PROMIS:

A Collaborative Approach to Defining and Improving Outcomes in Orthopaedics

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STANFORD
SCHOOL OF MEDICINE

Disclosures

No financial relationships to disclose

Chair of the OFAR Managerial Board

Patient Reported Outcomes

Outline

–Outcomes in Orthopaedics

–NIH PROMIS System

–Goals for The Future

Patient Reported Outcomes

- Patient Reported Outcomes (PROs)
  - Health status perceived by patients

Patient Reported Outcomes

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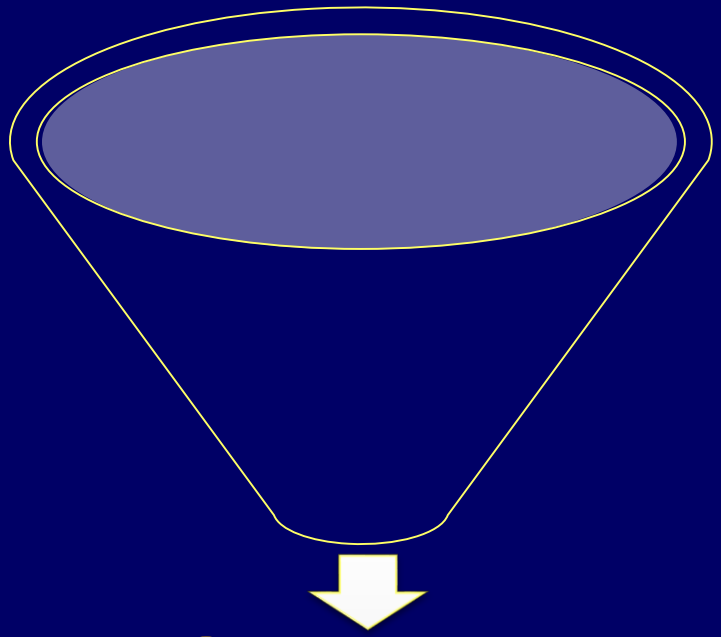
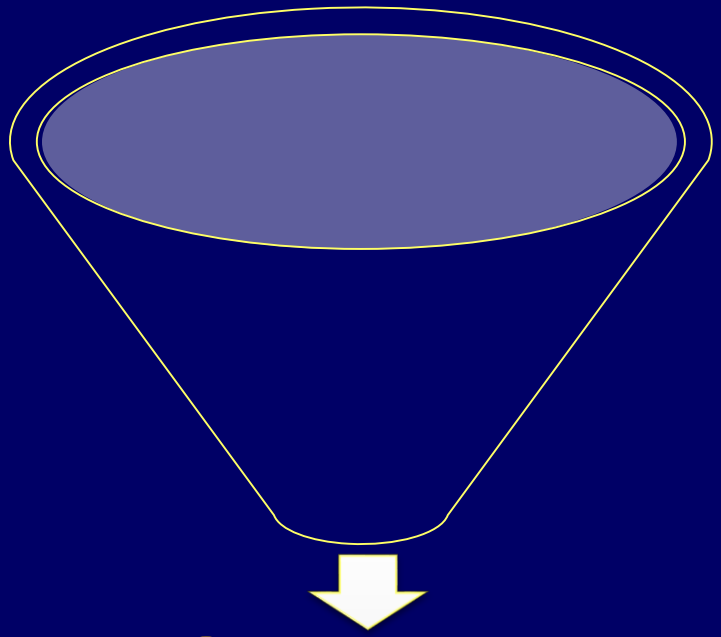


Patient Reported Outcomes

Clinical Findings

- Patient Reported Outcomes (PROs)
  - Health status perceived by patients

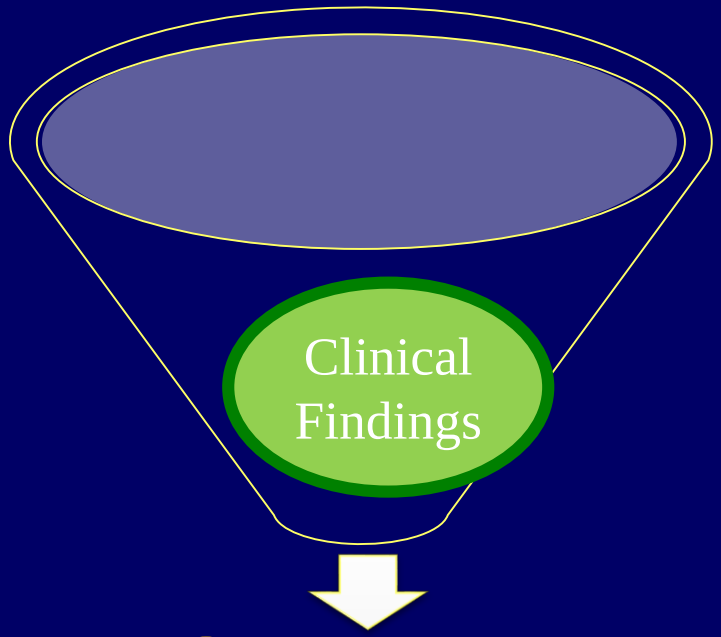


Outcomes

Patient Reported Outc

X-rays

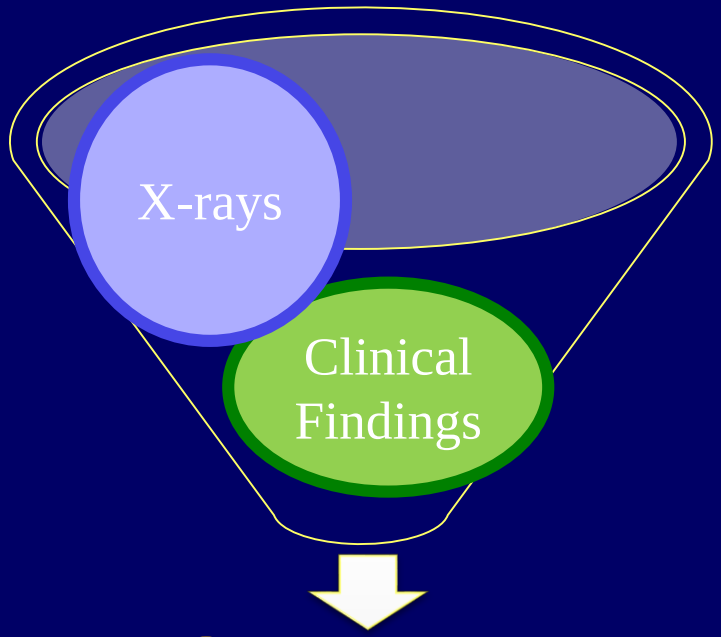
- Patient Reported Outcomes (PROs)
  - Health status perceived by patients



Patient Reported Outcomes

Patient Reported

- Patient Reported Outcomes (PROs)
  - Health status perceived by patients



Patient Reported Outcomes

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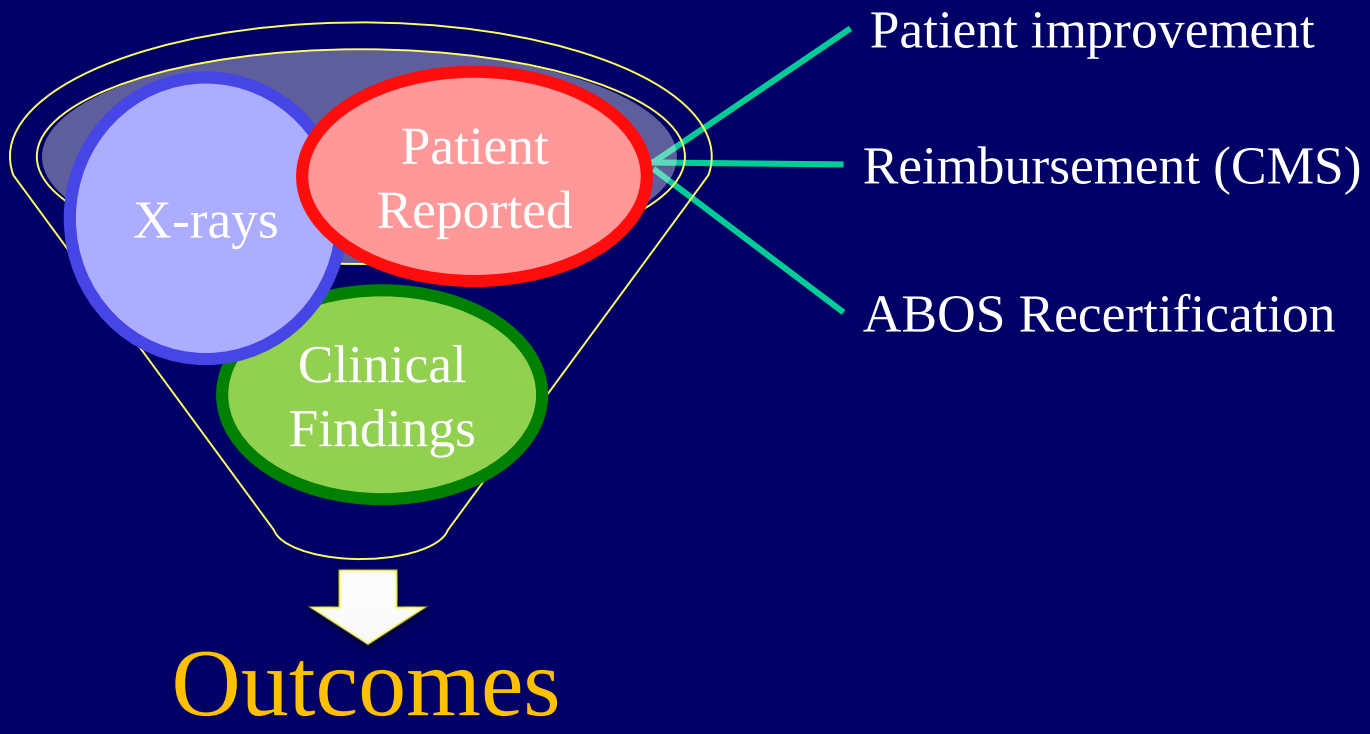
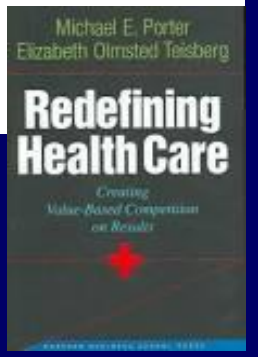


Patient Reported Outcomes

The NEW ENGLAND JOURNAL of MEDICINE
DECEMBER 23, 2010

What Is Value in Health Care?

