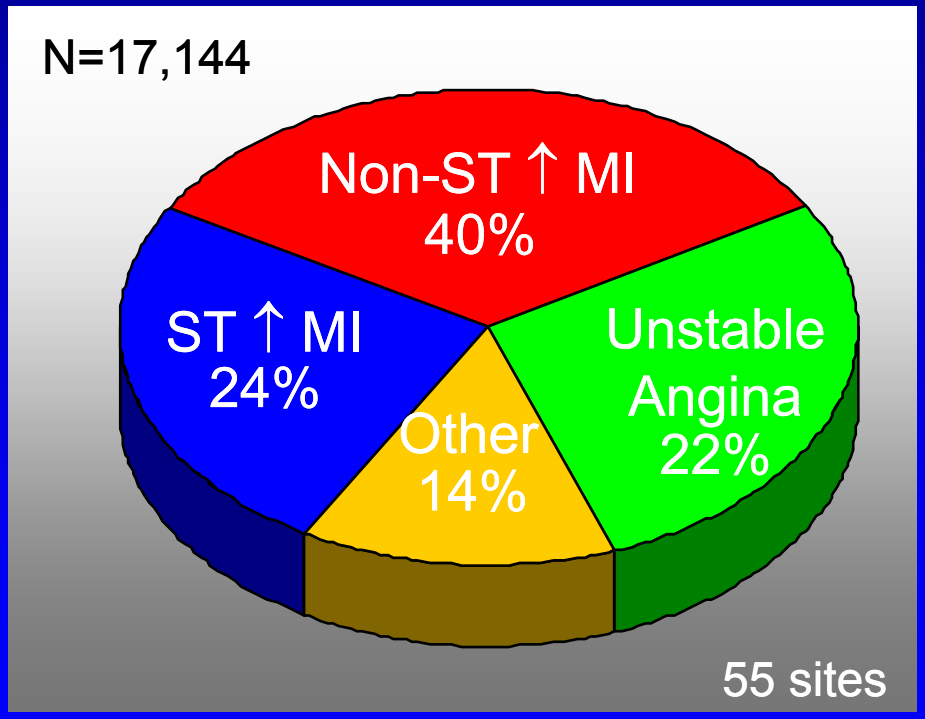
As of Q4 2007[1] and Q4 2008[2]

Presenting ECG* and Cardiac Marker Status

World[1]



Canada[2]

