Testimony on behalf of
THE SOCIETY OF THORACIC SURGEONS

Presented by

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The Society of Thoracic Surgeons

to the

MEDICARE COVERAGE ADVISORY COMMITTEE

July 14, 2004

Disclosure

- Consulting relationship with Medtronic; this company has no activity in TMR.
- No other relationship to Edwards or Cardiogenesis.
- I do not perform TMR or TMR + CABG in my clinical practice.
- My travel expenses for this testimony are paid by The Society of Thoracic Surgeons.

MCAC on TMR, July 14, 2004

Continuous Assessment of Quality and Performance in Medicine:

An Evidence-Based Platform for Technology Evaluation in Cardiothoracic Surgery

STS National Cardiac Database

- **1989-present**
- **Largest physician-led voluntary clinical database in medicine:**
  - > 2.5 M patient records, ~ 600 hospital participants
- **Duke Clinical Research Institute (DCRI) as warehouse/ analysis facility:**
  - Academic Research Organization with scientific objectivity
  - Semi-annual, site-specific feedback reporting of processes and outcomes
  - Local data benchmarked against regional, national benchmarks
  - Extensive system of data quality checks
- **Development of STS National Data Managers' Network**
- **Validation of voluntary Database:**
  - IA QIO Partnership: regional site auditing, comparative analysis with 94-99 Medicare CABG dataset (*Welke, Ann Thorac Surg 2004*)

MCAC Presentation

STS National Cardiac Database:

