Present Status & Future Perspective of Coronary Intervention

Angioplasty Summit TCTAP 2011
Seoul, Korea

David R. Holmes, MD
Mayo Clinic
Rochester, MN

MAYO CLINIC

Presenter Disclosure Information

David R. Holmes, Jr., M.D.

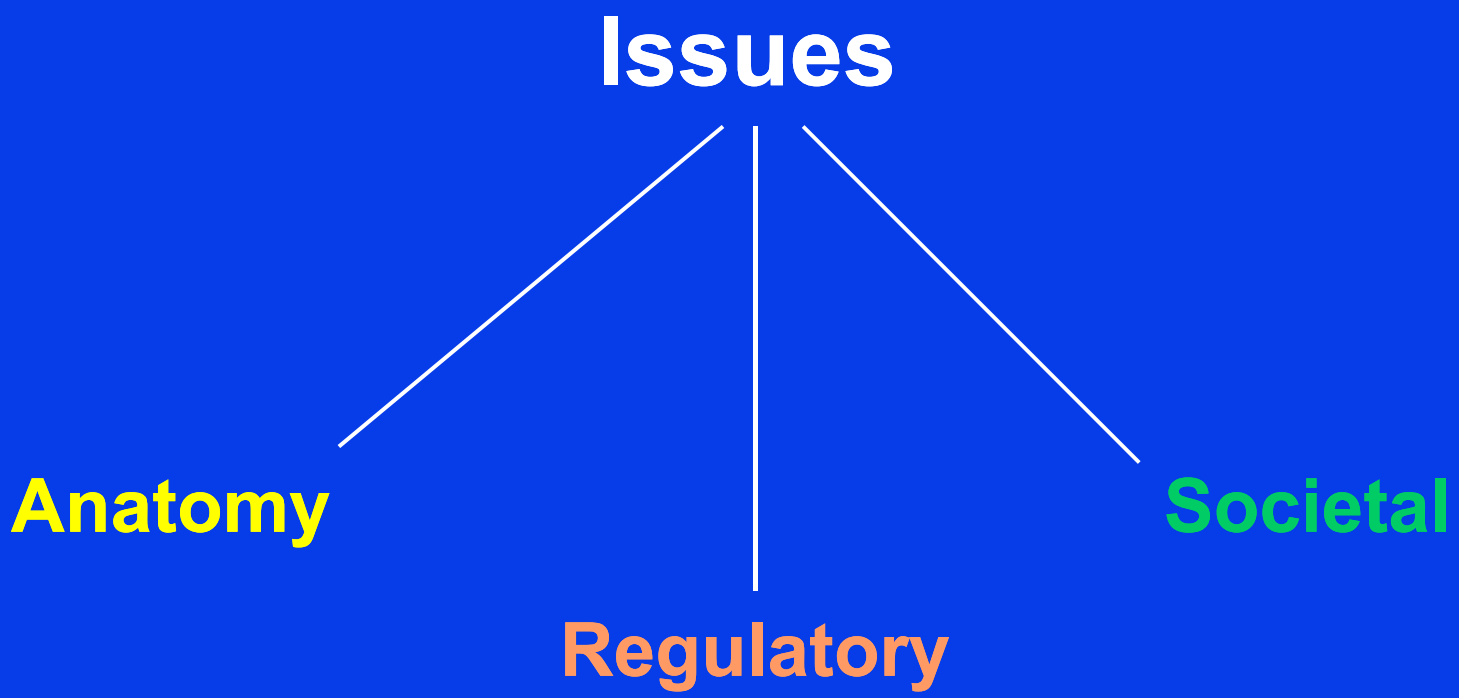
"Present Status & Future Perspective of Coronary Intervention"

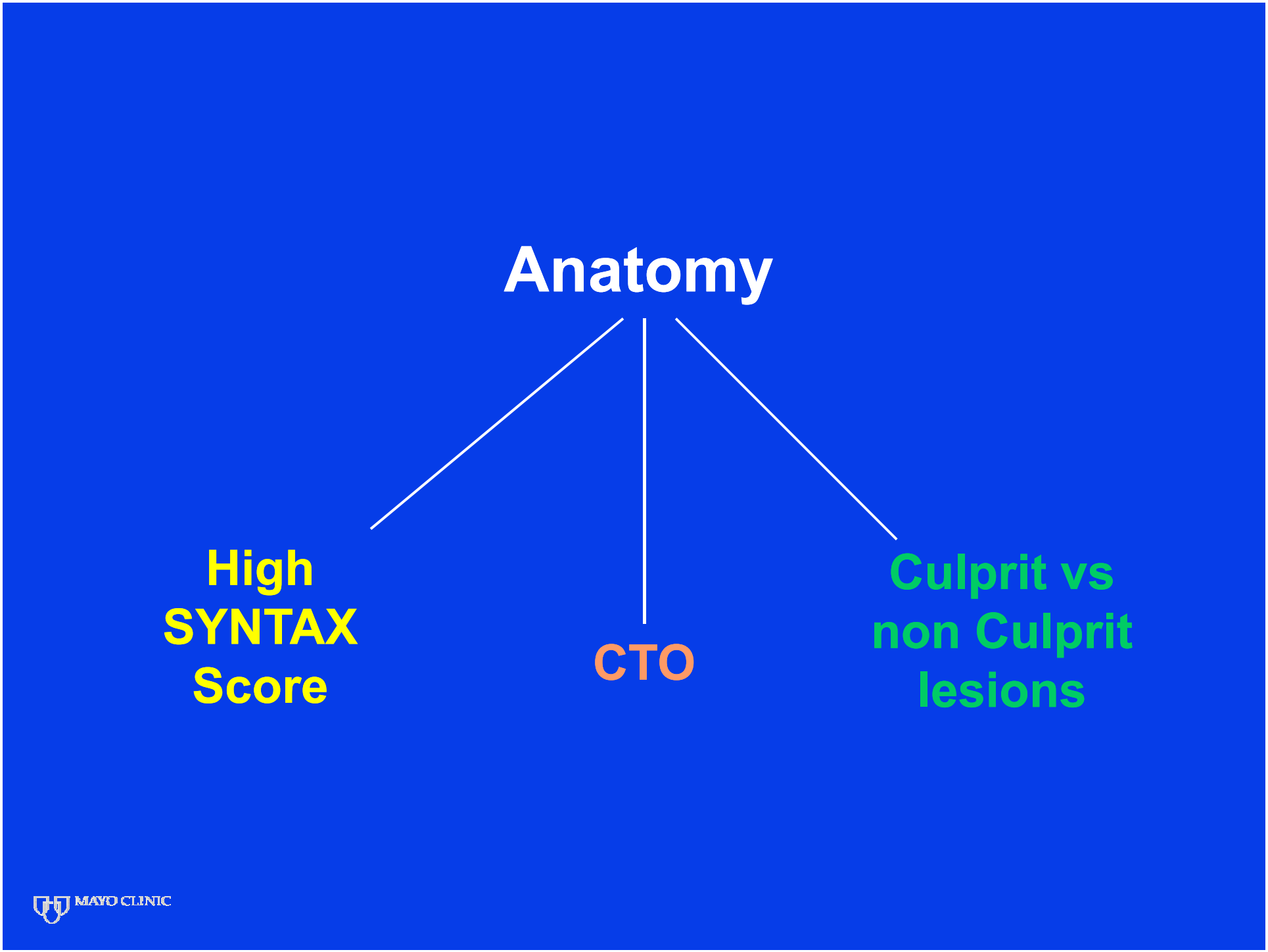
The following relationships exist related to this presentation:

None

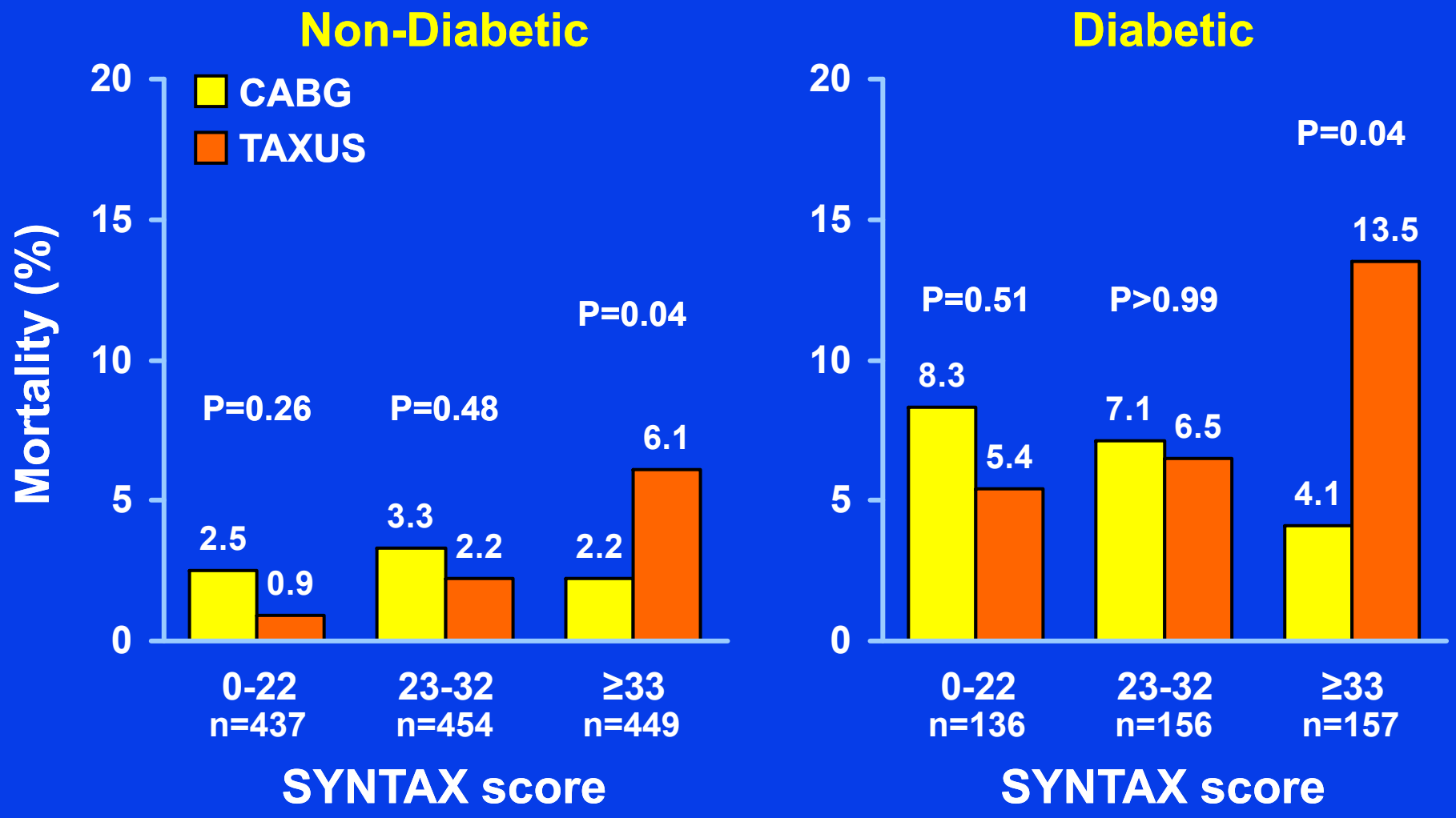
The Landscape

The Landscape




Anatomy
High SYNTAX Score
CTO
Culprit vs non Culprit lesions

Mortality by SYNTAX Score
3VD/LM Diabetic and Non-Diabetic Patients



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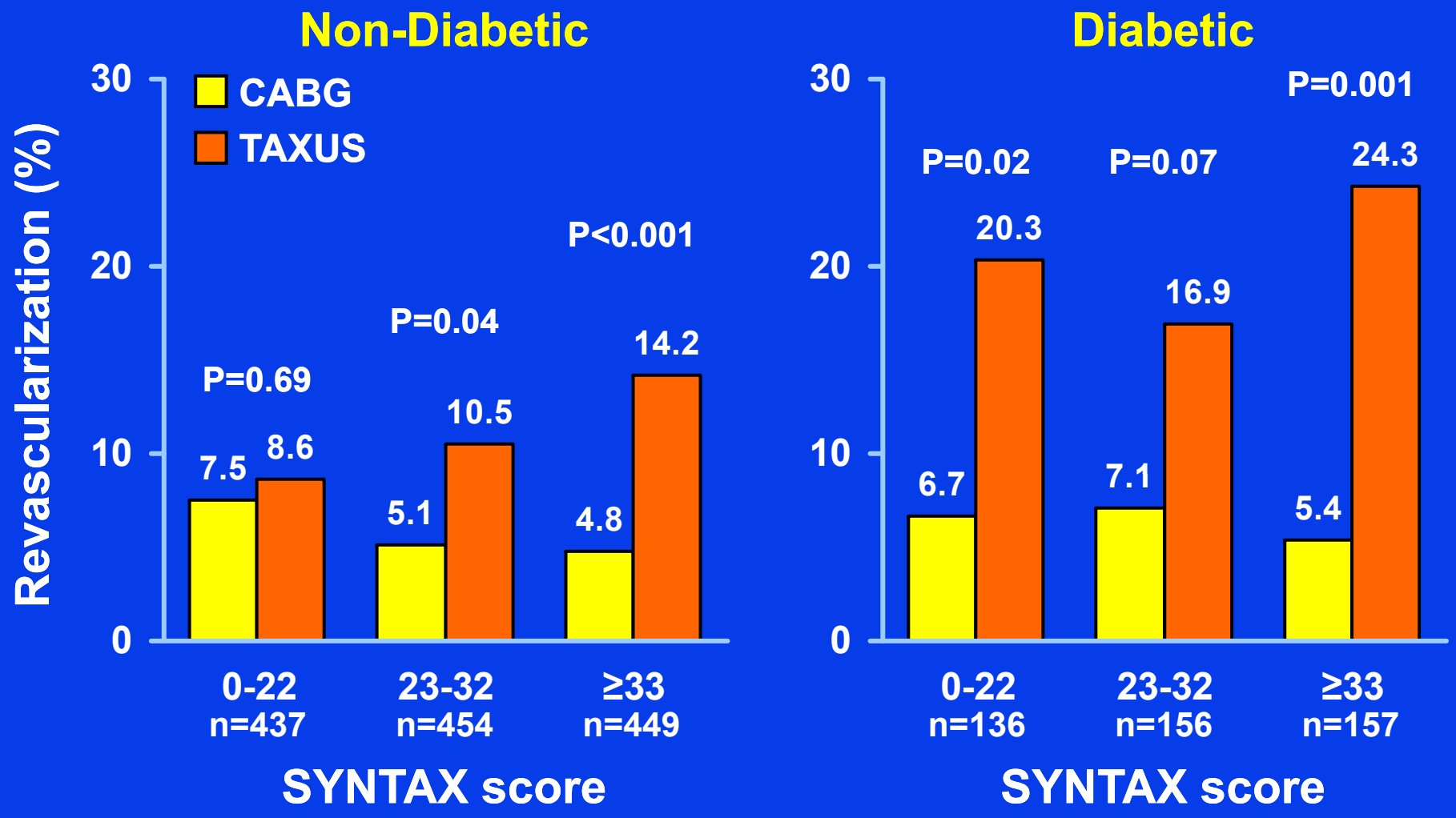
Banning A et al: JACC 55:1067, 2010

Revascularization by SYNTAX Score
3VD/LM Diabetic and Non-Diabetic Patients



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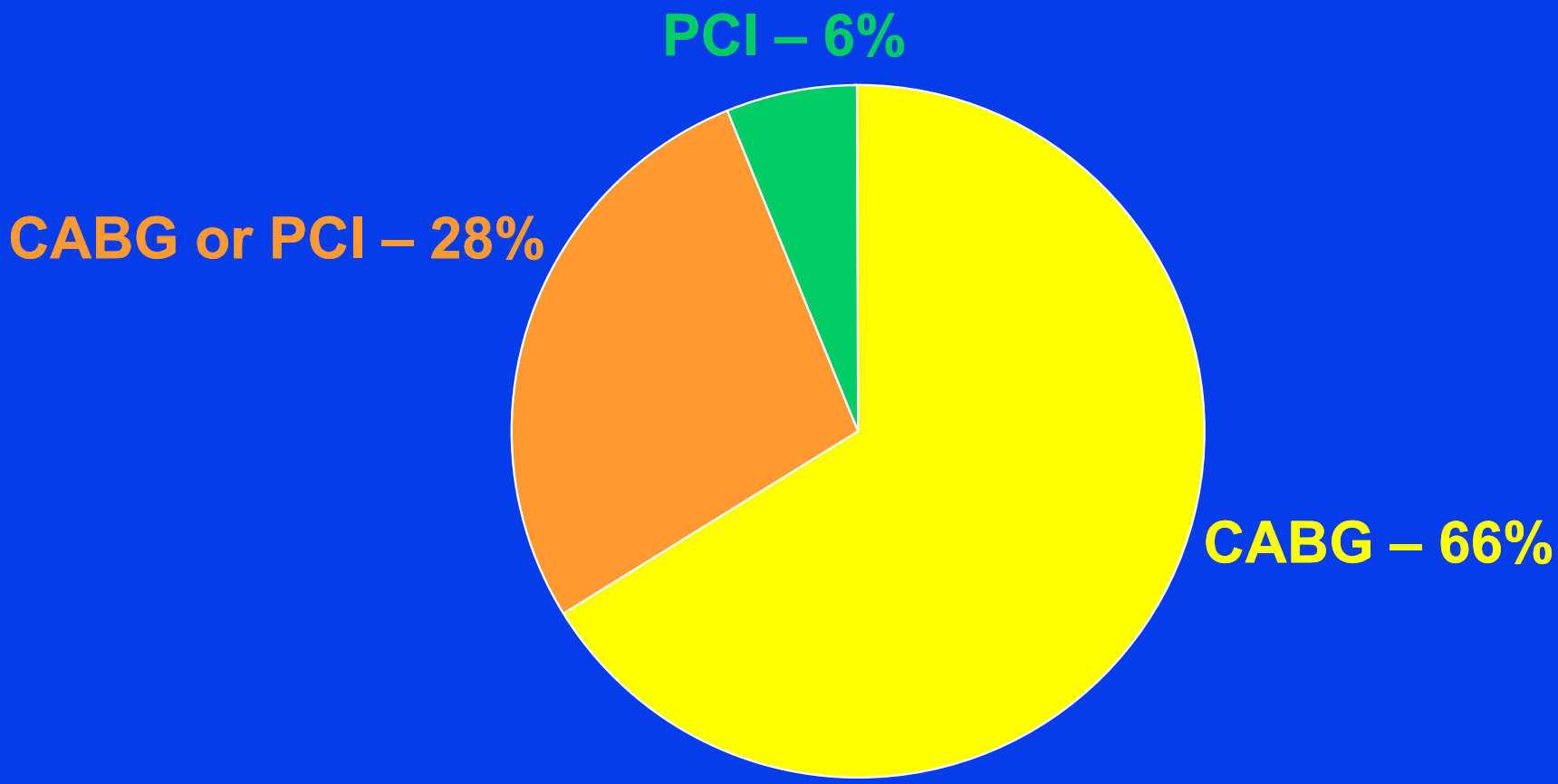
Banning A et al: JACC 55:1067, 2010