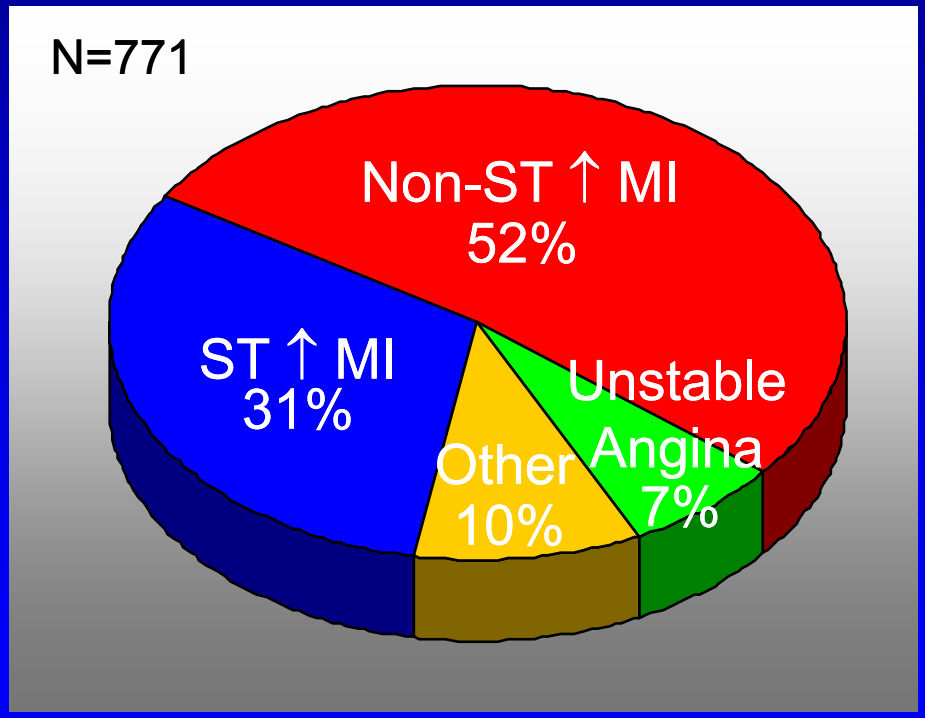


* based on site interpretation

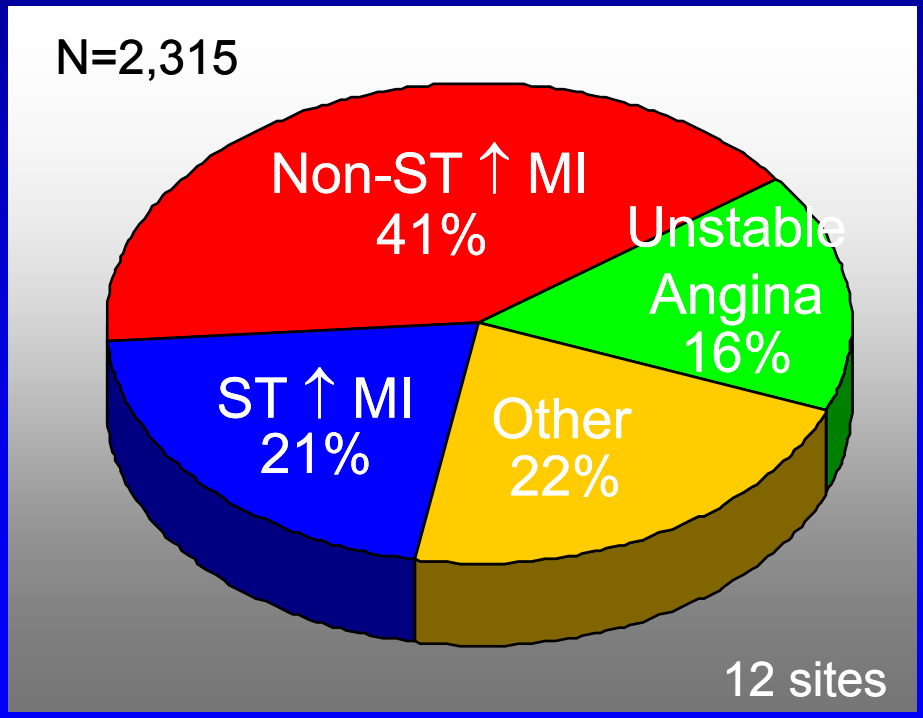
N=total; % as of Q4 2008

Presenting ECG* and Cardiac Marker Status

Surrey Memorial Hospital



British Columbia



* based on site interpretation + non-ACS *final* diagnosis

As of Q4 2007[1] and Q4 2008[2]

Patient Characteristics

	World[1] n=93,092	Canada[2] n=17,144	B.C.[2] n=2,315	SMH[2] n=771
Median Age (years)	66	67	66	61
>75 years (%)	27	30	27	21
Female (%)	33	35	31	27
Prior MI (%)	29	33	24	26

N= total; % as of Q4 2007[1] and Q4 2008[2]

