Patient Reported Outcome Measures - PROMs Moderation: **Dr. Heidemarie Haeske-Seeberg,** Bereichsleiterin Qualitätsmanagement und klinisches Risikomanagement der Sana Kliniken AG **Prof. Lutz Fritsche,** Vorstand Medizin der Johannesstift Diakonie	Saal Berlin 2	**PROM-Fragebögen - was macht Sinn?** **PROM bei IQM** **PROM Realität werden lassen** **Erfahrungen mit PROMs/Chancen und Herausforderungen**	**Prof. Matthias Rose,** Direktor Med. Klinik m.S. Psychosomatik der Charité **Prof. Lutz Fritsche,** Vorstand Medizin der Johannesstift Diakonie **Dr. Valerie Kirchberger,** Chief Medical Officer der HRTBT Medical Solutions GmbH **Dr. Florian Rüter,** Leiter Qualitätsmanagement und Value Based Healthcare des Universitätsspitals Basel

PRO-Fragebögen – Was macht Sinn?

5. QMR-Kongress
Versorgungsqualität gestalten
Mai 2022

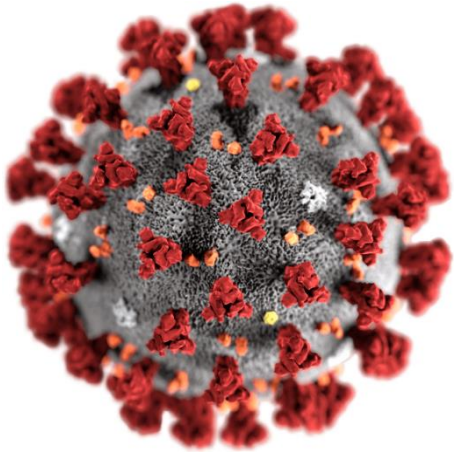
Matthias Rose

Department of Psychosomatic Medicine
Center for Internal Medicine and Dermatology
Charité Universitätsmedizin Berlin, Germany