3 Vessel & Left Main Disease
Post SYNTAX

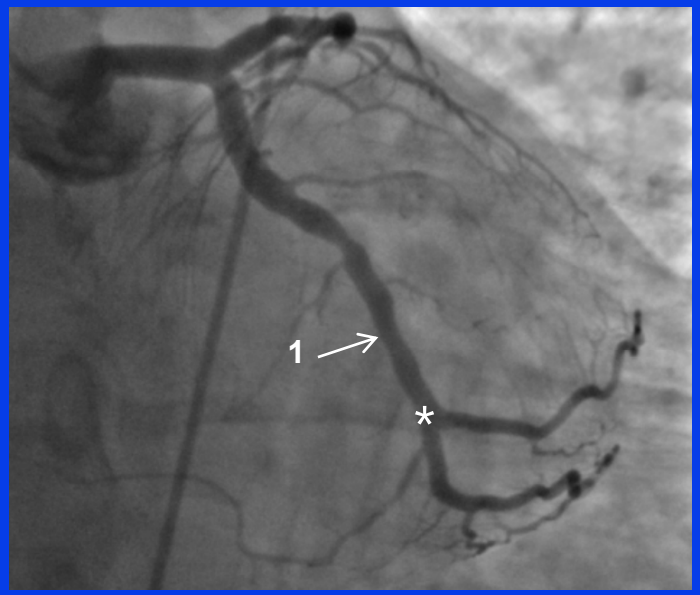


CTO
Issues

- Boutique item or not
- Evidence based RCT's – do we need them?
- Case selection
- Procedural performance
- Radiation exposure

Larry and Earl's New Fishfinder

PROSPECT 82910-012: Index 2/13/06



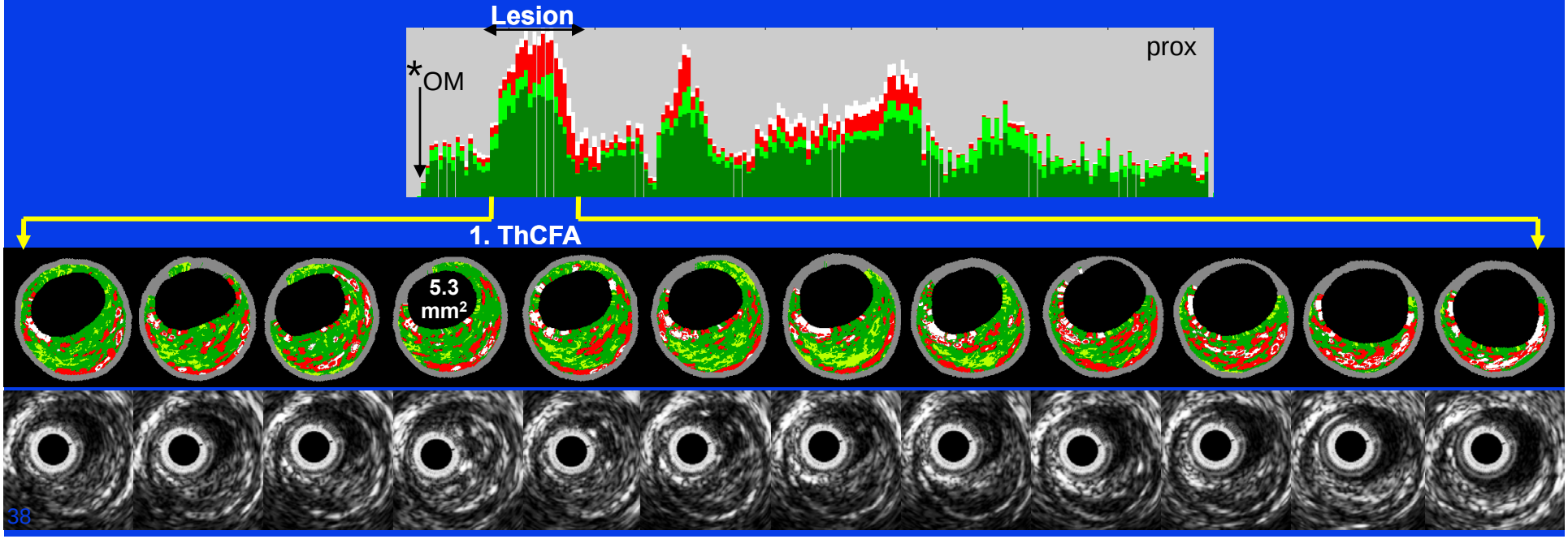
Baseline PLCX

QCA: RVD 2.82 mm,

DS 28.6%, length 6.8 mm

IVUS: MLA 5.3 mm²

VH: ThCFA



ORIGINAL ARTICLE

A Prospective Natural-History Study of Coronary Atherosclerosis

Conclusions – In patients who presented with ACS and underwent PCI, MACE occurring during follow-up were equally attributable to recurrence at the site of culprit lesions and to nonculprit lesions. Although nonculprit lesions that were responsible for unanticipated events were frequently angiographically mild, most were thin-cap fibroatheromas or were characterized by a large plaque burden, a small luminal area, or some combination of these characteristics, as determined by gray-scale and radiofrequency intravascular ultrasonography.

the Providing Regional Observations to Study Predictors of Events in the Coronary Tree (PROSPECT) investigation are listed in the Supplementary Appendix, available at NEJM.org.

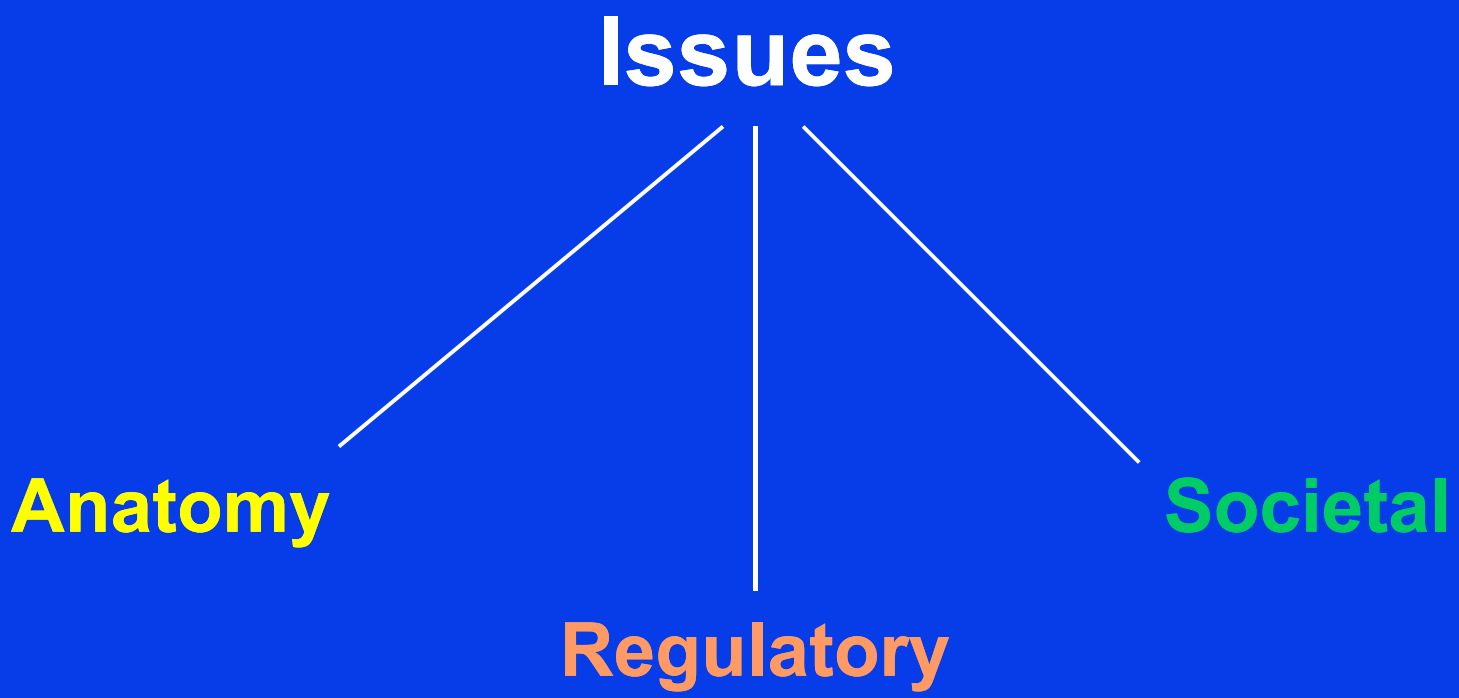
N Engl J Med 2011;364:226-35.

events were more likely than those not associated with recurrent events to be characterized by a plaque burden of 70% or greater (hazard ratio, 5.03; 95% confidence interval [CI], 2.51 to 10.11; P<0.001) or a minimal luminal area of 4.0 mm² or less (hazard ratio, 3.21; 95% CI, 1.61 to 6.42; P=0.001) or to be classified on the basis of radiofrequency intravascular ultrasonography as thin-cap fibroatheromas (hazard ratio, 3.35; 95% CI, 1.77 to 6.36; P<0.001).

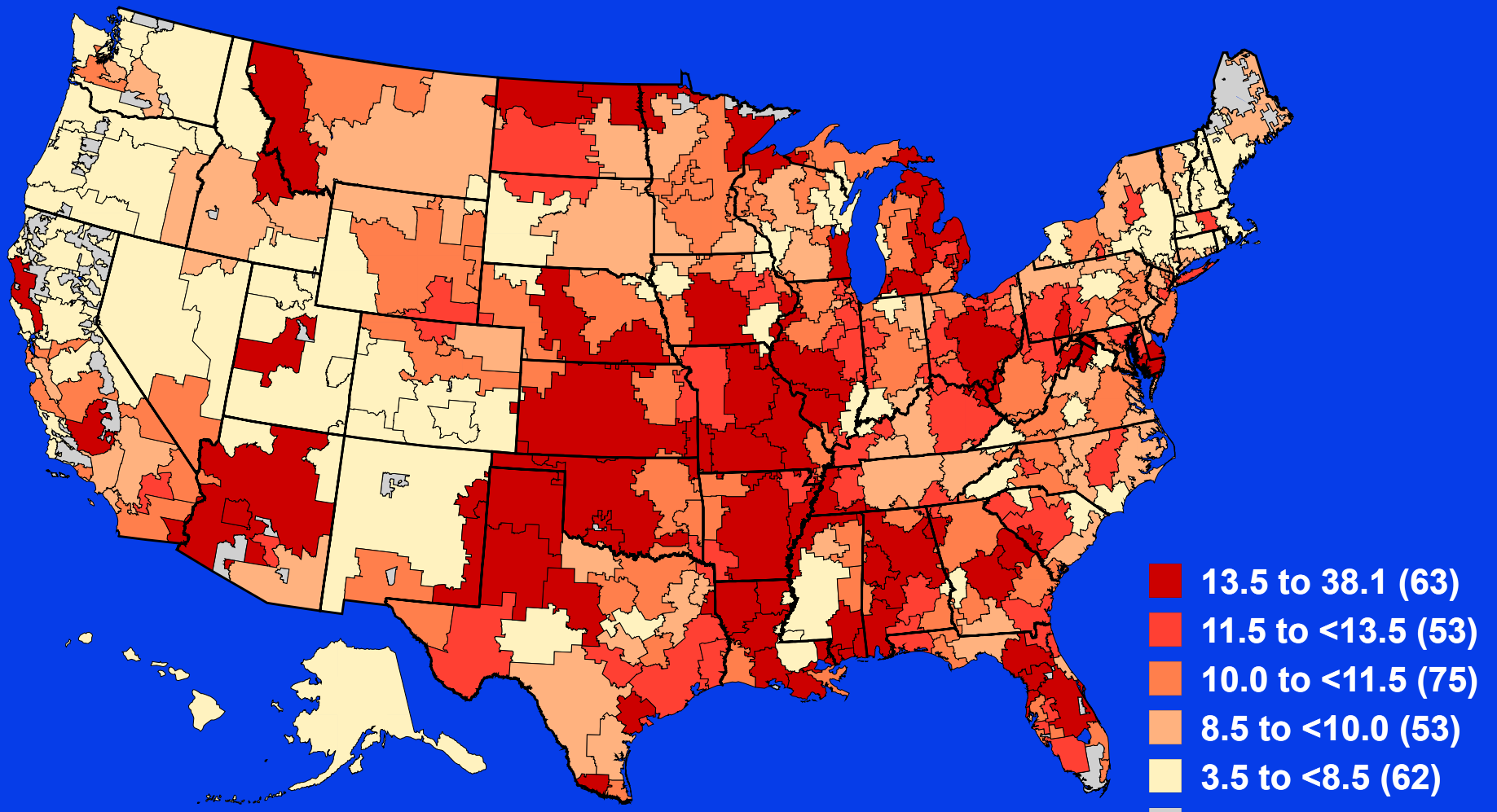
CONCLUSIONS

In patients who presented with an acute coronary syndrome and underwent percutaneous coronary intervention, major adverse cardiovascular events occurring during follow-up were equally attributable to recurrence at the site of culprit lesions and to nonculprit lesions. Although nonculprit lesions that were responsible for unanticipated events were frequently angiographically mild, most were thin-cap fibroatheromas or were characterized by a large plaque burden, a small luminal area, or some combination of these characteristics, as determined by gray-scale and radiofrequency intravascular ultrasonography. (Funded by Abbott Vascular and Volcano; ClinicalTrials.gov number, NCT00180466.)

The Landscape



Variation in Care
PCI Rates per 1,000 Medicare Enrollees (2002-03)

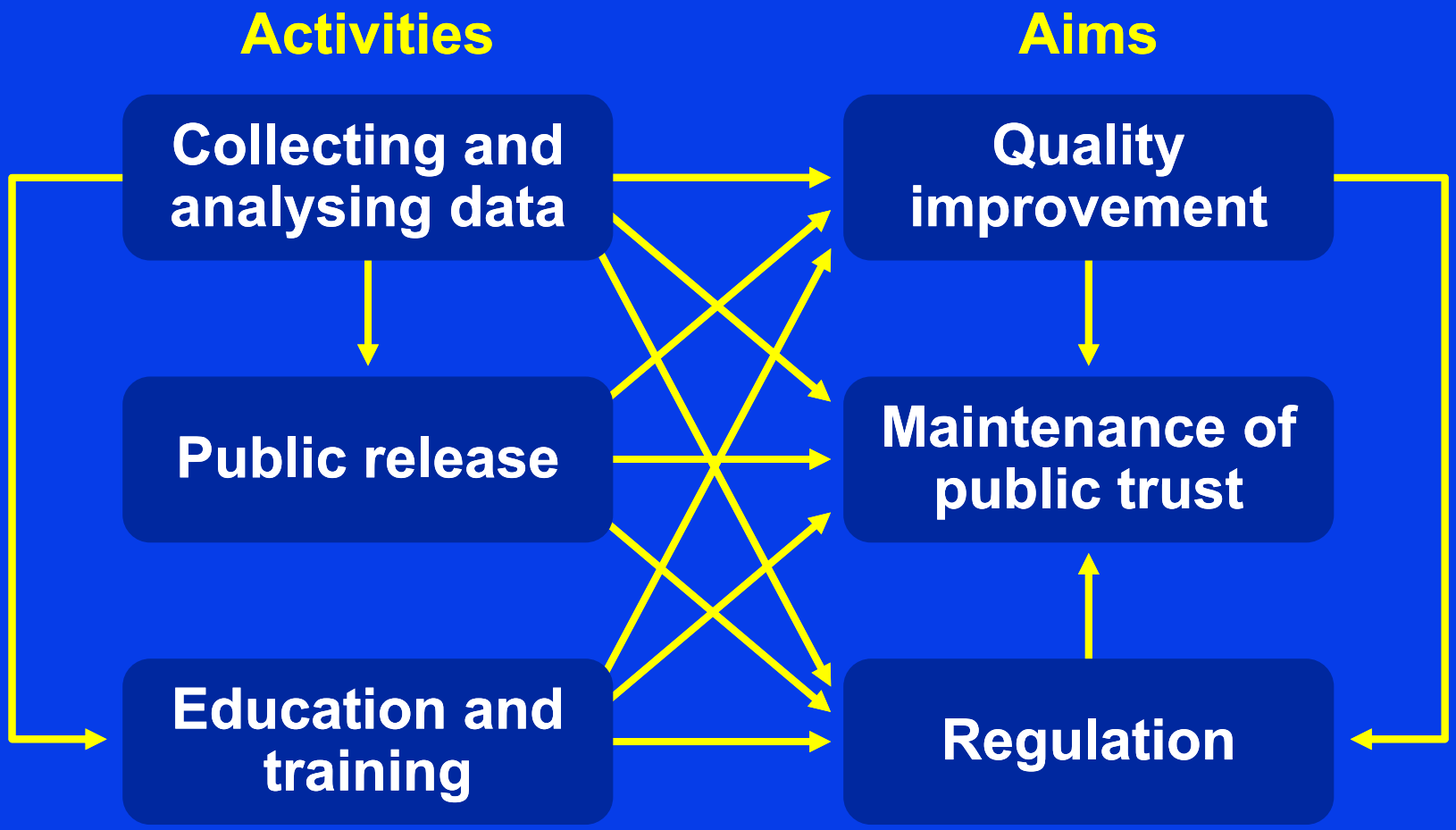


http://www.dartmouthatlas.org/

What can we do to address variation, misuse and overuse?

(and underuse!)