I. Outcomes Assessment

II. Evaluate National Care Processes

III. Assess CQI in Medicine

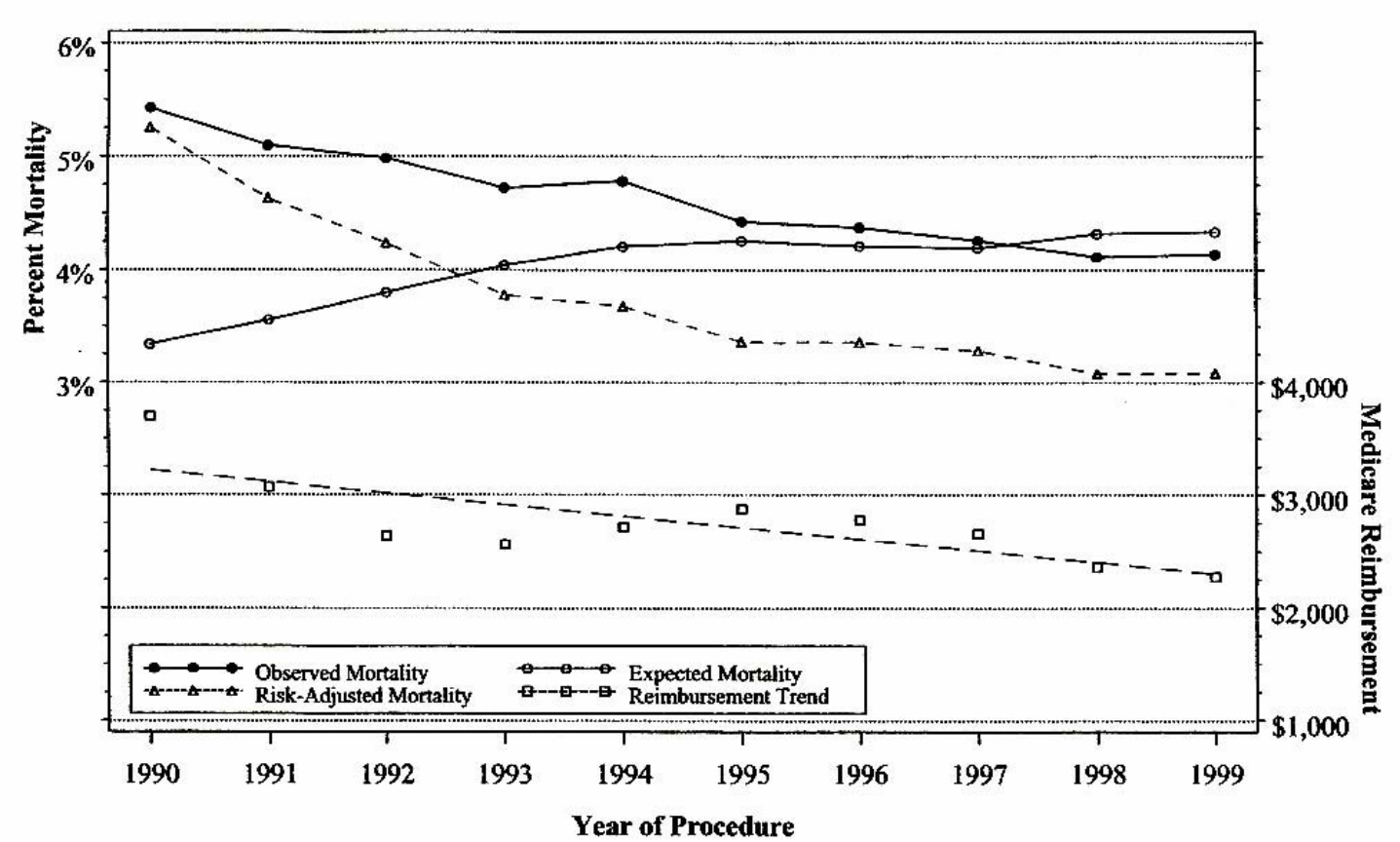
IV. Observational Data Limitations

V. Observational Data Attributes

VI. Future Direction and Opportunities

I. Assess Outcomes: CABG Expected vs. Risk-Adjusted Mortality

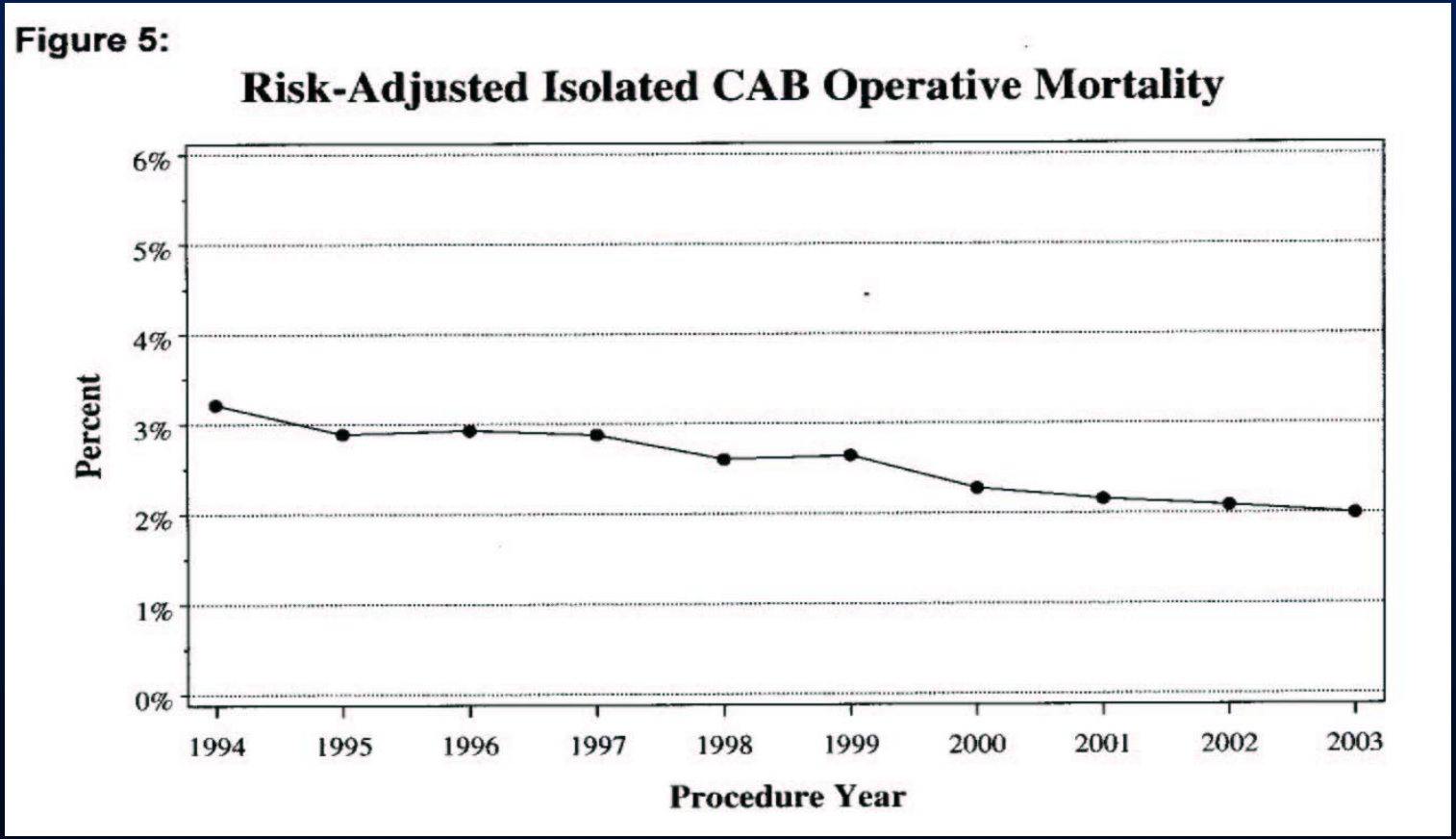
N = 629,491 Medicare Pts



Ferguson TB Jr. et al. Ann Thorac Surg 2002; 73:480-490

I. Assess Outcomes: Current CABG Mortality, 2003

Spring, 2004 Executive Summary



II. Evaluate National Care Processes

ORIGINAL CONTRIBUTION

Preoperative β-Blocker Use and Mortality and Morbidity Following CABG Surgery in North America

T. Bruce Ferguson, Jr, MD
Laura P. Coombs, PhD
Eric D. Peterson, MD, MPH
for the Society of Thoracic Surgeons National Adult Cardiac Surgery Database

Context β-Blockade therapy has recently been shown to convey a survival benefit in preoperative noncardiac vascular surgical settings. The effect of preoperative β-blocker therapy on coronary artery bypass graft surgery (CABG) outcomes has not been assessed.

Objectives To examine patterns of use of preoperative β-blockers in patients undergoing isolated CABG and to determine whether use of β-blockers is associated with lower operative mortality and morbidity.