www.patient-centered-outcomes-research.org

Treatment

Disease

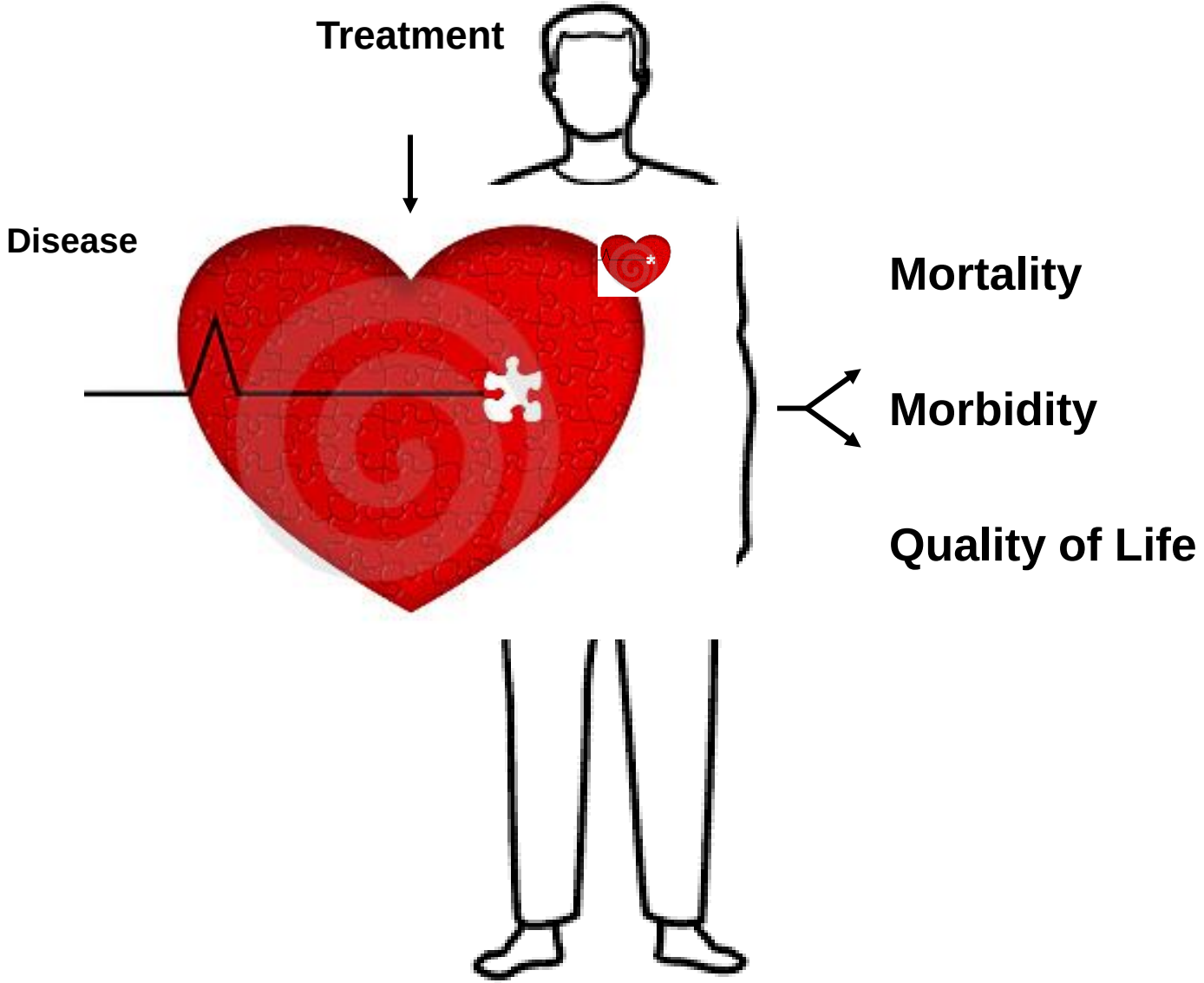


Mortality