The Responsibilities of a Professional Society



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ACC Guidelines
Unprotected Left Main Coronary Artery Disease

2004/2005/2007 recommendation	2009 PCI focused update recommendations	Comments
Class IIa		
1. It is reasonable that patients undergoing PCI to unprotected left main coronary obstructions be followed up with coronary angiography between 2 and 6 months after PCI (level of evidence C)		Deleted recommendation (no longer recommended)
Class IIb		
	1. PCI of the left main coronary artery with stents as an alternative to CABG may be considered in patients with anatomic conditions that are associated with a low risk of PCI procedural complications and clinical conditions that predict an increased risk of adverse surgical outcomes (level of evidence B)	New recommendation
Class III		
2005 PCI Guideline, Section 5.1 PCI is not recommended in patients with […] f. Left main disease and eligibility for CABG (*level of evidence C*)		Modified recommendation (bullet "f") from Section 5.1 and bullet "e" from Sections 5.2 and 5.3, are no longer current; see 2009 Class IIb recommendation #1)
2005 PCI guideline, Sections 5.2, 5.3 PCI is not recommended in patinets with […] e. Left main disease and eligibility for CABG (*level of evidence C*)		

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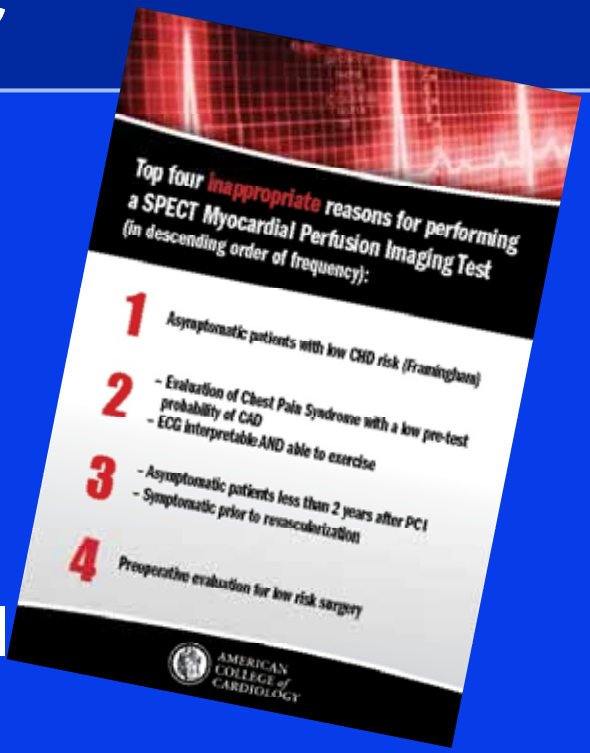
Appropriate Use Criteria

- Diagnostic effectiveness
- Therapeutic effectiveness
- Patient empowerment

Existing AUC

- SPECT-MPI (Updated 2009)
- CCT/MRI (Updated 2010)
- TTE/TEE
- Stress Echocardiography (Updated 2010)
- Coronary Revascularization: PCI
- SPECT-MPI Update

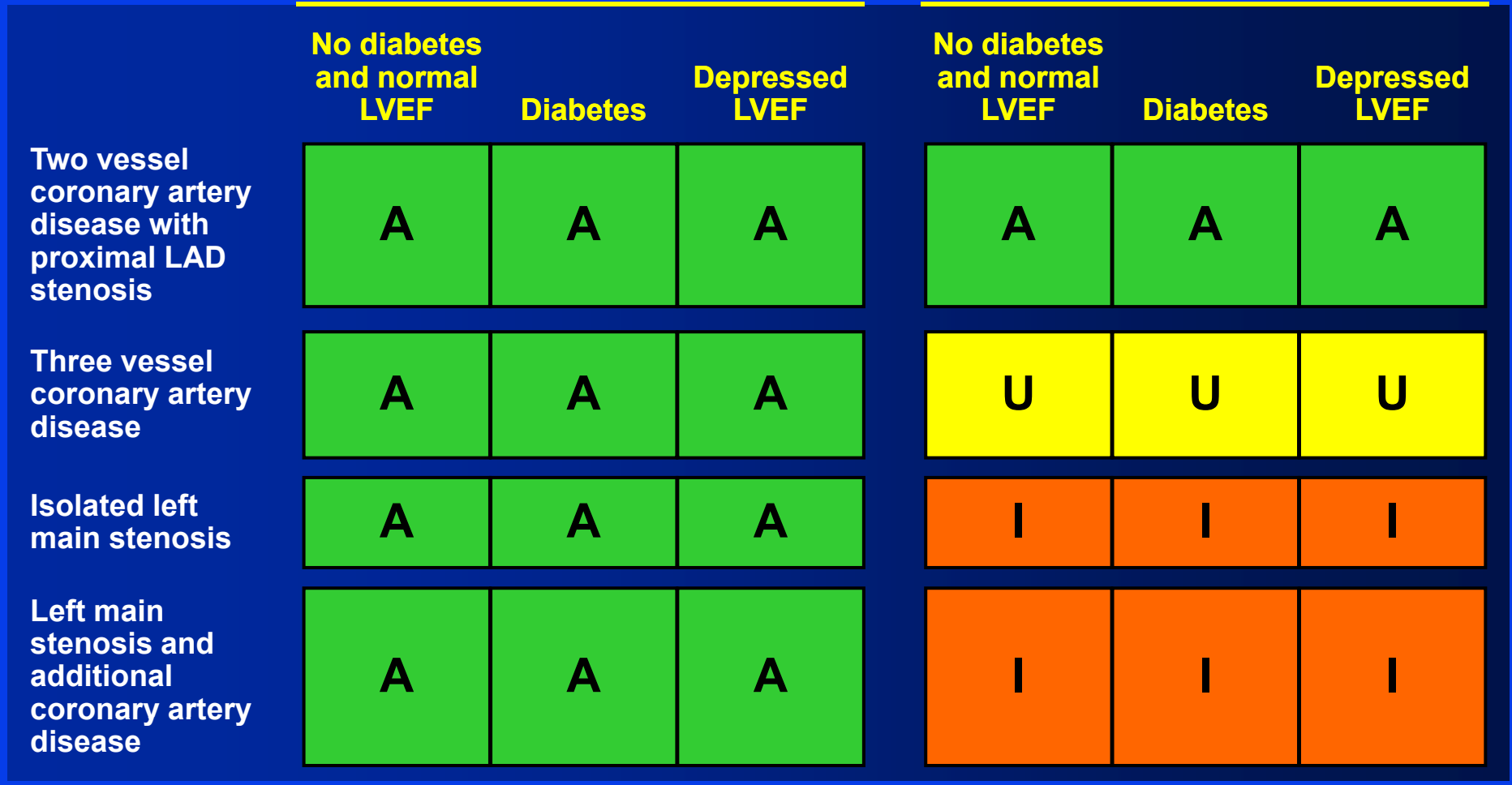


- In Progress: Peripheral Vascular Disease, Diagnostic Cath

The Revascularization AUC

180 clinical scenarios in acute and chronic CAD patient presentation

Method of Revascularization of Advanced Coronary Artery Disease
Patients Without Prior Bypass Surgery



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Appropriate Use Criteria

- 85 cardiologists from 10 U.S. institutions
- Review of AUC criteria prior to AUC publications
- Purpose: compare consistency of AUC among broad range of cardiologists and the AUC technical panel

Chan et al: JACC 2011; 57:1546-53

Agreement Between the AUC Technical Panel and Survey Participants in Ratings of Appropriateness for Coronary Revascularization

Indications	N	All Physicians (n = 85)	Interventionalist?	
			Yes (n = 44)	No (n = 41)
All	68	84%	84%	85%
Appropriate	36	94%	94%	89%
Uncertain	22	73%	73%	73%
Inappropriate	10	70%	70%	100%

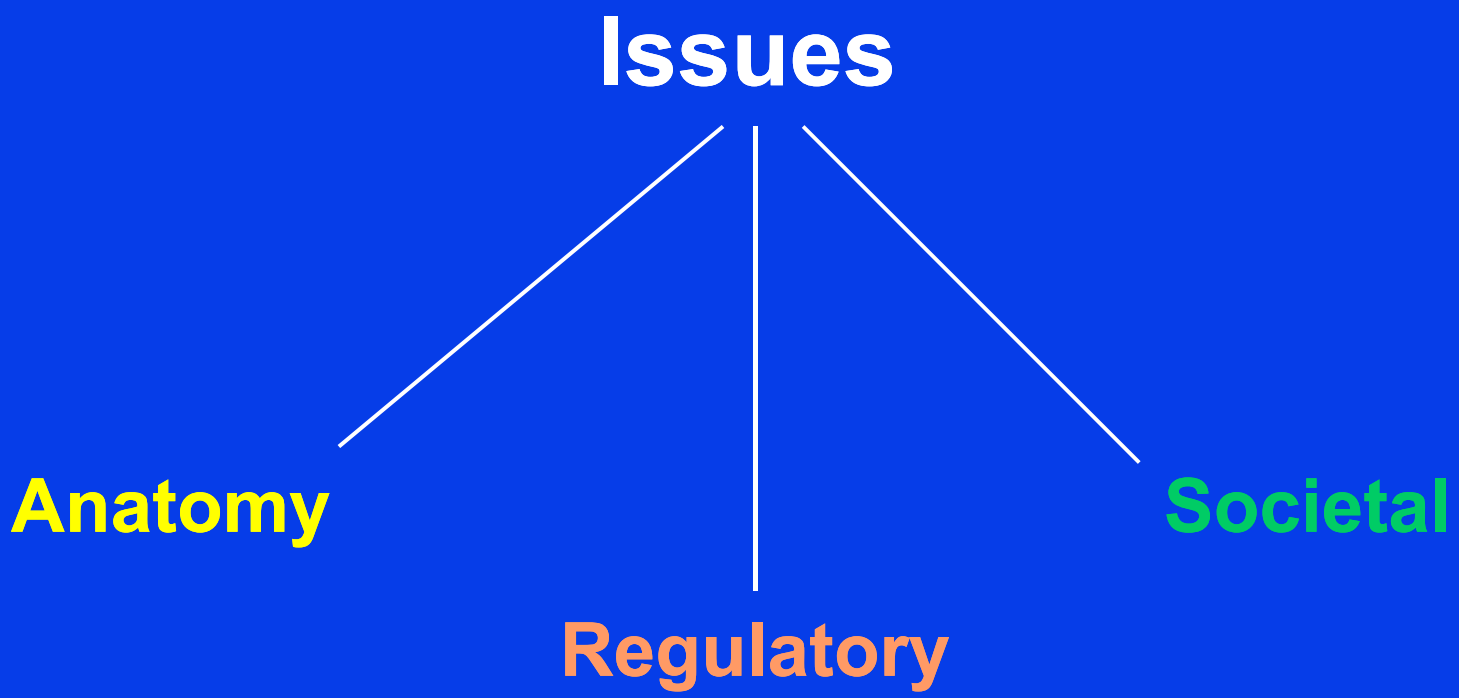
Chan et al: JACC 2011; 57:1546-53

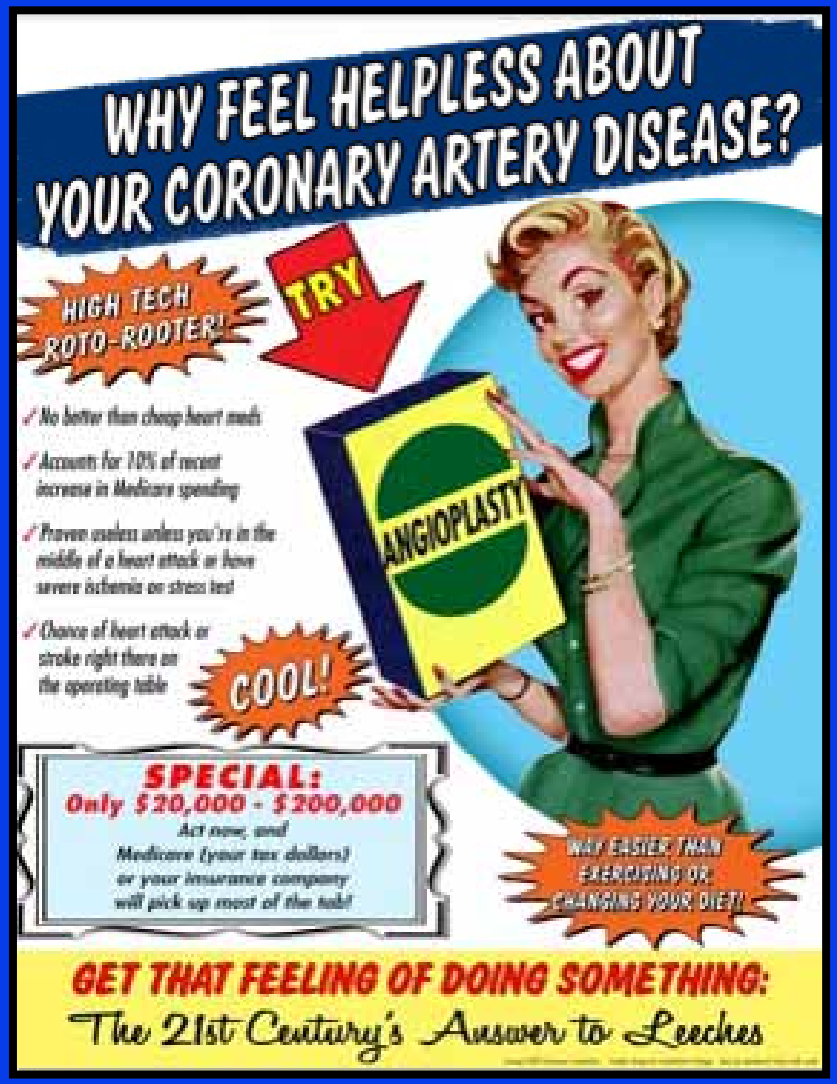
Appropriate Use Criteria

- Good overall concordance in assessments of appropriate use of coronary revascularization between physicians and AUC Technical Panel
- Marked variation in ratings between individual physicians and the AUC Technical Panel

Chan et al: JACC 2011; 57:1546-53

The Landscape



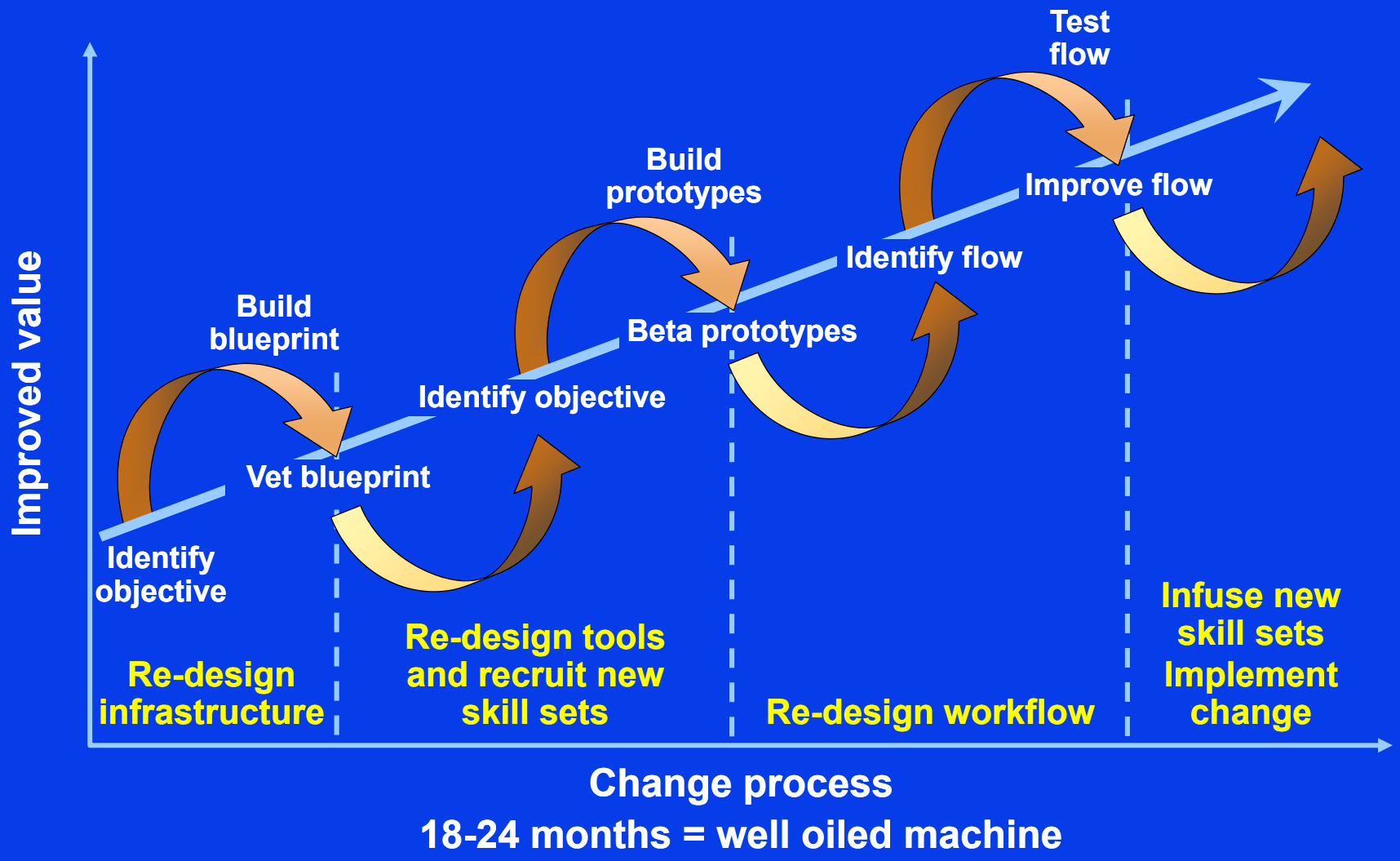

WHY FEEL HELPLESS ABOUT YOUR CORONARY ARTERY DISEASE?
HIGH TECH ROTO-ROOTER!
TRY
ANGIOPLASTY
No better than cheap heart meds
Accounts for 10% of recent increase in Medicare spending
Proven useless unless you're in the middle of a heart attack or have severe ischemia on stress test
Chance of heart attack or stroke right there on the operating table
COOL!
SPECIAL:
Only $20,000 - $200,000
Act now, and Medicare (your tax dollars) or your insurance company will pick up most of the tab!
WAY EASIER THAN EXERCISING OR CHANGING YOUR DIET!
GET THAT FEELING OF DOING SOMETHING:
The 21st Century's Answer to Leeches


WAS YOUR STENT UNNECESSARY?
1-888-DR-LEGAL
COLKITT LAW FIRM, PC
Colkitt Law Firm, P.C. Indiana, PA., 15701
with offices in Pittsburgh and Johnstown
2530

Dr. Oz – Stents Unnecessary?

Using Revascularization AUC to Improve Quality and Reduce Unnecessary Spending

Change is an Iterative, Collaborative Process



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Personalized Lifelong Learning

Keeping current is my biggest challenge. I know I have Maintenance of Certification requirements, I know with the rate of development my gaps grow with each day that passes, I no longer have an unbiased perspective assuring me I am doing OK and recommending things I can do to be the best.