Design, Setting, and Patients Observational study using the Society of Thoracic Surgeons National Adult Cardiac Surgery Database (NCD) to assess β-blocker use and outcomes among 629 877 patients undergoing isolated CABG between 1996 and 1999 at 497 US and Canadian sites.

Main Outcome Measure Influence of β-blockers on operative mortality, examined using both direct risk adjustment and a matched-pairs analysis based on propensity for preoperative β-blocker therapy.

Results From 1996 to 1999, overall use of preoperative β-blockers increased from 50% to 60% in the NCD (P< .001 for time trend). Major predictors of use included recent

During the past 2 decades, β-adrenergic blockade has been demonstrated to improve acute outcomes and long-term prognosis in ischemic heart disease.[1-9] β-Blocker therapy has also been demonstrated to reduce perioп-

Surgery for Acquired Cardiovascular Disease

Internal thoracic artery grafting in the elderly patient undergoing coronary artery bypass grafting: Room for process improvement?

T. Bruce Ferguson, Jr, MD
Laura P. Coombs, PhD
Eric D. Peterson, MD, MPH

Objective: The acute and long-term benefits of internal thoracic artery grafting are clear in younger patients undergoing coronary artery bypass grafting. The elderly, however, face higher surgical risks and have shorter life expectancy, and thus the

ACD

629,877 CABG Pts
497 sites, 1996-1999
OR 0.94 (0.91-0.97)

JAMA 2002; 287:2221-7

99,942 pts age > 75 yrs
495 sites, 1996-1999
OR 0.85 (0.75-0.91)