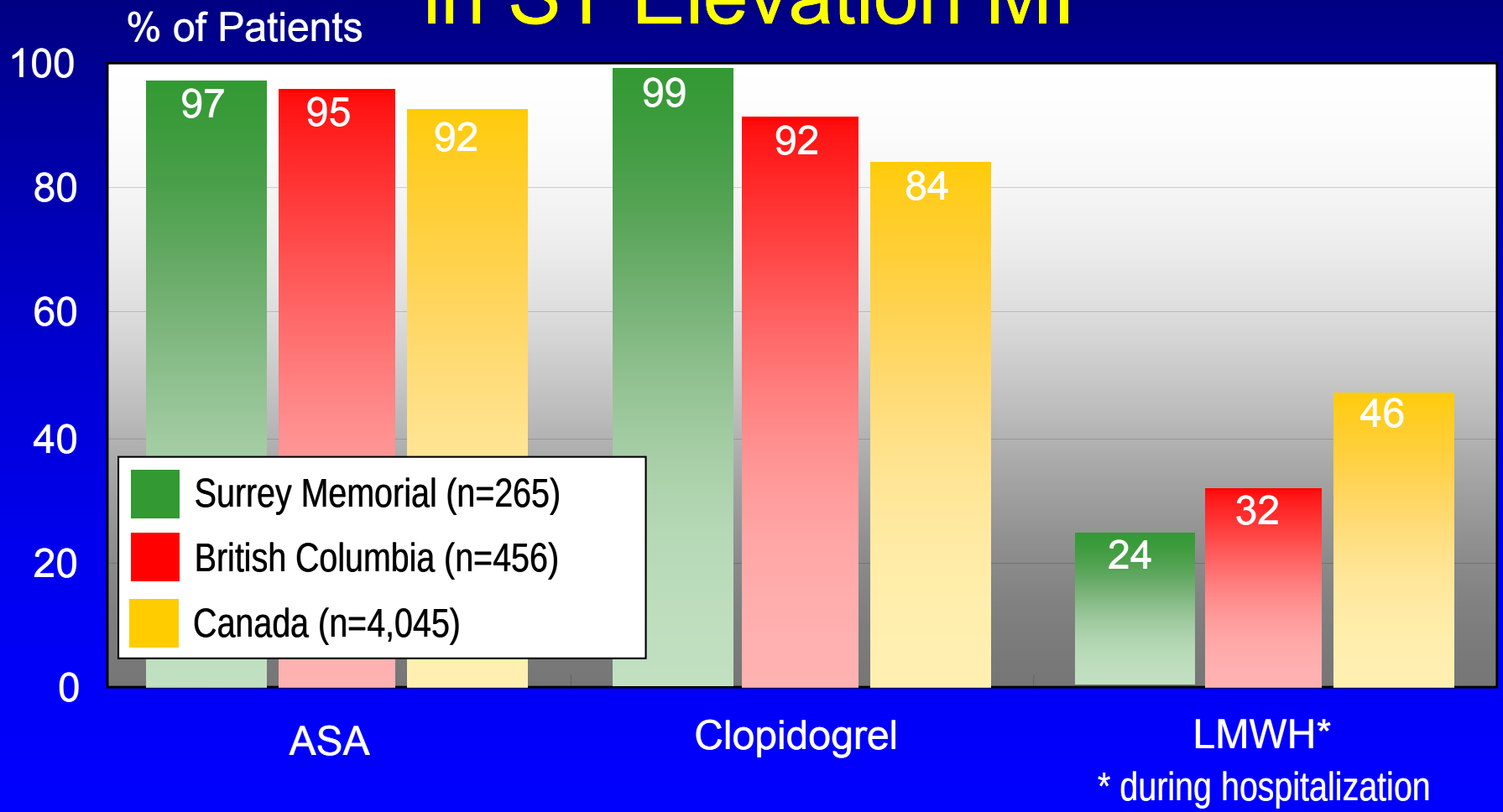
In-Hospital Procedures

(%)	World[1] n=93,092	Canada[2] n=17,144	B.C.[2] n=2,315	SMH[2] n=771
Angiography	70	67	87	94
PCI	34	33	46	58
CABG	4	4	2	-

GRACE GRACE2 CANRACE

N=total; % as of Q4 2008

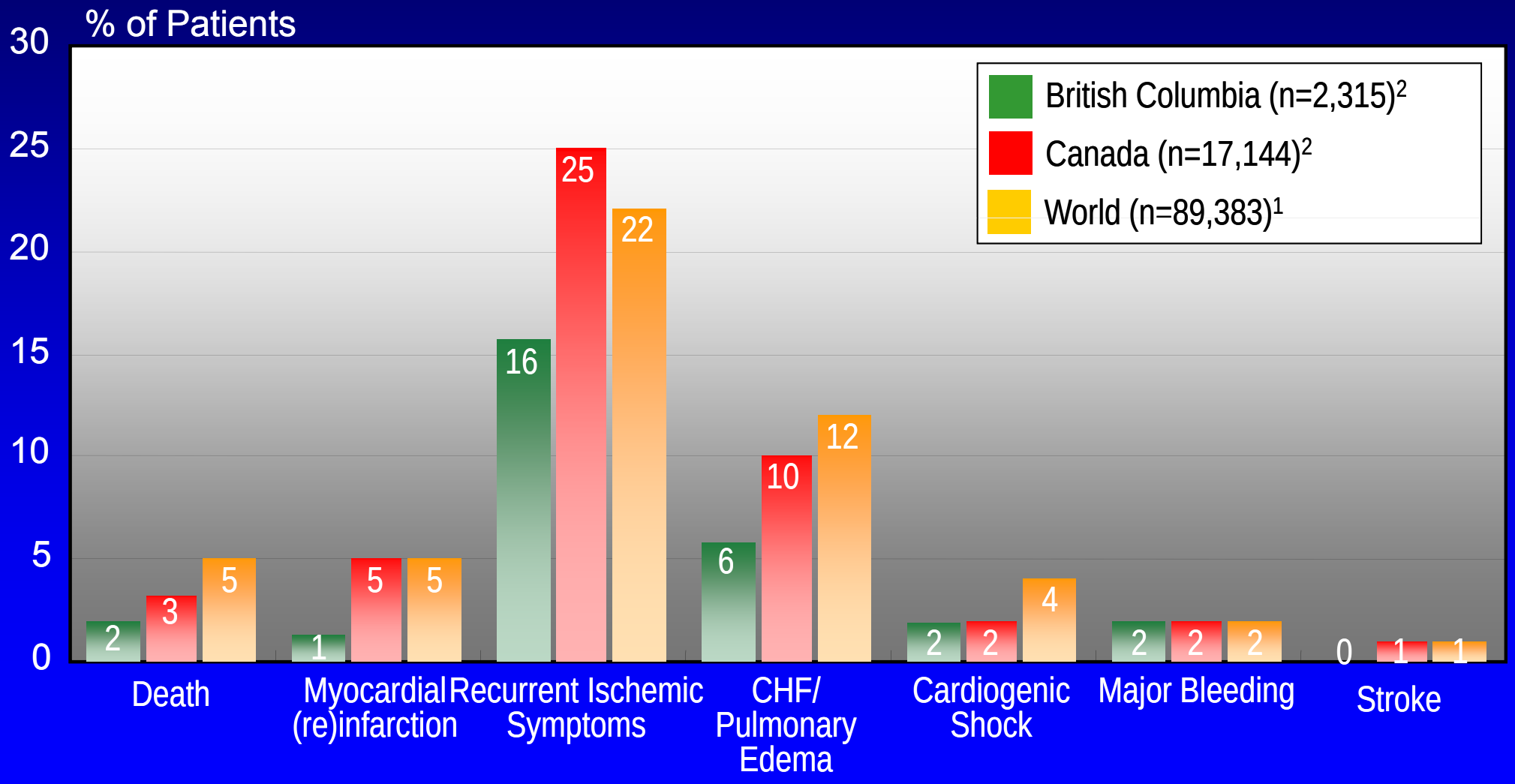
Selected Admission Therapies in ST Elevation MI



