Developing and Implementing a Patient Reported Outcomes Network in Canada: Potential Benefits and Challenges
Montreal, QC, Canada

Integrating PROMIS in Arthritis Clinical Care: Feasibility, Impact, and Content Validation

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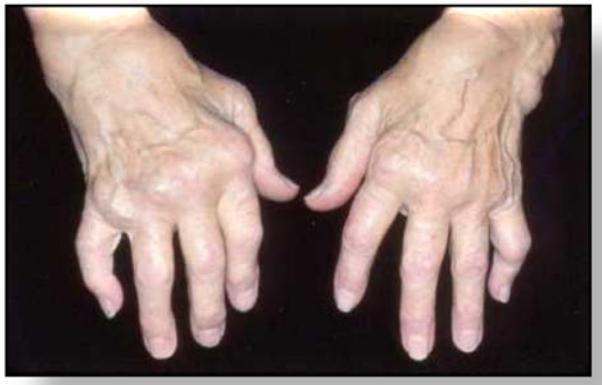
Rheumatoid Arthritis

- Rheumatoid arthritis (RA) is a chronic, systemic, and frequently disabling disease that affects up to 1% of the population
- Associated with considerable disease- and treatment-related morbidities and premature mortality
- Multiple aspects of physical, emotional, and social health are impacted
- **Current measures** used in clinical care to guide treatment decisions **have limited inclusion of patient-valued outcomes**



Current Outcome Measures Used in RA Clinical Trials and Decision Making

- RA Core Set: Swollen Joints, Tender Joints, Patient Global Assessment, MD Global Assessment, Patient Assessment of Pain, HAQ-DI, ESR/CRP

- DAS– Swollen Joints, Tender Joints, ESR/CRP, *Patient Global Health*
- CDAI—Swollen Joints, Tender Joints, *Patient Global Assessment of Disease,* MD Global Assessment
- SDAI–- CDAI+ CRP