JTCVS 2002; 123:869-80

III. Assess CQI in Medicine

A National Randomized Trial in Continuous Quality Improvement

T. Bruce Ferguson, Jr. MD, PI

Eric D. Peterson, MD, MPH

The Society of Thoracic Surgeons

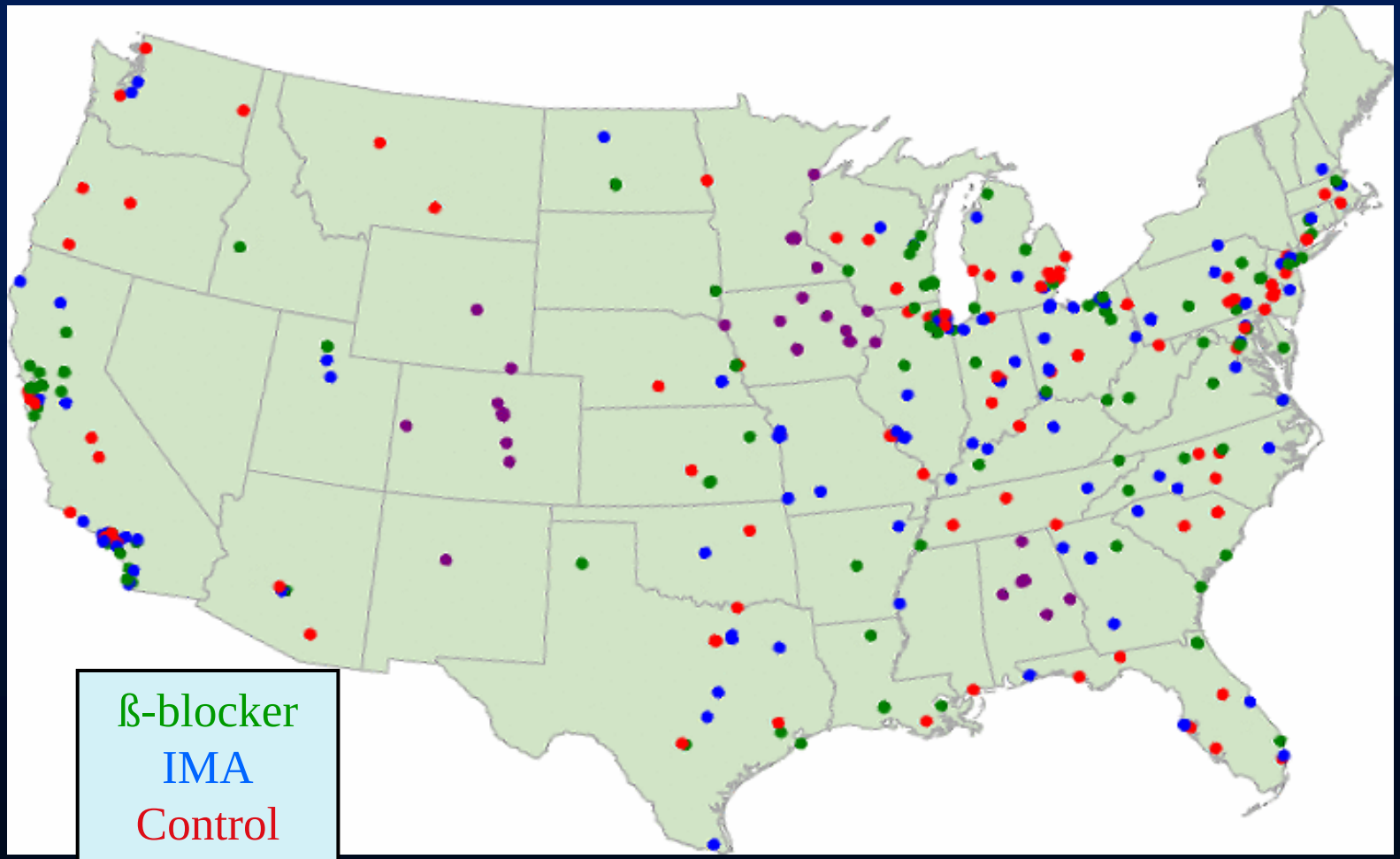
The Duke Clinical Research Institute

Funded by a grant from the Agency for Healthcare Research and Quality (AHRQ) (HS 10403) to the STS

CQI in CABG: 1999-2002

- Randomized Clinical Trial to determine if Continuous Quality Improvement (CQI) can be used by a Medical Specialty Society to improve care nationwide
- 359 sites randomized, plus 40 Consortium sites in MN, CO, NM, WY, IA
  - largest previous multi-center trial in CQI had 31 sites
  - rigorous demonstration of efficacy of CQI had not been successful in Medicine

National Randomization Sites



CQI in CABG Trial

ORIGINAL CONTRIBUTION

Use of Continuous Quality Improvement to Increase Use of Process Measures in Patients Undergoing Coronary Artery Bypass Graft Surgery

A Randomized Controlled Trial

T. Bruce Ferguson, Jr, MD
Eric D. Peterson, MD, MPH
Laura P. Coombs, PhD
Mary C. Eiken, RN, MS
Meghan L. Carey, MS
Frederick L. Grover, MD
Elizabeth R. DeLong, PhD
for the Society of Thoracic Surgeons and the National Cardiac Database

Context A rigorous evaluation of continuous quality improvement (CQI) in medical practice has not been carried out on a national scale.