Michael E. Porter, Ph.D.

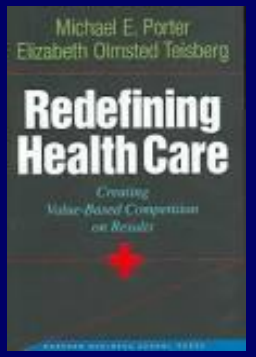


"Measuring, reporting and comparing outcomes are perhaps the most important steps toward **improving outcomes** and **reducing costs**"

Porter ME, NEJM Dec, 2010

Patient Reported Outcomes

$$\text{Value} = \frac{\text{Outcome}}{\text{Cost}}$$

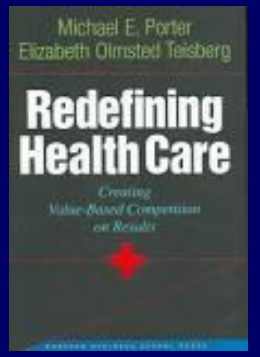


Porter ME, NEJM Dec, 2010

Patient Reported Outcomes

$$\text{Value} = \frac{\text{Outcome}}{\text{Cost}}$$

$ $ $ $ $ $ $

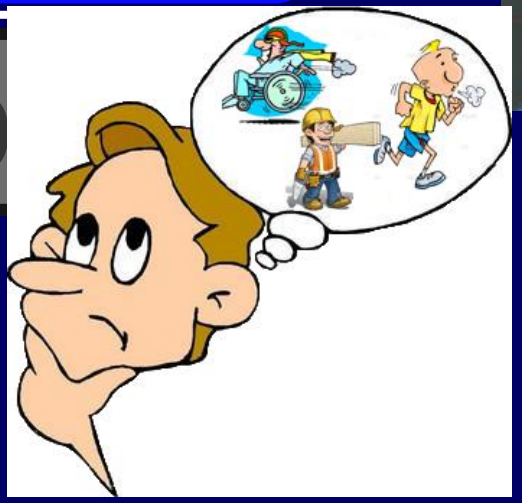


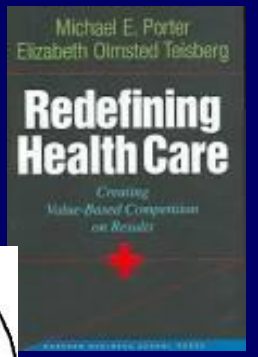
Porter ME, NEJM Dec, 2010

Patient Reported Outcomes

Value = Outcome / Co

$ $ $ $





Porter ME, NEJM Dec, 2010

Outcome Instruments

Global Health Scales

- SF-36 36 items
- SF-12 12 items
- EQ-5D 5 items
- HAQ 20 items
- SMFA 46 items
- UCLA Activity Score 10 items

Outcome Instruments

Disease or Region Specific Scales

Shoulder/Elbow

- ASES
- Constant
- DASH

Hand/Wrist

- DASH
- BCTQ
- MHQ

Knee/ACL

- KOOS
- Lysholm
- IKDC

Spine

- SRS-22
- NDI & ODI
- CSOQ

Arthroplasty

- Harris hip score
- WOMAC
- AKSS
- Oxford Scales

Outcome Instruments

Disease or Region Specific Scales

- Foot/ankle lacks such an instrument
- Current foot/ankle PROs
  - 139 unique PRO scales
  - 55 scales used more than once
  - 28 scales used five times or more
  - Most common:
    - AOFAS scales

Hunt and Hurwit, 2013 *JBJS Am*

Outcome Instruments

AOFAS scales

- The not so good with AOFAS scales
  - Have not been shown to be valid or reliable
  - Small number of response categories
    - Absolute descriptors (“No pain”, “No limitations”)
    - Limits precision
    - Score clustering
  - Physician-entered variables
    - No standard measuring technique
    - Poor inter-observer variability and reliability
  - No clear guidelines for data interpretation

Outcome Instruments

AOFAS scales

AOFAS position statement (2011):

"Scores from the AOFAS Clinical Scoring Systems have not been found to be valid or reliable, and therefore their **continued use is not recommended**"

Pinsker and Daniels, 2011 *FAI*

Outcomes in Foot and Ankle

OFAR Network

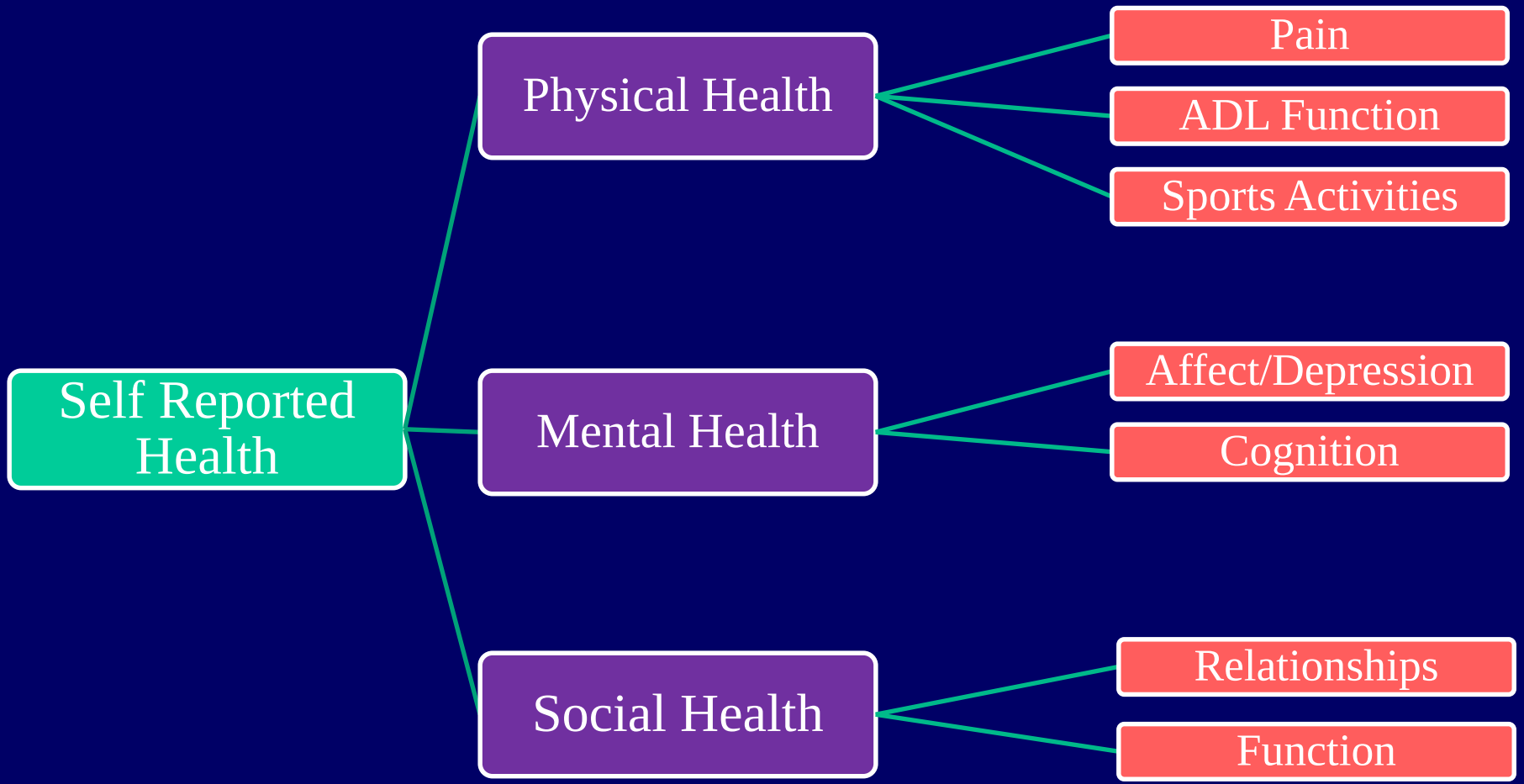
AMERICAN ORTHOPAEDIC FOOT & ANKLE SOCIETY

National Orthopaedic Foot and Ankle Outcomes Research Network

Part of OFAR mission is to help providers define **outcome metrics** for QI and research

Foot and Ankle Outcomes

Domains



Patient Reported Outcomes

Outline

–Outcomes in Orthopaedics

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–Goals for The Future

Foot and Ankle Outcomes

Data Collection

Patient Reported Outcomes Measurement Information System

– Web-based PRO data collection system

– Efficient, Precise, Valid measures

– No Cost (currently sponsored by NIH)

– Adds Computer Adaptive Testing (CAT)