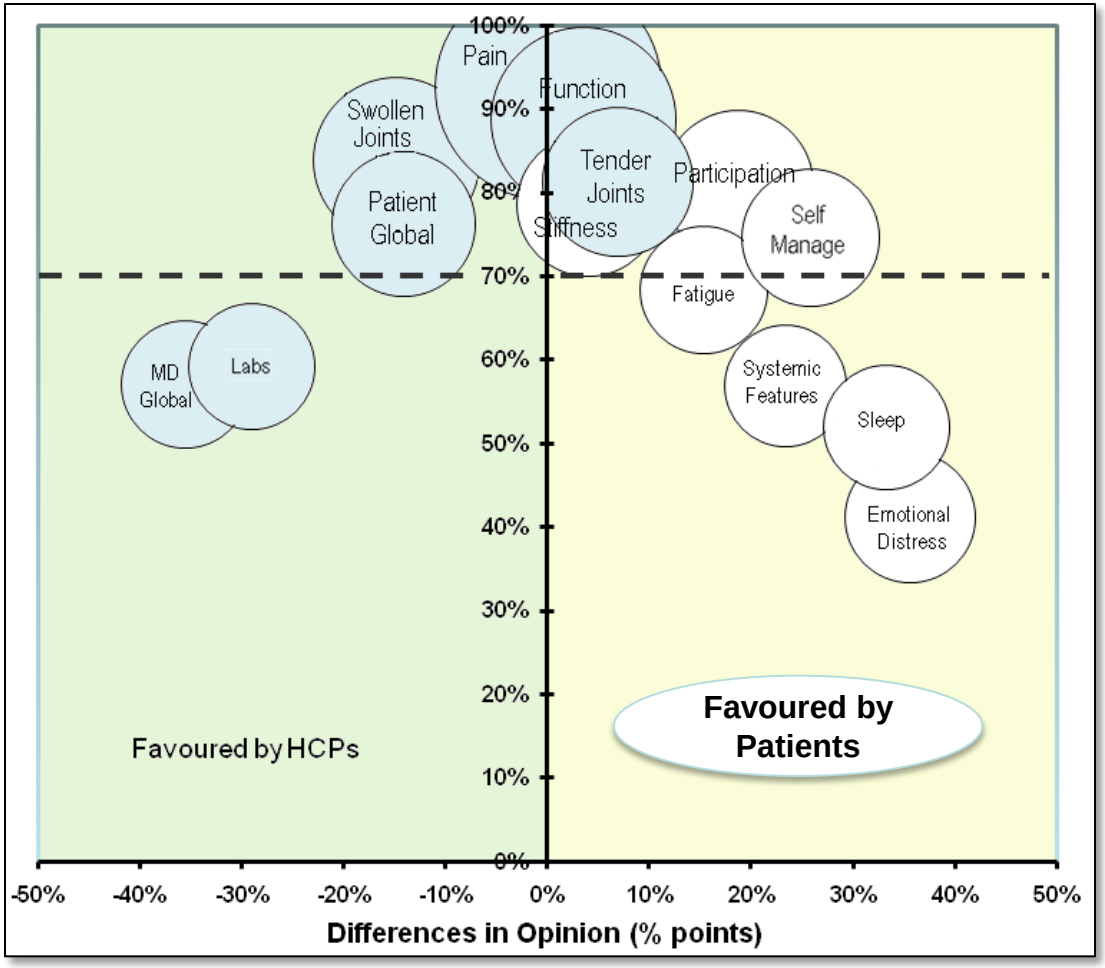
OMERACT

- Outcome Measures in Rheumatology
- Established in 1992 to Develop, Improve, Validate Outcome Measures for Clinical Trials
  - RA Core Set, RA Remission, OA Response, MRI RAMRIS, Psoriatic arthritis Core Set, etc
- Evolved to encompass spectrum of rheumatic diseases and settings (RCT, LOS, practice)

- Filter 1.0: Truth, Discrimination, Feasibility
- Filter 2.0: Framework for developing Core Outcome Sets

- Patient inclusion in research process since 2002
  - Resulted in addition of Fatigue to recommended RA Core Set

RA Patients and Providers have Different Perspectives When Rating the Importance of Disease Signs and Symptoms: RA Flare



Bartlett SJ et al, *Ann Rheum Dis* 2012; Bingham CO et al, *Ann Rheum Dis* 2012; Bingham CO et al *J Rheumatol* 2009, Hewlett SH, et al, *Rheumatology* 2010; Bingham CO et al, *J Rheumatol* 2011; Alten R et al, *J Rheumatol* 2011; Bykerk VB, et al, *J Rheumatol 2013* (in press)

Patient-Reported Outcome Measurement Information System (PROMIS®)
www.nihpromis.org

- Developed to improve the precision of evaluating Health Related Quality of Life (HRQoL) across multiple areas of physical, mental, and social health

- Tested mostly in research settings
- *Limited evaluation in clinical care settings*
- *Limited evaluation in specific disease states*

- Domains identified by RA patients are included in PROMIS

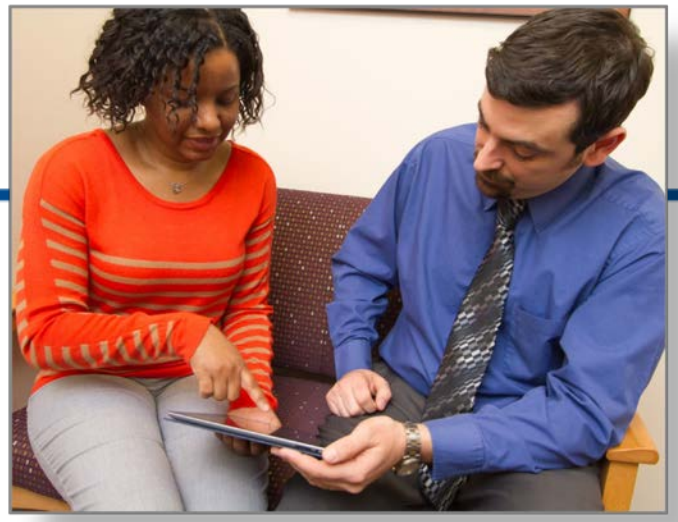
- Evaluation of PROMIS in RA has been limited to assessments of physical function
  - Addresses floor and ceiling effects of HAQ and SF12