Objective To test whether low-intensity CQI interventions can be used to speed the national adoption of 2 coronary artery bypass graft (CABG) surgery process-of-care measures: preoperative β-blockade therapy and internal mammary artery (IMA) grafting in patients 75 years or older.

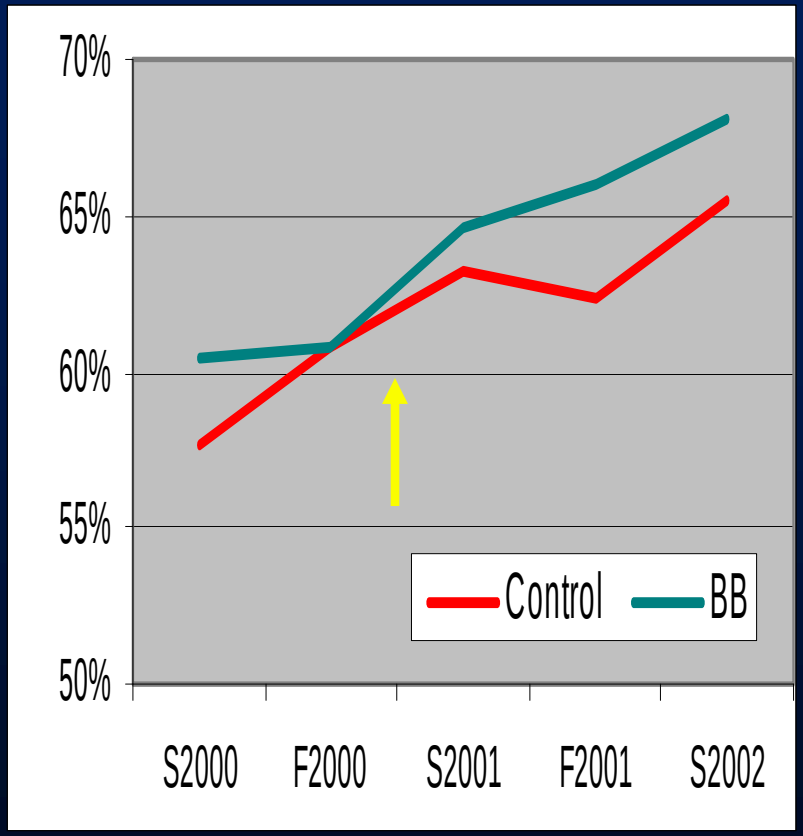
Design, Setting, and Participants Three hundred fifty-nine academic and nonacademic hospitals (treating 267 917 patients using CABG surgery) participating in the Society of Thoracic Surgeons National Cardiac Database between January 2000 and July 2002 were randomized to a control arm or to 1 of 2 groups that used CQI interventions designed to increase use of the process-of-care measures.

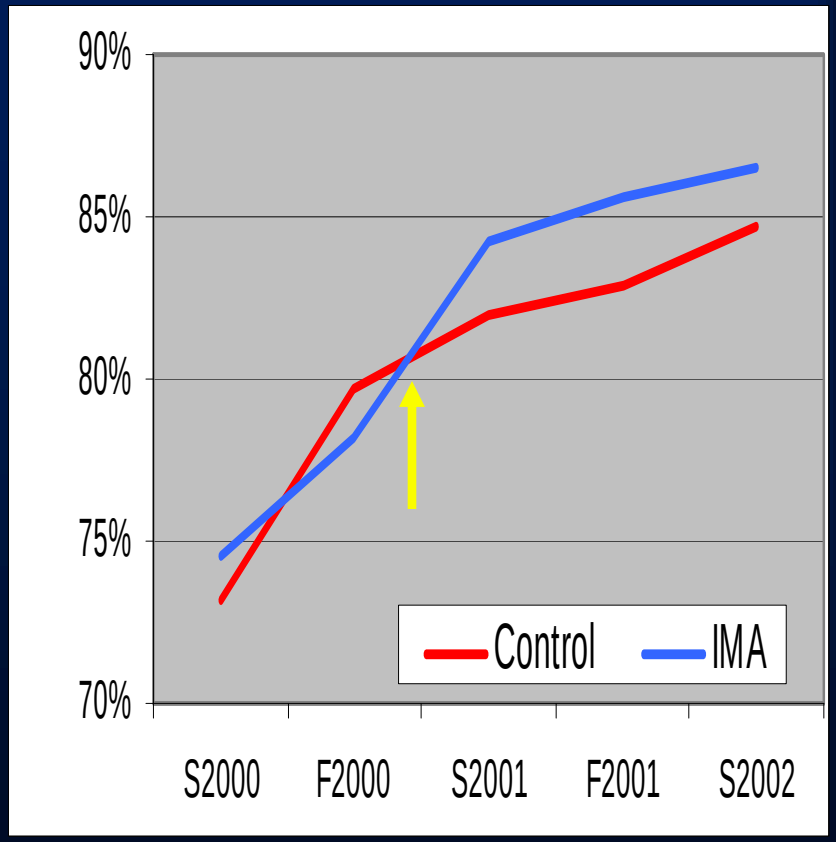
Intervention Each intervention group received measure-specific information, including a call to action to a physician leader; educational products; and periodic longitudinal, nationally benchmarked, site-specific feedback