GRACE™ GLOBAL REGISTRY OF ACUTE CORONARY EVENTS | GRACE² GLOBAL REGISTRY OF ACUTE CORONARY EVENTS | CANRACE

As of Q4 2007[1] and Q4 2008[2]

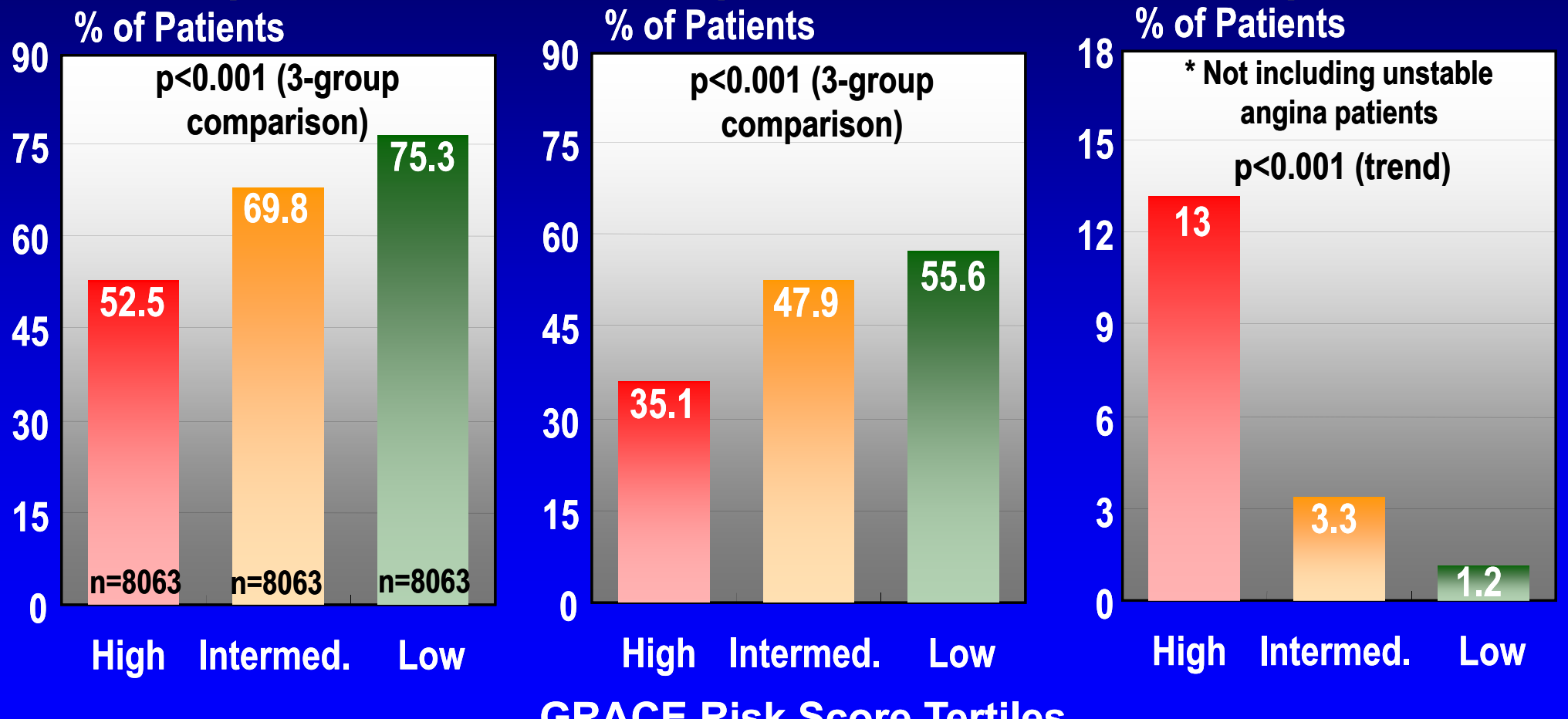
In-Hospital Events



How Can GRACE 2 Improve the Quality of Care at My Hospital?