PCORI Pilot Project Objectives

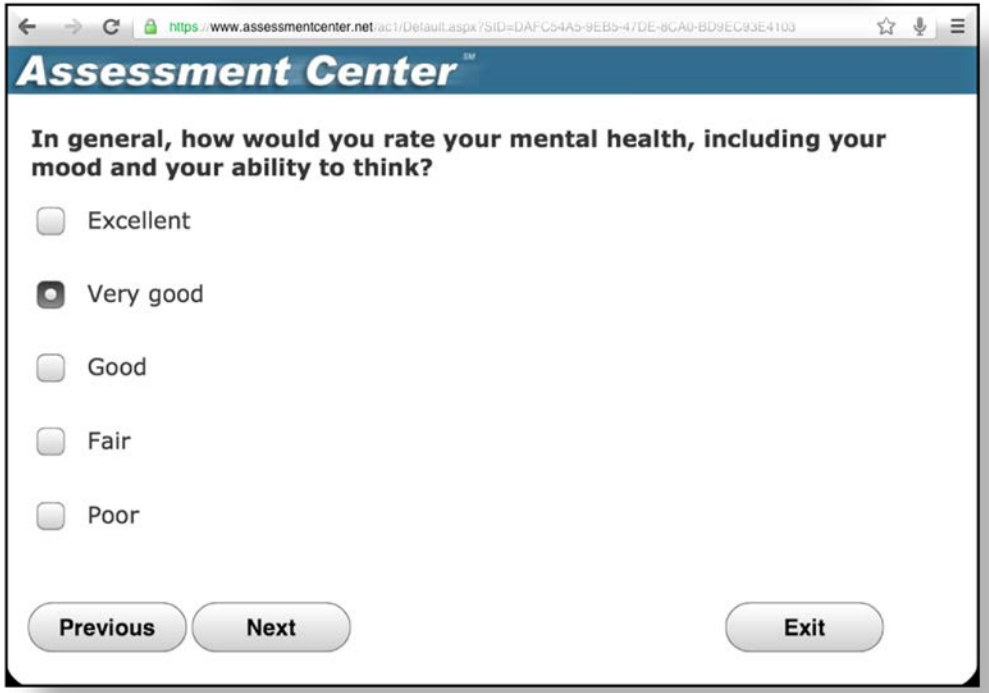
- **Hypothesis tested:**
  - Integrating PROs into routine care will improve the assessment of patient-valued symptoms and influence medical decision-making

- **Objective:**
  - To evaluate the feasibility and impact of integrating PROMIS® in RA patients seen in a busy clinical practice setting
    - Acceptability to Patients and Providers
    - Integration within Practice Workflow
    - Patient-Care Team Interactions
    - Shared Decision-Making
    - Validity and Responsiveness of PROMIS measures

Research Methods (1)

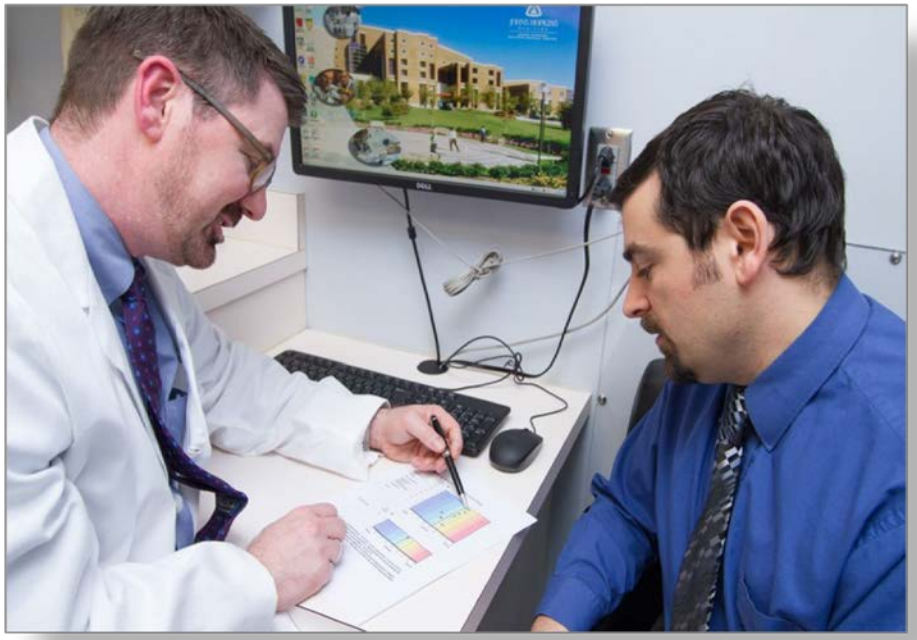


- People with RA seen in routine clinical care are eligible
- Assessment Center programmed with PROMIS instruments and legacy measures
- In waiting room, patient given an iPAD linked to online AC module
- PROMIS SFs, CATs, and other measures completed