Foot and Ankle Outcomes

Data Collection

Computer Adaptive Testing (CAT)

based on

Item Response Theory

Computer Adaptive Testing

Example of Classical Test Theory: **Foot Function Index**

How much difficulty did you have:

Walking around the house?	No difficulty	1	2	3	4	5	6	7	8	9	10	Unable to do
Walking on uneven ground?	No difficulty	1	2	3	4	5	6	7	8	9	10	Unable to do
Walking four or more blocks?	No difficulty	1	2	3	4	5	6	7	8	9	10	Unable to do
Climbing stairs?	No difficulty	1	2	3	4	5	6	7	8	9	10	Unable to do
Descending stairs?	No difficulty	1	2	3	4	5	6	7	8	9	10	Unable to do
Standing on tip toe?	No difficulty	1	2	3	4	5	6	7	8	9	10	Unable to do
Getting out of a chair?	No difficulty	1	2	3	4	5	6	7	8	9	10	Unable to do
Climbing up or down curbs?	No difficulty	1	2	3	4	5	6	7	8	9	10	Unable to do
Walking fast or running?	No difficulty	1	2	3	4	5	6	7	8	9	10	Unable to do

- 23 questions total
- Score calculated on a scale of 100

Computer Adaptive Testing

Example of Item Response Theory: **CAT**

- Uses a Bank of Validated Questions
- Questions selected based on patient's response to previously administered questions
- Asks only the most pertinent and informative items
- Produces score with high level of precision using the minimal possible number of questions

Computer Adaptive Testing

Physical Function CAT

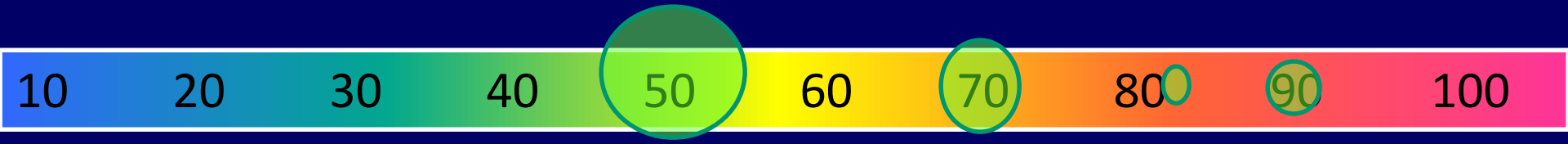
1. Unable to do
2. With much difficulty
3. With some difficulty
4. With a little difficulty
5. Without any difficulty

I can walk several steps.

I can run a mile.

I can run 5 miles.

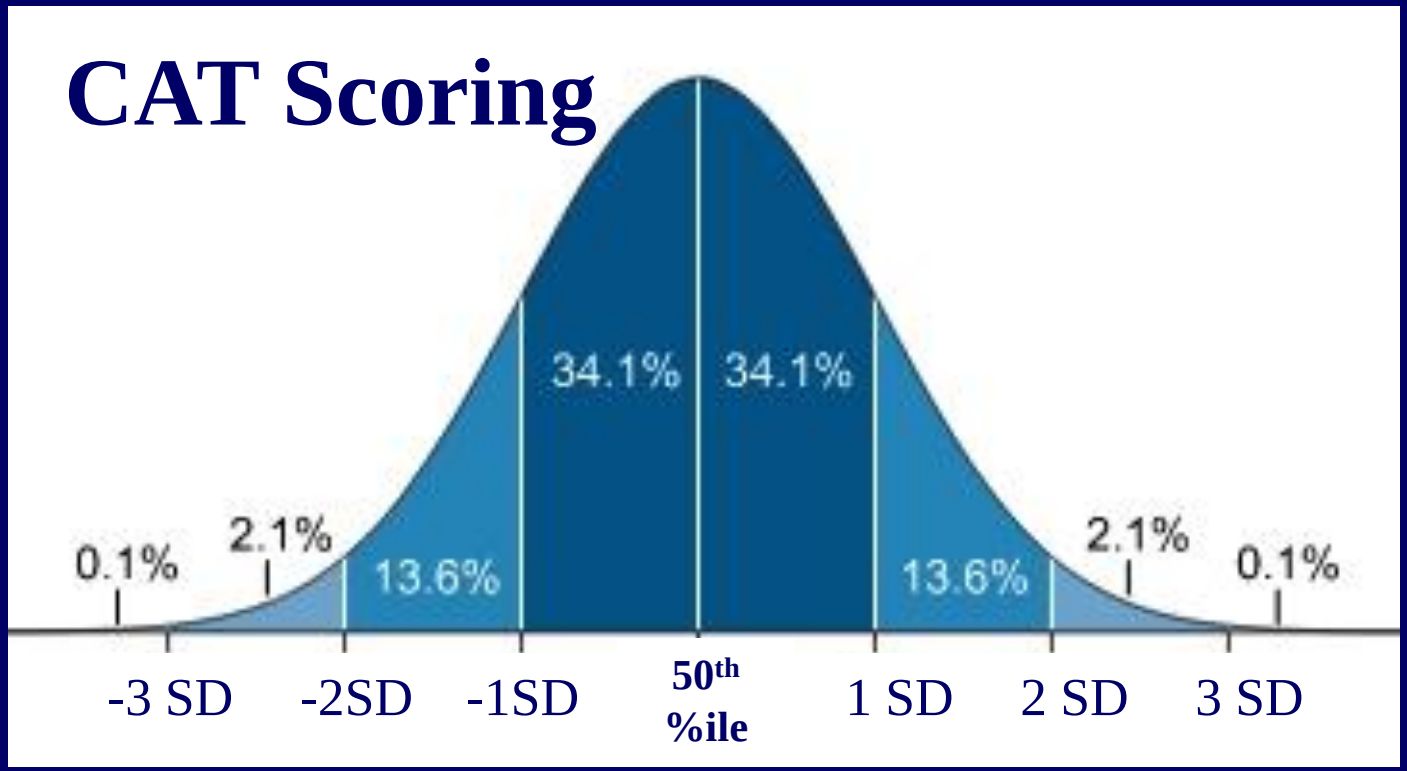
I can run 10 miles.



Same score with good precision in 4 questions

Computer Adaptive Testing

Physical Function CAT



- T score is reported (50 = average)
- Each SD = 10

NIH PROMIS

A New Paradigm?

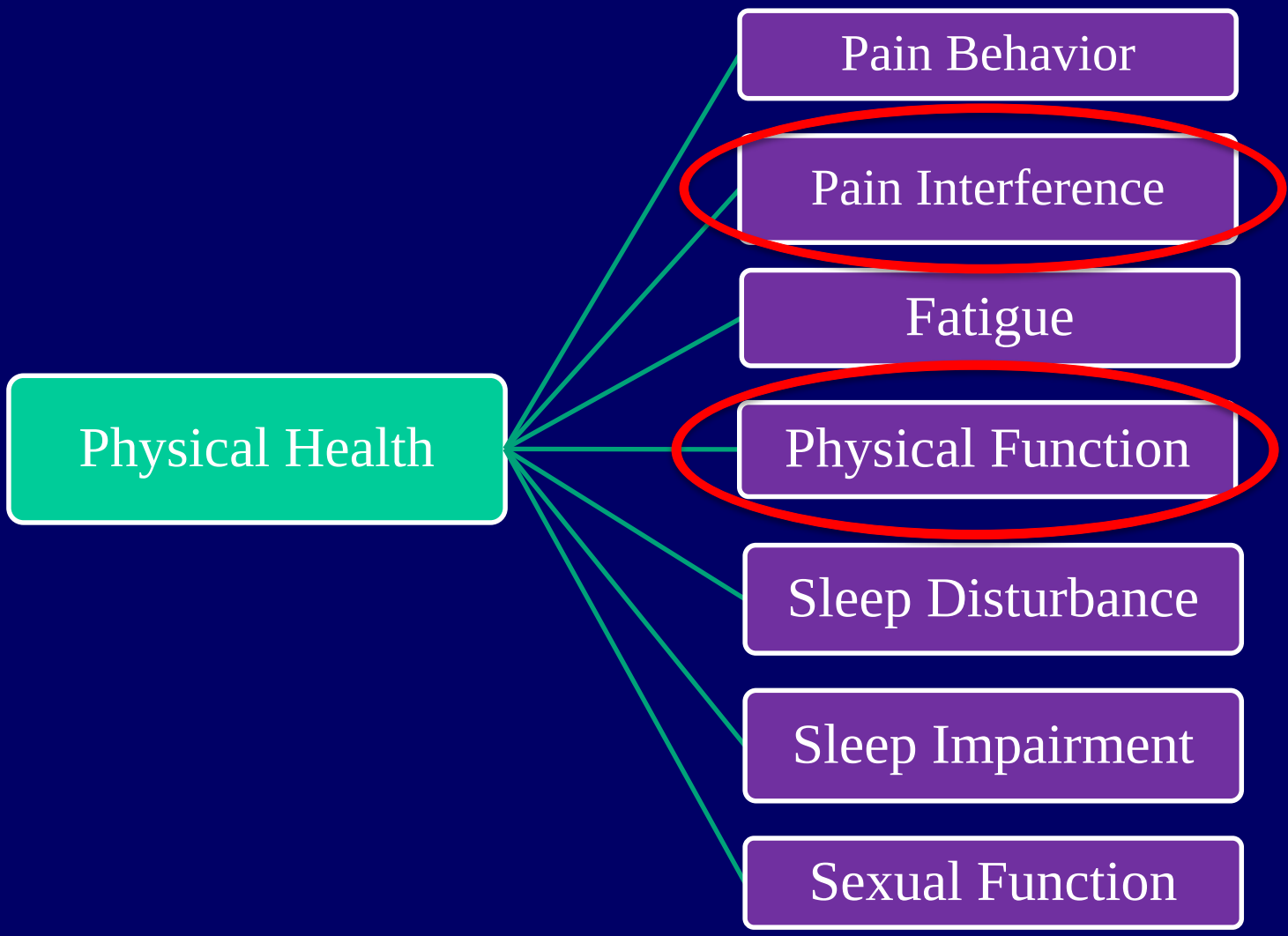
Domain-specific

Not

Disease-specific

Applies to different diseases, not only orthopaedic

PROMIS Physical Health Banks



NIH PROMIS

A New Paradigm?