IN 1917 ERNEST CODMAN, MD, A

JAMA 2003; 290:49-56

Results: Site-Level Trends





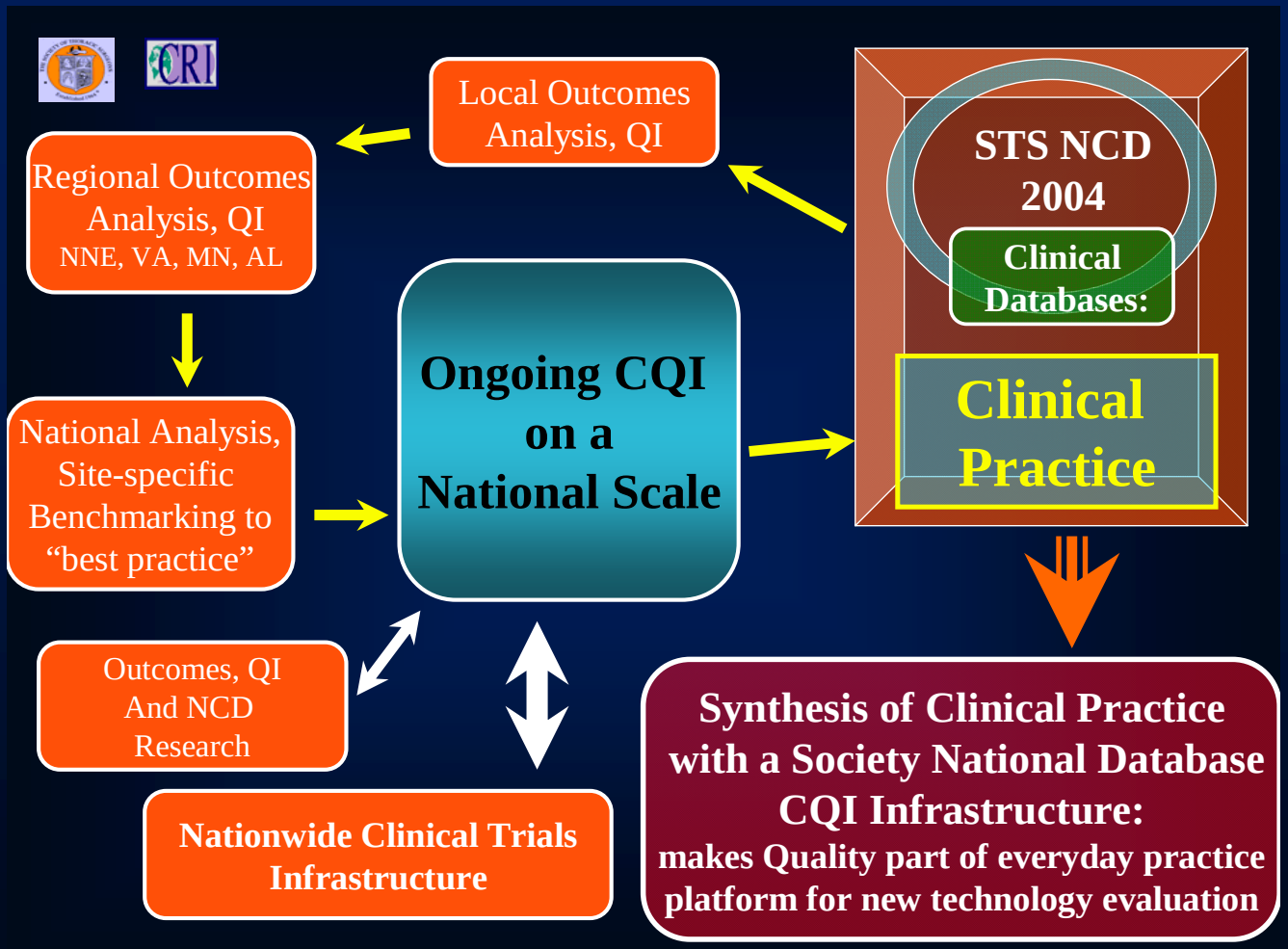
Documented nationwide positive impact on care quality in 18 months

