Peripheral Academic Research Consortium (PARC) Meeting

February 3rd, 2012 FDA Headquarters

Quality in the Treatment of PAD

Lesion Definitions…and other things

Thomas T. Tsai, MD, MSc

Director, Interventional Cardiology

Denver VA Medical Center

University of Colorado Denver

Outline

- Case
- Why measure quality for PVI?
- What and how to measure? The CART Model
- Future directions

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Outline

- **Case**
- Why measure quality for PVI?
- What and how to measure? The CART Model
- Future directions

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Peripheral Vascular Case Presentation

54 yo male with a 6 month history of **progressive bilateral lower extremity claudication**. When getting the mail (25 yards), "I have to sit on my bumper and rest before coming back to the house" (**Rutherford 3-4**)

PMHx: IDDM, CAD s/p PCI to LAD and RCA, HTN, Hyperlipidemia

Quit Tobacco 18 months ago

PE and Studies:

--BP 165/90, HR 80

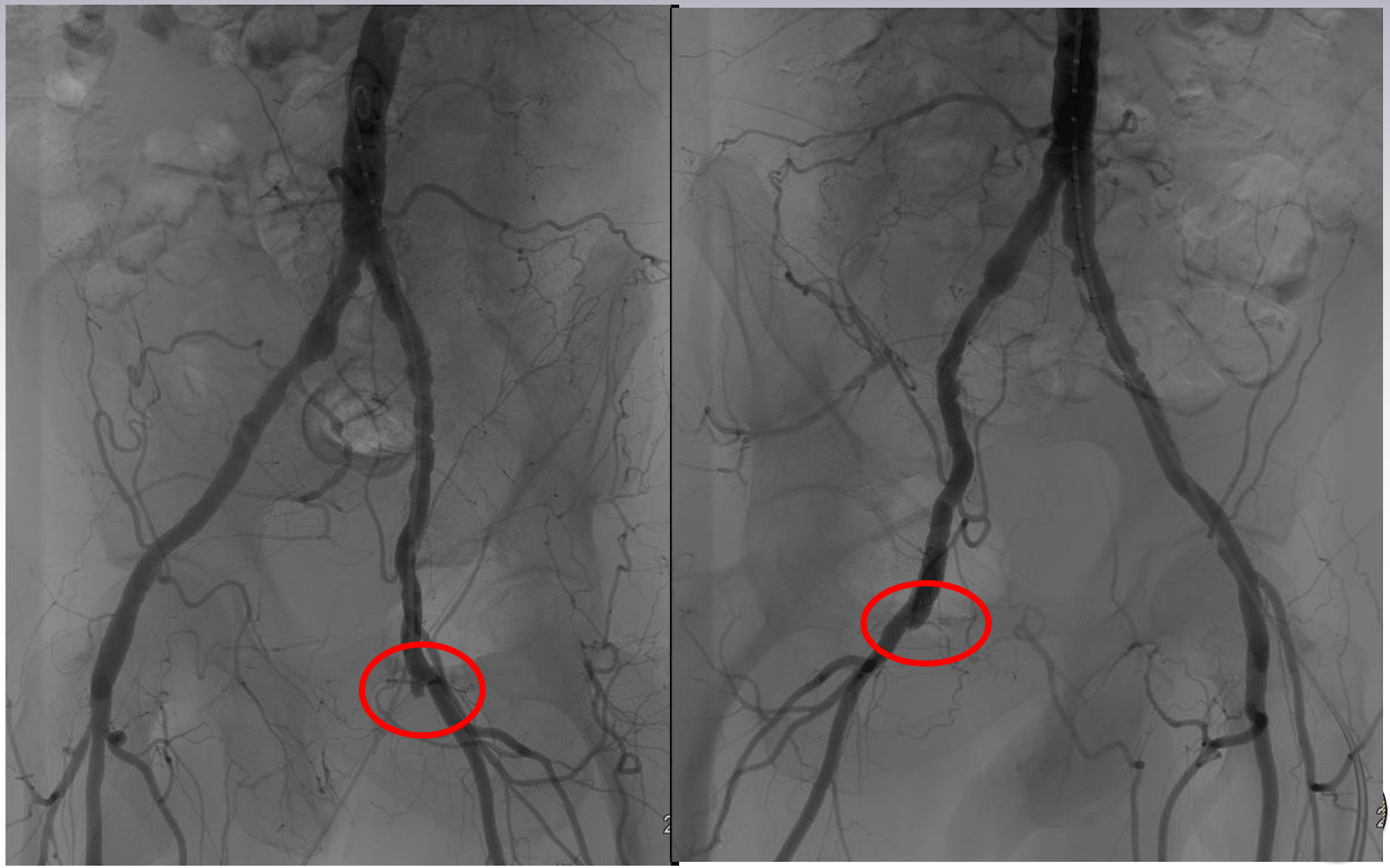
--2+ bilateral CFA, bilateral nonpalpable DP and PT, monophasic

--**Right ABI 0.68 Left ABI 0.71**

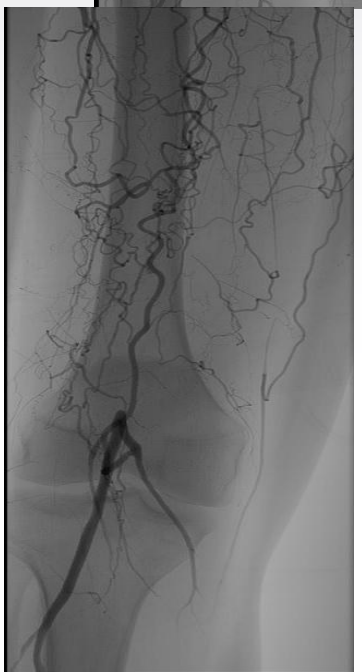
--**CTA bilateral SFA occlusions**

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Case



Case



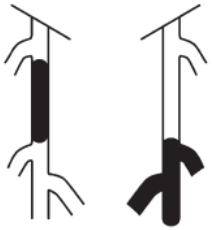
TASC C-D Lesions

Type C lesions

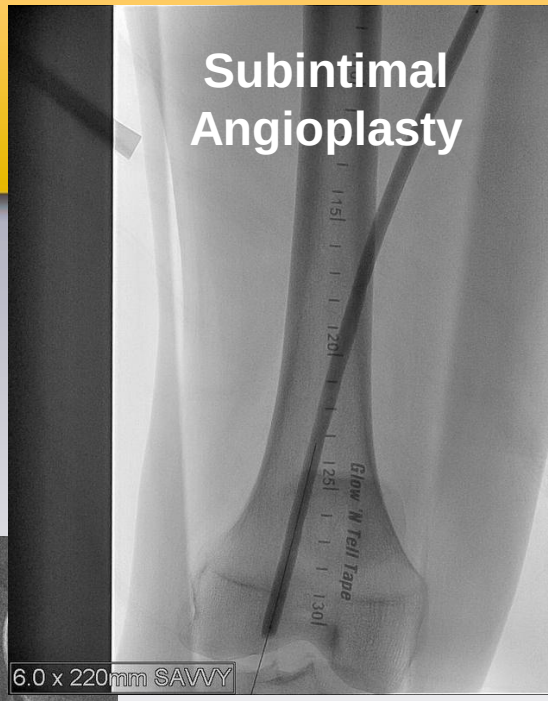
- Multiple stenoses or occlusions totaling >15 cm with or without heavy calcification
- Recurrent stenoses or occlusions that need treatment after two endovascular interventions

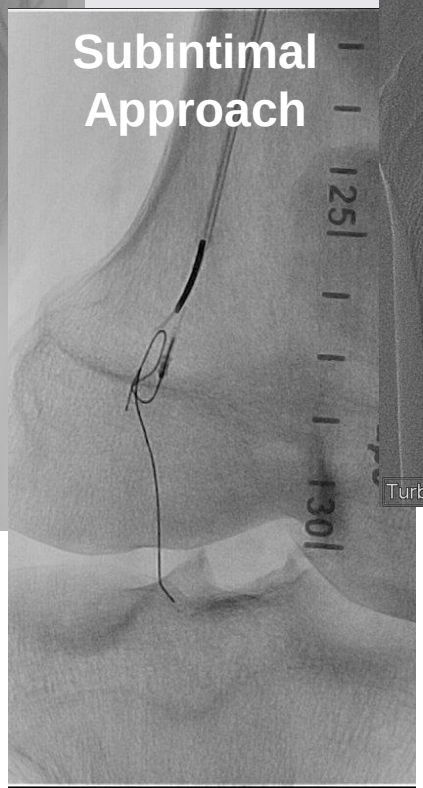
Type D lesions

- Chronic total occlusions of CFA or SFA (>20 cm, involving the popliteal artery)
- Chronic total occlusion of popliteal artery and proximal trifurcation vessels



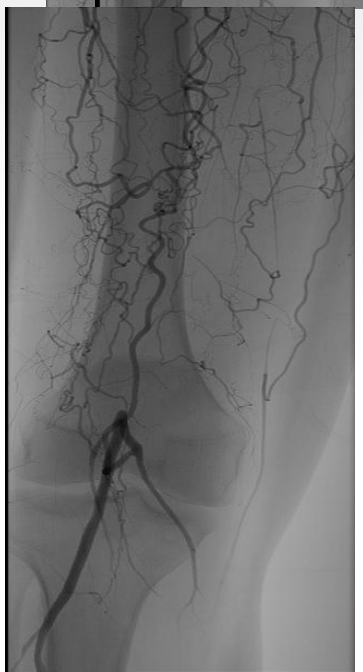
Case





CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Case



How did we do?

- Same day discharge
- Technical features
  - Procedural success
  - Technical success
  - No Complications
- He's feeling great
- BUT WHAT IF…….

Without Measurement, Anecdotes reign Supreme!

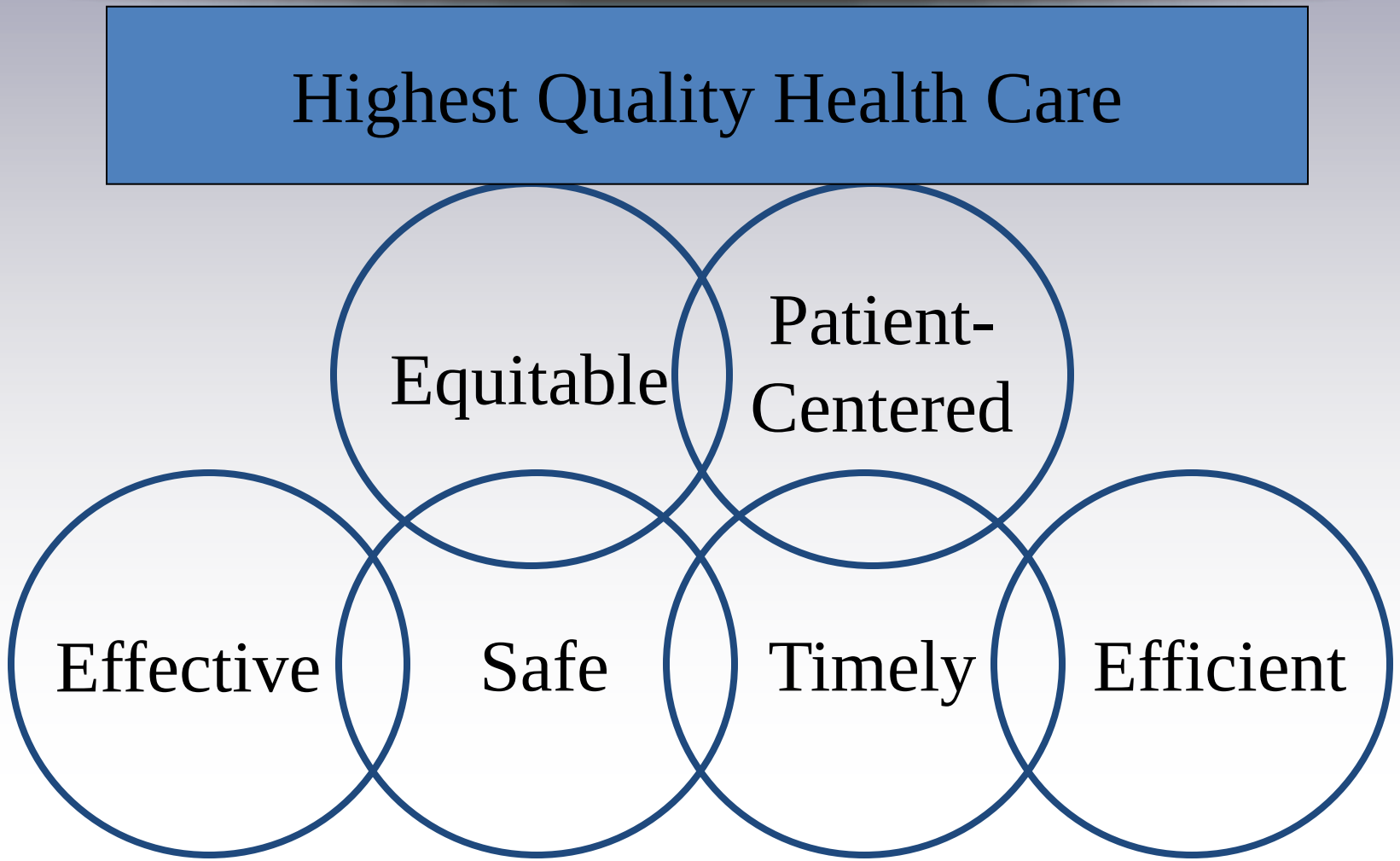
CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Outline