OFAR Pilot Study

OFAR Network

The Pilot Project

Baylor/UTSW
Campbell Clinic
HSS
Orthocarolina
Stanford University
University of Arizona
University of Iowa
UCLA
Univ. of Rochester
University of Utah

10 Pilot Sites

OFAR Network

The Pilot Project

Foot & Ankle International
2014, Vol. 35(9) 847–854

DOI: 10.1177/1071100714544157
fai.sagepub.com

The Orthopaedic Foot and Ankle Outcomes Research (OFAR) Network: Feasibility of a Multicenter Network for Patient Outcomes Assessment in Foot and Ankle

Kenneth J. Hunt, MD[1], Ian Alexander, MD[2], Judith Baumhauer, MD[3], James Brodsky, MD[4], Christopher Chiodo, MD[5], Timothy Daniels, MD[6], W. Hodges Davis, MD[7], Jon Deland, MD[8], Scott Ellis, MD[8], Man Hung, PhD[9], Susan N. Ishikawa, MD[10], L. Daniel Latt, MD, PhD[11], Phinit Phisitkul, MD[12], Nelson Fong SooHoo, MD[13], Arthur Yang, MS[1], Charles L. Saltzman, MD[9], and OFAR (Orthopaedic Foot and Ankle Outcomes Research Network)

Hunt et al. 2014 FAI

OFAR Network

The Pilot Project

- Each site:
  - Enrolled 30 patients undergoing surgery for:

Ankle/Hindfoot

- Ankle Arthritis
- Ankle Instability
- Flatfoot Deformity

Forefoot

- Bunions
- Hammer toe(s)
- Hallux rigidus

OFAR Network

The Pilot Project

- PROMIS system used for patient surveys
  - Demographic and comorbidity data
  - PRO data

Computer Adaptive Tests

- Physical Function CAT
- Pain Interference CAT

Legacy Instruments

- Foot and Ankle Ability Measure (FAAM)
- Foot Function Index (FFI)

OFAR Network

The Pilot Project

- PROMIS system used for patient surveys
  - Demographic and comorbidity data
  - PRO data

Computer Adaptive Tests

- Physical Function CAT
- Pain Interference CAT

Legacy Instruments

- Foot and Ankle Ability Measure (FAAM)
- Foot Function Index (FFI)

- **3 month** enrollment period
- Data collected
  - **Pre-op**
  - **6 months** post-op

OFAR Pilot Project

Total Enrollment

328 total patients enrolled

Table 1: Patient Demographic characteristics

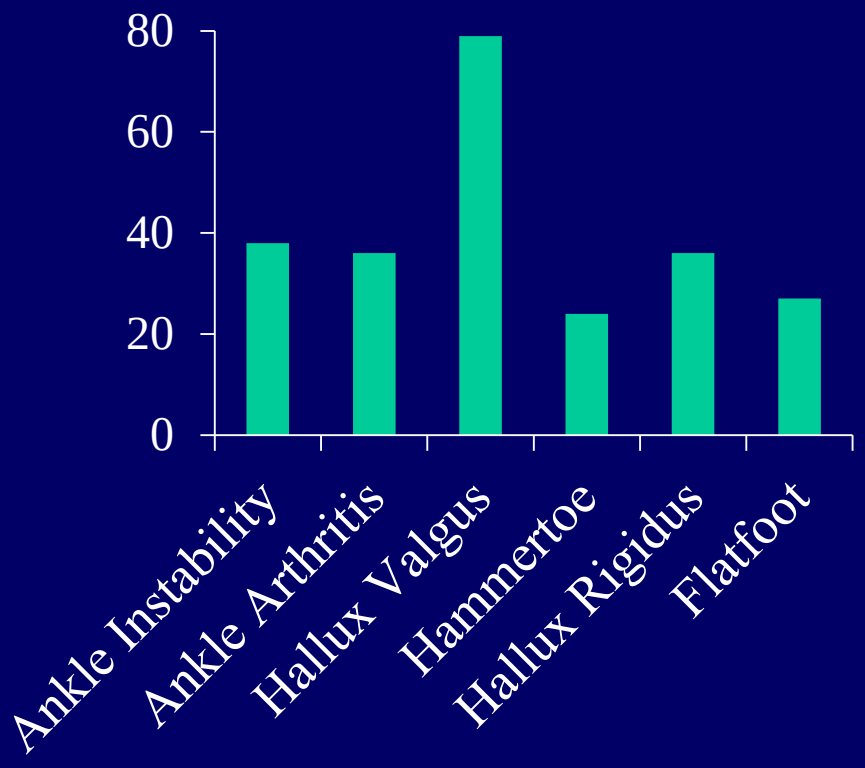
Variables	Mean (SD)	Min	Max	n (%)
Age	51 (15)	18	81	
Gender				
Male				74 (30.3%)
Female				170 (69.7%)
Race				
White				208 (87.0%)
Black or African American				11 (4.6%)
Asian				8 (3.3%)
White & Asian				1 (0.3%)
American Indian or Alaska Native				1 (0.3%)
Other				10 (3.5%)
Ethnicity				
Not Hispanic or Latino				184 (94.8%)
Hispanic or Latino				10 (5.2%)
Diabetes				
No				269 (95.1%)
Yes				14 (4.9%)
Rheumatoid Arthritis				
No				258 (91.2%)
Yes				25 (8.8%)

OFAR Pilot Project

Total Enrollment

328 total patients enrolled

Ankle Instability	38
Ankle Arthritis	36
Hallux Valgus	79
Hammertoe	24
Hallux Rigidus	36
Flatfoot	27
Other/Missing	43



OFAR Pilot Project

Efficiency

CAT vs. Legacy Scales

Item Counts

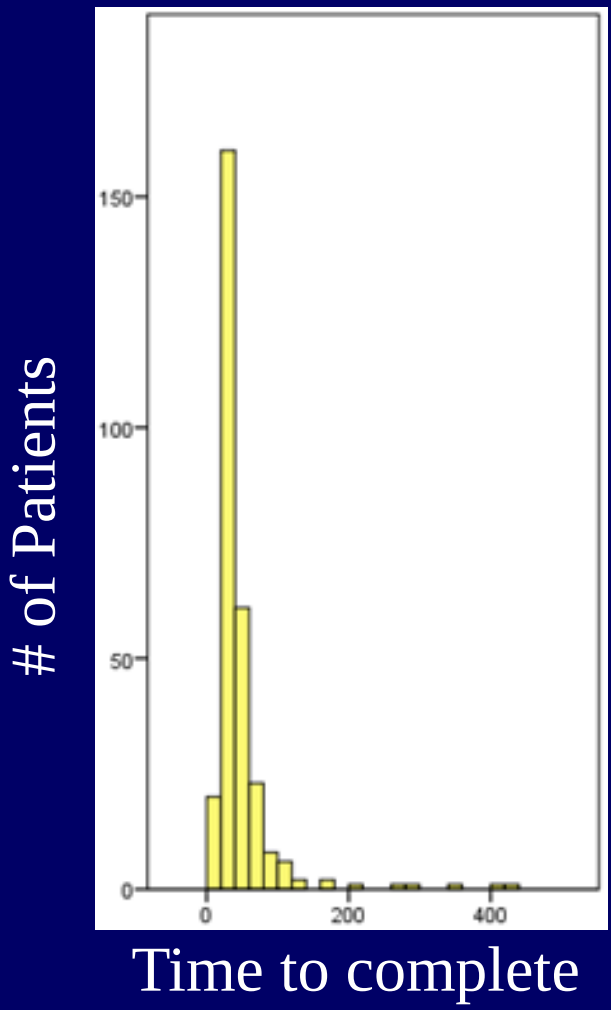
- Physical Function CAT 4.3 questions
- Pain Interference CAT 4.3 question
- FAAM 28.0 questions
- FFI 23.0 questions