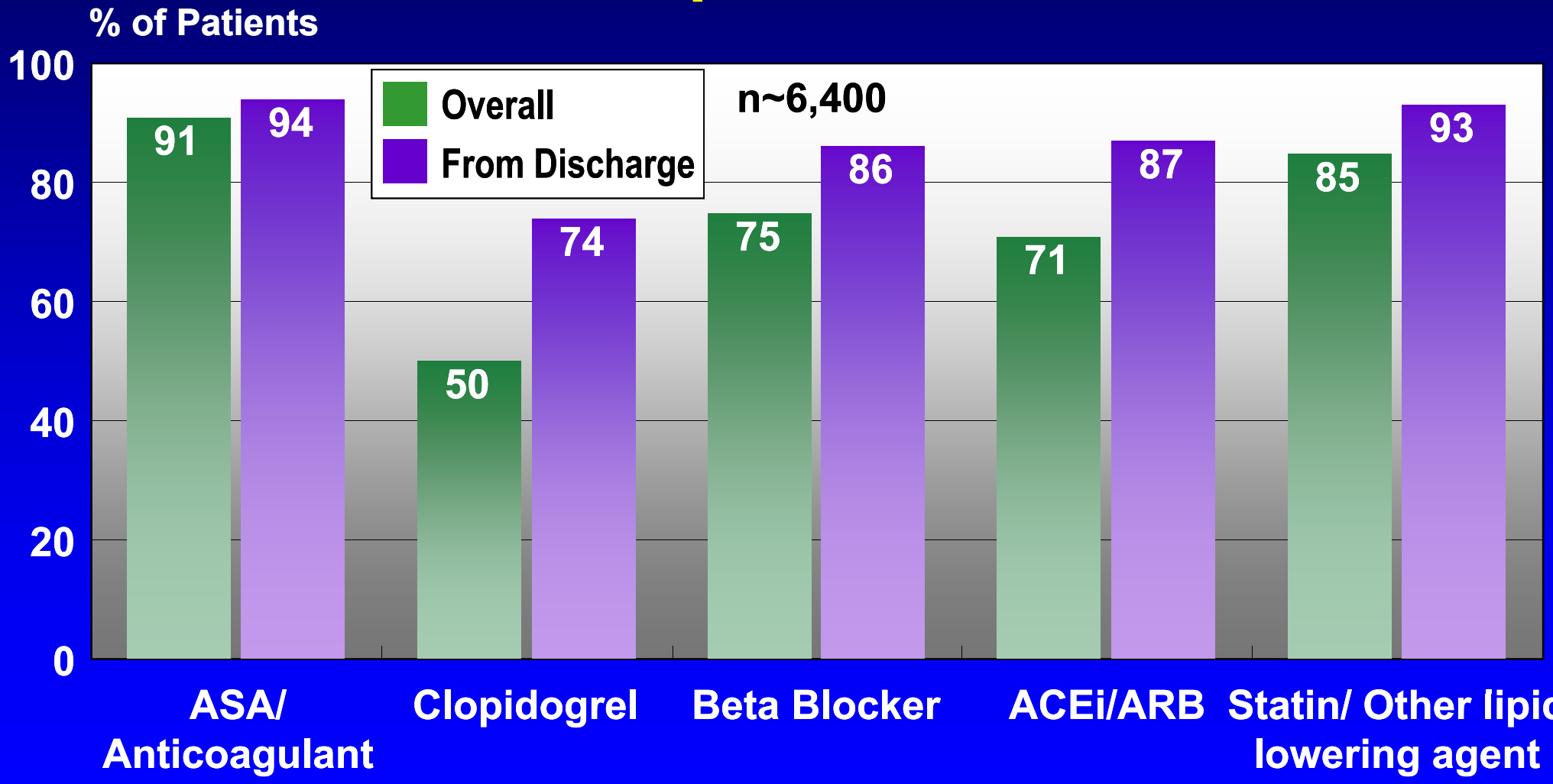
- You need to know what you are doing so you can compare yourself to others and strive for inprovement
- Quarterly reports of *your* hospital data (including key performance indicators) allows a sequence of rapid continuous quality improvement cycles
- Networking with others interested in improving the quality of ACS care
- Allows for development of research infrastructure for other projects