- Case
- **Why measure quality for PVI?**
- What and how to measure?
- Future directions

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

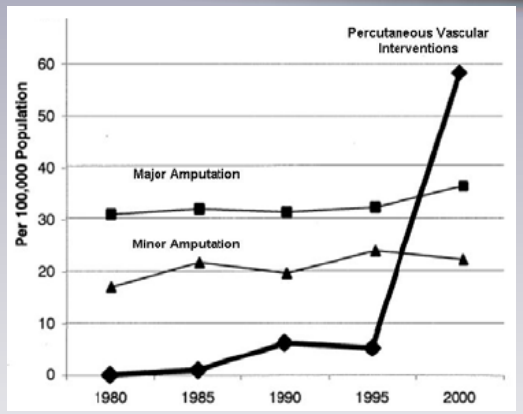
Our Goal for the Treatment of PAD Patients

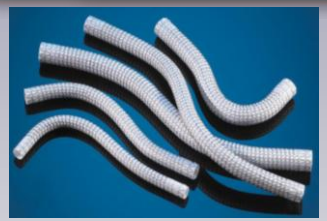


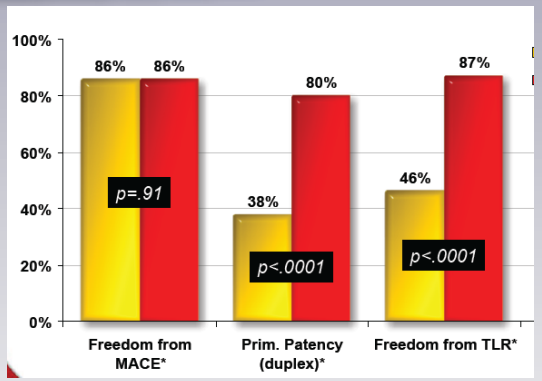
Institute of Medicine. Crossing the Quality Chasm:
A New Healthcare System for the 21st Century
National Academy Press

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

PVI's QUALITY CHASM







Efficient

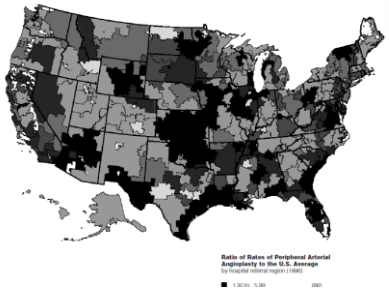
Safe

Patient Centered

Effective

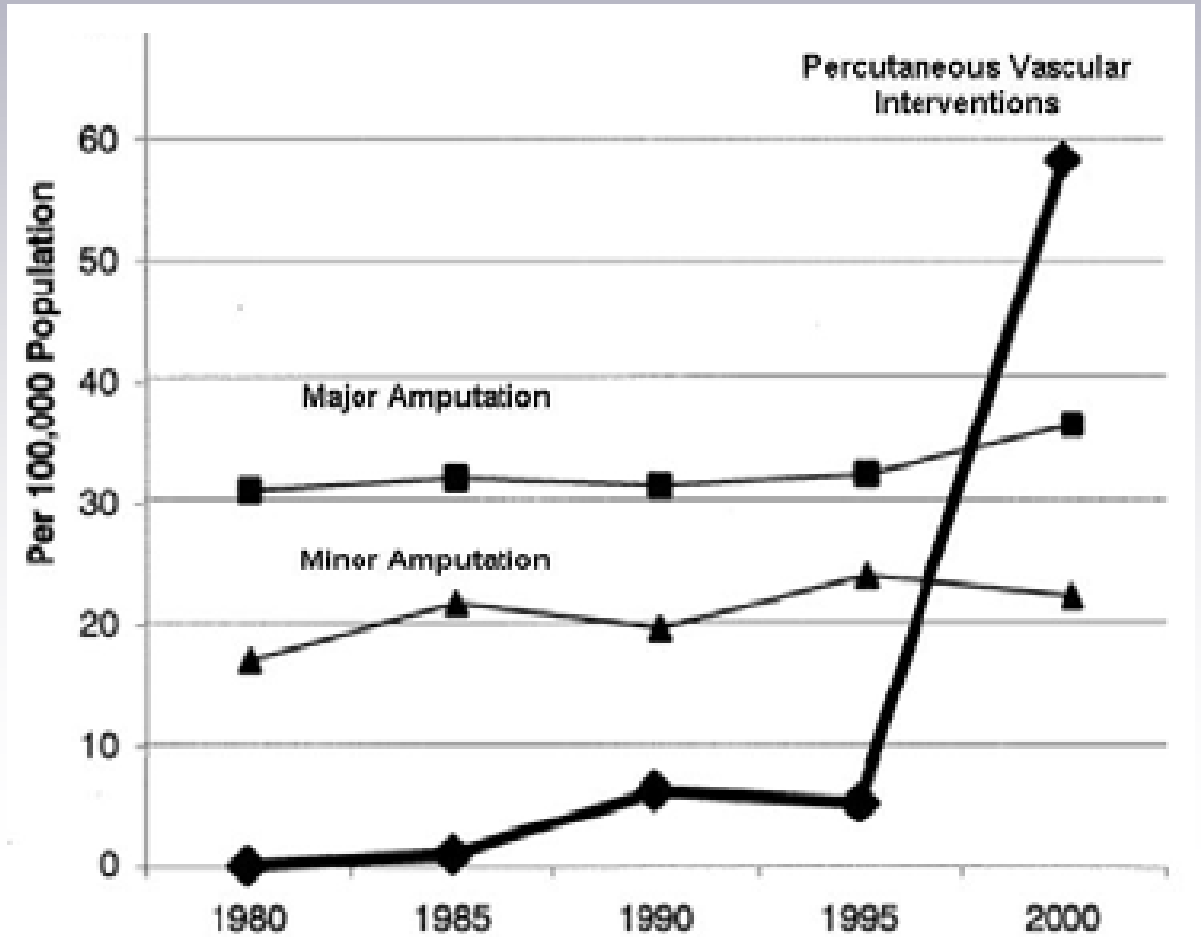
Equitable

Timely



CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

The use of PVI for symptomatic PAD has exploded over the last decade



Anderson PL et al. *J Vasc Surg.* 2004;39(6):1200-1208

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

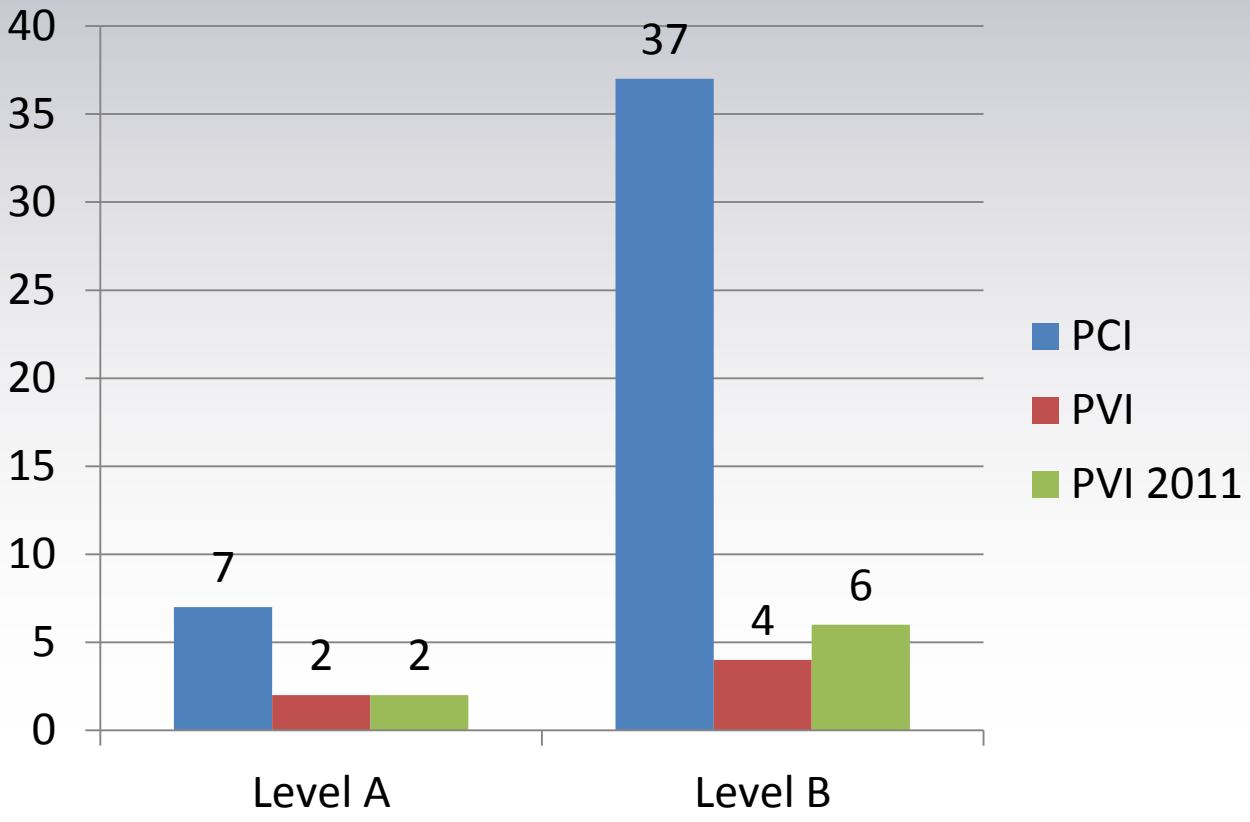
In 2012 there is very little consensus on the recommendations for PVI procedures

Classification of Recommendation

Level of Evidence	Class I	Class IIa	Class IIb	Class III
	"Evidence and/or General Agreement beneficial, useful, effective"	"Conflicting evidence, DOO, In favor of"	"Conflicting evidence, DOO, Less well established"	"Evidence and/or General Agreement Should NOT, Harmful
A: RCTs or Meta-analyses	• Recommendation that procedure or treatment is useful/effective • Sufficient evidence from multiple randomized trials or meta-analyses	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation that procedure or treatment not useful/effective and may be harmful • Sufficient evidence from multiple randomized trials or meta-analyses
B: RCT or non-randomized	• Recommendation that procedure or treatment is useful/effective • Limited evidence from single randomized trial or non-randomized studies	• Recommendation in favor of treatment or procedure being useful/ effective • Some conflicting evidence from single randomized trial or non-randomized studies	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from single randomized trial or non-randomized studies	• Recommendation that procedure or treatment not useful/effective and may be harmful • Limited evidence from single randomized trial or non-randomized studies
C: Expert Opinion, Case Studies, Standard of care	• Recommendation that procedure or treatment is useful/effective • Only expert opinion, case studies, or standard-of-care	• Recommendation in favor of treatment or procedure being useful/ effective • Only diverging expert opinion, case studies, or standard-of-care	• Recommendation's usefulness/efficacy less well established • Only diverging expert opinion, case studies, or standard-of-care	• Recommendation that procedure or treatment not useful/effective and may be harmful • Only expert opinion, case studies, or standard-of-care