OFAR Pilot Project

Efficiency

Time to Complete Instrument

- PF CAT 0:46 seconds

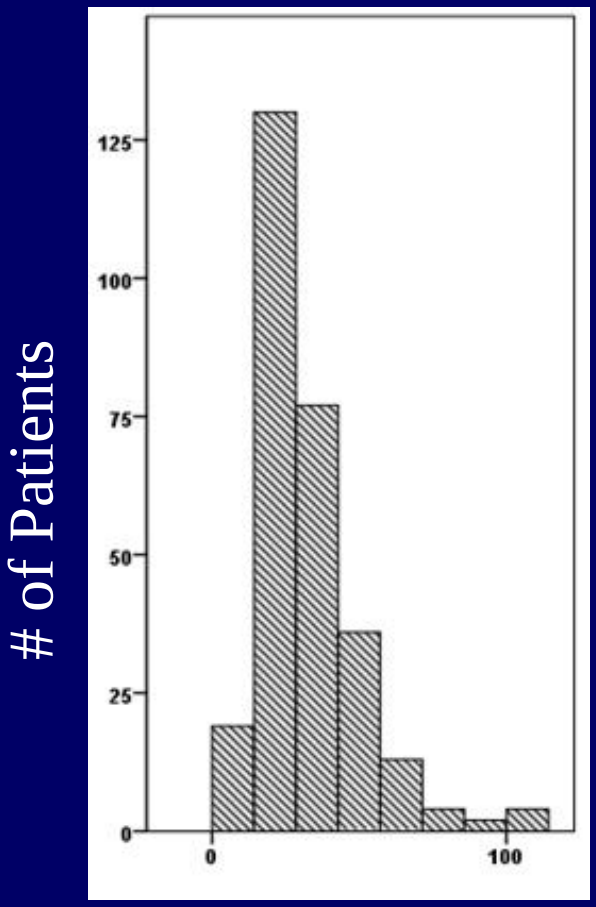


OFAR Pilot Project

Efficiency

Time to Complete Instrument

- PF CAT 0:46 seconds
- Pain CAT 0:33 seconds

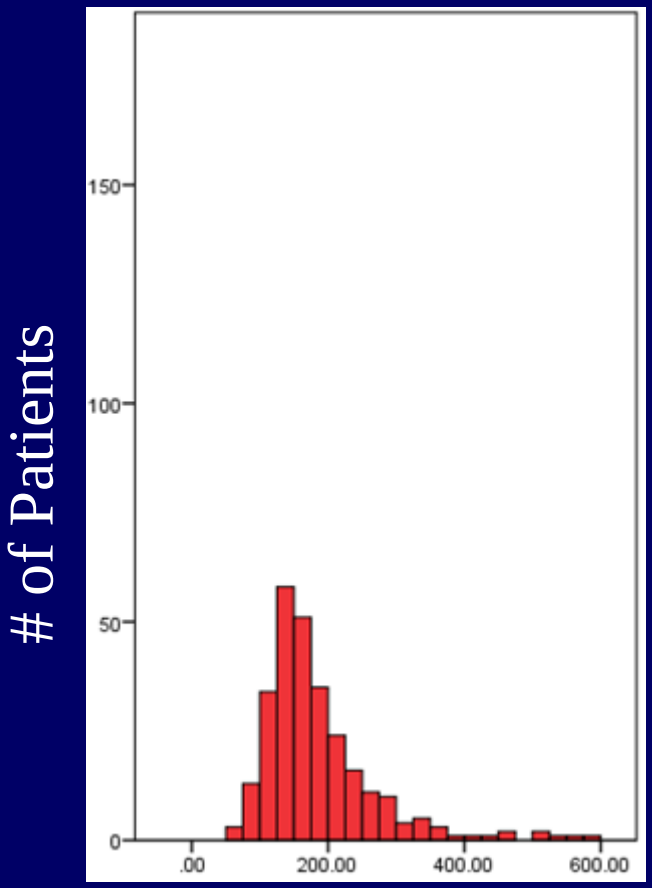


OFAR Pilot Project

Efficiency

Time to Complete Instrument

- PF CAT 0:46 seconds
- Pain CAT 0:33 seconds
- FFI 3:16



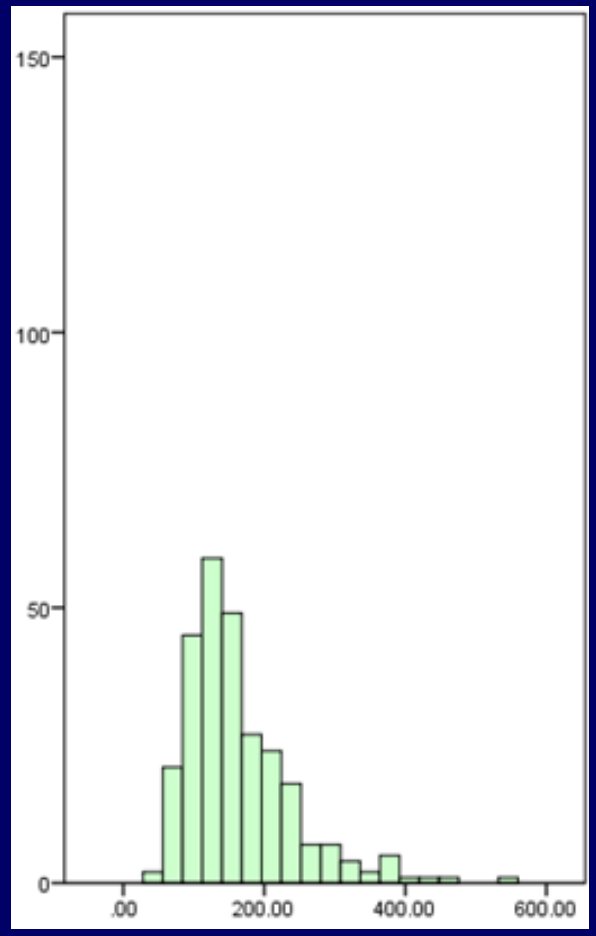
OFAR Pilot Project

Efficiency

Time to Complete Instrument

- PF CAT 0:46 seconds
- Pain CAT 0:33 seconds
- FFI 3:16
- FAAM 2:54

¼ the time to complete CATs



OFAR Pilot Project

Psychometric properties of PROMIS instruments

Validation of PROMIS® Physical Function Computerized Adaptive Tests for Orthopaedic Foot and Ankle Outcome Research

Man Hung PhD, MSTAT, MED, Judith F. Baumhauer MD, MPH, L. Daniel Latt MD, PhD, Charles L. Saltzman MD, Nelson F. SooHoo MD, Kenneth J. Hunt MD, and National Orthopaedic Foot & Ankle Outcomes Research Network

Hung et al. 2013 CORR

Psychometric Comparison of the PROMIS Physical Function CAT With the FAAM and FFI for Measuring Patient-Reported Outcomes

Foot & Ankle International®
2014, Vol. 35(6) 592–599

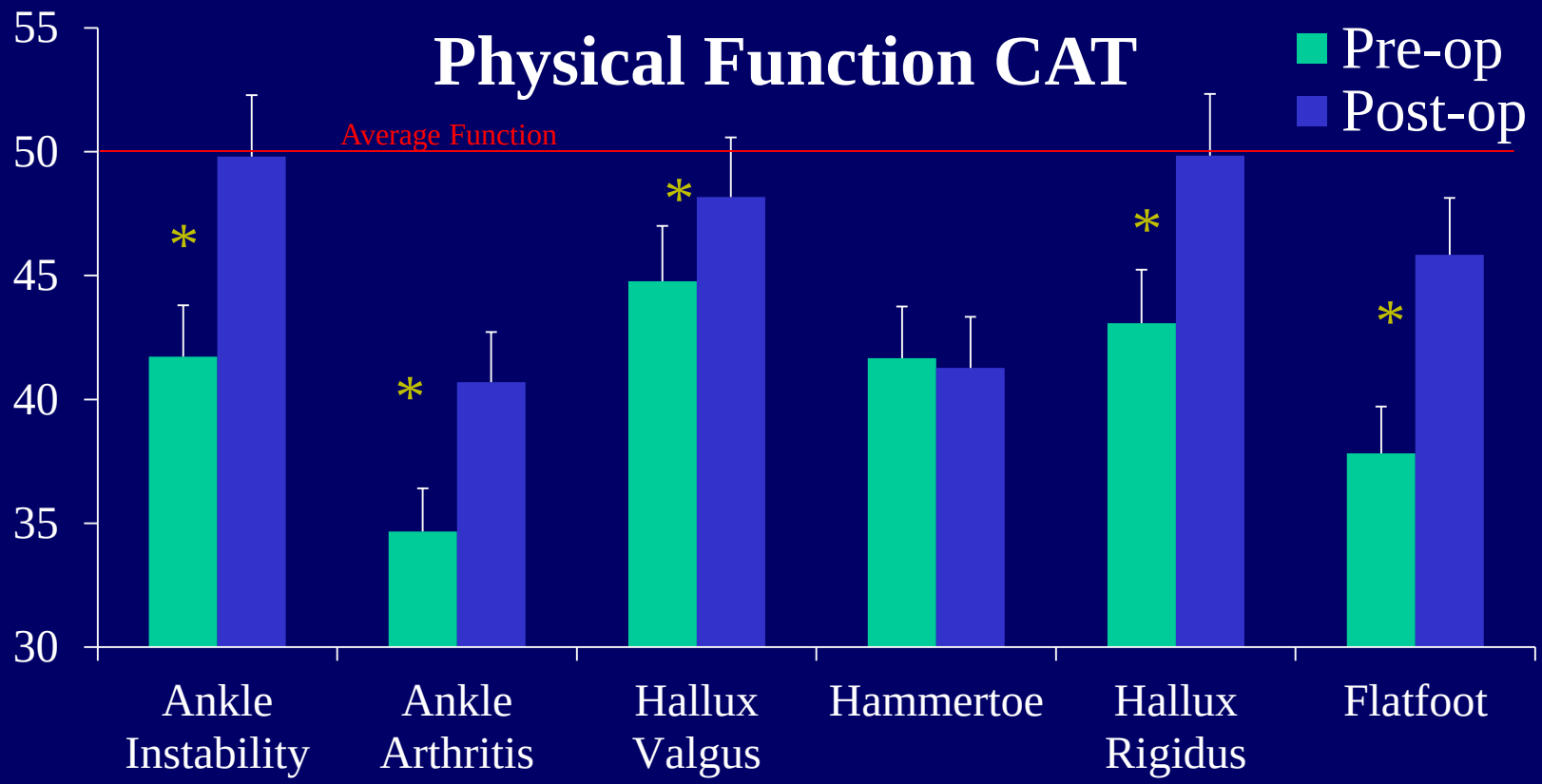
DOI: 10.1177/1071100714528492
fai.sagepub.com