Research Methods (2)

- Routine clinic visit with provider takes place
- Review/discussion of PROMIS results
- Patient and provider rate “value” of information, and impact on clinical decision-making (survey)
- Interviews and focus groups with patients, providers, clinic and research staff



Mixed Methods Analytic Approach

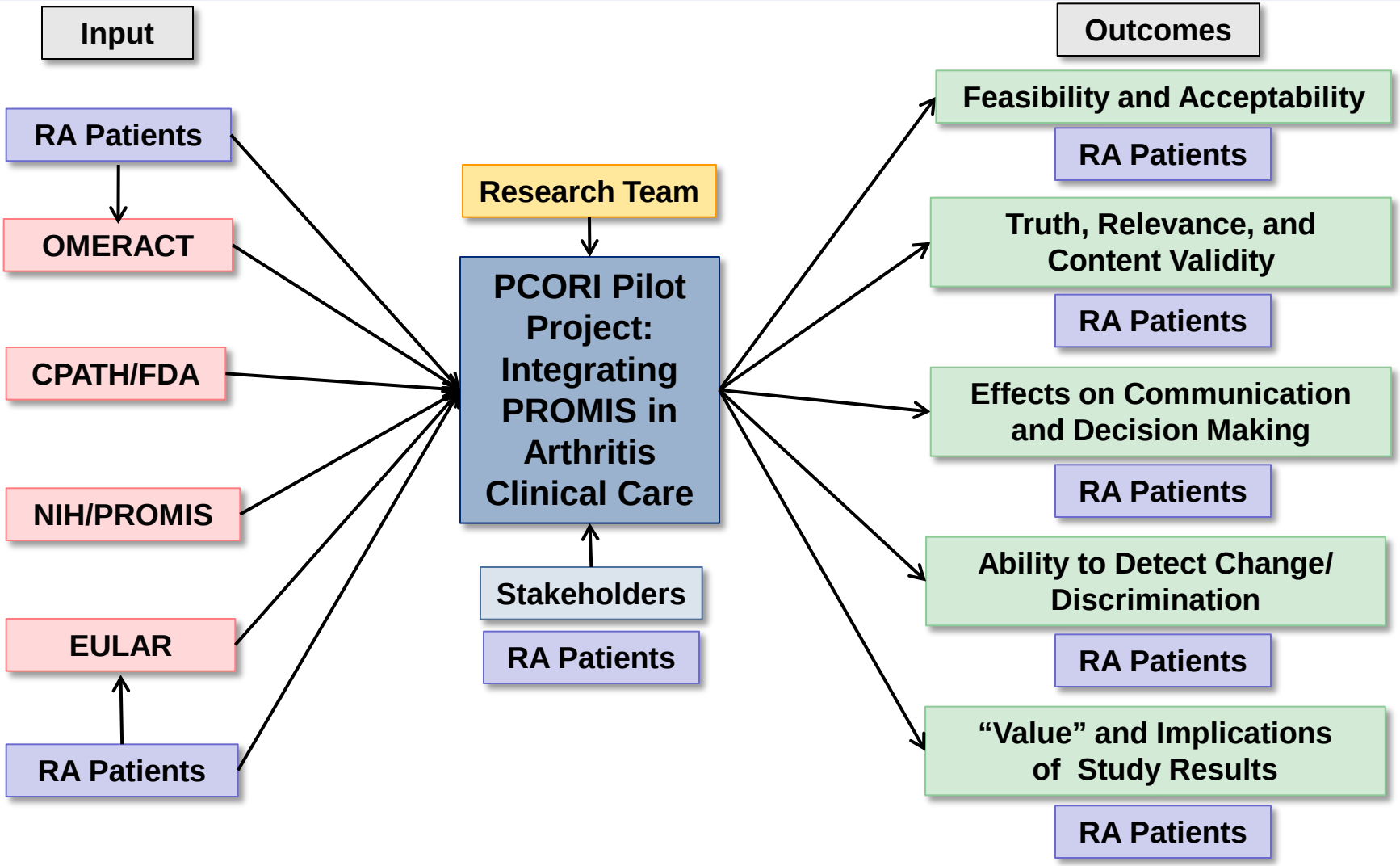
- Qualitative (Surveys, Interviews, Focus Groups)
  - Patients
  - Providers
  - Clinic Staff
  - Research Staff
  - Stakeholders
- Quantitative
  - PROMIS Data
  - “Legacy” PROs
  - Standard Clinical Outcomes
  - Validation