Beginning of 52-week educational initiative

Personal Lifelong Learning Portfolio

- Ability to access specific chunks of clinical documents
- Point-of-care MOC
- Practice guidelines
- My transcript and self-assessments
- Personalized blended curriculum

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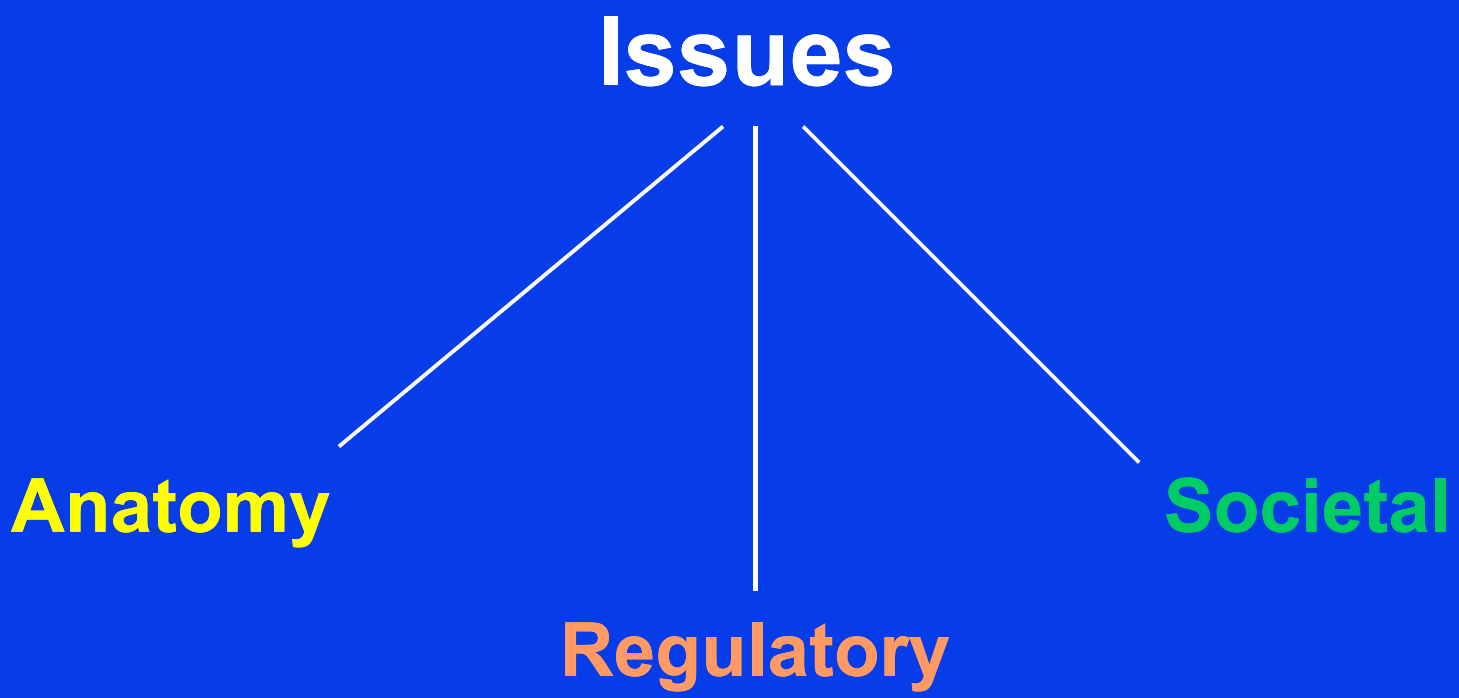
The Landscape



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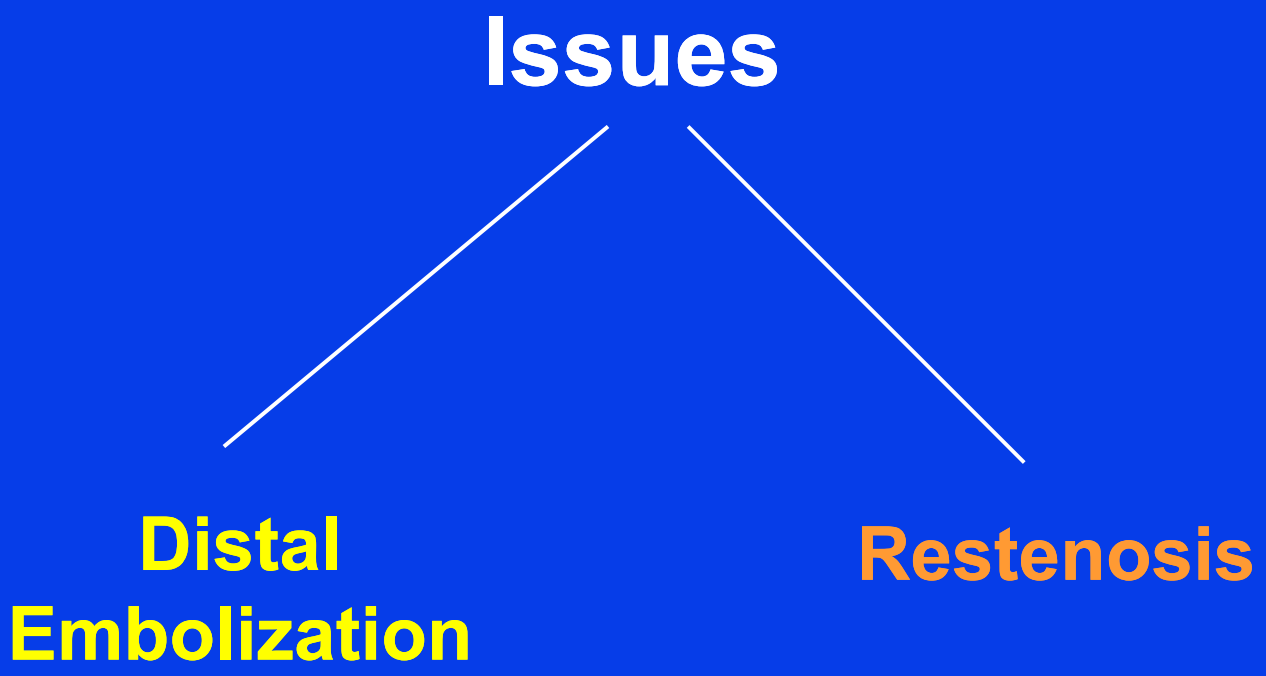
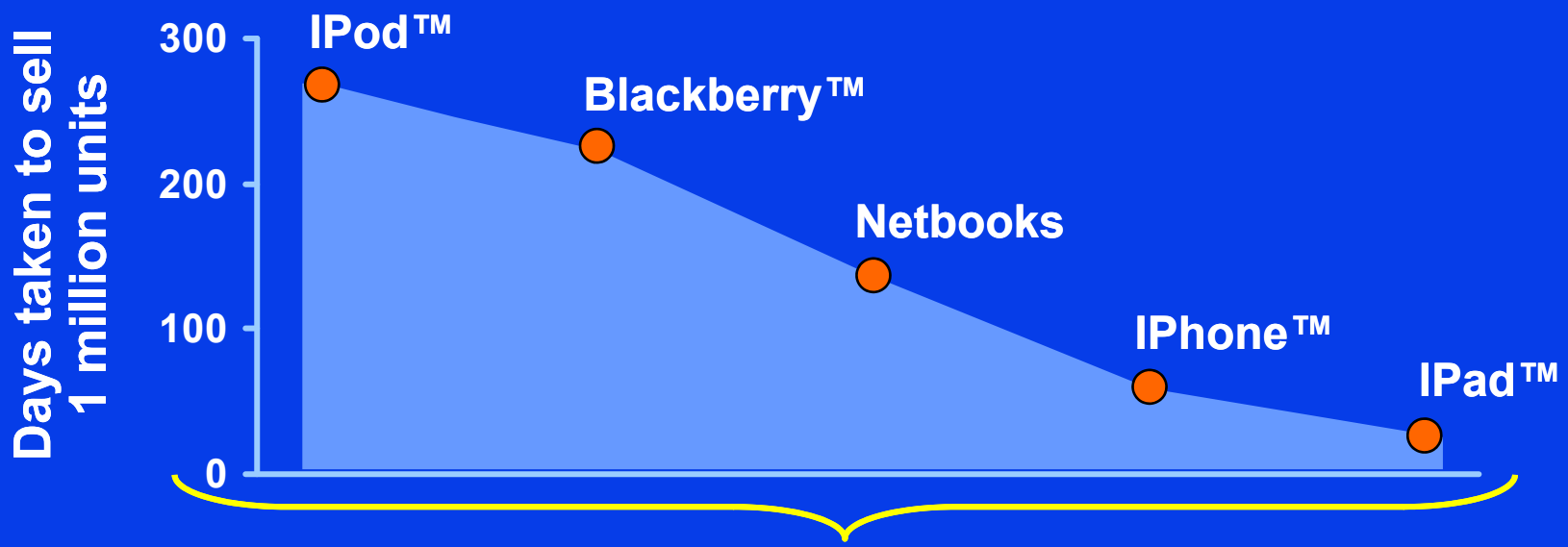
Vein Grafts



The Pace of Innovation
Adoption of New Technology



Why?

£↓ + Declining input and manufacturing costs have lowered prices to drive faster adoption

+ Shrinking form factors have unleashed the potential of devices by eliminating mobility constraints

+ Enhanced computing power and improved user-interfaces have drastically increased device usability

+ Technologies have evolved from static creation devices to dynamic consumption and connection devices

Deloitte UK and Gartner Research (www.gartner.com)

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Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3106481

Subject: Accessible Information

Background: BU3

Banner/brdr: 0-40-159/BU41

Side title: YW105

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Text: WT/BK

Highlight: YO114

Subdue: BU31

Footnotes: BU41

Plot/brdr: open/BU41
x, y only

PPT shooting instructions
PPT File to Server
(2 images)

Artist: ma Due Date: 4-20-2011

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Match: Mayo2bu-2002 (CP1111378)

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Vision for Lifelong Learning Division

"Education is part of the Cure…"

Pat O'Gara 2000

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Annual Curriculum Planning – April, 2012

Review competency milestones by pathway

↓ **Review performance**

Outcomes reports, evaluations and assessments ⟷ **Data/gaps from quality and science**

↓ **Planning by pathway**

- Cardiac arrhythmias
- Cardiac function and heart failure
- Congenital cardiology
- Hypertension, lipids and prevention
- Imaging and diagnostic testing
- Interventional cardiology
- Lifelong learning/MOC
- Myocardial ischemia and infarction
- Quality of care and outcomes assessment
- Valvular heart disease
- Vascular disease

Develop success metrics based on competency milestones

Assessment, evaluation and outcome planning by activity

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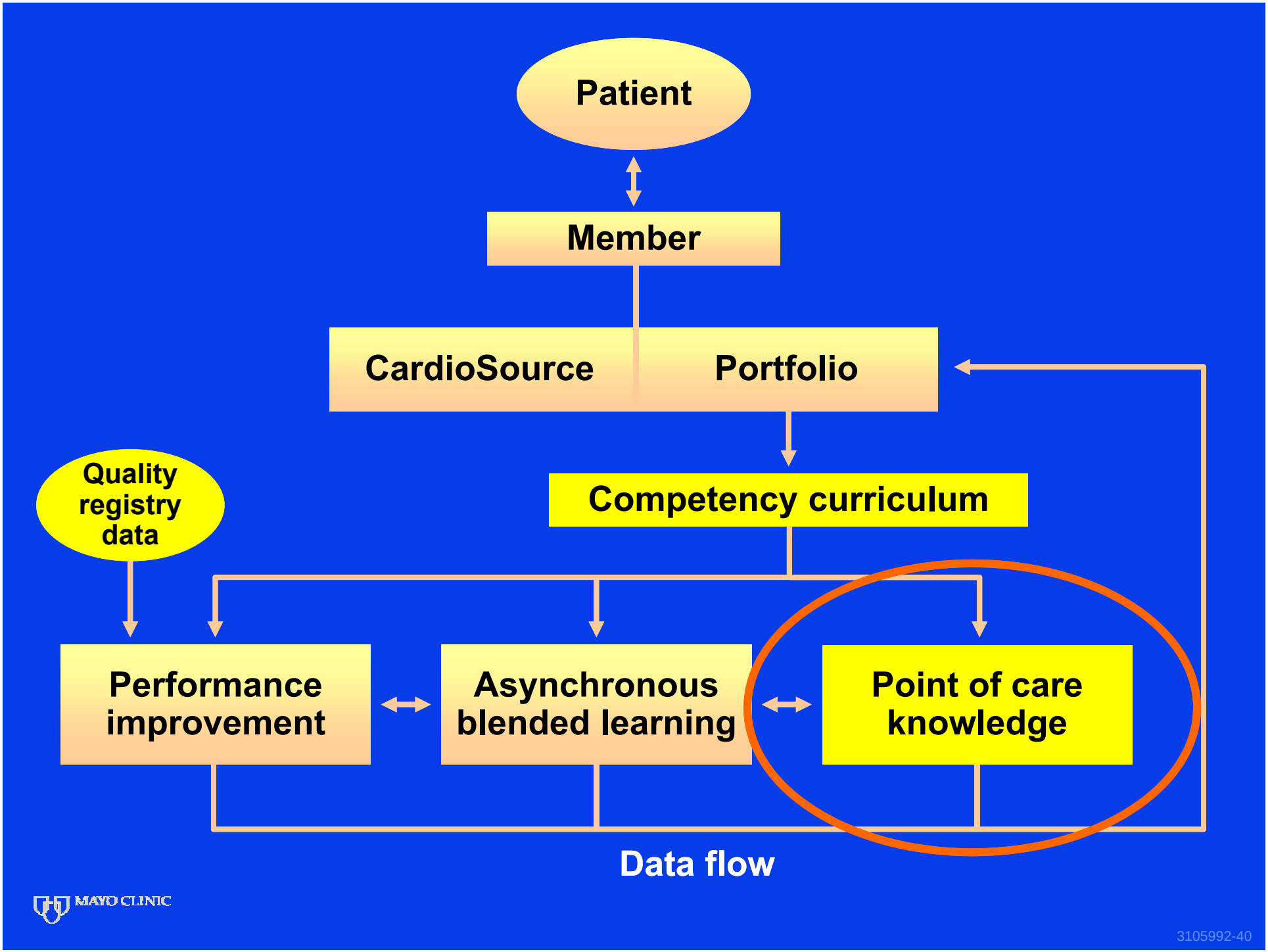
Patient
Member
CardioSource
Portfolio
Quality registry data
Competency curriculum
Performance improvement
Asynchronous blended learning
Point of care knowledge
Data flow
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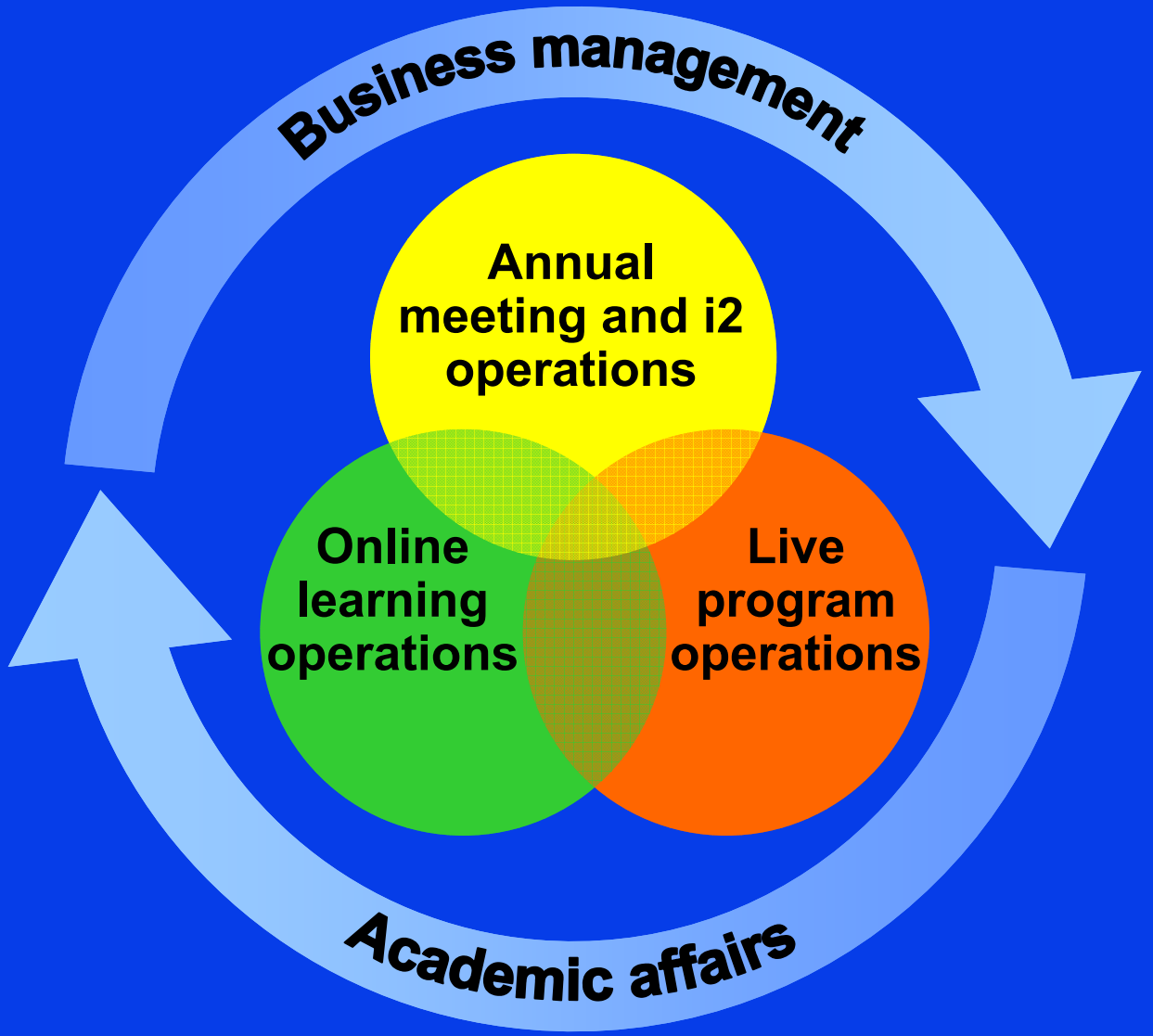
3105992-40


Business management
Annual meeting and i2 operations
Online learning operations
Live program operations
Academic affairs

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Lifelong Learning Division

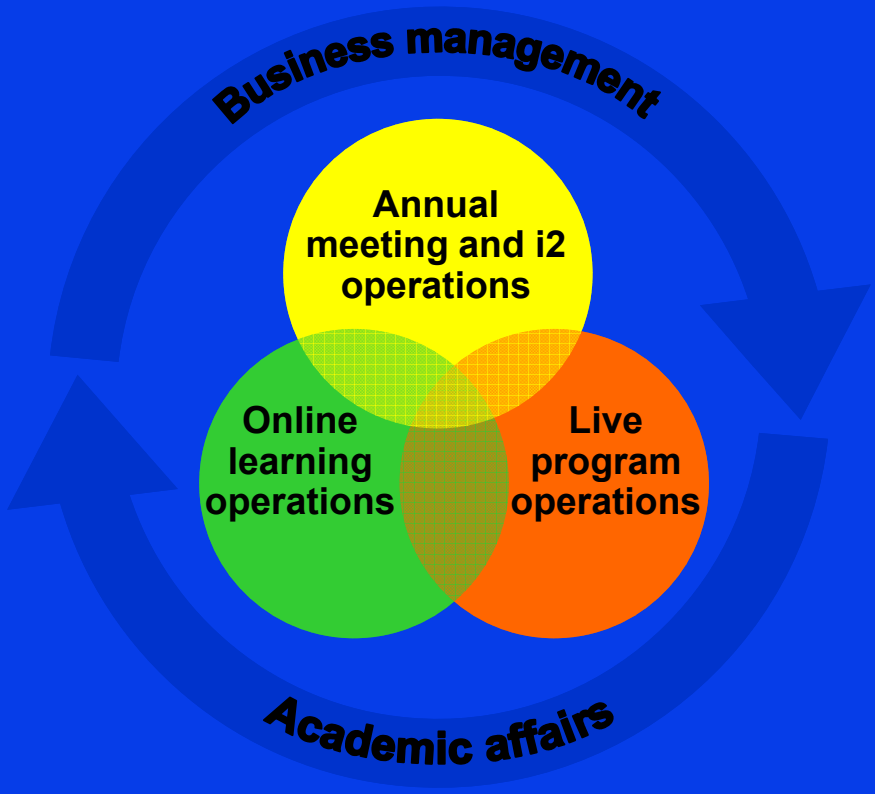
- Foundation of strategically focused departments
  - Academic affairs
  - Business management
- Overarching compass by which operational groups design, develop and disseminate
- Department missions are distinct, but also innately connected
- Unified circle of strategic influence governing the entire division

A Well Coordinated Team Effort

- **Strategic departments will build the essential frameworks and plans for success**
- **Operational groups will deliver the right content, at the right time, in the right format to our member and non-member learners**

A Well Coordinated Team Effort

- Strategic departments will build the essential frameworks and plans for success
- Operational groups will deliver the right content, at the right time, in the right format to our member and non-member learners



Getting There

- Joe's Direct Report meetings: leadership expectations
- Town meetings
- Work groups
  - Curriculum planning
  - Academic affairs
  - Business management
  - Online operations
  - Live operations
- May 31st retreat
- June: Work flow re-engineering
- Committee Alignment for Success

Academic Affairs: Mission

The Academic Affairs Department transforms scientific, regulatory and environmental forces shaping cardiovascular healthcare into an integrated system for performance improvement and lifelong learning

"A team of strategic experts grounded in science and education inspiring and infusing lifelong learning principles into practice"

Business Management: Mission

The Business Management Department strategically plans educational products, services and experiences to optimize quality and drive revenue for continued growth and leadership

"A team of experts grounded in keeping stakeholders aligned, identifying market opportunities, meeting member needs and leading education quality and continual improvement"