Hung et al. 2014 FAI

OFAR Pilot Project

Psychometric Properties

- *Responsiveness*:



OFAR Pilot Project

Psychometric Properties

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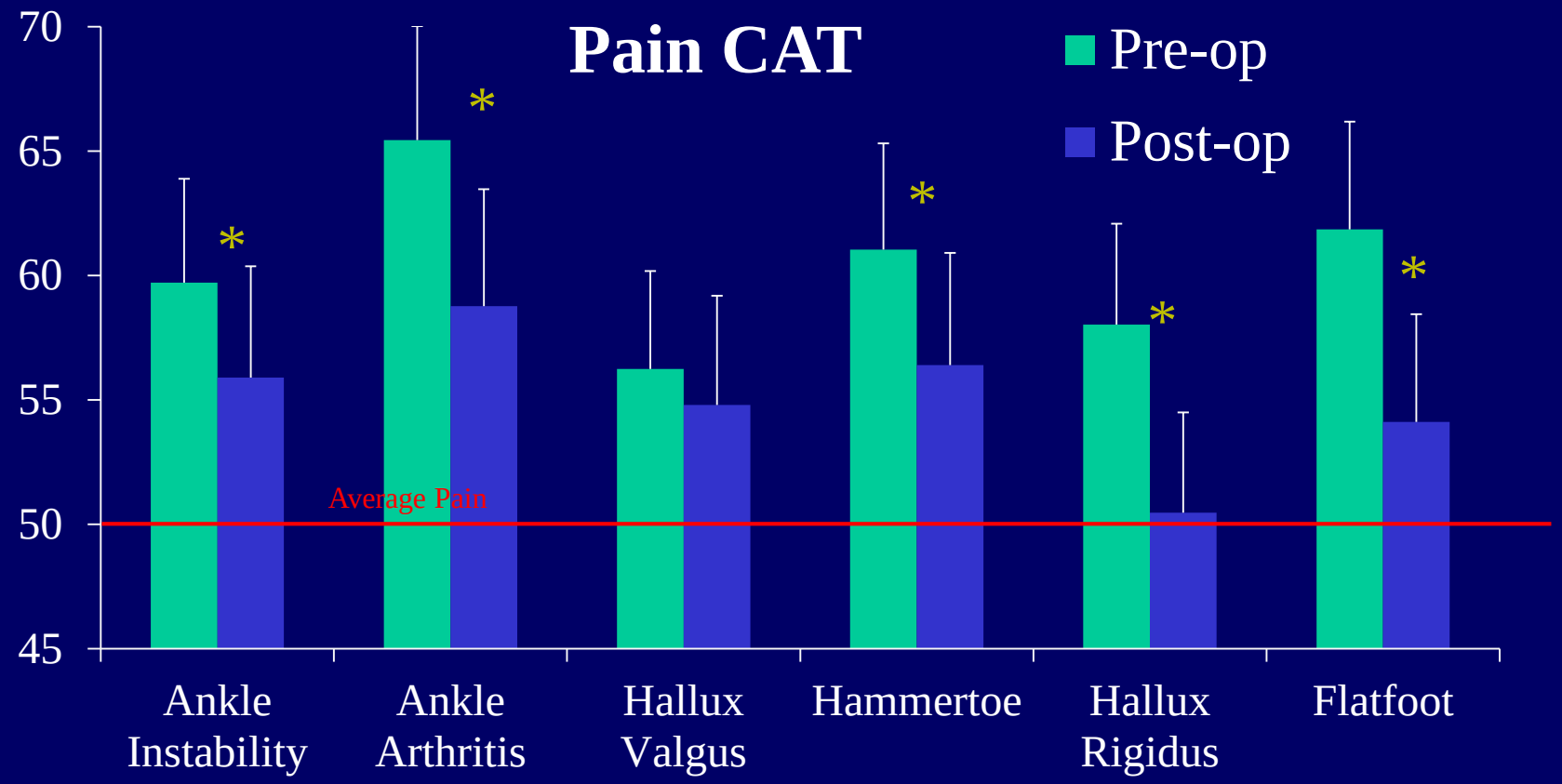

OFAR Pilot Project

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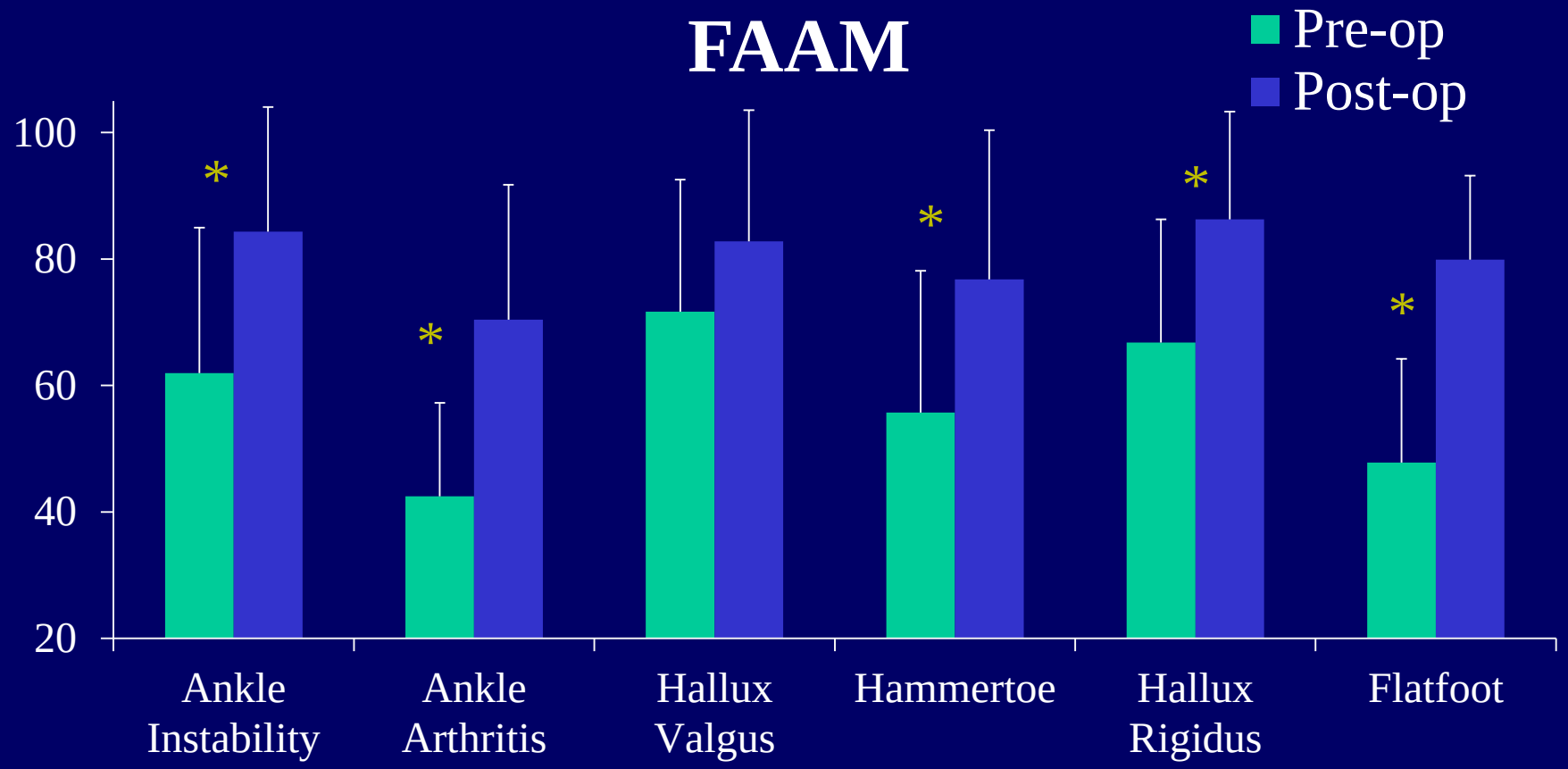