Selection of Domains

Patient Identified Domain	Legacy Measure	PROMIS SF, Scale or Score	PROMIS Item	PROMIS CAT
Global Assessment	VAS	Global 1.1	G1, G2	
Pain	VAS	Pain Intensity 3a	G7	Pain Interference
Physical Function	MHAQ	Global Physical Score	G6, G3	Physical Function
Participation	None		G9r G5	Participation Satisfaction
Fatigue	VAS	Fatigue	G8	Fatigue
Systemic Features	Global VAS		G1, G2	
Sleep	None			Sleep Disturbance Sleep Interference
Emotional Distress	None	Global Mental Score	G4, G10	Depression Anxiety Anger

Other Measures: Patient assessed disease change, Minimal important difference, Patient acceptable symptom state, Flare assessment, Stiffness, Self-management

Multilevel Mixed Methods Approach with Patient Incorporation throughout Research Process



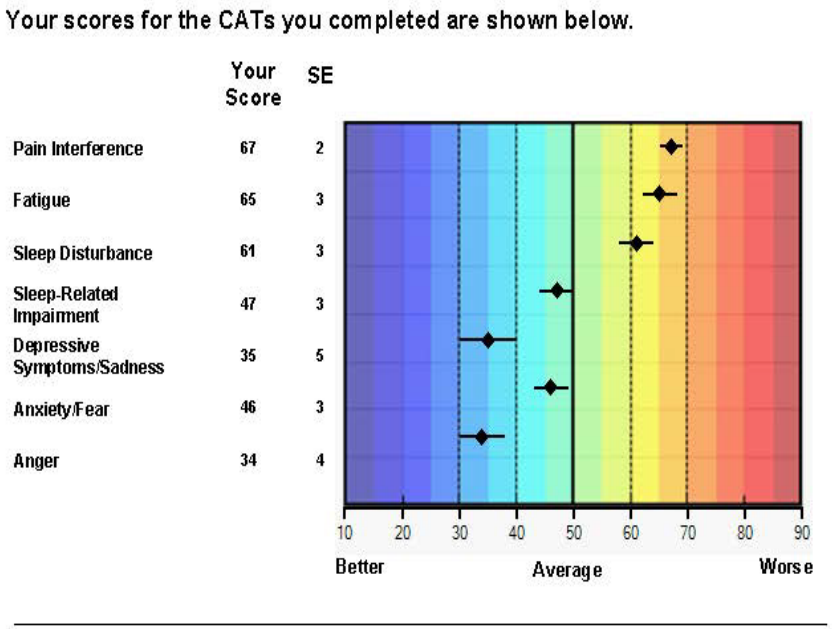
Preliminary Results
PROMIS In Clinic: Feasibility

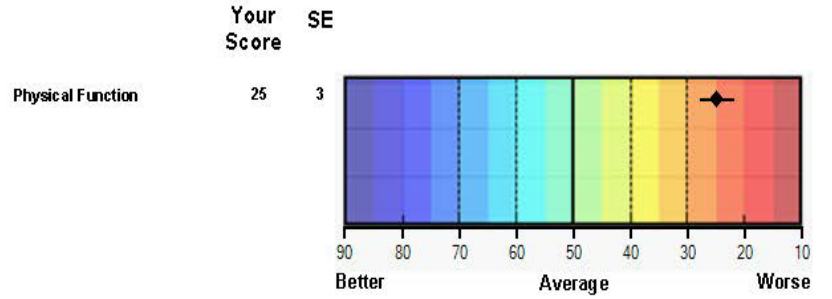
- 12 PROMIS Instruments Administered:
  - Global health, Pain (Intensity, Interference), Fatigue, Physical function, Sleep (Disturbance, Interference), Depression, Anxiety, Cognition general concerns, Social roles (Participation, Satisfaction)