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING PROGRAM

PVI have very few Level I or IIa recommendations



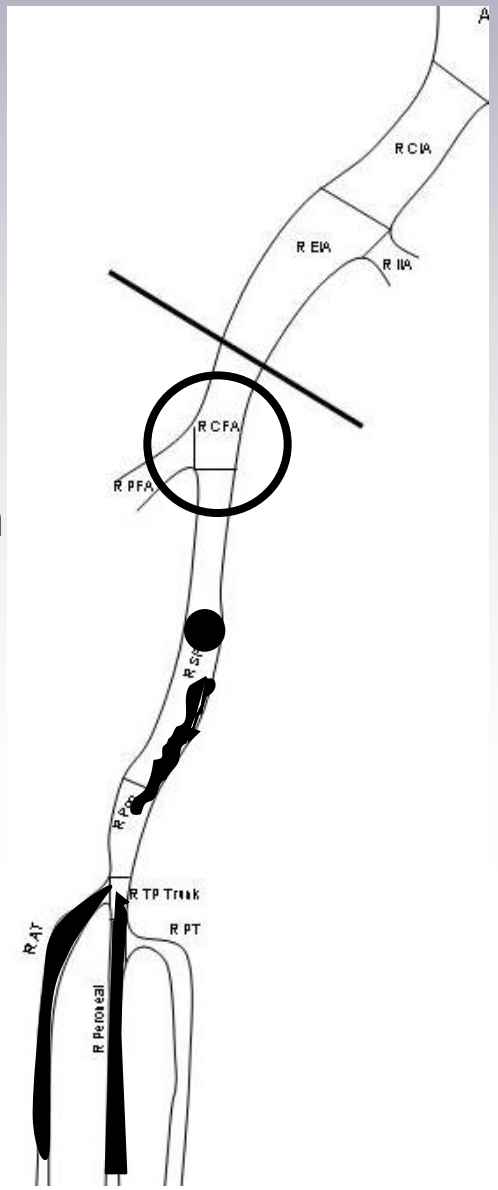
ACC/AHA PCI Guidelines 2005
ACC/AHA PAD Guidelines 2006

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Heterogeneous Anatomic Factors

↓ Procedural Success

1. Location
2. Occlusion vs Stenosis
3. Diffuse vs Focal Disease
4. Lesion and Vessel Calcification
5. Poor inflow or Tibial Run-off



Restenosis rates

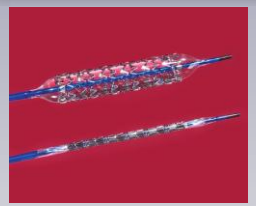
Iliac
10%-20%

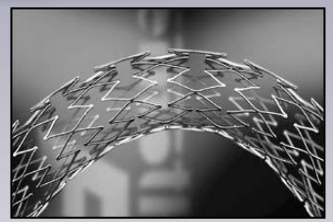
Superficial femoral/ popliteal artery
20%-60%

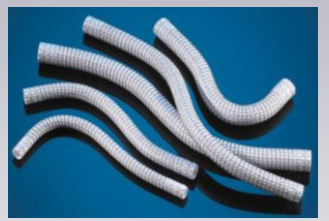
Tibioperoneal
30%-75%

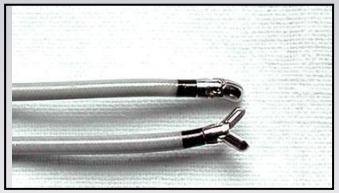
CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

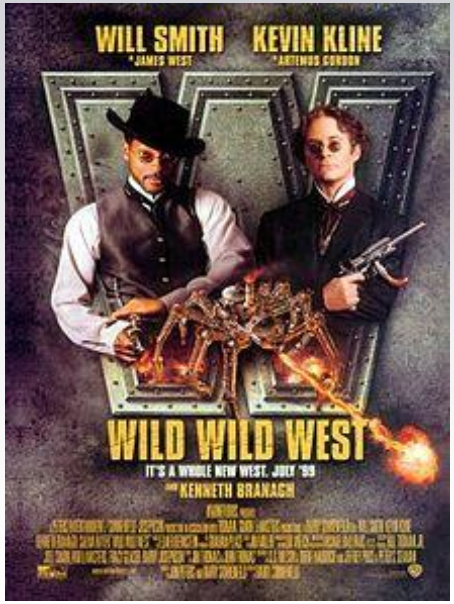
“The Wild Wild West”

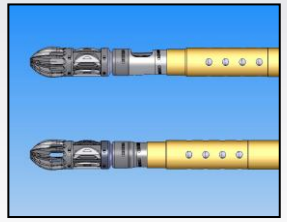


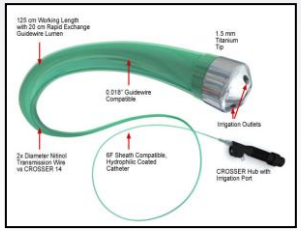


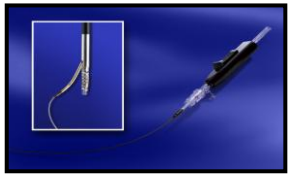


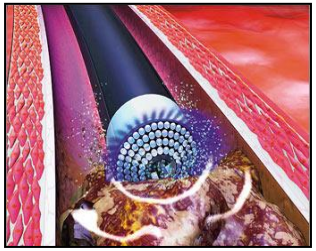






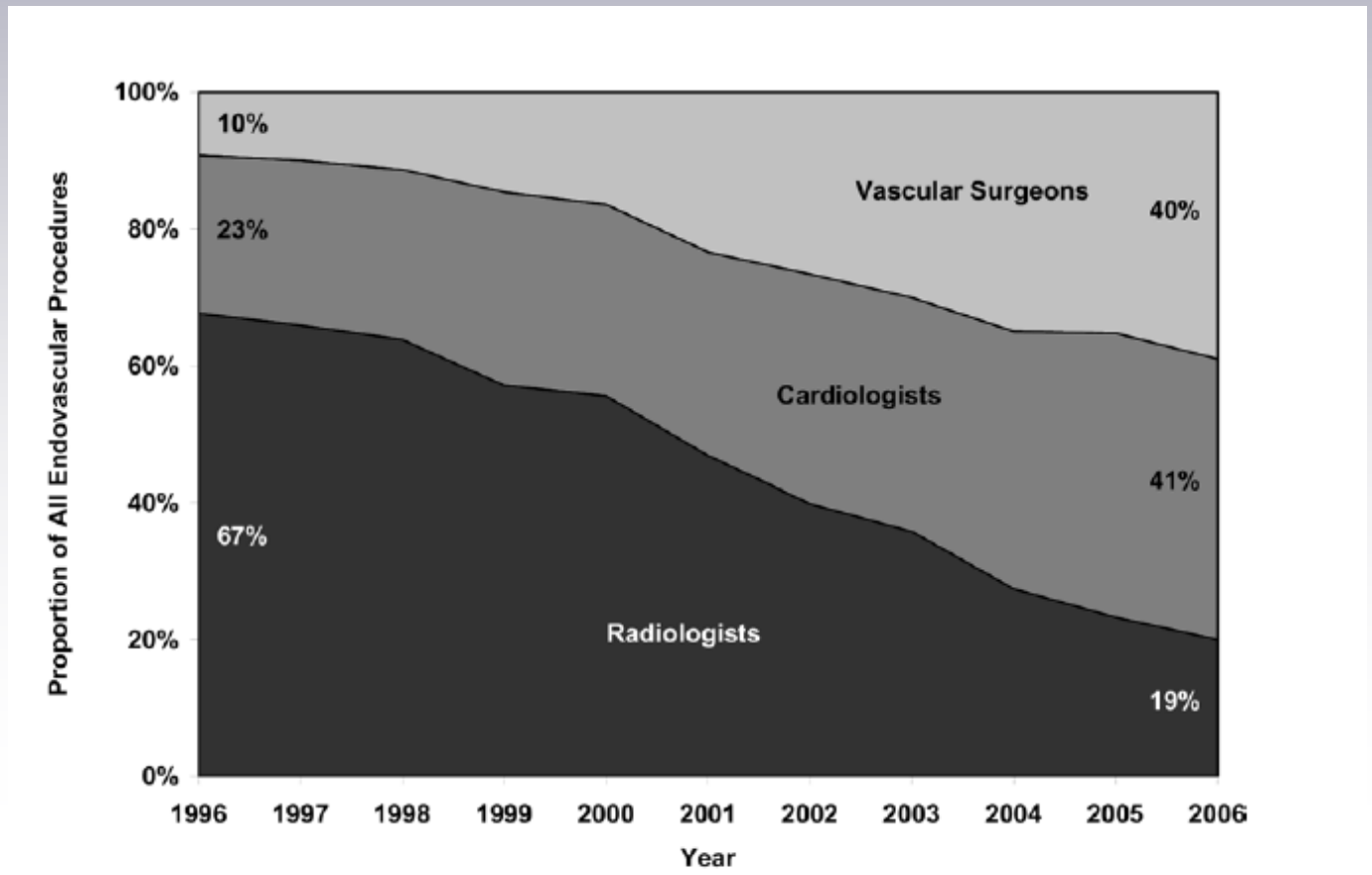






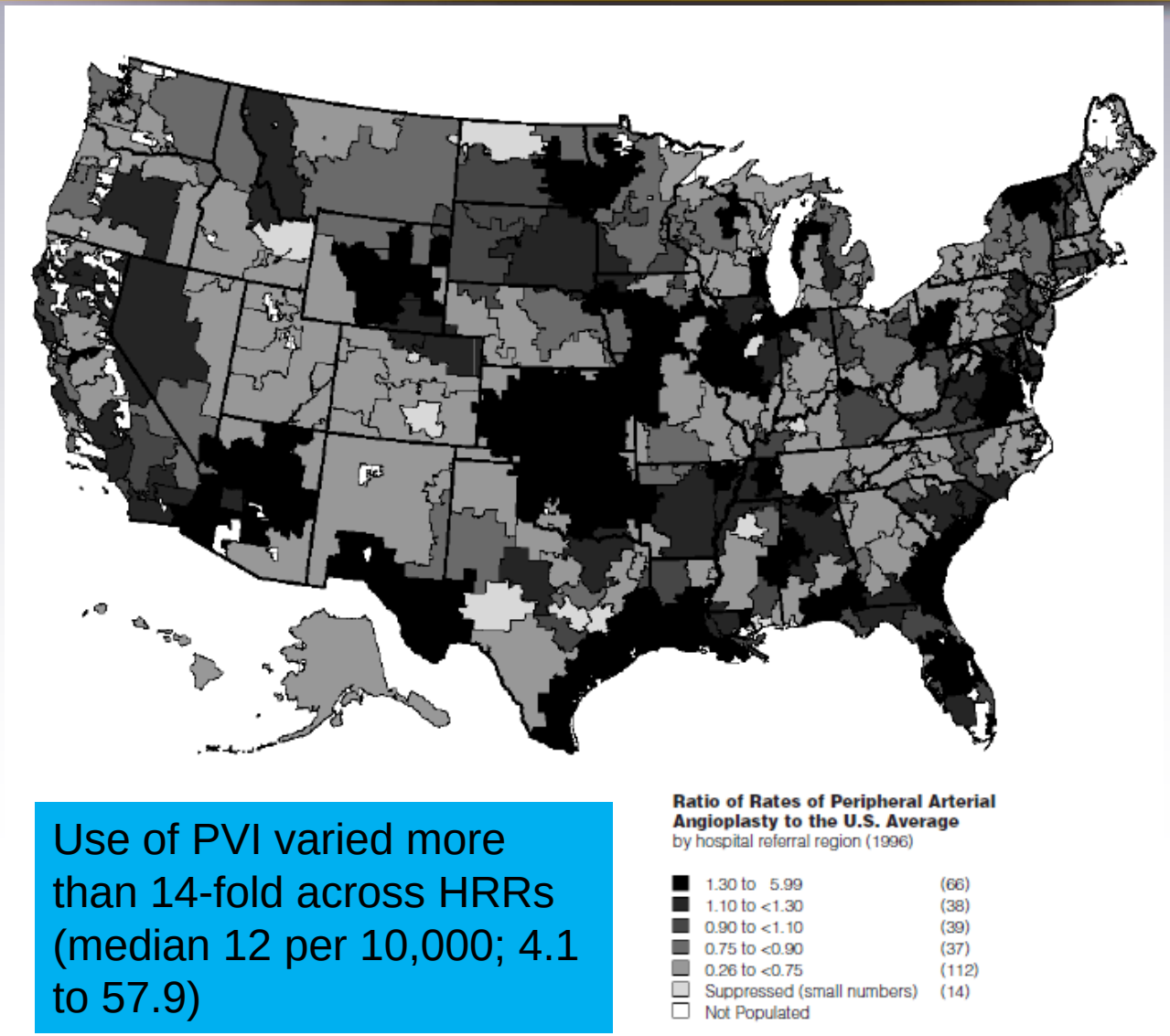
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Too Many Cooks in the Endo Kitchen?