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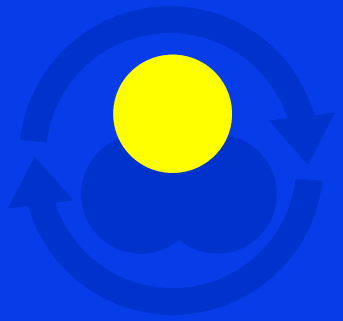
Annual Meeting Operations: Mission

Annual Meeting Operations executes strategic intent through designing, developing and implementing innovative annual scientific conventions and derivative meetings

“A team of operational experts in delivering scientific and clinical content through innovative medical education conventions”



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Live Program Operations: Mission

Live Program Operations executes strategic intent through designing, developing and implementing innovative live educational programs and activities

“A team of operational experts in delivering scientific and clinical content through innovative live programs and activities”

Online Learning Operations: Mission

Online Operations executes strategic intent through designing, developing and implementing innovative online educational activities and managing the Lifelong Learning Portfolio toolset

“A team of operational experts in delivering scientific and clinical content through innovative online programs and activities”

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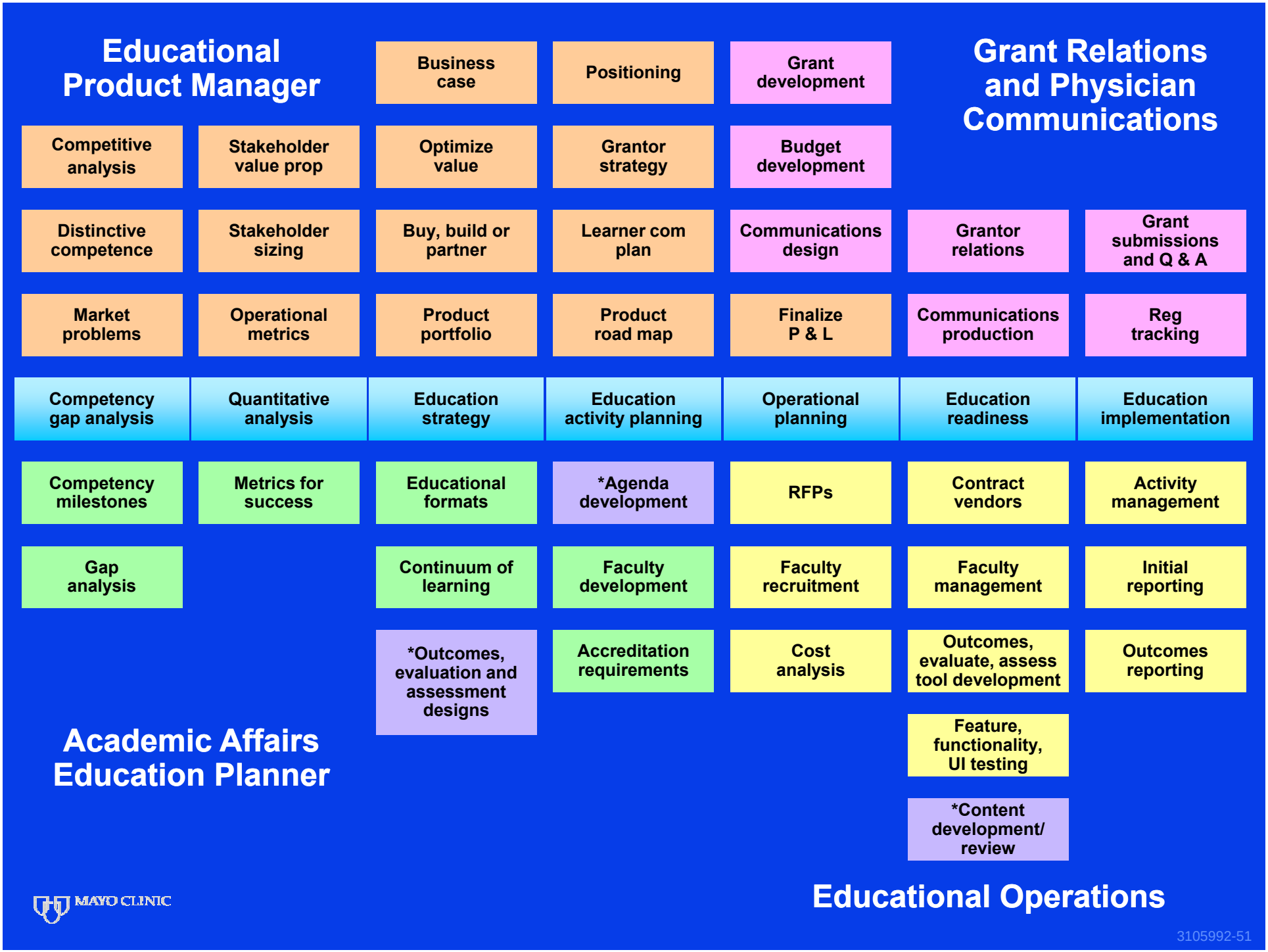
Educational Product Manager
Business case
Positioning
Grant development
Grant Relations and Physician Communications
Competitive analysis
Stakeholder value prop
Optimize value
Grantor strategy
Budget development
Distinctive competence
Stakeholder sizing
Buy, build or partner
Learner com plan
Communications design
Grantor relations
Grant submissions and Q & A
Market problems
Operational metrics
Product portfolio
Product road map
Finalize P & L
Communications production
Reg tracking
Competency gap analysis
Quantitative analysis
Education strategy
Education activity planning
Operational planning
Education readiness
Education implementation
Competency milestones
Metrics for success
Educational formats
*Agenda development
RFPs
Contract vendors
Activity management
Gap analysis
Continuum of learning
Faculty development
Faculty recruitment
Faculty management
Initial reporting
*Outcomes, evaluation and assessment designs
Accreditation requirements
Cost analysis
Outcomes, evaluate, assess tool development
Outcomes reporting
Feature, functionality, UI testing
*Content development/ review
Academic Affairs Education Planner
Educational Operations
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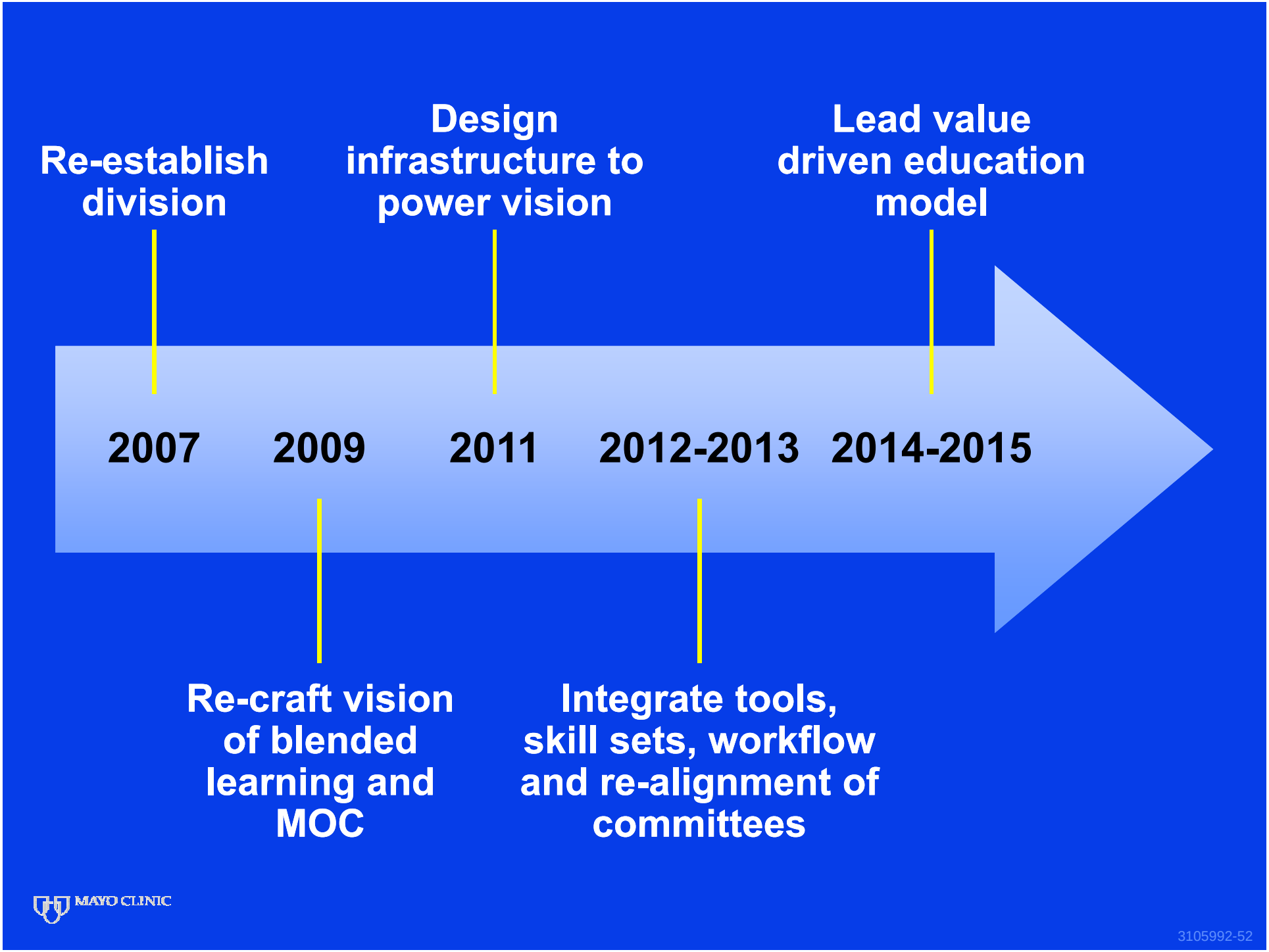
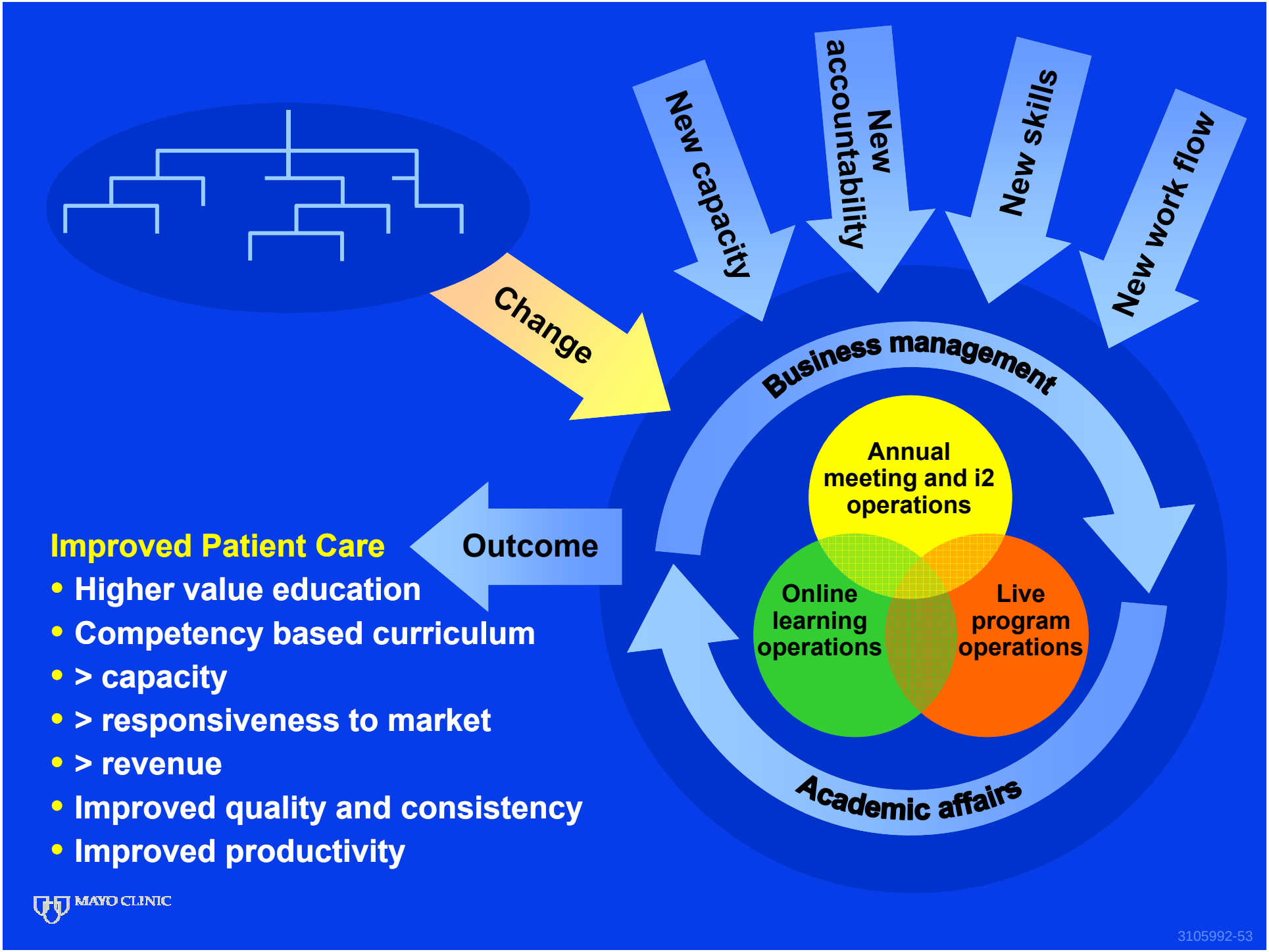
3105992-51


Re-establish division
Design infrastructure to power vision
Lead value driven education model
2007
2009
2011
2012-2013
2014-2015
Re-craft vision of blended learning and MOC
Integrate tools, skill sets, workflow and re-alignment of committees


New capacity
New accountability
New skills
New work flow
Change
Business management
Annual meeting and i2 operations
Online learning operations
Live program operations
Academic affairs
Outcome
Improved Patient Care
• Higher value education
• Competency based curriculum
• > capacity
• > responsiveness to market
• > revenue
• Improved quality and consistency
• Improved productivity
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3105992-53

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3105992

Subject: Ed Vision Slides

Background: BU3
Banner/brdr: 0-40-159/BU41
Side title: YW105
• /colhdgs: YW105
Text: WT/BK
Highlight: YO114
Subdue: BU31
Footnotes: BU41

Plot/brdr: open/BU41
x, y only

PPT shooting instructions
PPT File to Server
(18 images)

Artist: ma Due Date: 4-20-2011

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Match: Mayo2bu-2002 (CP1111378)

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Addressing Variation in Care
The Case for Appropriate Use

David R. Holmes, MD
Mayo Clinic, MN

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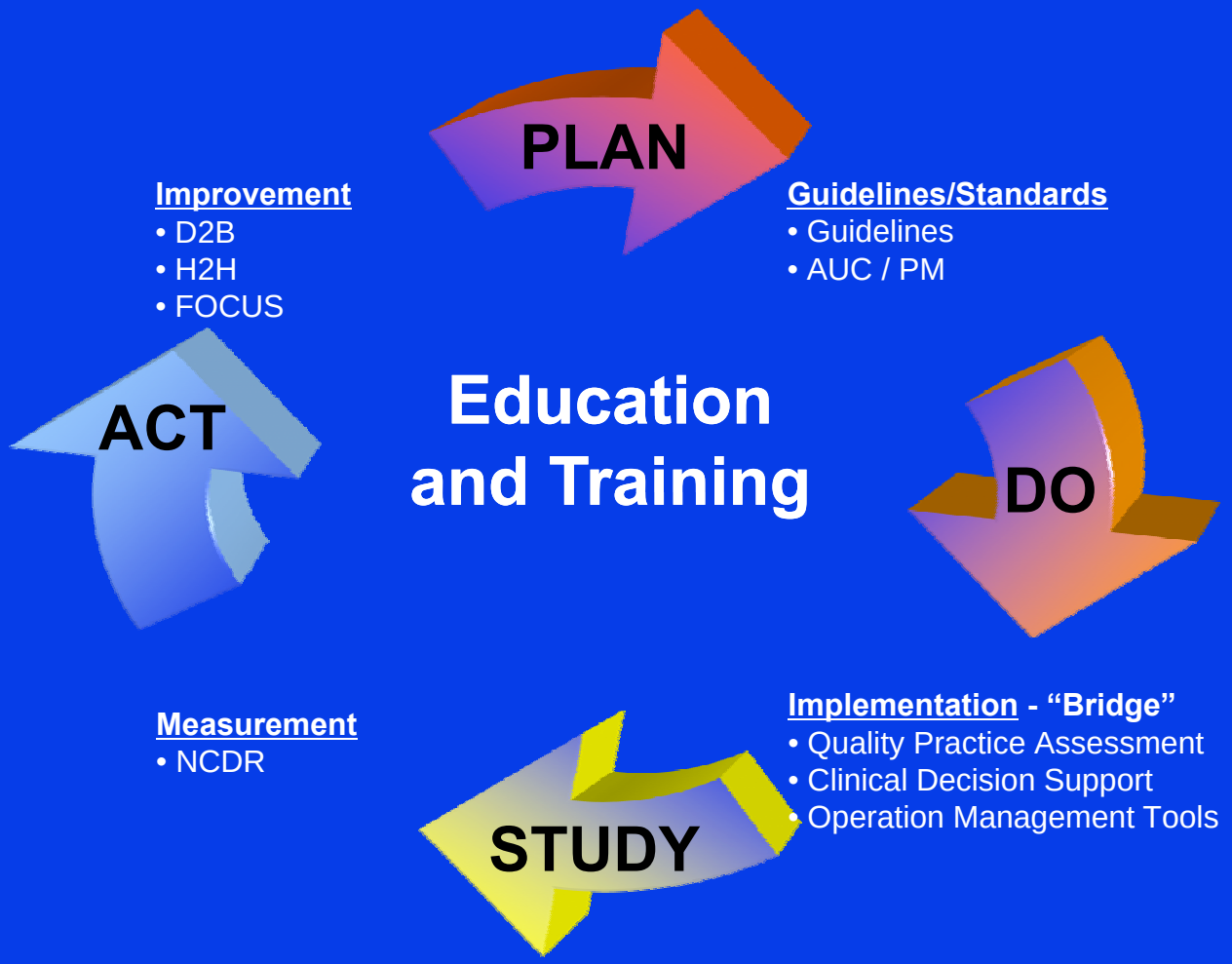
ACC Quality Approach