(n=107)	Mean	SD	Median	Min	Max
Time to Complete (minutes)	12.1	4.5	10.8	5.7	32
Number of Questions	67.8	9.5	65.0	58	98

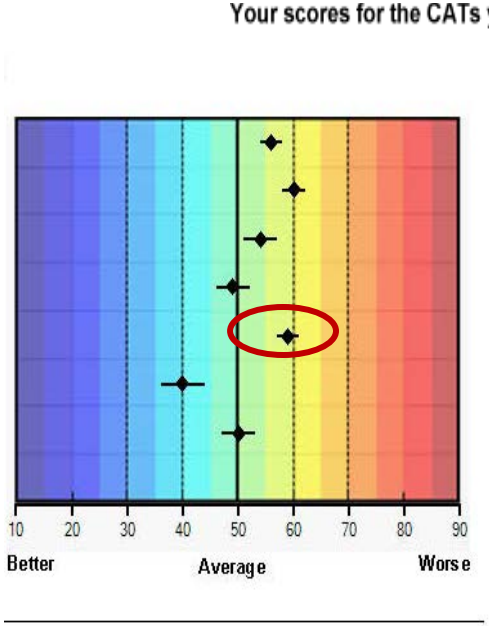
- Time for completion includes clinic interruptions (moving to rooms, vital signs, etc.)
- Interviews ongoing with patients, providers, and clinic staff to determine effect on clinic flow

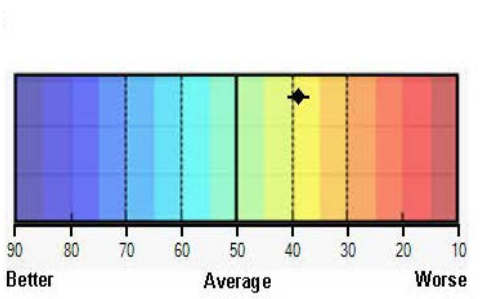
Example PROMIS Reports



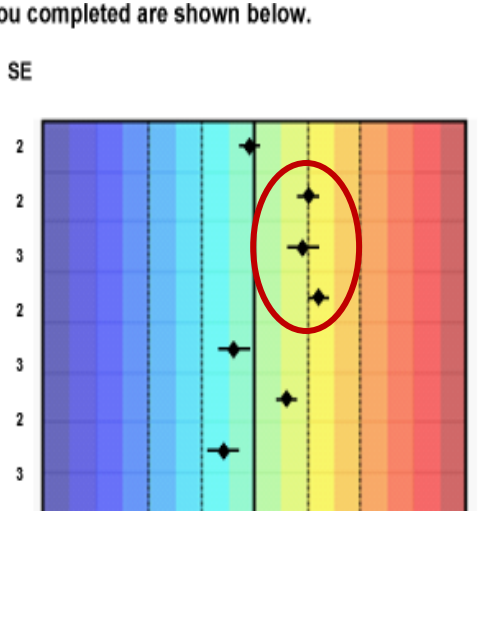


Active RA





Mild RA
Breakup w/ Sig Other



RA in Remission
Poor Sleep 2º Sinus Surgery

Preliminary Observations: Clinical Decision-Making

- New comorbidities and symptoms have been identified by PROMIS measures that did not surface during the usual clinical encounter
  - E.g., fatigue, sleep, depression, anxiety
- Some of these resulted in changes in RA therapy to address symptoms, referrals for evaluation of symptoms, and/or treatment of comorbidities