Goodney PP et al, J Vasc Surg 2009;50:54-60.

Recipe for Large Regional Variation



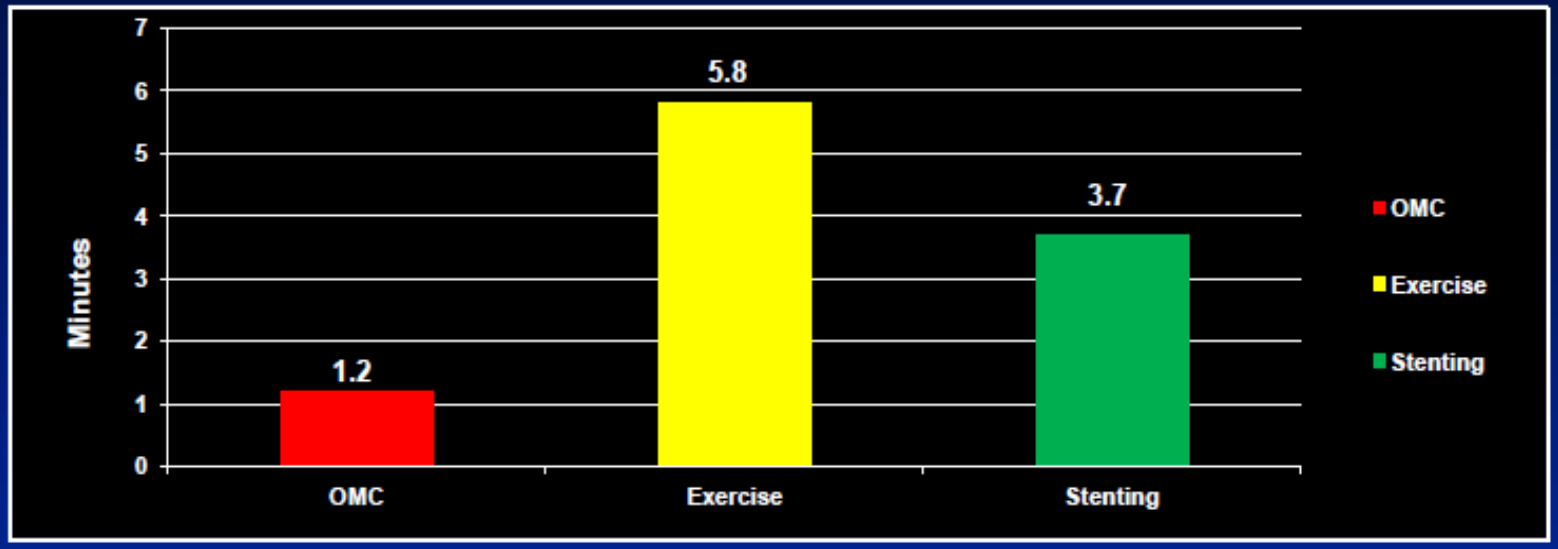
Use of PVI varied more than 14-fold across HRRs (median 12 per 10,000; 4.1 to 57.9)

Axelrod, DA et al. Eff Clin Prac. 2001;4:191-198

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING PROGRAM

CLEVER – Primary Endpoint

Change from Baseline to Six (6) Months

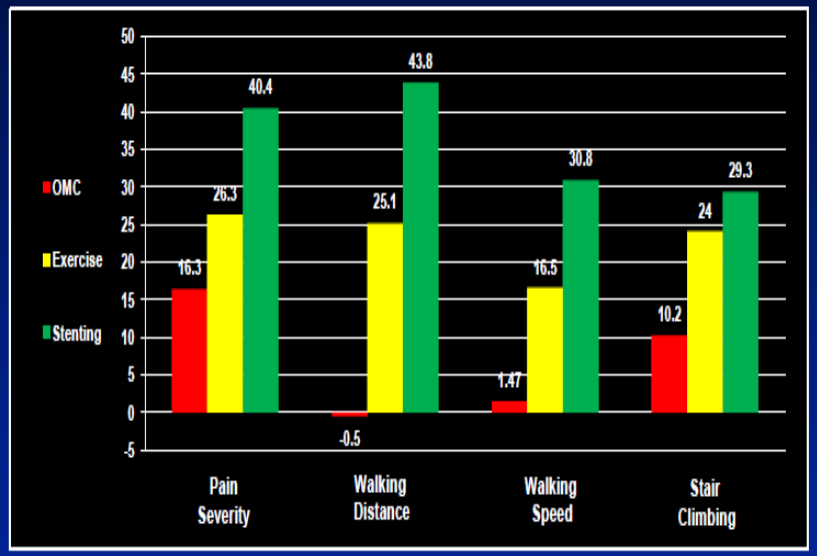


Pair-Wise Comparisons		
	Difference (minutes)	P Value
Exercise vs. OMC	4.6 (95% CI, 2.7-6.5)	<0.001
Stenting vs. OMC	2.5 (95% CI, 0.6-4.4)	0.02
Exercise vs. Stenting	2.1 (95% CI, 0.0-4.2)	0.04

CLEVER – Secondary Endpoints

Walking Impairment Questionnaire

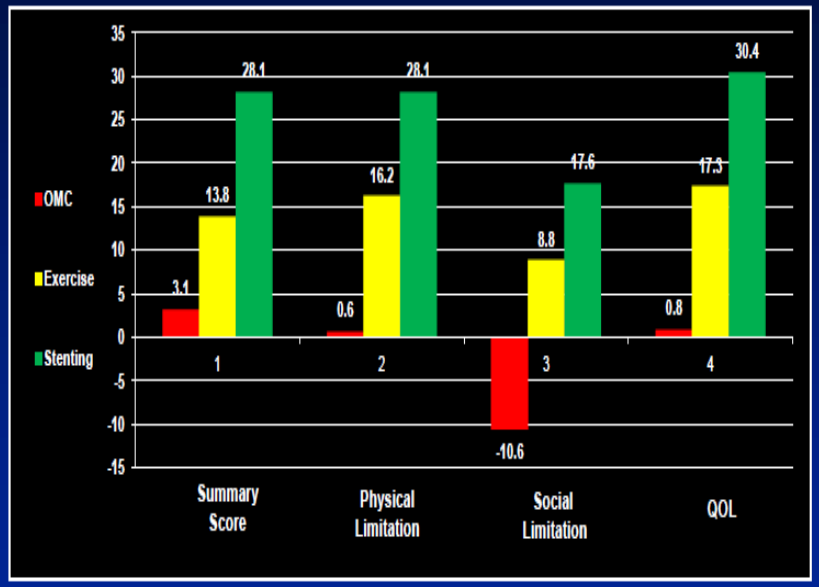
Change from Baseline to Six (6) Months



	P Value	P Value	P Value	P Value
SE vs. OMC	0.25	0.007	0.007	0.07
ST vs. OMC	<0.001	<0.001	<0.001	0.05
ST vs. SE	0.01	0.03	0.007	0.53

Peripheral Artery Questionnaire

Change from Baseline to Six (6) Months



	P Value	P Value	P Value	P Value
SE vs. OMC	0.03	0.02	0.02	0.03
ST vs. OMC	<0.001	<0.001	0.001	<0.001
ST vs. SE	0.04	0.001	0.16	0.005

Outline

- Case
- Why measure quality for PVI?
- **What and how to measure? The CART Model**
- Future directions

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Audit and Feedback—A Key First Step

"If you don't know how you are doing, you can't get better."

-Donald Berwick, M.D.
Institute for Healthcare Improvement

INSTITUTE FOR HEALTHCARE IMPROVEMENT

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING PROGRAM

The Storm Before the Calm

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Comparative Effectiveness Research to the Rescue

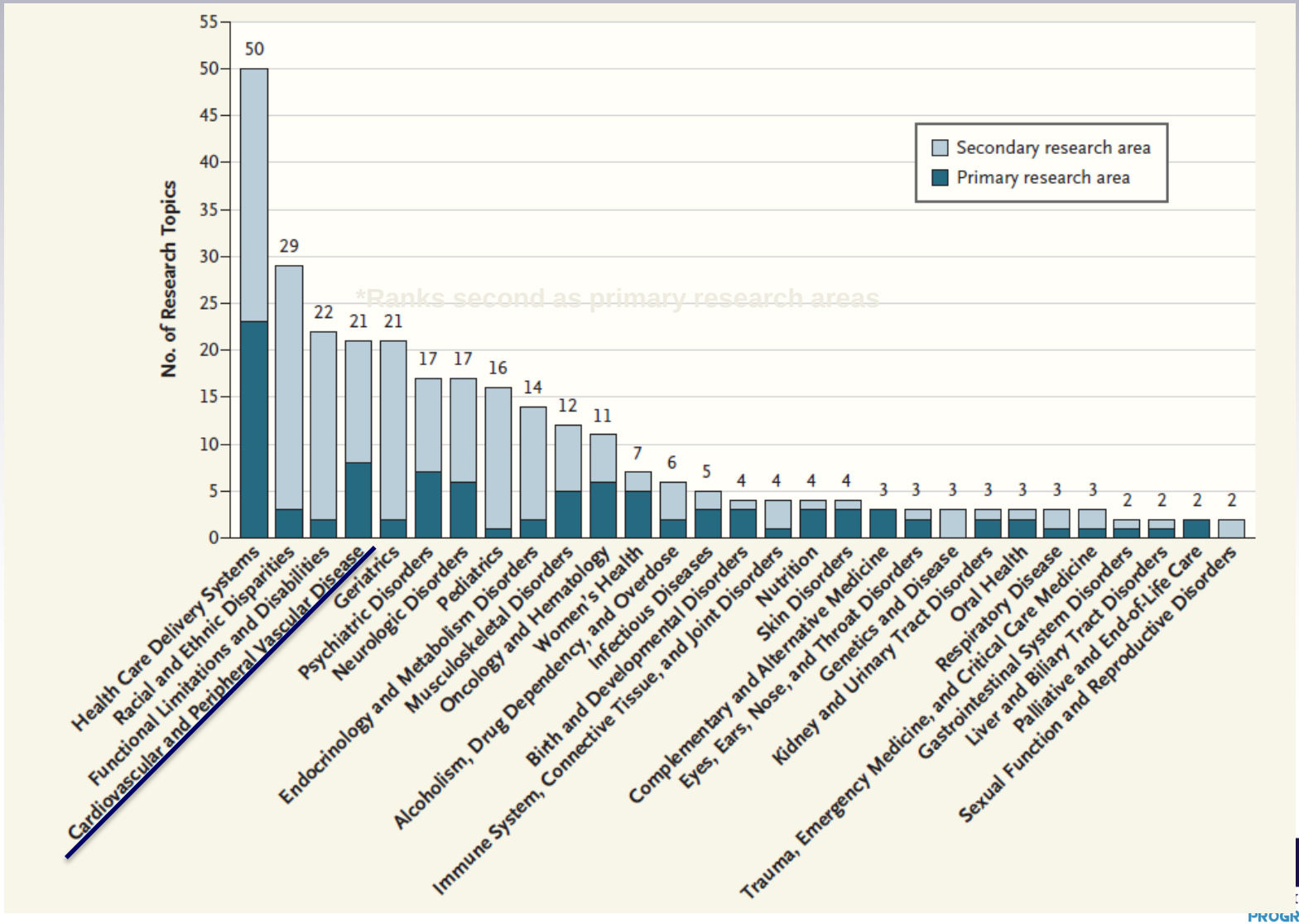
- ....which interventions are most effective for which patients under specific circumstances
- Assist "Stakeholders" in making informed decisions

The American Recovery and Reinvestment Act of 2009 included $1.1 billion for comparative effectiveness research

The Institute of Medicine released the top 100 topics

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Cardiovascular and Peripheral Vascular Disease ranks SECOND



Show Me THE DATA!