An end-to-end, system that translates science into practice

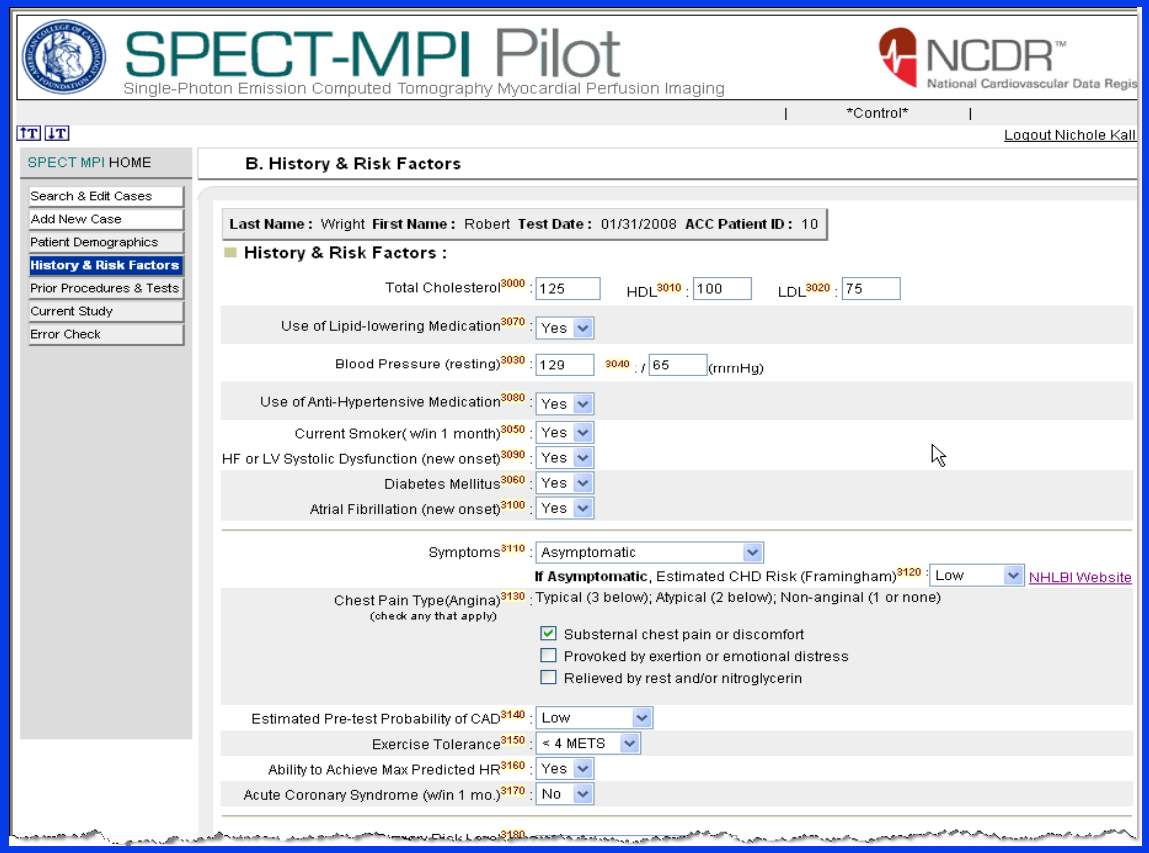


ACC Translation of Science

- Guidelines: 19 topics plus 3 new topics in process
- Performance Measures: 6 topics plus 2 new topics in process
- AUC: 5 topics plus 1 new topic in process
- Data Standards: 5 topics plus 1 new topic in process

The Case for AUC

- **FOCUS and potential imaging savings UnitedHealthCare SPECT-MPI Pilot**



AUC Revascularization

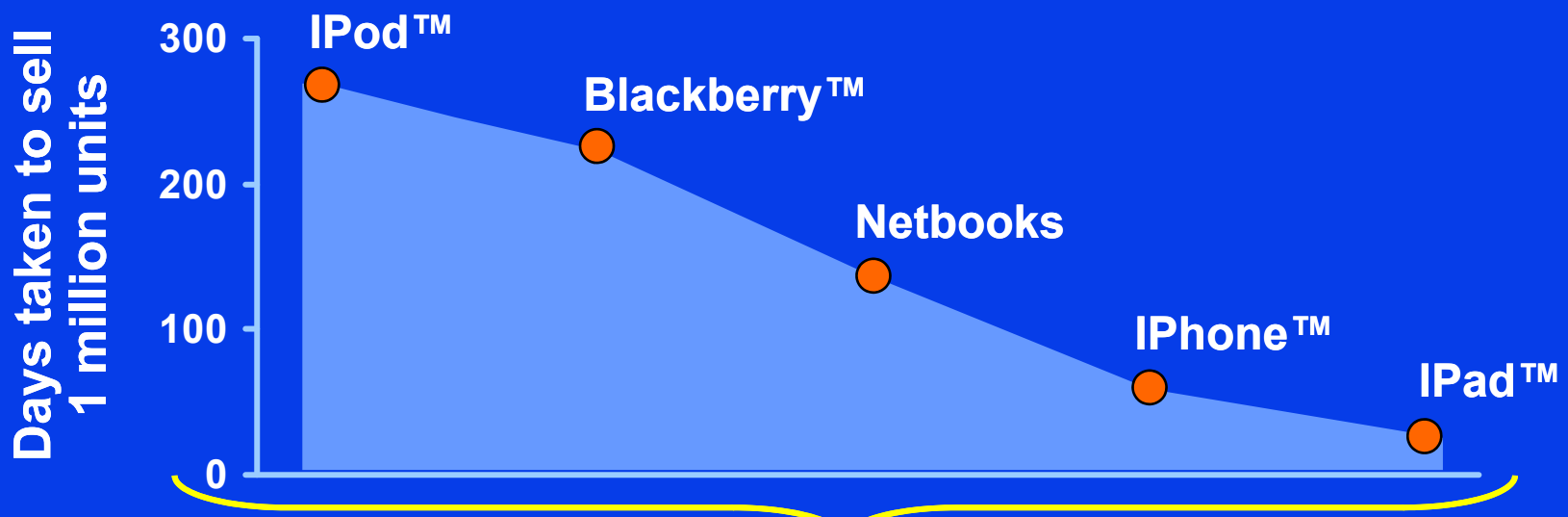
- Define key variables for appropriate use
  - Medication
  - Symptom status
  - Non-invasive test results
  - Coronary artery anatomy
- Embedded in NCDR CathPCI Registry
- Opportunity for shared decision making

"*Science* tells us what we can do;

Guidelines what we should do;

Registries what we are actually doing."

The Pace of Innovation
Adoption of New Technology



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+ Enhanced computing power and improved user-interfaces have drastically increased device usability

+ Technologies have evolved from static creation devices to dynamic consumption and connection devices

Deloitte UK and Gartner Research (www.gartner.com)

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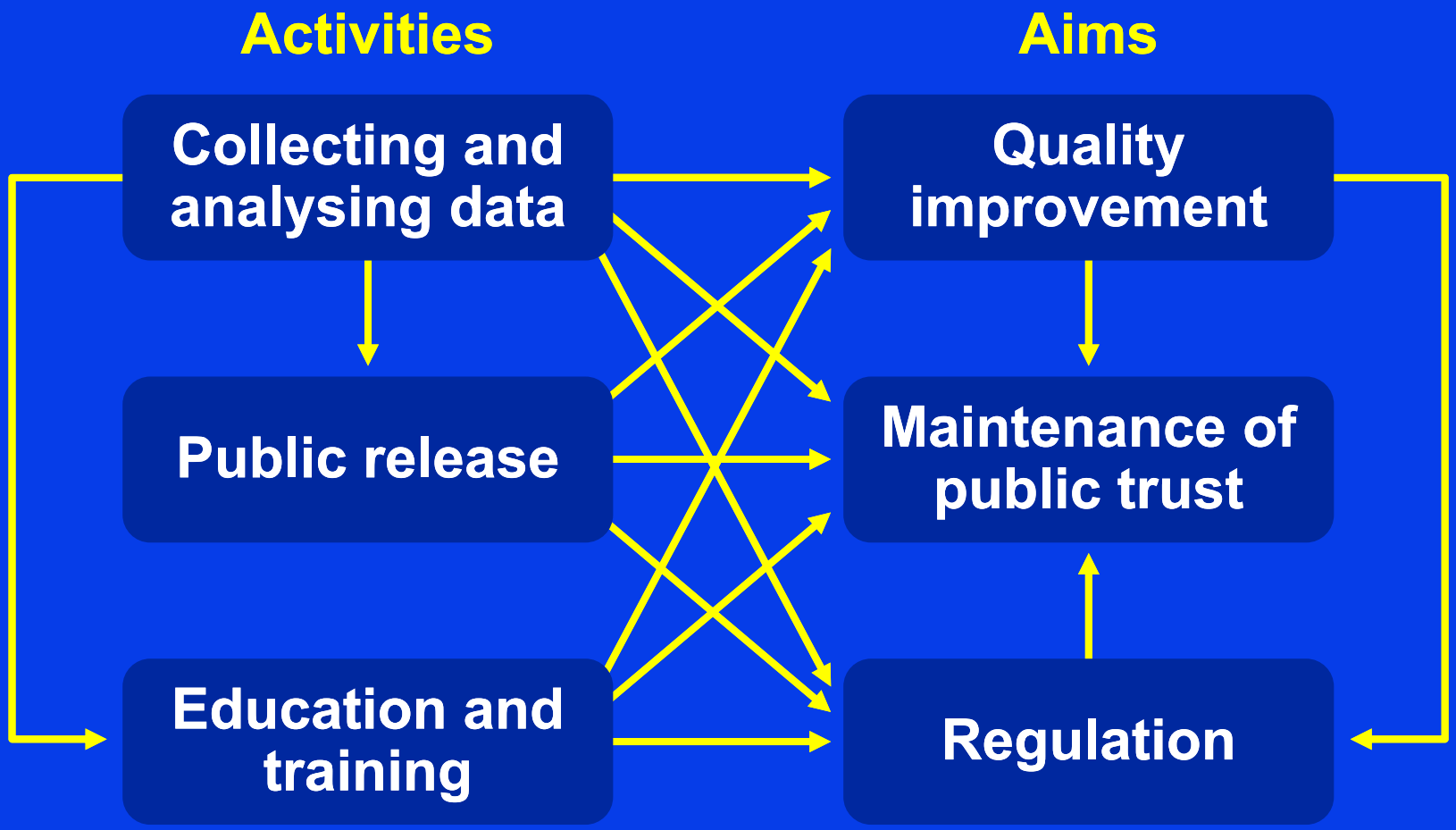
The Responsibilities of a Professional Society
The SCTS Model



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Previous Coronary Stent Implantation and Cardiac Events in Patients Undergoing Noncardiac Surgery

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Jill P. Pell, MSc, MBChB, MD, FFPHM, FESC; David E. Newby, PhD, BM, DM, FRCP; on behalf of the
Scottish Coronary Revascularisation Register Steering Committee

Background—Noncardiac surgery performed after coronary stent implantation is associated with an increased risk of stent thrombosis, myocardial infarction, and death. The influence of stent type and period of risk still have to be defined.

Methods and Results—We linked the Scottish Coronary Revascularisation Register with hospital admission data to undertake a Scotland-wide retrospective cohort study examining cardiac outcomes in all patients who received drug-eluting or bare-metal stents between April 2003 and March 2007 and subsequently underwent noncardiac surgery. Of 1953 patients, 570 (29%) were treated with at least 1 drug-eluting stent and 1383 (71%) with bare-metal stents only. There were no differences between drug-eluting and bare-metal stents in the primary end point of in-hospital mortality or ischemic cardiac events (14.6% versus 13.3%; $P=0.3$) or the secondary end points of in-hospital mortality (0.7% versus 0.6%; $P=0.8$) and acute myocardial infarction (1.2% versus 0.7%; $P=0.3$). Perioperative death and ischemic cardiac events occurred more frequently when surgery was performed within 42 days of stent implantation (42.4% versus 12.8% beyond 42 days; $P<0.001$), especially in patients revascularized after an acute coronary syndrome (65% versus 32%; $P=0.037$). There were no temporal differences in outcomes between the drug-eluting and bare-metal stent groups.

Conclusions—Patients undergoing noncardiac surgery after recent coronary stent implantation are at increased risk of perioperative myocardial ischemia, myocardial infarction, and death, particularly after an acute coronary syndrome. For at least 2 years after percutaneous coronary intervention, cardiac outcomes after noncardiac surgery are similar for both drug-eluting and bare-metal stents. (***Circ Cardiovasc Interv***. **2010;3:236-242.**)

Key Words: angioplasty ■ myocardial infarction ■ stents ■ surgery ■ survival

Introduced in the 1990s, bare-metal coronary stent implan- Treatment of patients with dual antiplatelet therapy (aspirin

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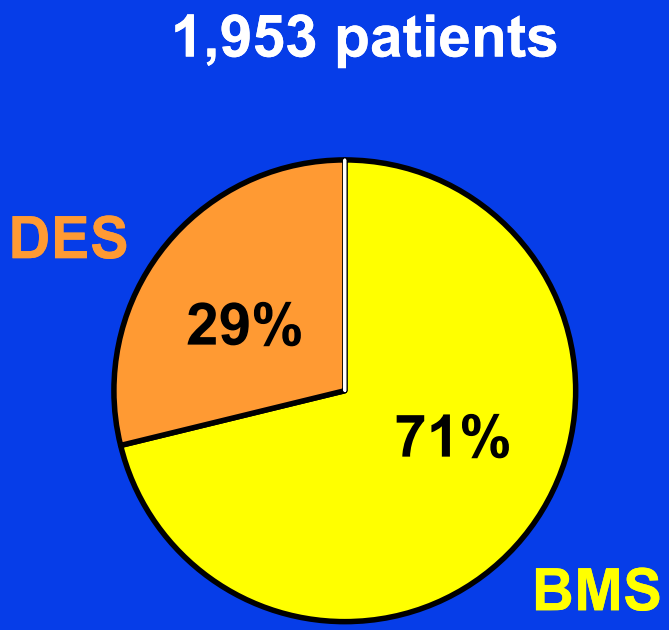
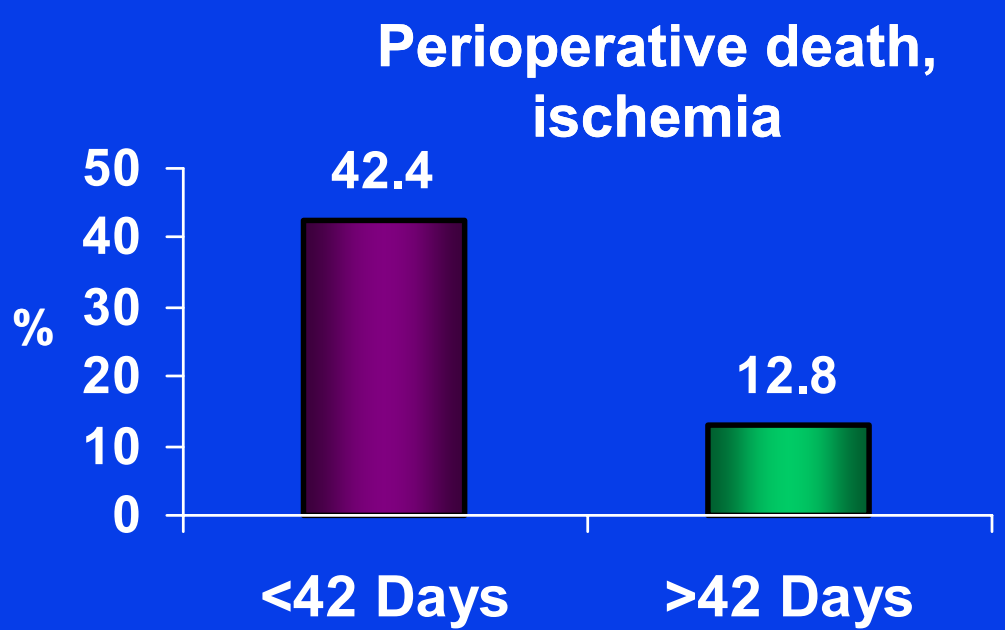
Conclusions – Patients undergoing noncardiac surgery after recent coronary stent implantation are at increased risk of perioperative myocardial ischemia, myocardial infarction, and death, particularly after an acute coronary syndrome. For at least 2 years after percutaneous coronary intervention, cardiac outcomes after noncardiac surgery are similar for both drug-eluting and bare-metal stents.

Stent Implantation & Non Cardiac Surgery
Scottish Coronary Revascularization Register

- Patients treated with stent implantation 2003-2007 who underwent non coronary surgery





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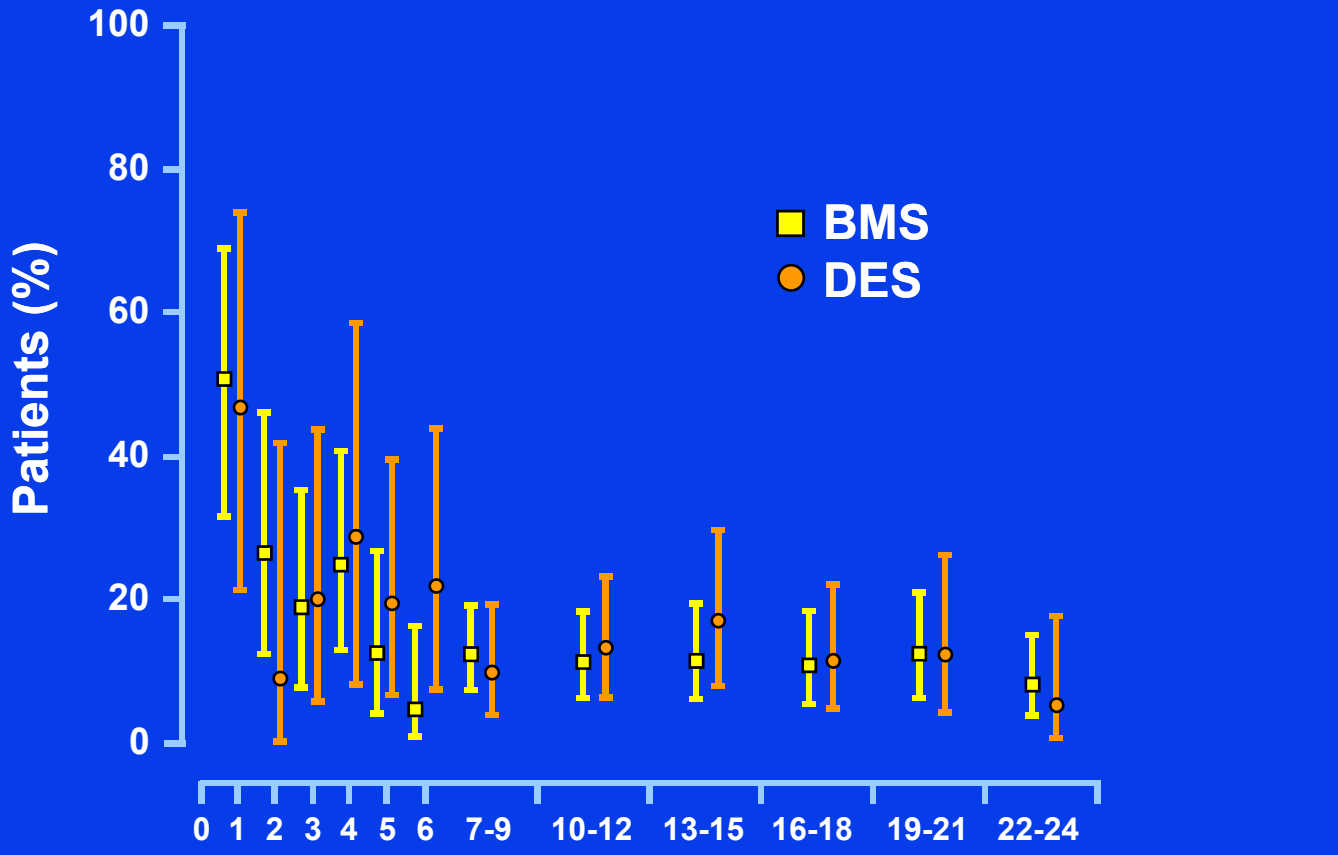
Cruden et al: Circ Cardiovasc Interv 3:236, 2010