Management and Outcomes in ACS Patients By GRACE Risk Score

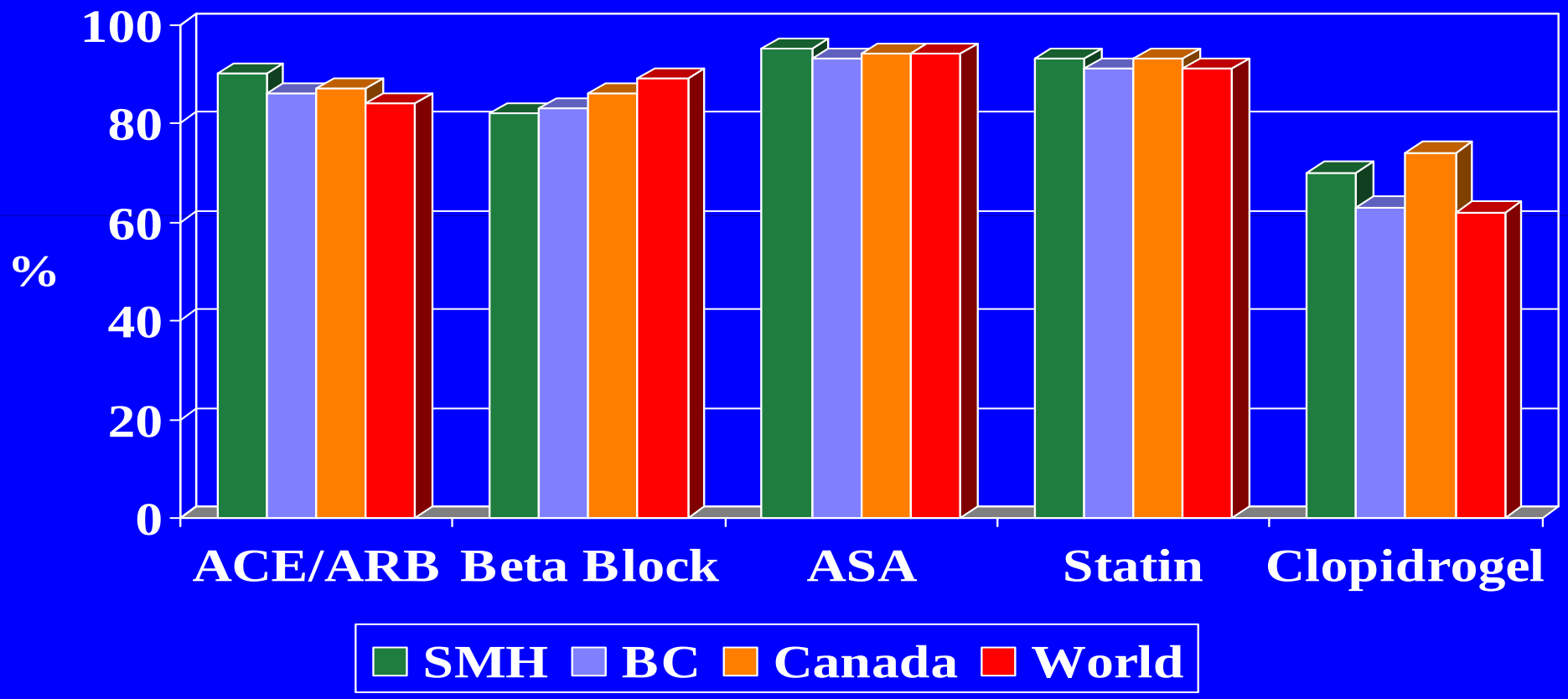


Fox et al *Heart* 2007;93:177-82