Defining the "Key Data Elements" that best characterize PAD patients and their treatments

Multi-institutional, multi-disciplinary, multi-society committee of physicians

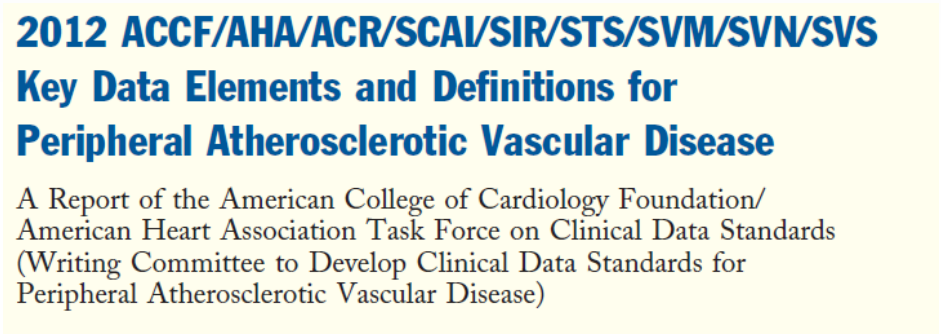
CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

PAD Advisory Committee to the VA (PAC-VA)

Physician	Hospital	Specialty
Ivan Casserly, MD	U Colorado Hospital	Interventional Cardiology
Chandan Devireddy, MD	Emory University	Interventional Cardiology
Susan Fitzgerald	ACC	Admin
Thomas Gross, MD	FDA	Admin
P. Michael Grossman, MD	University of Michigan	Interventional Cardiology
Michael Jaff, DO	Massachusetts General Hospital	Vascular Medicine
Arie Mahrer, MD	Stratton VA Medical Center	Interventional Radiology
Peter Nelson, MD	University of Florida	Vascular Surgery
John Rumsfeld, MD, PhD	Denver VA/U of Colorado	General Cardiology
Kenneth Rosenfield, MD	Massachusetts General Hospital	Interventional Cardiology
Thomas T. Tsai, MD, MSc	Denver VA/U of Colorado	Interventional Cardiology
Christopher White, MD	Ochsner Clinic Foundation	Interventional Cardiology

Which Variables? Lesion Information

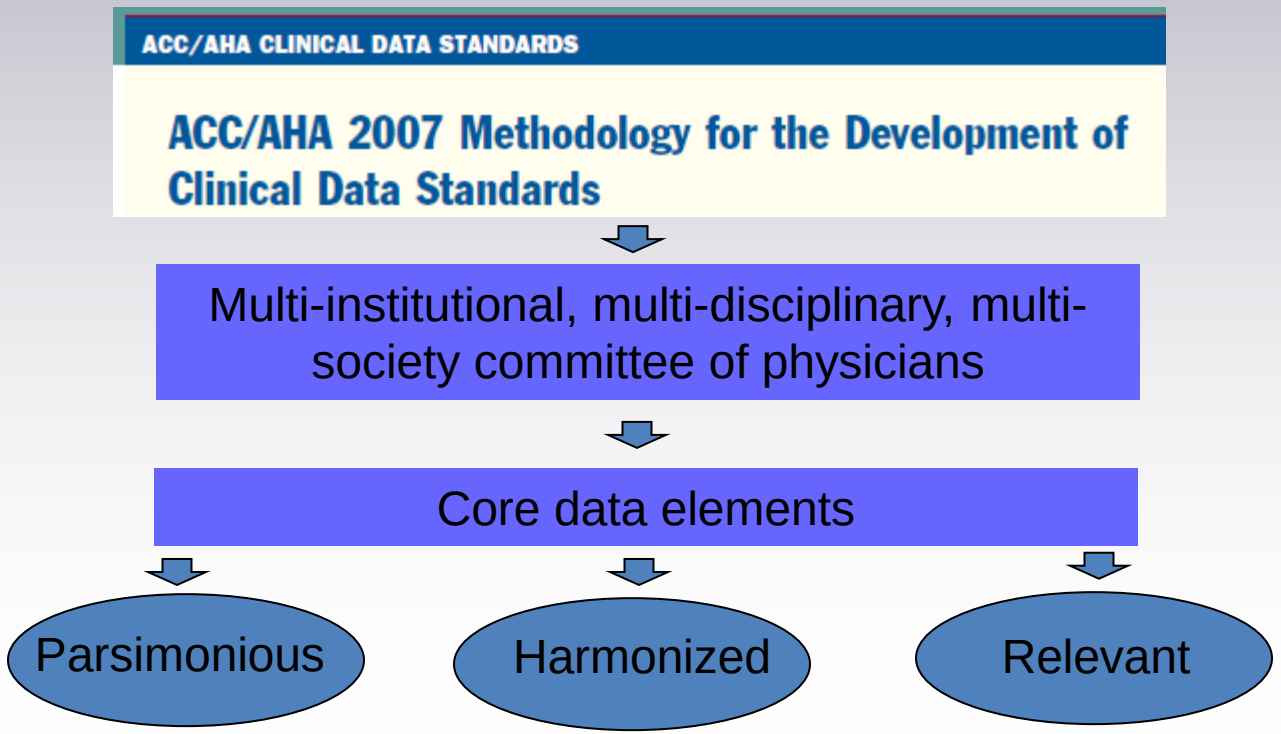
- Transactional? Report generation?
- Goal based….metrics, performance measures
- Research: Support CER
- Support Device Surveillance?
- Harmonized: NCDR, SVS, ACC, RCT's, FDA, informed by all stakeholders



CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Show Me Some DATA!

Defining the "Key Data Elements" that best characterize PAD patients and their treatments



Patient Factors	Indications, sidedness, severity of presentation, ankle brachial index
Procedural Factors	Access site, catheter size, antegrade vs. retrograde, vessel location, segment, highest stenosis, length, diameter, restenosis, in-stent restenosis, post stenosis, bifurcation, previously treated, recanalization, device diameter, device length, device success, adjunct tools, procedural success
Complications	Dissection, embolus, thrombosis, abrupt closure, vessel perforation requiring treatment, vascular complication, emergent vascular surgery

Clinical Registries as Engines for Quality Improvement

In-hospital Registry → Cross sectional studies Quality Management

In-hospital Registry + Claims Data → Longitudinal studies

In-hospital Registry + Clinical/Device Information + Longitudinal Outcomes → Comparative Effectiveness