Intervention #1

STS NCD: Quality Evaluation Platform?

- NCD:
  - 15 years of measure collection and outcomes analyses
  - Risk-adjusted mortality, morbidity, PLOS
  - Local, regional and national programs for quality evaluation and quality improvement
- Meets all criteria for a successful quality improvement information system *(Eddy, Health Affairs, 1998)*
- Validated national platform for CQI
- Assess and analyze the incorporation of new technical advances, benchmarked against national norms of existing technology, use and practice

STS NCD Quality Platform



IV. NCD – Observational Data Limitations

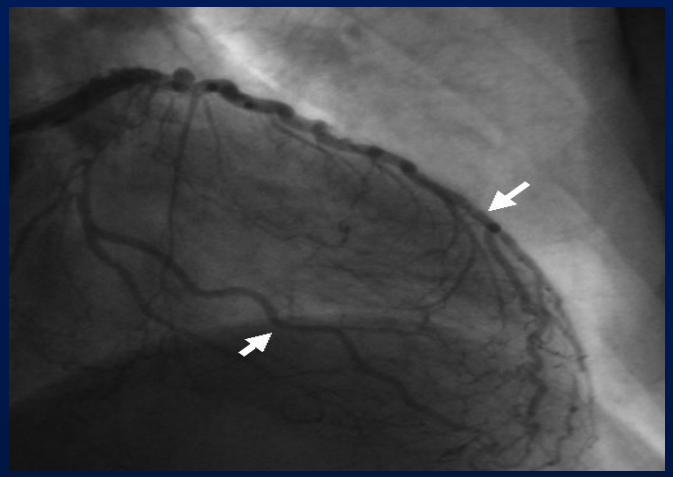
- Comparing Technologies:
  - Lack of control populations/subsets
    - » Even with propensity analyses, populations not equivalent
      - Limitation in JACC paper analysis (Peterson, et al, 2003)
  - Some variables can't be quantified
    - » In TMR, diffuseness of coronary arterial disease
      - Limitation in JACC paper analysis (Peterson, et al, 2003)
  - Clinical circumstances contain factors still not completely understood
    - » Intraoperative factors in TMR cases

Peterson Analysis Update

	CABG Only			CABG + TMR	
	All	TMR Sites Only		STS Update	*Peterson*
	1998 - 2003			1998-2003	*1998-2001*
N	932,715	593,463		5618	*2475*
DM (%)	34	34	*	50	*50*
IDDM (%)	10	10	*	19	-
Renal Failure (%)	5	5	*	7	-
PVD (%)	16	16	*	20	-
Prior CVA (%)	7	7	*	9	-
Prior MI (%)	46	46	*	49	*50*
hyperlipidemia (%)	62	63	*	73	*68*
hypertension (%)	72	72	*	80	*76*
Reoperation (%)	9	9	*	26	*28*

**** = p < 0.001 CABG Only vs. STS update CABG + TMR***

Diffuseness of Coronary Disease



V. NCD – Observational Data Attributes

- Tracking trends in care processes and outcomes of clinical procedures
- Evaluating Risk Profiles:
  - Trends over time, using clinical data and risk-adjustment
  - Comparison between populations (“higher risk”)
- Evolving Clinical Circumstances: Derive new information
- Differences between Trials and “Real Life” Clinical Practice
- Making procedures safer and better:
  - Devices: post-market data collection and analysis
  - Contemporaneous observational analyses for trials
  - Availability of nationally benchmarked practice information for stakeholders

VI. Future Direction and Opportunities

- Initial and Ongoing Evaluation of Technologies:
  - Combination of Trials data and experience, coupled with CQI-based national observational data and experience
  - "Close the gap between Trials data and real life"
- Partnerships between stakeholders:
  - share evidence-based information
  - provide best evidence to all involved stakeholders, including patients