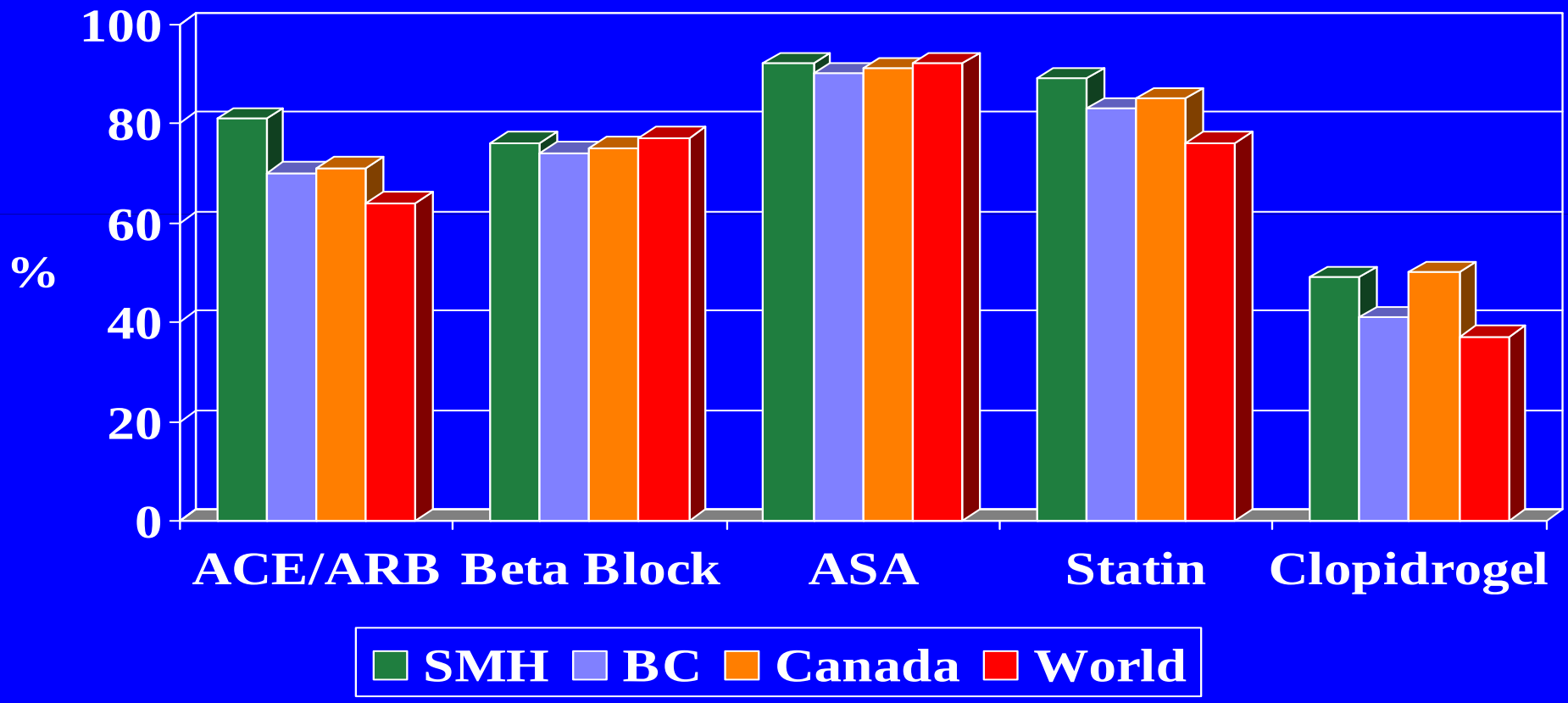
6 Month Follow-Up Selected Medications



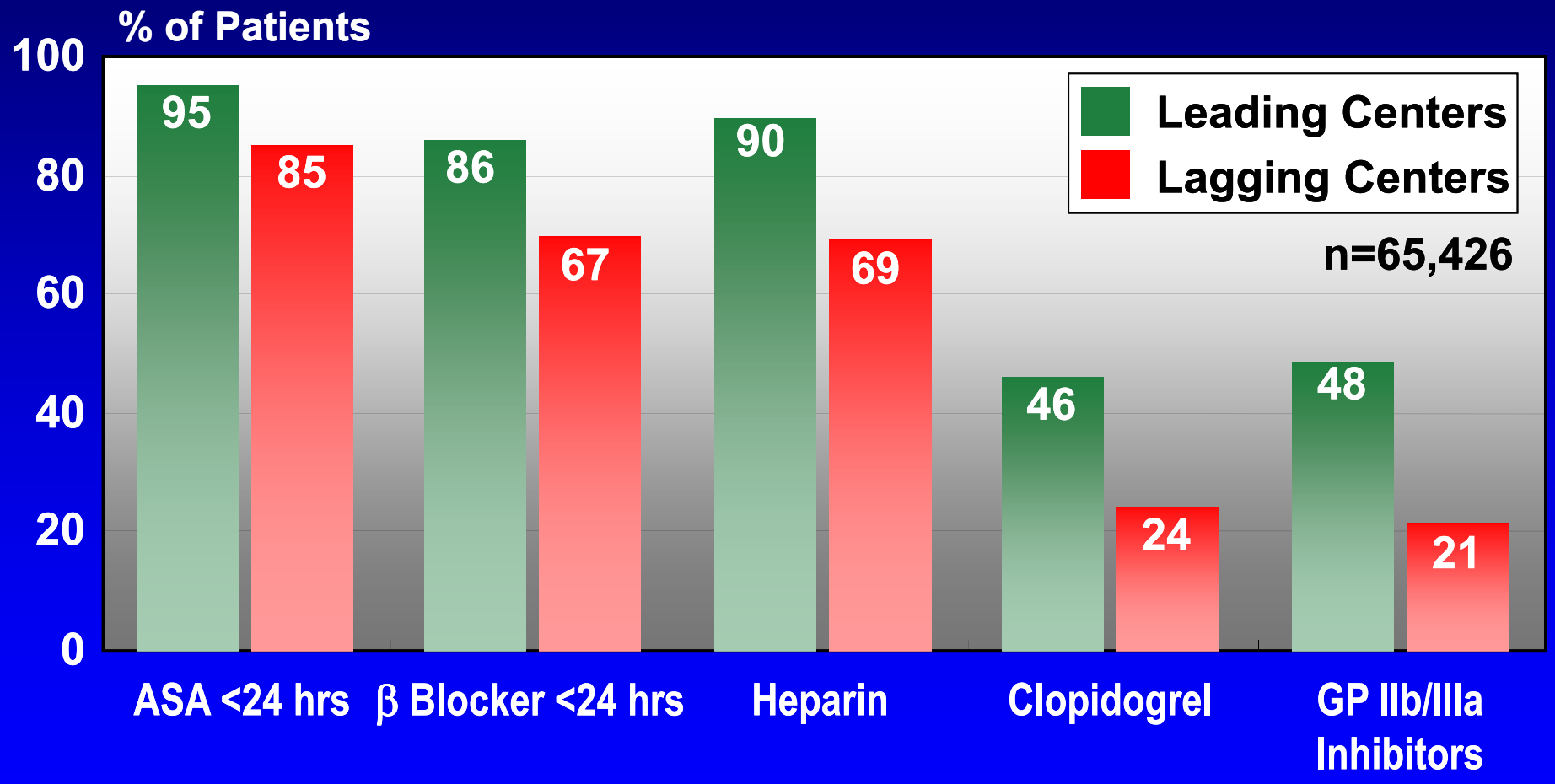
6 month Follow up MEDs Maintenance Current vs DC RX