OFAR Pilot Project

Psychometric Properties

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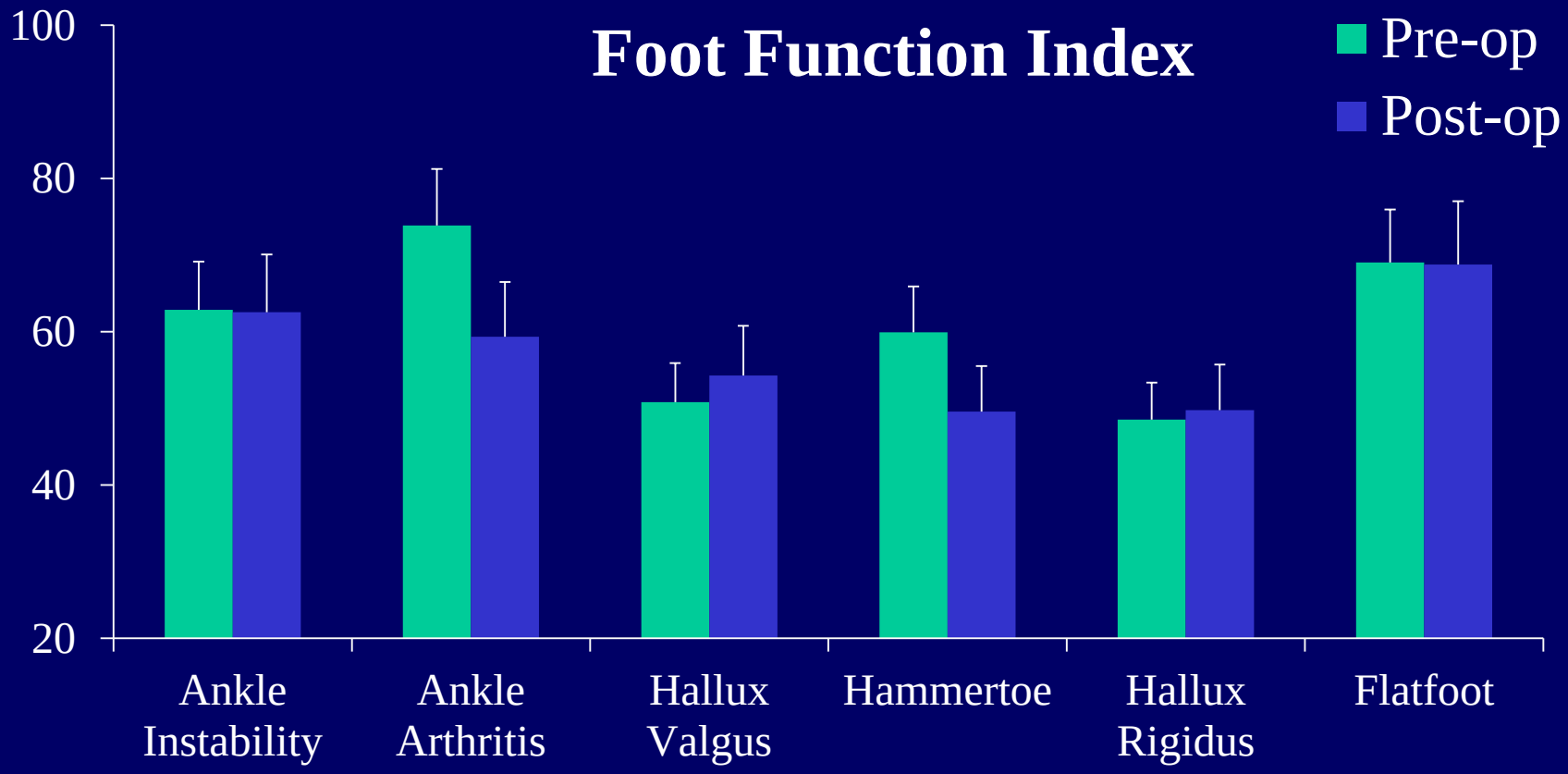

OFAR Pilot Project

Psychometric Properties

- *Construct validity*:
  - Rasch model
  - High for all instruments
- *Convergent validity*
  - Pearson correlation

	PF CAT	FAAM	FFI
PF CAT	**1.000**	**0.785**	**0.792**
FAAM		**1.000**	**0.685**
FFI			**1.000**

- We are measuring what intended to measure

OFAR Pilot Project

Psychometric Properties

- *Reliability*: High for all instruments

	Person Reliability	Item Reliability
PF CAT	**0.96**	**0.99**
FAAM	**0.95**	**0.99**
FFI	**0.93**	**0.99**

OFAR Pilot Project

Psychometric Evaluation of PF CAT

Physical Function CAT

- *Instrument coverage:*
  - Minimal ceiling effect (SEM 0.3195%)
  - No floor effect
- *Precision:*
  - High across a broad range of physical function

Hung et al., CORR in press

NIH PROMIS

A New Paradigm?

CAT scales vs. Legacy Scales

- All PROMIS CAT iten
- Lower test burden*
  - CAT surveys completed
  - 3-8 questions on averag
  - Eliminates unnecessary
- Better Precision
- Floor/Ceiling effects can be eliminated

*Does not interfere with clinical productivity

Hunt et al., 2014 FAI
Hung et al., 2013 CORR

NIH PROMIS

A New Paradigm?

PROMIS CATs in Orthopaedics

Evaluation of the PROMIS Physical Function Computer Adaptive Test in the Upper Extremity

Tyser et al., 2014 JHSA

Psychometric Properties of the PROMIS Physical Function Item Bank in Patients With Spinal Disorders

Hung et al., 2014 Spine

Computerized Adaptive Testing Using the PROMIS Physical Function Item Bank Reduces Test Burden With Less Ceiling Effects Compared With the Short Musculoskeletal Function Assessment in Orthopaedic Trauma Patients

Hung et al., 2014 JOT

Validation of GAITRite and PROMIS as High-Throughput Physical Function Outcome Measures Following ACL Reconstruction

Papuga et al. 2014 JOR

Evaluation of the PROMIS Physical Function Item Bank in Orthopaedic Patients

Patient Reported Outcomes

Outline

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–Goals for The Future

NIH PROMIS

Moving Forward

PROMIS NIH Roadmap Initiative

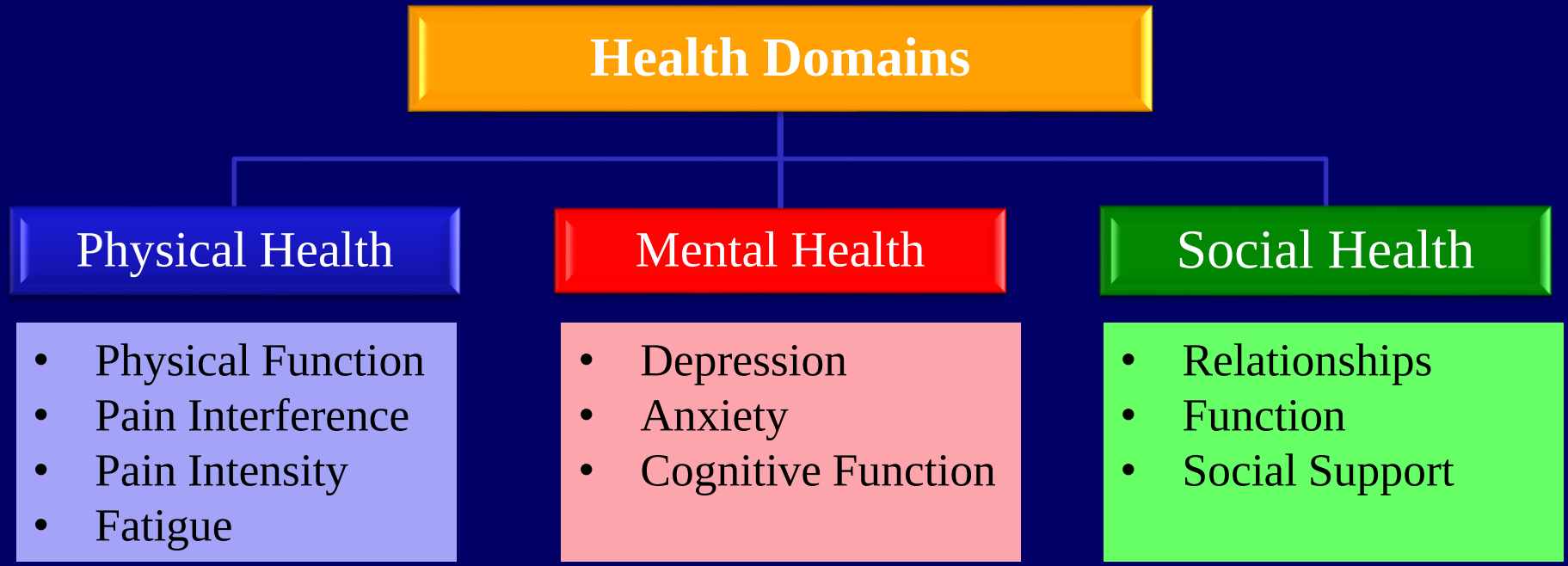
- NIH committed to improve and standardize measurement of PRO
  - More than **$90 million** invested since 2004
  - Goal is widespread adoption by all specialties
  - Across the entire US population
- PROMIS CATs are open source
  - AssessmentCenter.net
  - RedCAP, EPIC, Ipad App

Outcomes in Foot and Ankle

Moving Forward

Measuring Outcomes

- Physical Function is an important domain
- But it is not the ***only*** domain



Outcomes in Foot and Ankle

Moving Forward

Measuring Outcomes

- Physical Function is an important domain
- But it is not the ***only*** domain
- Establish Normative data for populations

Outcomes in Foot and Ankle

Moving Forward

Where we are heading:

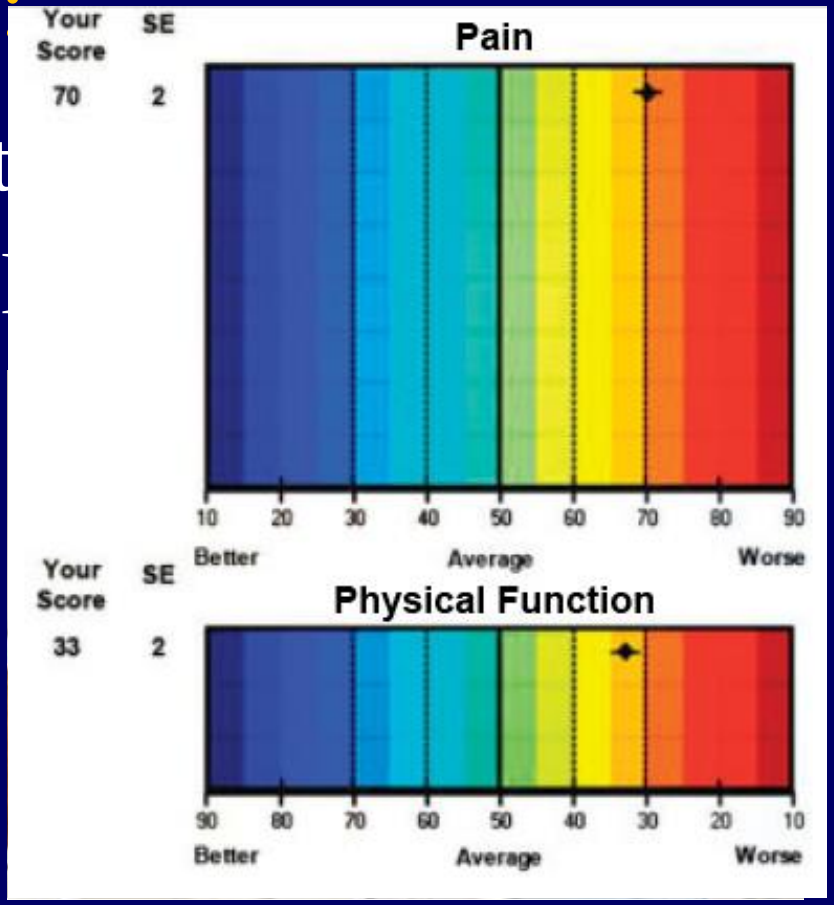
- Patients complete questionnaire

Outcomes in Foot and Ankle

Moving Forward

Where we are heading:

- Patients complete quest
- Instantly scored and up
- Upon entering room
  - Know PRO scores
  - Population norms
  - Historical values
  - Will intervention help?