Peterson, ED Maximizing Comparative Effectiveness

CART CLINICAL ASSESSMENT, REPORTING, and TRACKING PROGRAM

Augment the Registry with Key Variables

In-hospital Registry

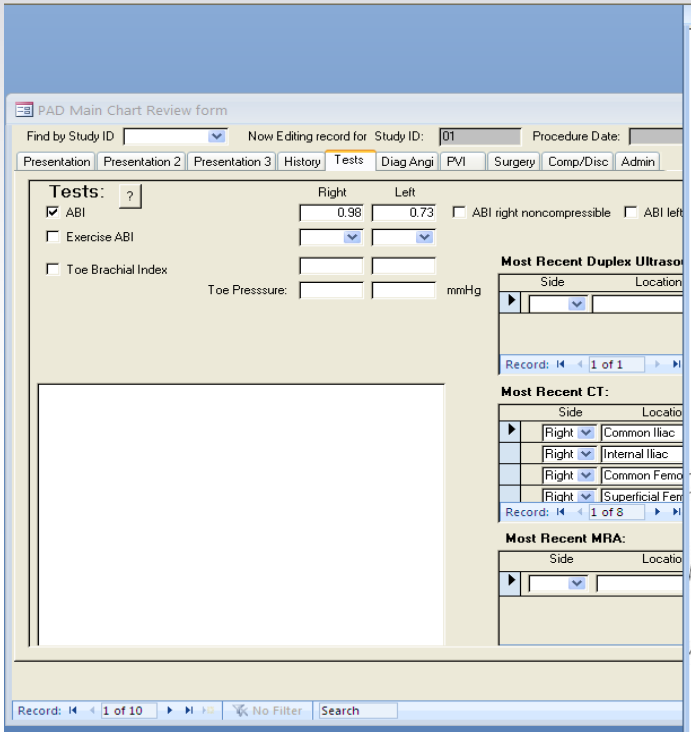
Clinical/Device Information

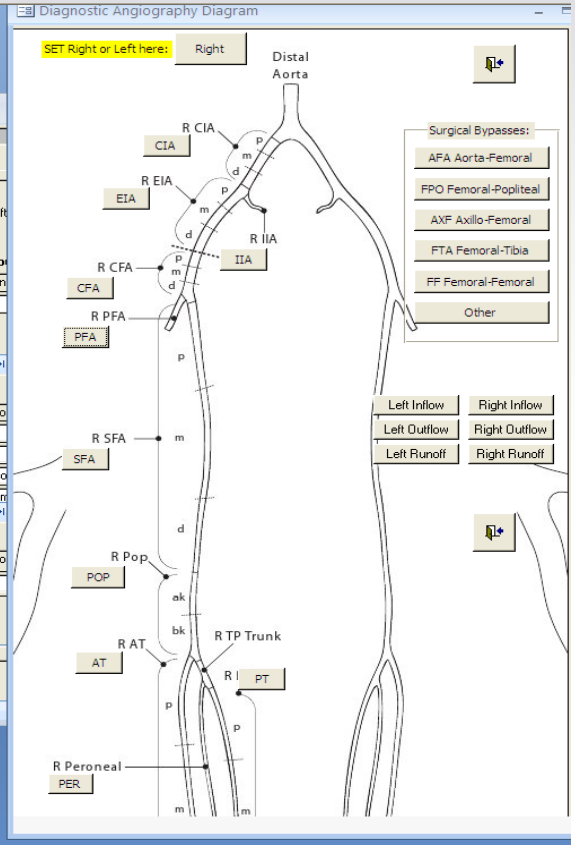
Longitudinal Outcomes

→

Comparative Effectiveness
Quality Improvement

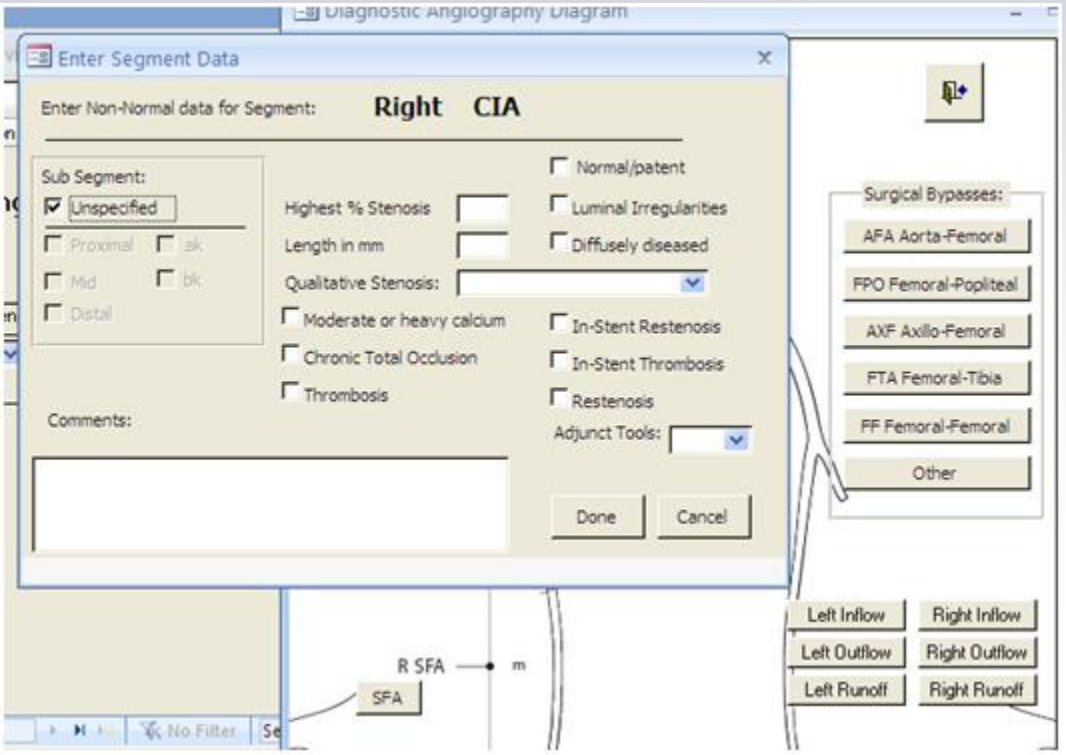
Clinical/Device Information

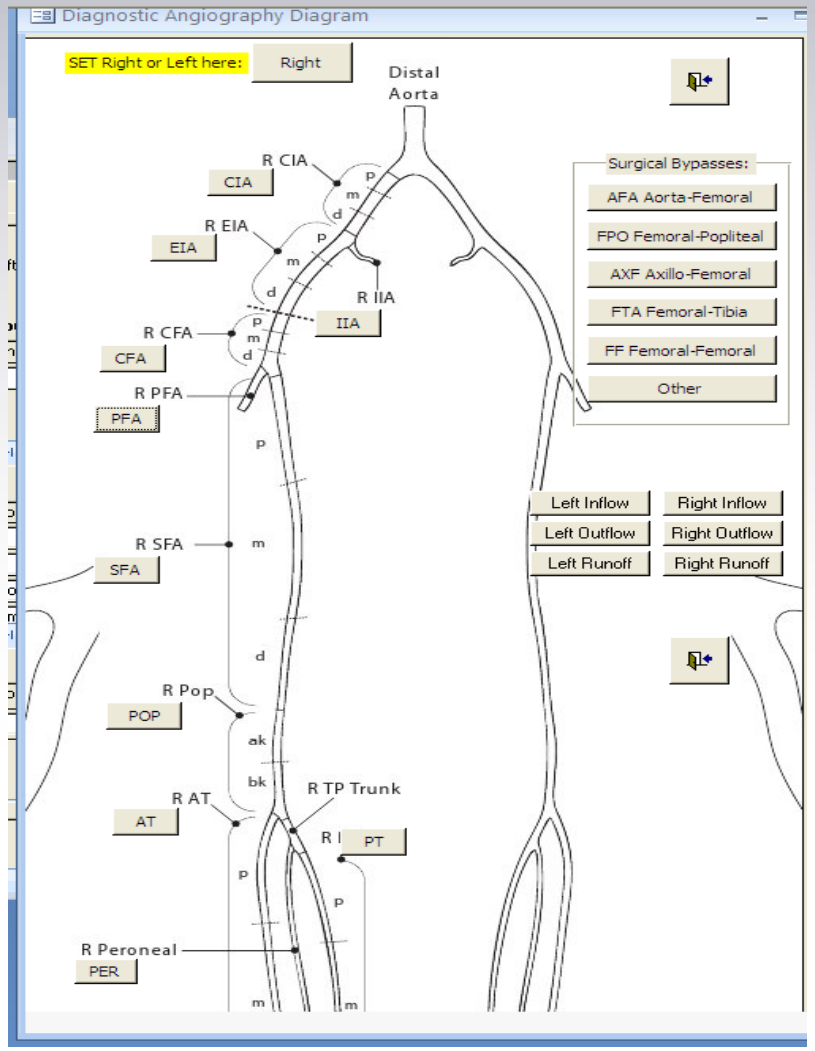




So what lesion elements will be in a transaction clinical application ?

CART PERIPHERAL
VA CLINICAL ASSESSMENT, REPORTING, and TRACKING PROGRAM



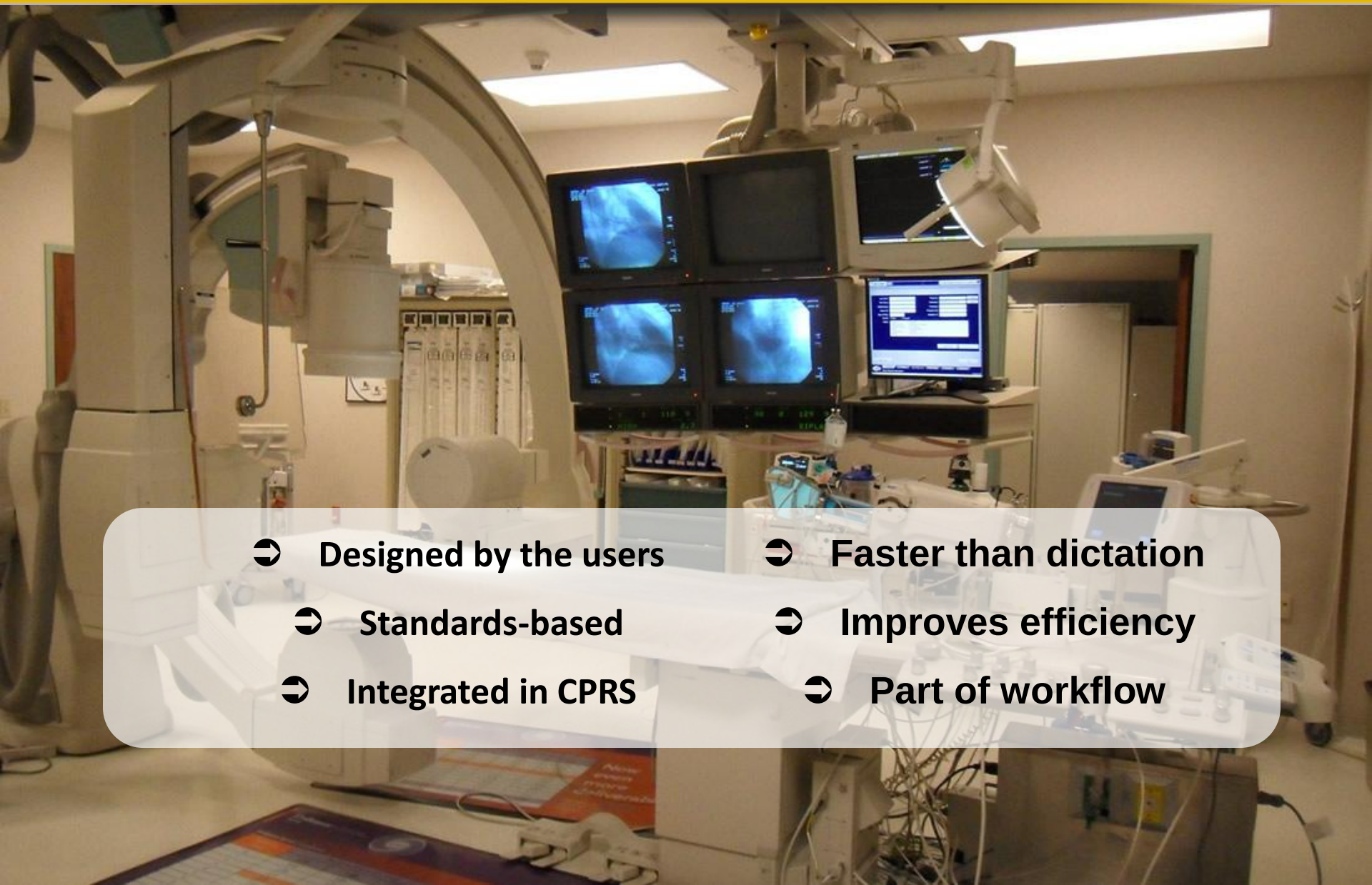


Data Elements and Definitions

B	C	M	N
element name	Definition	Keep?	Selections
Characteristics: Normal	**Indicate if the vessel is normal without stenosis or vessel abnormalities**	**yes**	**yes/no**
Heavy Calcium	Indicate if moderate or heavy calcium is present in the vessel segment	maybe	yes/no
Chronic Total Occlusion	**Indicate if the segment with 100% pre-procedural stenosis was presumed to be 100% occluded for at least 3 months previous to this procedure and not related to a clinical event prompting (or leading) this procedure (CathPCI 4.0).**	**yes**	**yes/no**
Thrombus	Indicate if thrombus is present as assessed by baseline angiography and suggested by certain angiographic features: haziness, reduced contrast density or contrast persistence, irregular lesion contours, or globular filling defects (CathPCI4.0)	maybe	yes/no
Eccentric	Indicate if an eccentric plaque is present defined as a stenosis noted to have one of its luminal edges in the outer one quarter of the apparently normal lumen	no	yes/no
Luminal Irregularities	Indicate if luminal irregularities are present defined as irregularities in the vessel lumen <30% in stenosis in the vessel	no	yes/no
Diffusely diseased	Indicate if the vessel segment is diffusely diseased defined as > half of the segment length and >30% stenosis	no	yes/no
In-Stent Restenosis	Indicate if the lesion is within a previously placed stent. In-stent restenosis is defined as a previously stented lesion that has 50% or greater stenosis	no	yes/no
In-Stent Thrombosis	Indicate if the previously stented lesion shows the presence of thrombus in the stent	no	yes/no
Restenosis	Indicate if restenosis is within a previously angioplastied site. Balloon angioplasty restenosis is defined as a previously angioplastied lesion that has 50% or greater stenosis	no	yes/no
Adjunct Tools	Indicate which adjunctive tools are used		
	Translesional gradient	maybe	
	Intravascular Ultrasound (IVUS)	maybe	
Translesional Gradient	Indicate if a translesional was performed to consider lesion significance	maybe	yes/no
	Indicate the translesional gradient	maybe	
Intravascular Ultrasound	Indicate if intravascular ultrasound was performed to confirm stenosis or lesion	maybe	yes/no

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

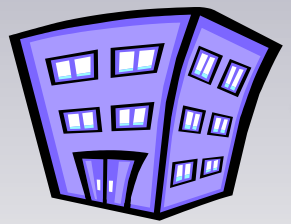
The Clinical Model



- Designed by the users
- Standards-based
- Integrated in CPRS
- Faster than dictation
- Improves efficiency
- Part of workflow

The Conventional Approach

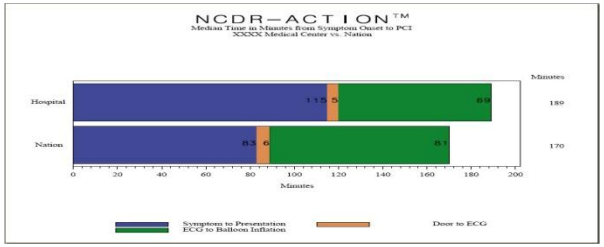
Home



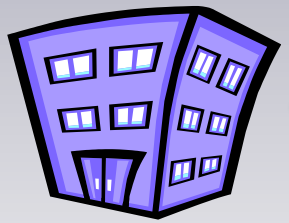
"Errors in Translation"

"Medical Record"

NCDR™
National Cardiovascular Data Registry



The Transactional Approach



"Abstractors"

Assessment

"Errors in translation"

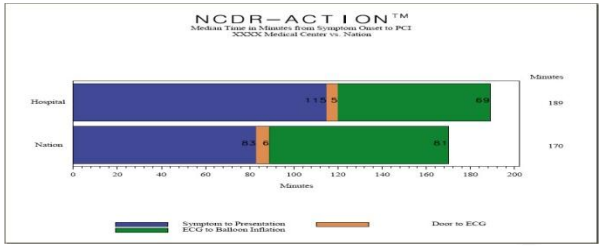
Quality and Management

"Medical Record"

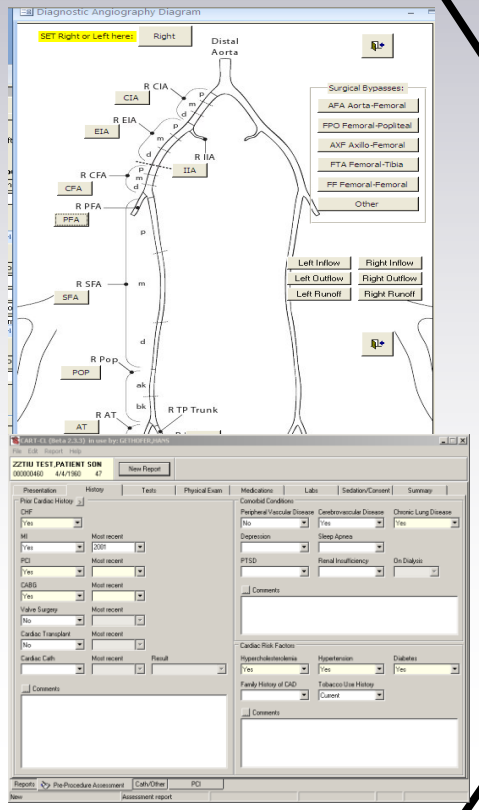
PVI Report

CER

SQL



Elements Should Serve A Purpose (Reporting?)