6 month Follow up MEDS
Current RX



Leading and Lagging Hospital Quartiles: Acute Care

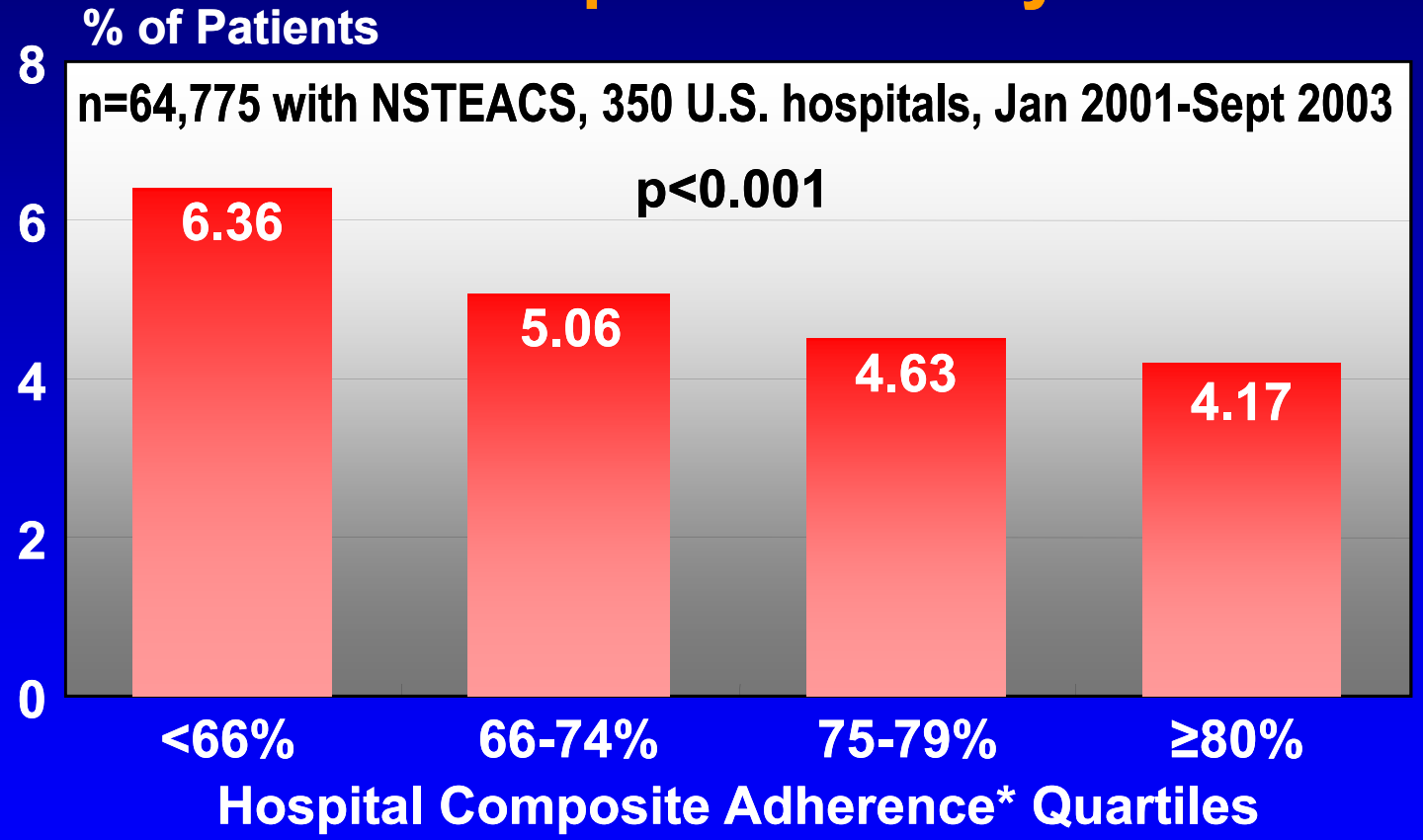


Adapted from Peterson et al *J Am Coll Cardiol* 2004;43(suppl.):406A & Ohman et al *Am Heart J* 2004;148(suppl.):S34-9

Performance Matters!

Relationship between Process and Outcome

In-hospital Mortality



* Use of 9 ACC/AHA Class I care indicators (ASA, ß-blocker, heparin, GP IIb/IIIa inhib. ≤24 hrs; discharge ASA, ß-blocker, clopidogrel, ACEi, lipid-lowering med use) among eligible pts without contraindications (adjusted for pt + hospital features)

Peterson et al *JAMA* 2006;295:1912-20

Factors Associated with Improved Guidelines Adherence

- Survey of 316 hospitals participating in CRUSADE
- Correlation with guideline adherence
- Independent predictors associated with improved guideline adherence:
  - Moderate-to-strong administrative commitment to Quality Improvement (QI)
  - Moderate-to-strong collaboration between emergency physicians and hospital administration
  - Adequate nursing and pharmacist support
  - Use of a specified protocol-driven management algorithm for ACS

Mehta et al *Am Heart J* 2006;152:648-60