Outcomes in Foot and Ankle

Moving Forward

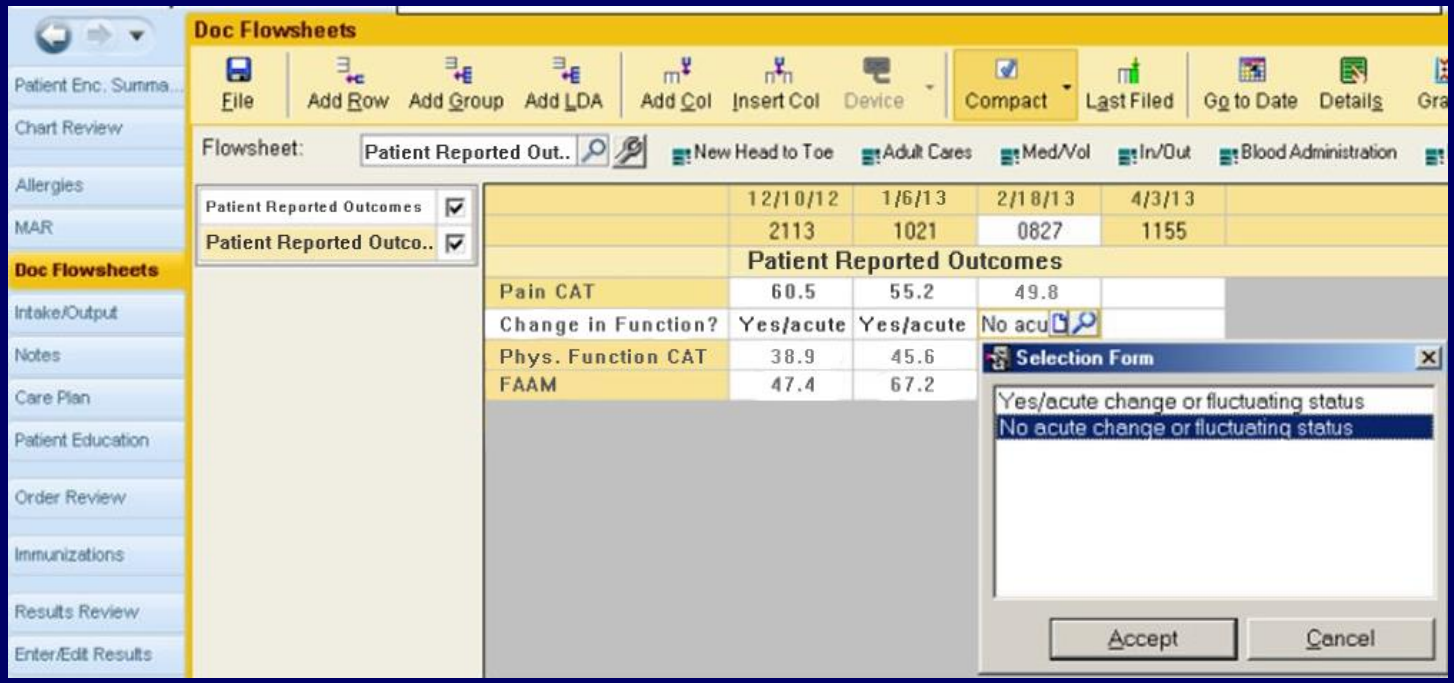
Where we are heading:

- Patients complete questionnaire
- Instantly scored and uploaded to EMR
- Upon entering room
- PRO scores part of clinic note

Outcomes in Foot and Ankle

Moving Forward

Where we are heading:

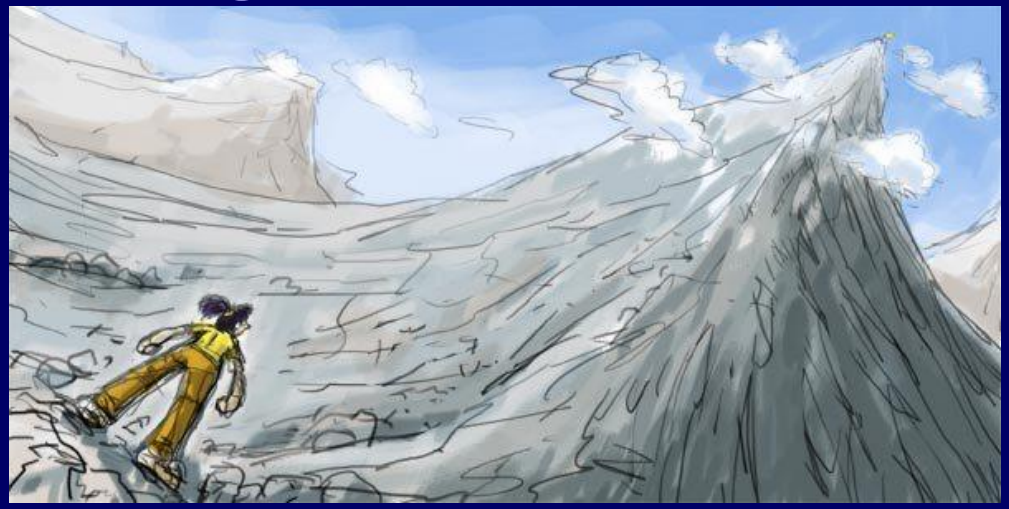


- Response to treatment can be monitored
- Comparison to internal and national standards

Outcomes in Foot and Ankle

Moving Forward

Our Ultimate Goal:

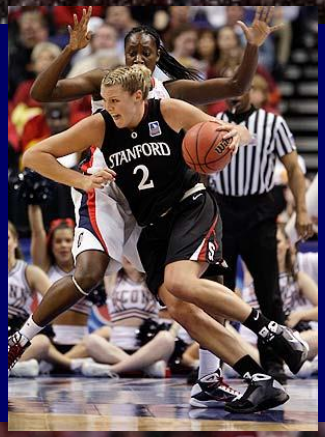


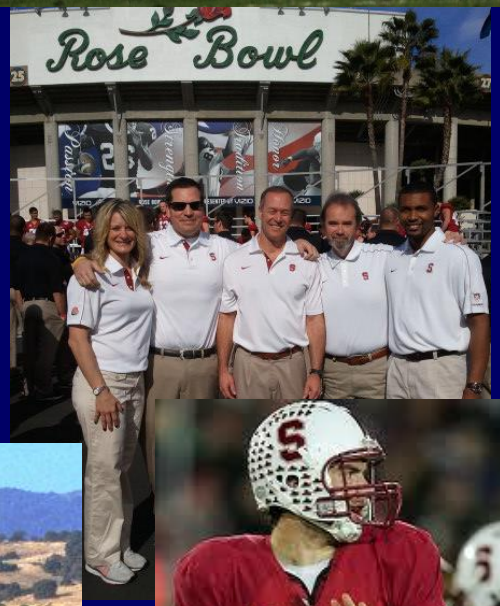
- Enhance our ability to assess patient outcomes
- Improve quality and generalizability of outcomes assessment
- Direct the conversation on quality assessment and appropriate allocation of HC resources

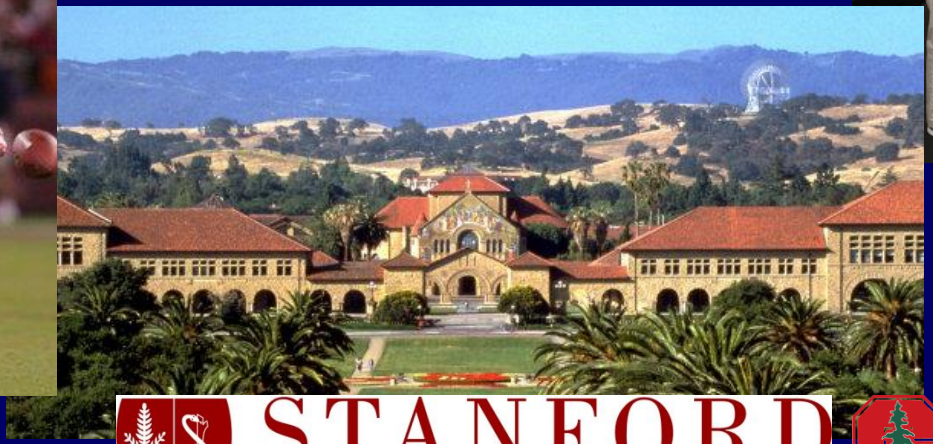
Thank You

OFAR Network

AOFAS/OEF







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