CART-Peripheral Database

VA Processes of Care
(e.g. medications, risk factor management, visits)

VA Outcomes of Care
(e.g. safety, mortality, amputation, TVR, PAQ)

External Care and Outcomes
(e.g. CMS, NCDR)

Device Surveillance
(UED's, FDA)

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

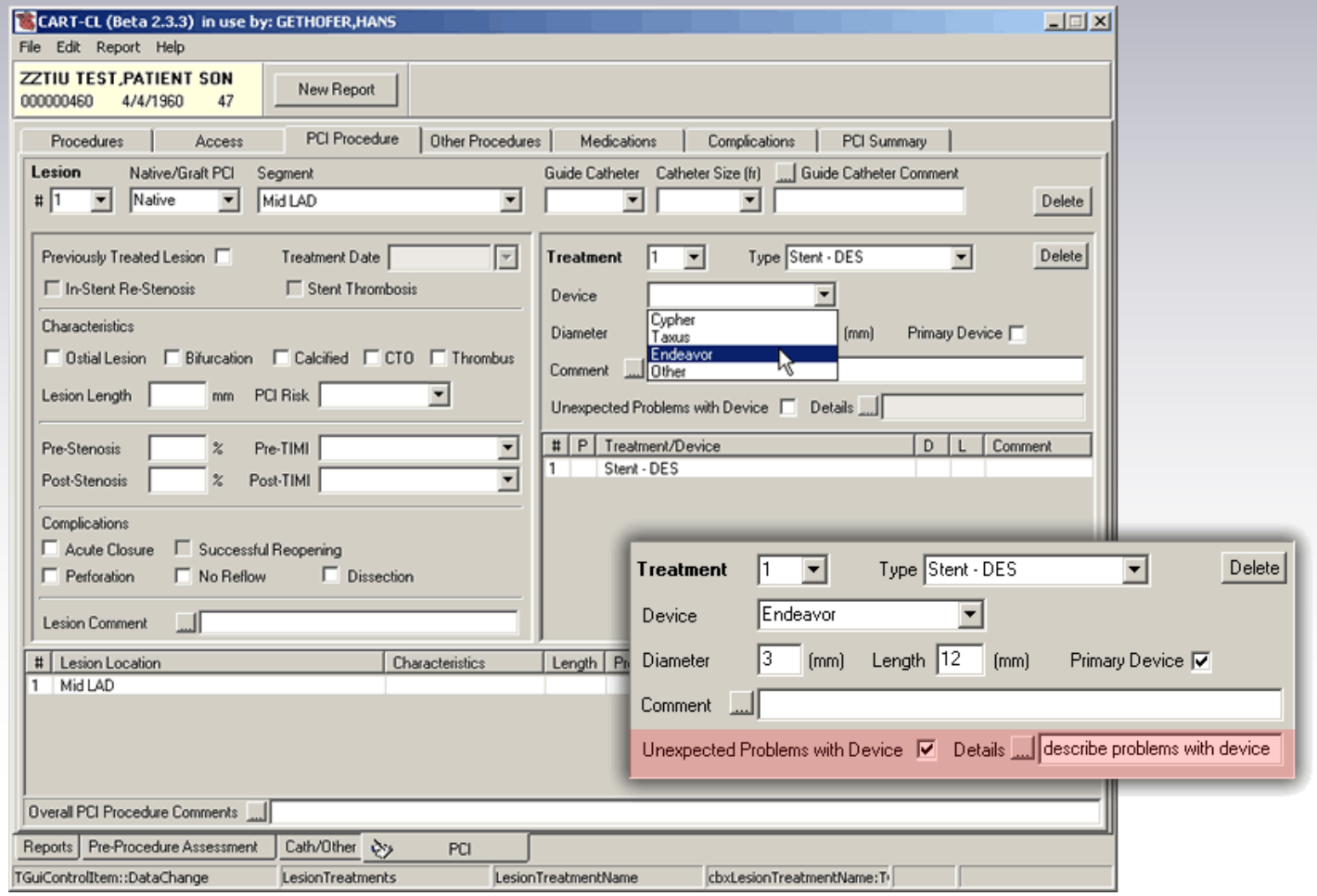
The Problems of Postmarket Surveillance

2007: 1 UED Reported from VA to FDA

???