Effect of Stent Type



Cruden et al: Circ Cardiovasc Interv 3:236, 2010

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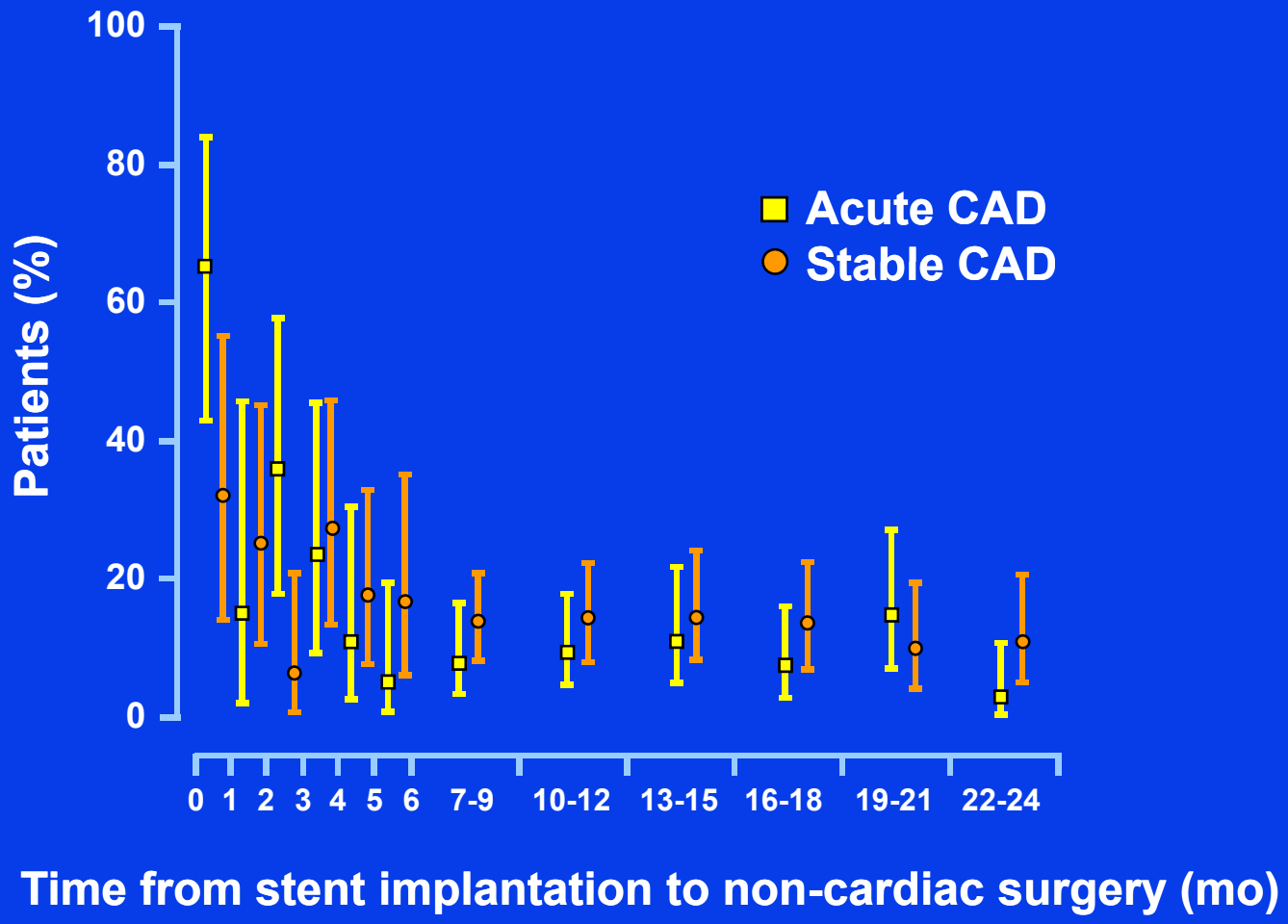
In-Hospital Mortality & Ischemic Cardiac Events



Cruden et al: Circ Cardiovasc Interv 3:236, 2010

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3107490-67

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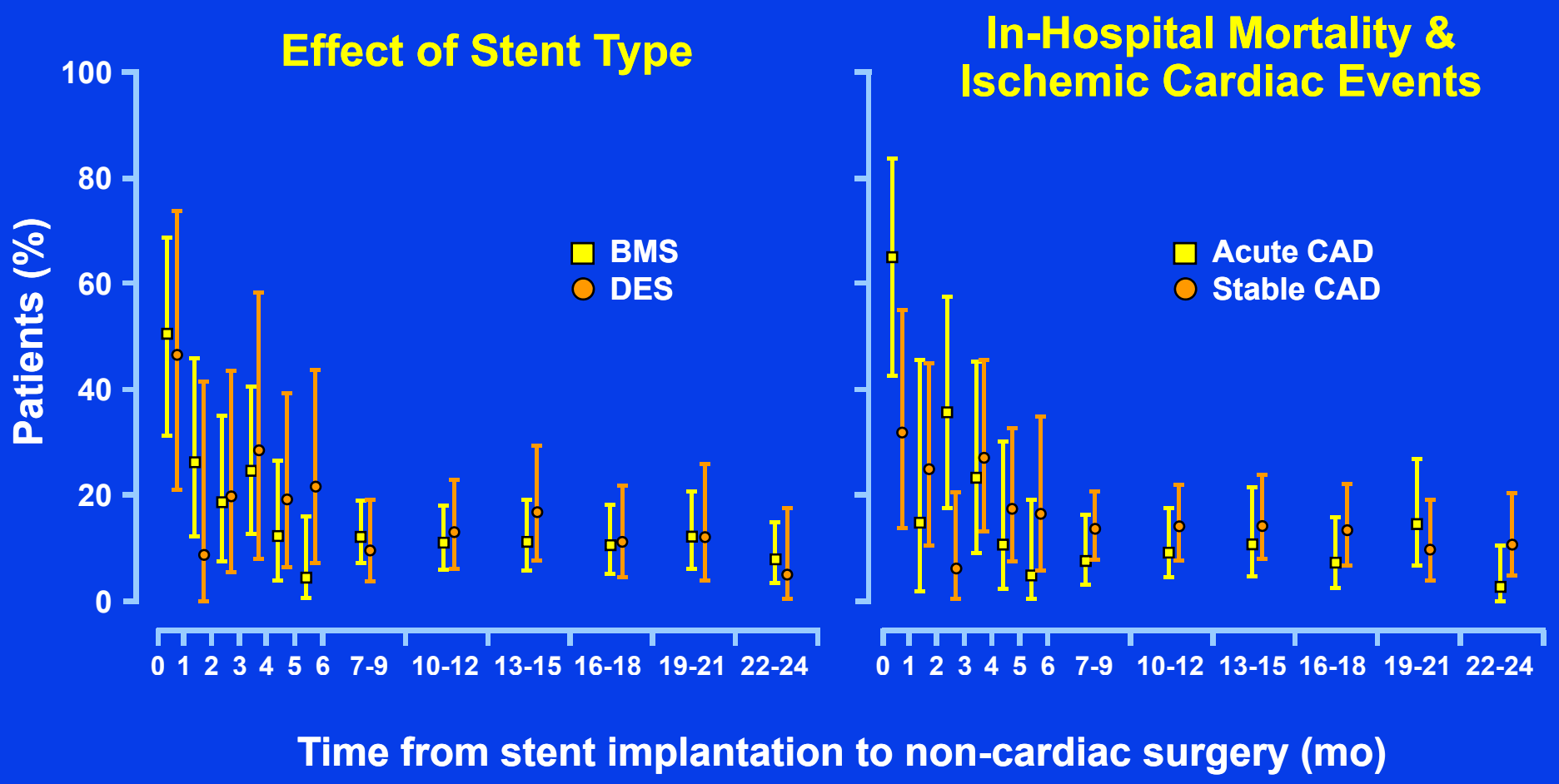

Cruden et al: Circ Cardiovasc Interv 3:236, 2010

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3107490-68

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Sub/drp–Job#: YW105/BK – 3107490

Subject: Stent Implantation in Noncardiac Surgery, Cruden

Background: BU (6-61-232)
Banner/brdr: BU4/BU41
Side title: YW105
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Text: WT/BK
Highlight: YO114
Subdue: BU31
Footnotes: BU41

Plot/brdr: open/BU41
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PPT shooting instructions
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Artist: KK Due Date: 4-22-2011

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Match: Mayo2bu-2002

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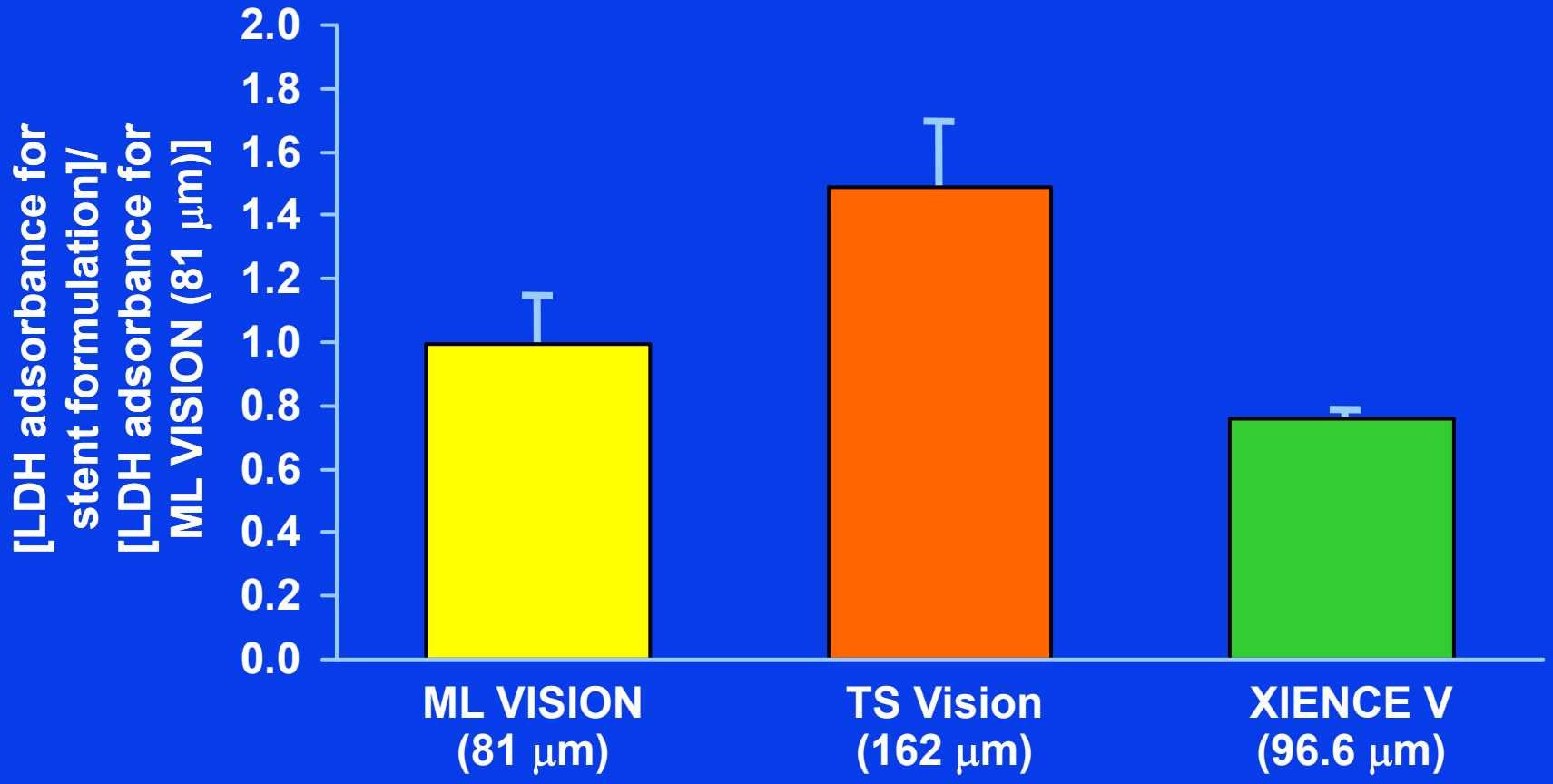
3107490-69

Ex Vivo Stent Thrombogenicity



Kolandaivelu et al: Circ 123:1400, 2011

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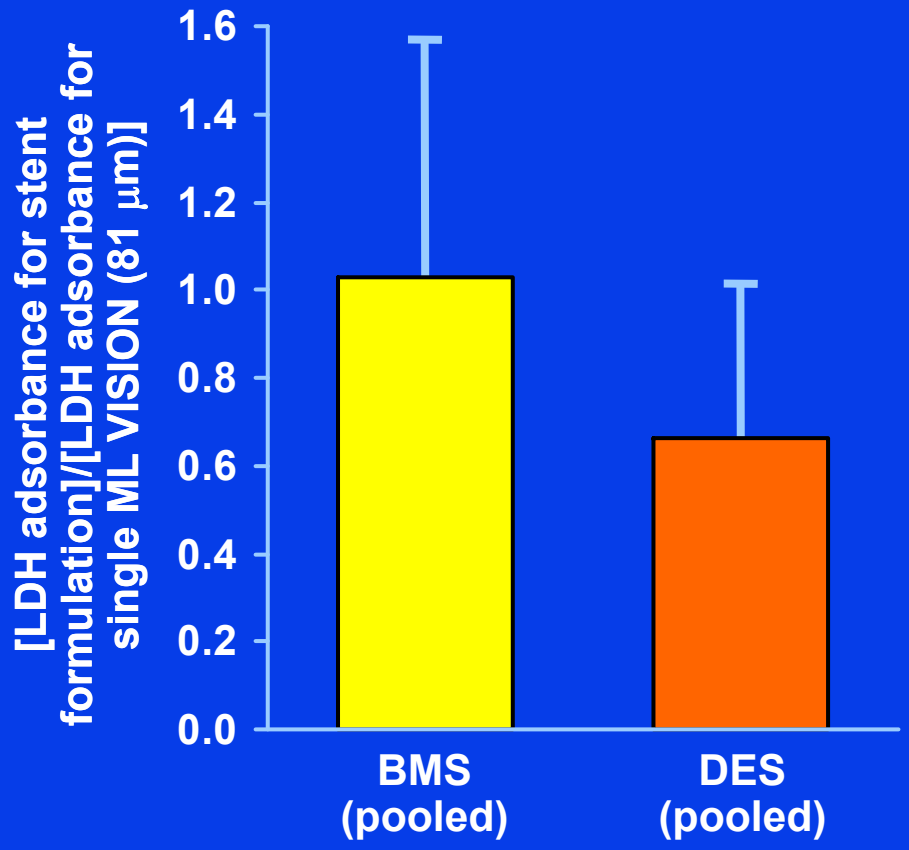
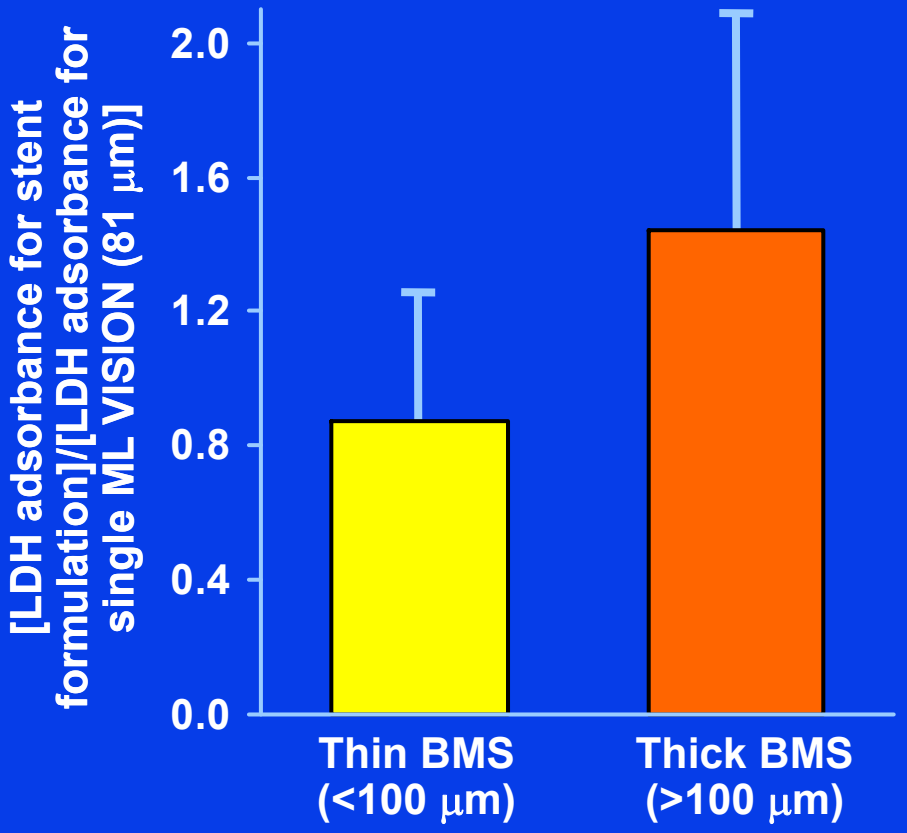
Ex Vivo Stent Thrombogenicity





Kolandaivelu et al: Circ 123:1400, 2011

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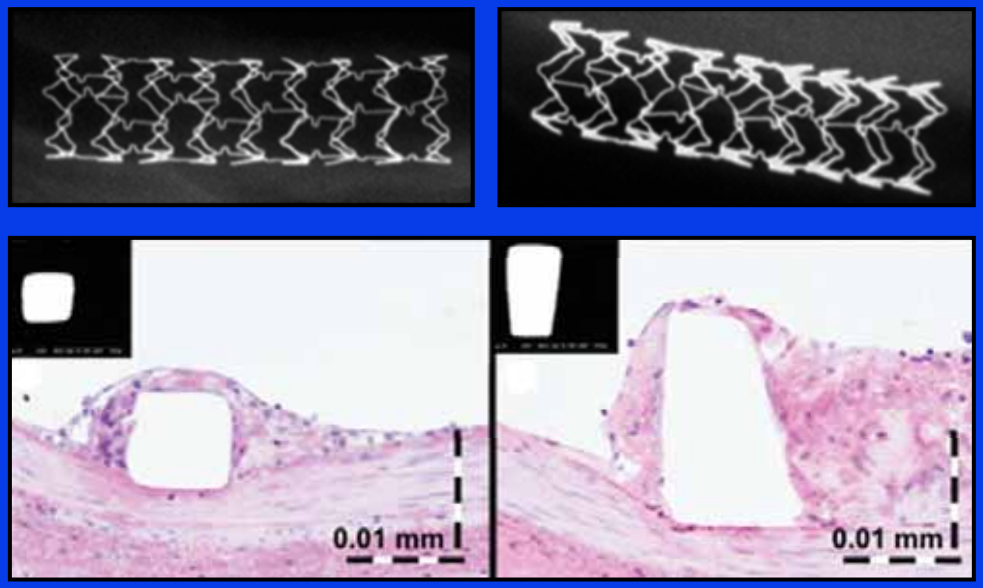
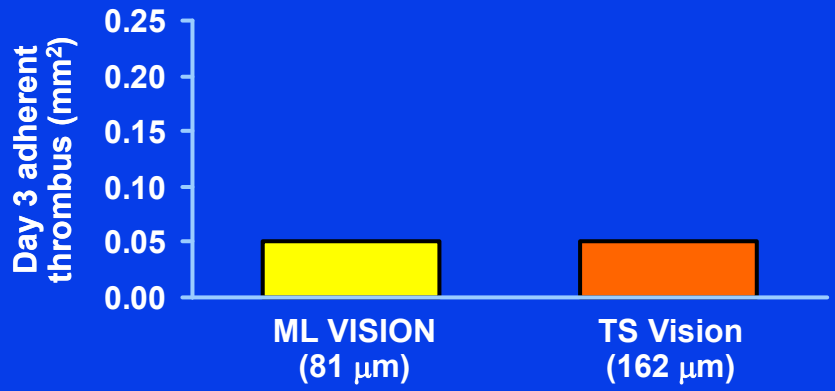
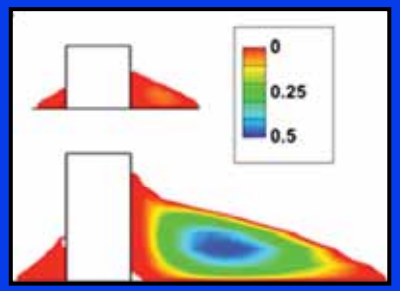
3107603-71