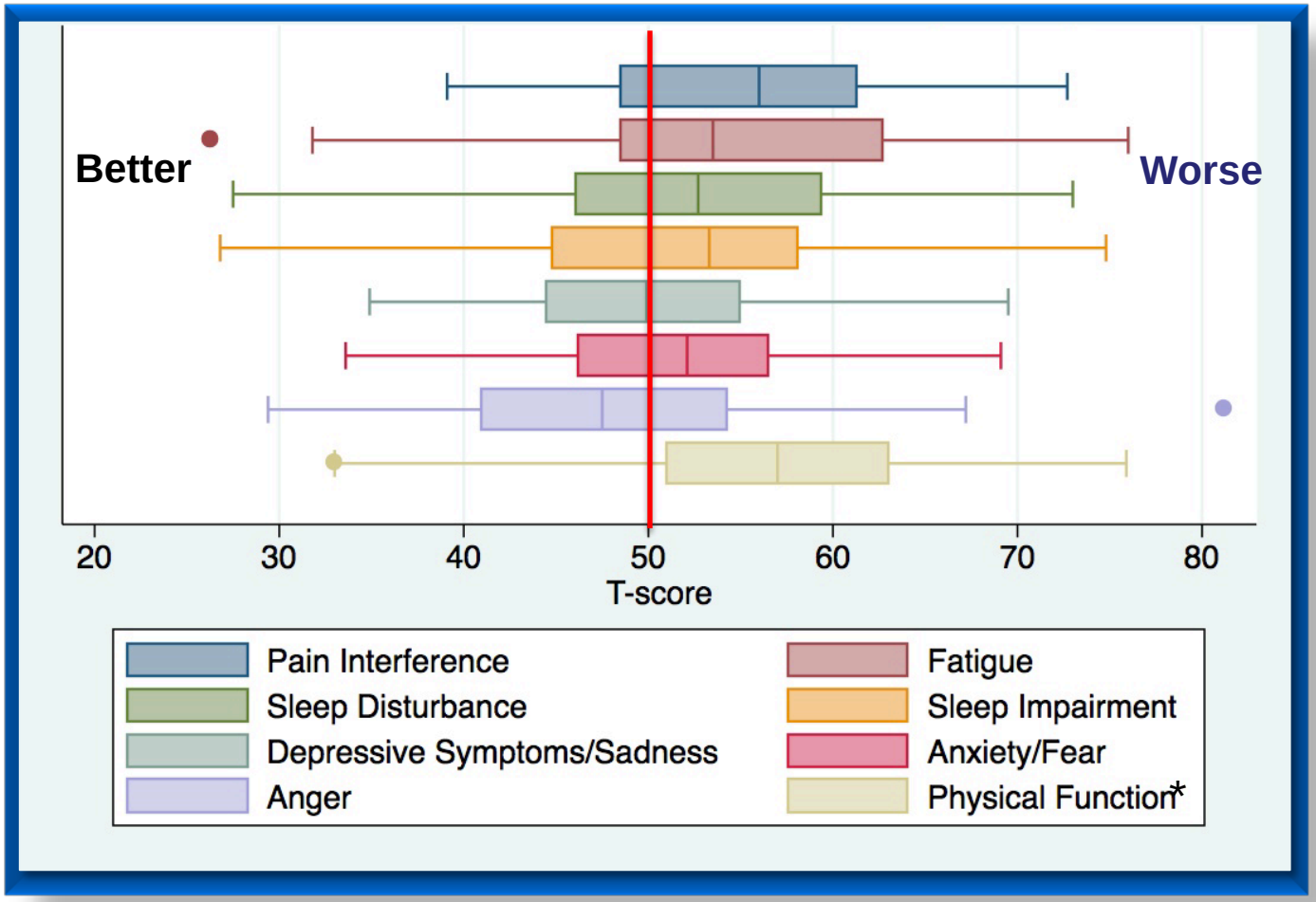
Participant Characteristics (n=107)

Variable	Value	Range
Sociodemographic		
Age (yrs.)	55.5 ± 13.0	22-85
Sex (% female)	53 (77%)	
Minority race (%)	17 (16%)	
Completed some college	74%	
RA Characteristics		
Disease duration (yrs.)	12.0 ± 9.3	1-41
CDAI	8.8 ± 8.7	0-33.5
MD Global Assessment (VAS)	15.7 ± 17.1	0-75
Patient Reported Outcomes		
Patient Global (VAS)	29.8 ± 26.6	
Pain (VAS)	33.2 ± 28.6	
MHAQ (0-3)	0.3 ± 0.4	

Values are mean ± SD, unless otherwise indicated

Bartlett SJ, Orbai AM, Duncan T, DeLeon E Bingham CO. Validity of PROMIS® CATs, Short Forms and Global Health Items in Rheumatoid Arthritis. *Qual Life Res* 2013; 22(Supp 1) 119: Abstract 3024

Preliminary Results
Distribution of Selected PROMIS CAT T-Scores in RA Patients (n=107)



*Scores inverted for demonstration

Regression coefficient, effect sizes and mean scores by CDAI disease activity level for legacy and PROMIS measures: Global and General Health