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

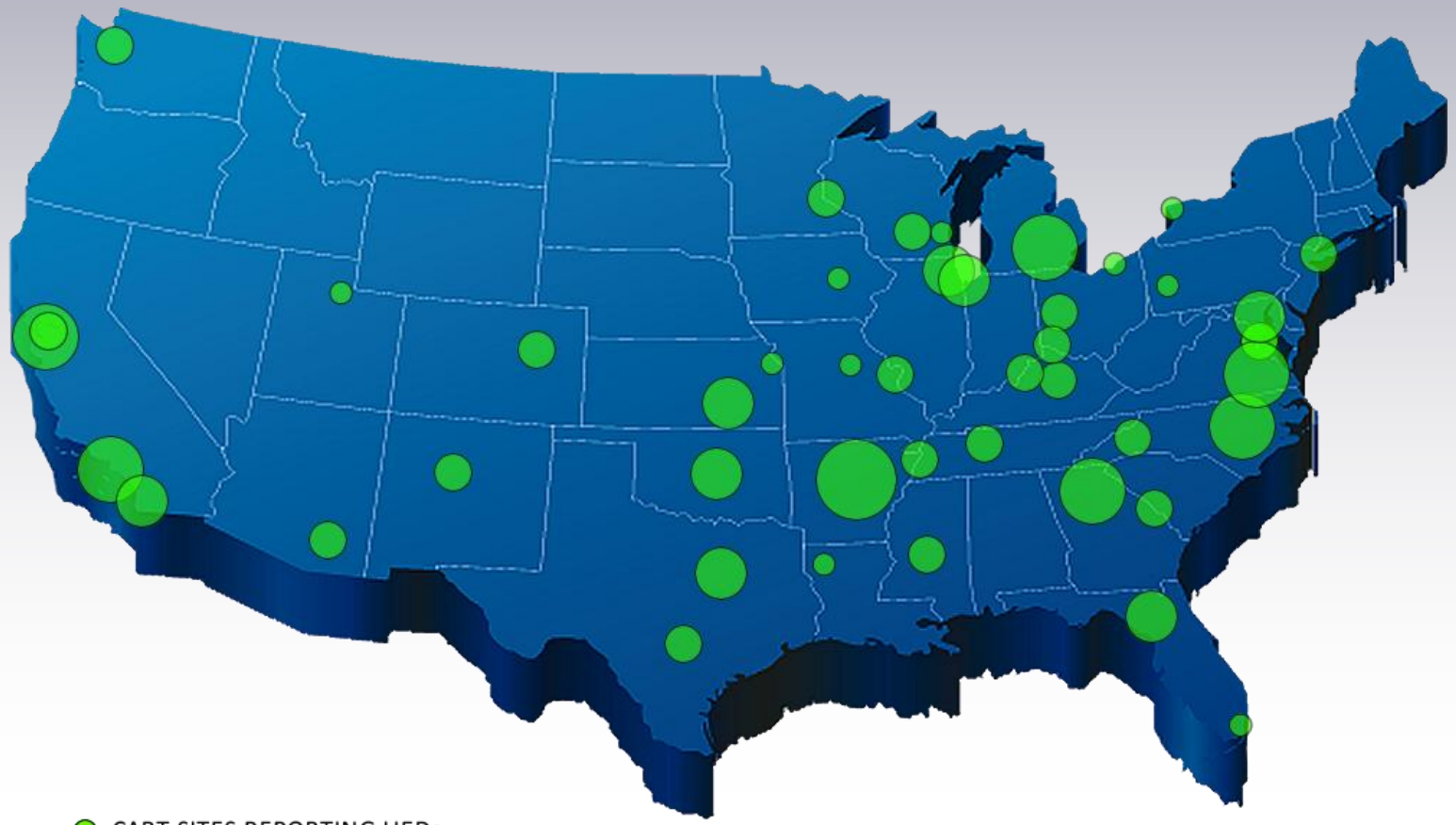
CART-CL Unexpected Complications



CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

CART SITES REPORTING UEDs

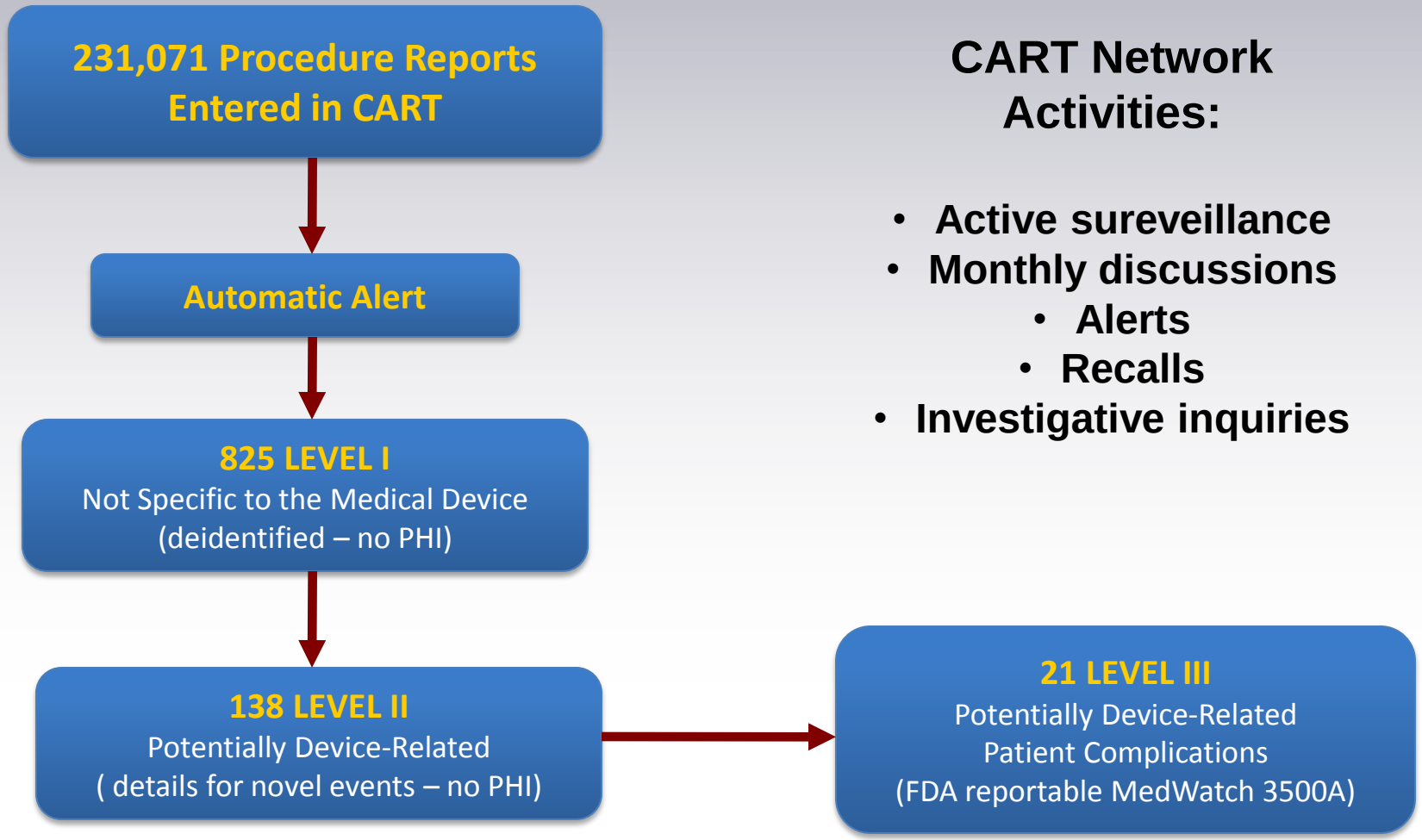
08/15/2006 – 05/31/2009



CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

CART-FDA Surveillance

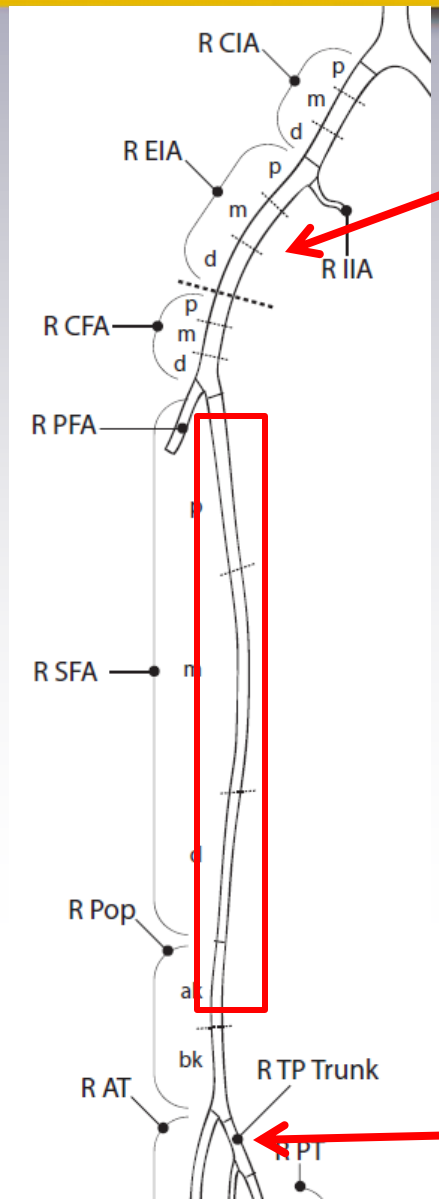
August 2006 – May 2011 (numbers approximate)



CART Network Activities:

- Active sureveillance
- Monthly discussions
- Alerts
- Recalls
- Investigative inquiries

The Matchup: Endo vs. Endo



No Significant Inflow Disease

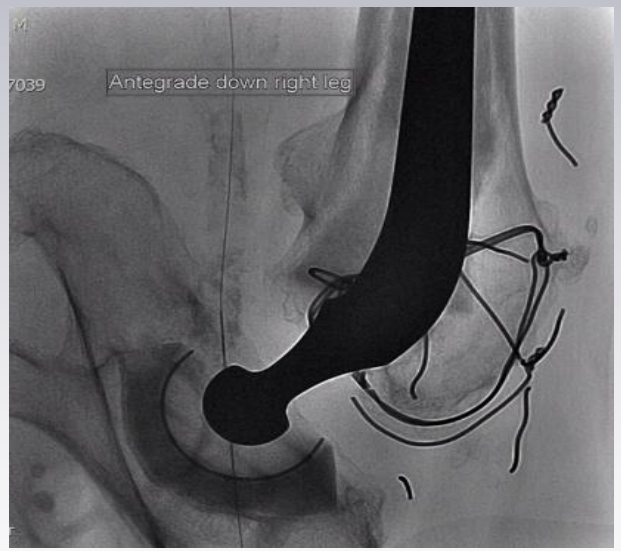
General Inclusion Criteria

- Rutherford 1-5 disease
- De novo or occlusive
- Restenotic lesions in SFA/Pop
- 1-3 cm above intercondylar notch
- Length considerations

At least 1 vessel runoff

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING PROGRAM

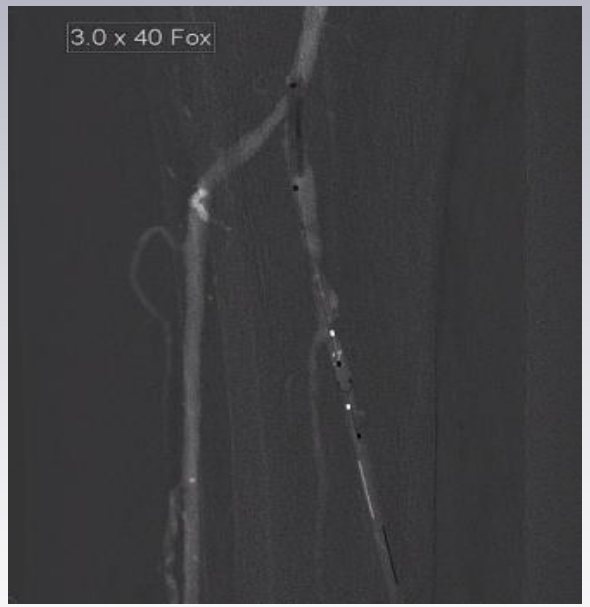
Which Variables? Lesion Information



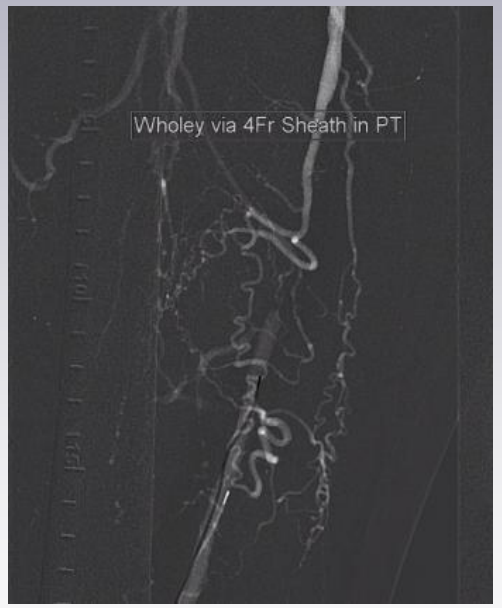
Does Calcium Matter?

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

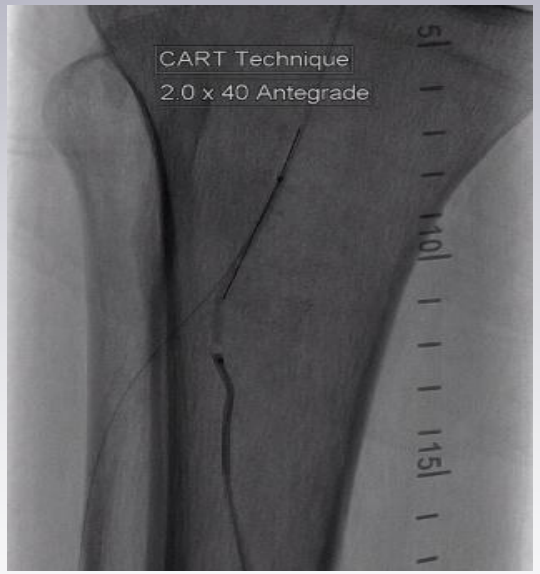
Which Variables? Lesion Information



Filter



Retrograde



CART

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Anecdote: How did we do?

- Same day discharge
- He's feeling great
- Laser is great
- Subintimal Outback works
- Subintimal PTA works
- I'll do that again next time

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Data: How we did

Primary Indication for Procedure: Claudication Rutherford 4
Preprocedure ABI:
Right: 0.68 Left: 0.71
Approach: Retrograde
Lesion #1: Side: R SFA

Appropriateness
Efficient
Equitable

Lesion Length: 200 mm
Characteristics: 2+ Calcium
Recanalization: Subintimal Outback
Pre-procedure stenosis: 100% **Post-procedure stenosis**: 10%

Tx Table-Primary Device	**Diameter**	**Length**	**Success**
Atherectomy: Laser Turbo Elite 2.0			
Balloon:Plain OptaPro	6 mm	100 mm	Y

Effective
Efficient

Peripheral Specific Complications
No complications
No UED

Safe

Baseline PAQ: 32.9
6 Mo Follow-up PAQ: 63.2

Effective
Patient Centered

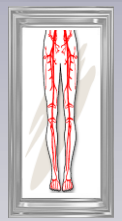
CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING PROGRAM

Outline

- Case
- Why measure quality for PVI?
- What and how to measure? The CART Model
- **Future directions**

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Synergy and Harmonization



PORTRAIT

Clinical Trials

CART PERIPHERAL
VA CLINICAL ASSESSMENT, REPORTING, and TRACKING PROGRAM

AHRQ
Decide-PAD

Clinical Data Standards

NCDR

PAD Guidelines

Mass Gen

PAD PM

BMC²

TASC²

Others?

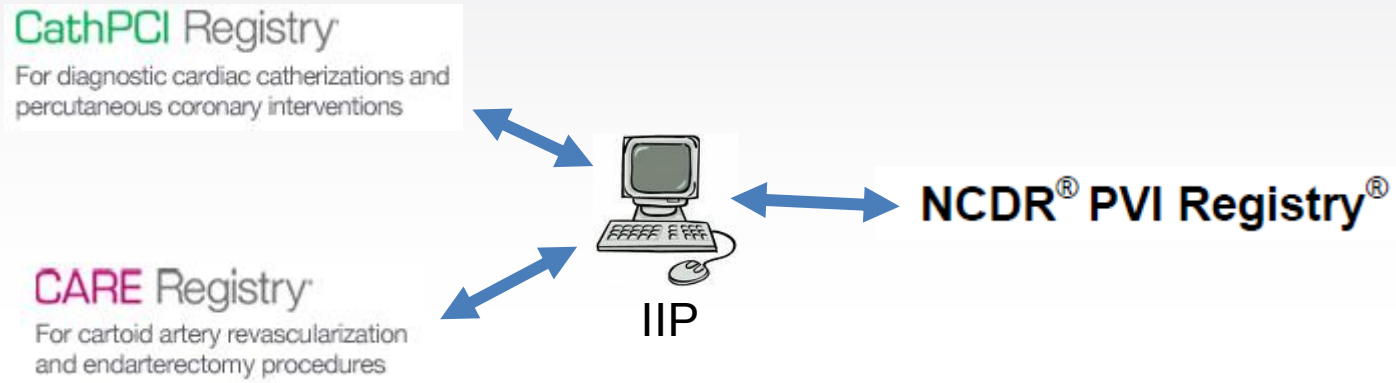
NCDR

COAP

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

NCDR Integrated Interventional Platform Workgroup

- Develop an integrated IT platform to integrate the NCDR CathPCI, CARE, and PVI data elements into a new integrated interventional procedure platform of the NCDR



CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING PROGRAM

Conclusions

- Harmonize and synergize data elements and definitions for peripheral vascular interventions
  - Apples to apples comparisons
  - Audit, benchmark and feedback
- Quality metrics and Performance measures
- Harmonized for greener pastures

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Questions and Discussion

Thank You!

Thomas.Tsai@va.gov

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

The Six Aims for Improving The Delivery and Quality of Care

- **Safe** — Avoiding complications, reducing errors
- **Effective** — Services based on scientific evidence
- **Patient Centered** — Respectful and responsive to individuals
- **Efficient** — Does not waste resources
- **Timely** — Decreasing wait times, improving flow
- **Equitable** — Consistent care regardless of patient characteristics and demographics

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

Quality Metrics, Performance Measures, etc.

Definitions

- **Quality Metrics**
  - Measures that have been developed to support self-assessment and quality improvement (QI) at the provider, hospital , and/or healthcare system level
  - AKA “test, quality, preliminary, candidate, test, evolving” measures,

- **Performance Measures**
  - Process, structure, efficiency, or outcome measures that have been developed using ACC/AHA methodology, including the process of public comment and peer review. External reporting.

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM

CART
CLINICAL ASSESSMENT, REPORTING, and TRACKING
PROGRAM