In Vivo Stent Thrombogenicity







Kolandaivelu et al: Circ 123:1400, 2011

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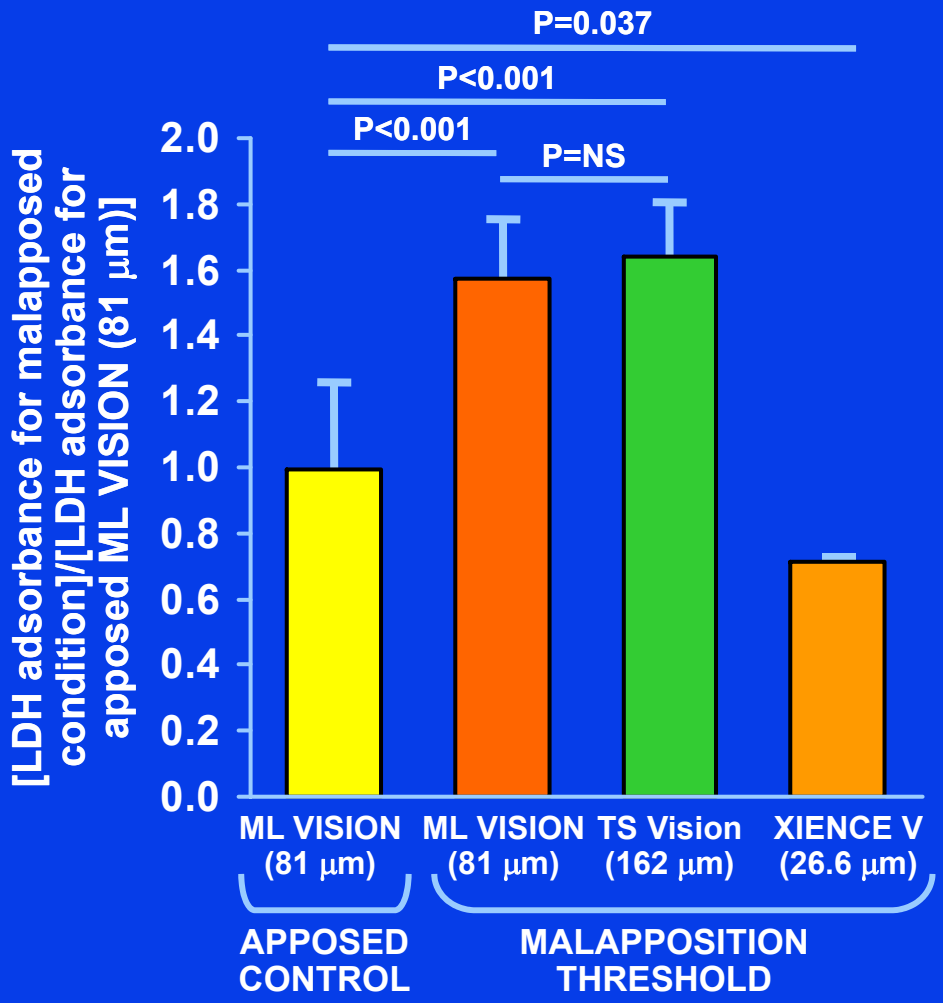
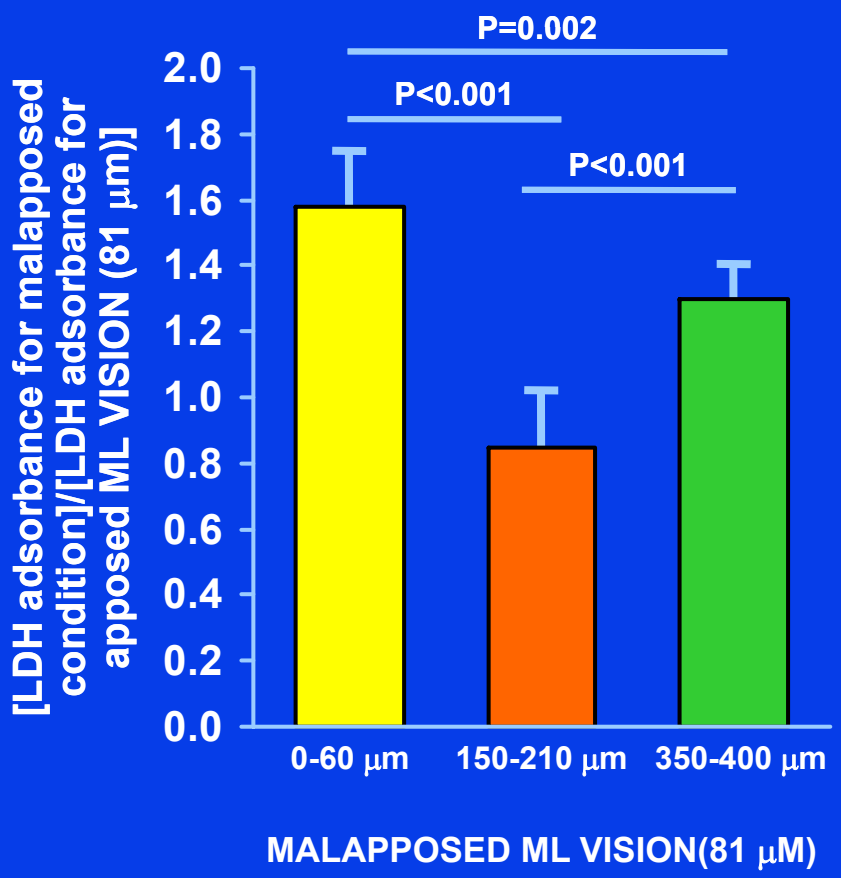
Ex Vivo Stent Thrombogenicity





Kolandaivelu et al: Circ 123:1400, 2011

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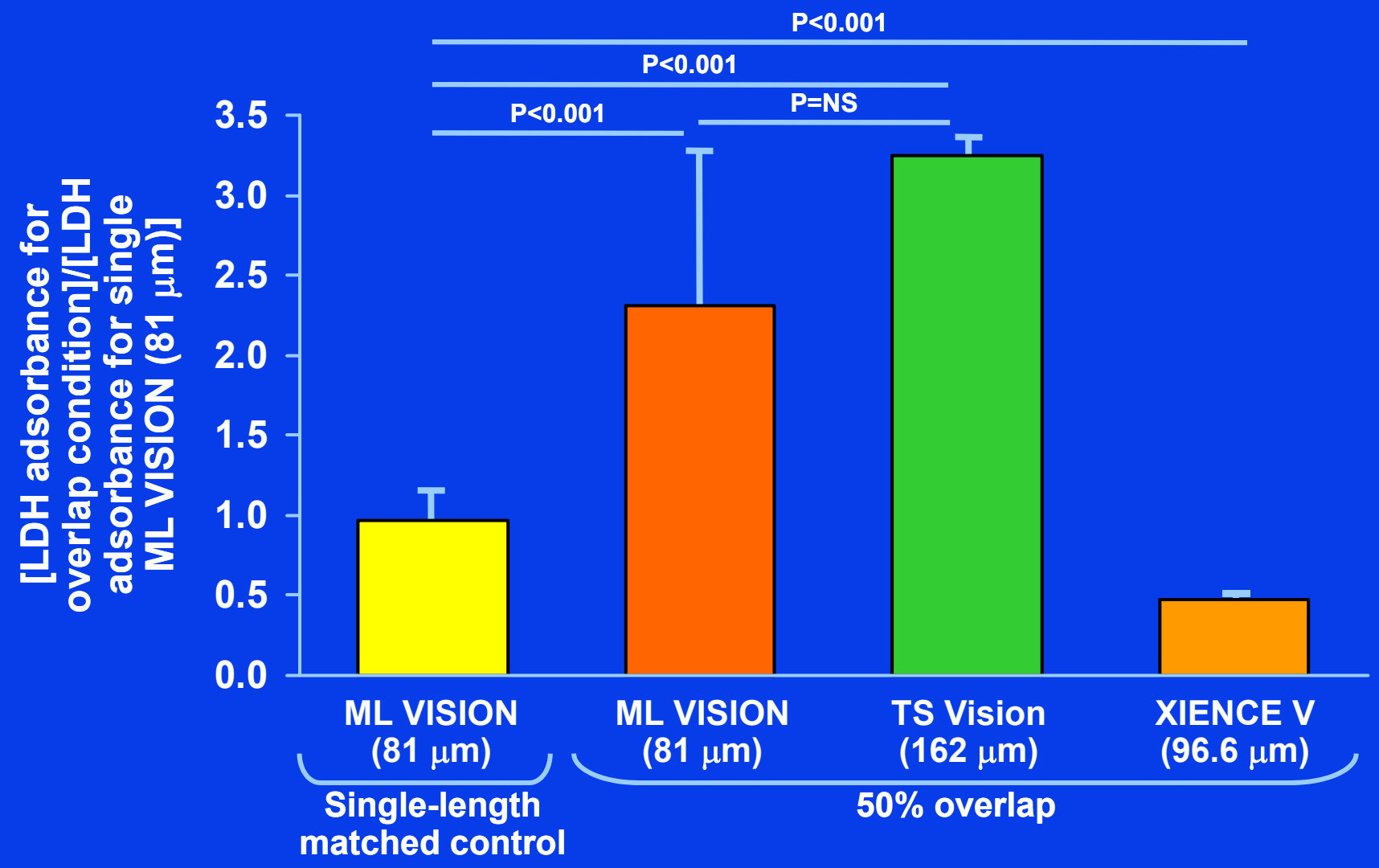
3107603-73

Ex Vivo Stent Thrombogenicity



Kolandaivelu et al: Circ 123:1400, 2011

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3107603

Subject: Stent Thrombogenicity, Kolandaivelu

Background: BU3
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Footnotes: BU41

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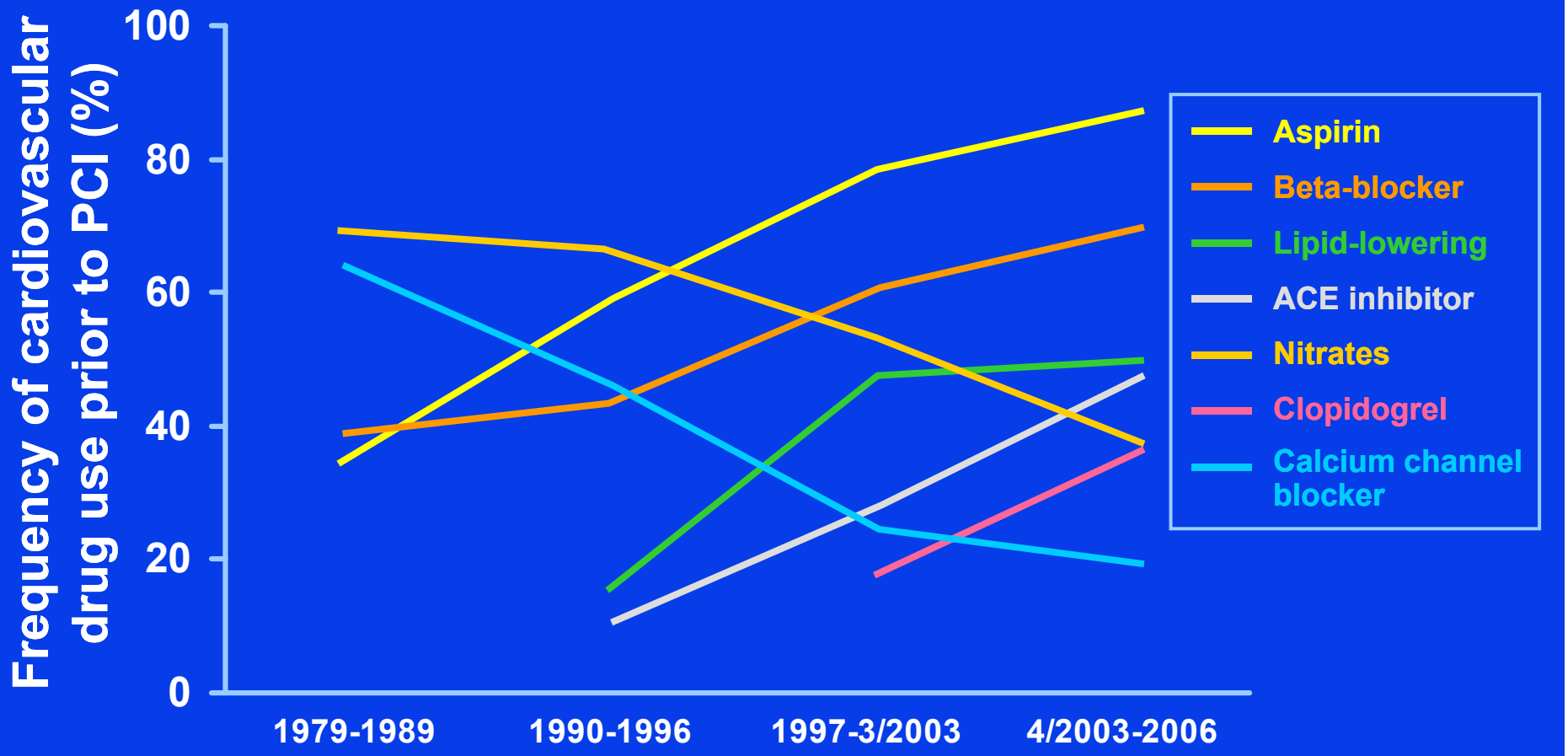
Trends in Medical Therapy



Hilliard et al: JACC:Cardio Vasc Interv, 3:172-9, 2010

MAYO CLINIC

3107483-76

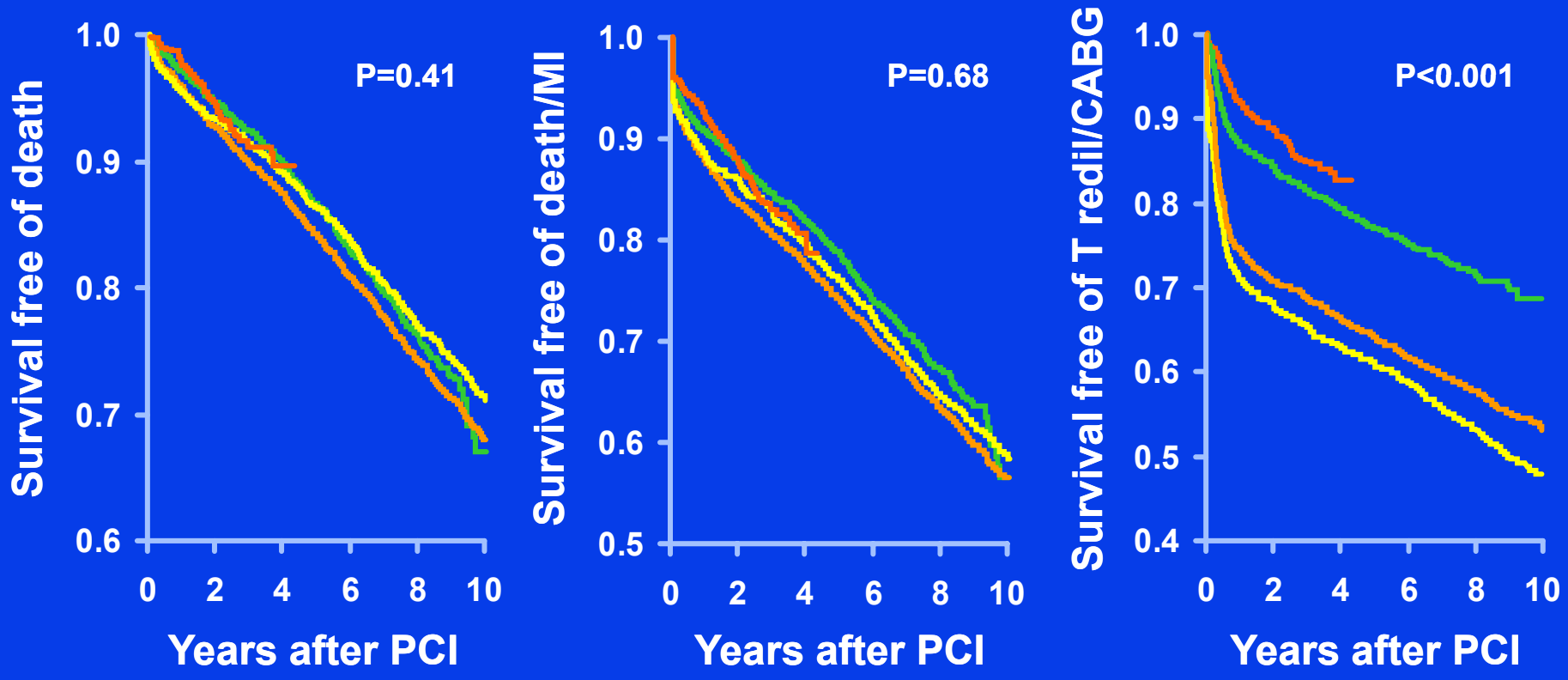
PCI and Stable CAD

- Single center analysis
- 8,912 patients undergoing elective PCI for 1979-2006

Time Periods	% Success	4-Year Death
PTCA	81%	11%
Early stent	92%	13%
BMS	96%	10%
DES	97%	10%

Hilliard et al: JACC:Cardio Vasc Interv, 3:172-9, 2010

Long-Term Mortality & Composite Endpoints



Hilliard et al: JACC:Cardio Vasc Interv, 3:172-9, 2010

MAYO CLINIC

3107483-78

JACC: CARDIOVASCULAR INTERVENTIONS
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CLINICAL RESEARCH

Percutaneous Revascularization for

eras depending on the dominant interventional strategy of that time: percutaneous transluminal coronary angioplasty, early stent, bare-metal stent, and drug-eluting stent.

Results Procedural success rates have improved (81%, 92%, 96%, and 97%, respectively, $p < 0.001$), and in-hospital mortality has decreased significantly (1.0%, 0.8%, 0.1%, and 0.1%, respectively, $p < 0.001$) over time. Kaplan-Meier estimates of mortality at 4 years were 11%, 13%, 10%, and 10%, respectively ($p = 0.4$). The 1-year target lesion revascularization rates in the 4 groups were 29%, 26%, 13%, and 8%, respectively ($p < 0.001$).

Conclusions Procedural success rates in contemporary practice of PCI for stable CAD are excellent with very low in-hospital mortality. Introduction of drug-eluting stents has reduced target lesion revascularization but not mortality among all comers. Outcomes similar to that observed in recent clinical trials are being achieved in routine clinical practice. (J Am Coll Cardiol Intv 2010;3:172–9)

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Sub/drp–Job#: YW105/BK – 3107483

Subject: Perc Revasc for Stable CAD, Hilliard

Background: BU (6-61-232)
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3107483-80