Variable	Source	B	Effect Size (β/SE)	Remission N=29	Low N=45	Moderate N=21	High N=12
Patient Global	VAS	17.8	8.4	5.5 + 6.5[a]	29.6 + 23.2[b]	50.0 + 21.4[c]	53.4 + 27.8[c]
MD Global	VAS	13.2	11.1	3.4 + 3.8[a]	10.9 + 9.5[b]	26.9 + 13.0[c]	43.8 + 22.6[d]
PROMIS Global Physical	Score	-5.6	-7.4	53.8 ± 6.9[a]	44.1 ± 8.2[b]	39.2 ± 5.6[c]	38.4 ± 6.3[c]
PROMIS Global Mental	Score	-3.1	-3.6	54.7 ± 8.1[a]	48.2 ± 8.2[b]	48.6 8.2[b]	44.1 ± 8.6[b]

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Regression coefficient, effect sizes and mean scores by CDAI disease activity level for legacy and PROMIS measures: Pain, Fatigue, and Physical Function

Variable	Source	B	Effect Size (β/SE)	Remission N=29	Low N=45	Moderate N=21	High N=12
Pain	VAS	17.6	7.4	6.2 ± 8.2[a]	35.7 ± 25.3[b]	54.1 ± 26.8[c]	52.4 ± 25.7[c]
PROMIS Pain Intensity	SF	4.1	5.7	38.4 ± 7.3[a]	46.3 ± 6.4[b]	48.7 ± 6.6[b]	50.3 ± 8.4[b]
PROMIS Pain Interfere	CAT	4.9	5.8	46.6 ± 7.9[a]	55.4 ± 8.4[b]	59.2 ± 4.7[b]	60.1 ± 10.7[b]
Fatigue	VAS	16.8	6.2	13.4 ± 18.1[a]	45.1± 28.3[b,c]	59.0 ± 28.3[c]	58.9 ± 25.7[c]
PROMIS Fatigue	SF	4.1	5.1	46.8 ± 7.1[a]	54.7 ± 9.1[b]	58.0 ± 5.2[b]	58.1 ± 8.1[b]
PROMIS Fatigue	CAT	5.6	6.2	46.2 ± 8.8[a]	55.3 ± 8.7[b]	60.0 ± 6.8[c]	62.0 ± 11.3[c]
mHAQ*	Scale	.2	5.2	0.1 ± 0.4[a]	0.3 ± 0.3[a]	0.5 ± 0.4[b]	0.7 ± 0.6[b]
PROMIS PF	CAT	-5.2	-6.7	50.4 ± 9.0[a]	43.0 ± 7.5[b]	38.7 ± 5.6[c]	35.2 ± 7.1[c]
PROMIS Anxiety	CAT	2.2	2.6	48.0 ± 7.5[a]	52.0 ± 9.1[b]	51.9 ± 7.3[a,b]	55.6 ± 8.2[b]

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Regression coefficient, effect sizes and mean scores by CDAI disease activity level for PROMIS measures: Emotional and Social Health

Variable	Source	B	Effect Size (β/SE)	Remission N=29	Low N=45	Moderate N=21	High N=12
PROMIS Anxiety	CAT	2.2	2.6	48.0 ± 7.5[a]	52.0 ± 9.1[b]	51.9 ± 7.3[a,b]	55.6 ± 8.2[b]
PROMIS Depression	CAT	2.4	2.6	47.1 ± 8.2[a]	49.5 ± 9.3[a]	51.5 ± 9.1[a]	54.4 ± 9.1[b]
PROMIS Anger	CAT	2.0	2.1	45.2 ± 8.4	46.8 ± 9.7	49.5 ± 11.1	51.1 ± 8.9
PROMIS Participation	CAT	-4.9	-5.9	55.9 ± 9.3[a]	50.0 ± 8.4[b]	46.2 ± 6.3[b]	40.7 ± 8.6[b,c]
PROMIS Satisfaction	CAT	-5.0	-5.2	55.3 ± 10.0[a]	47.3 ± 10.1[b]	44.6 ± 6.8[b,c]	39.8 ± 9.3[c]

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Conclusions

- Our preliminary data suggest that the integration of PROMIS CATs and short forms is possible within clinical care settings
- The immediate availability of results allows for evaluation and discussion with patients at the time of the clinic visit
- Our preliminary assessments indicate that PROMIS measures demonstrate considerable impact of RA across multiple areas of HRQL

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