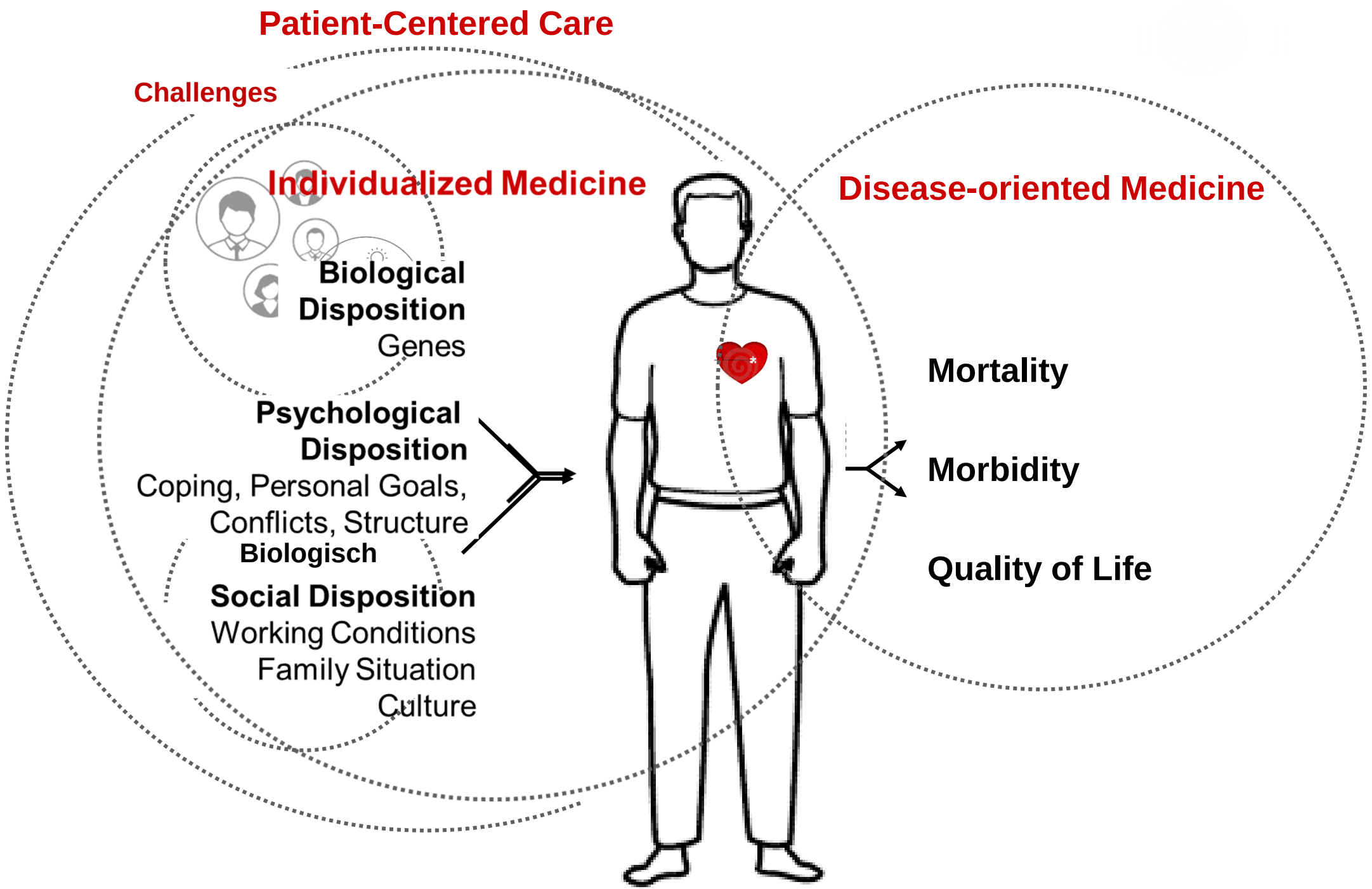
Morbidity

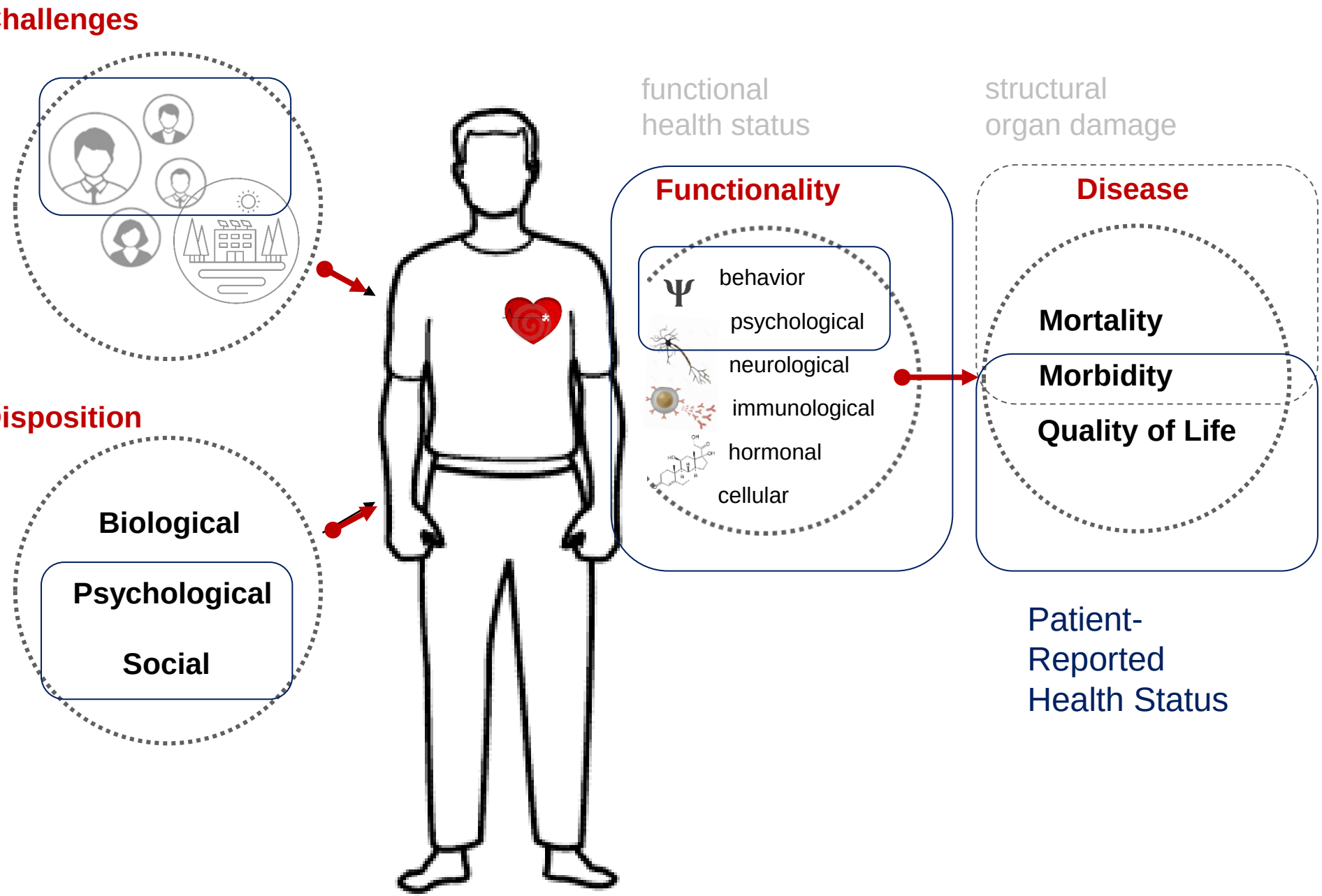
Quality of Life

Treatment Goals German Law
SGB V §35

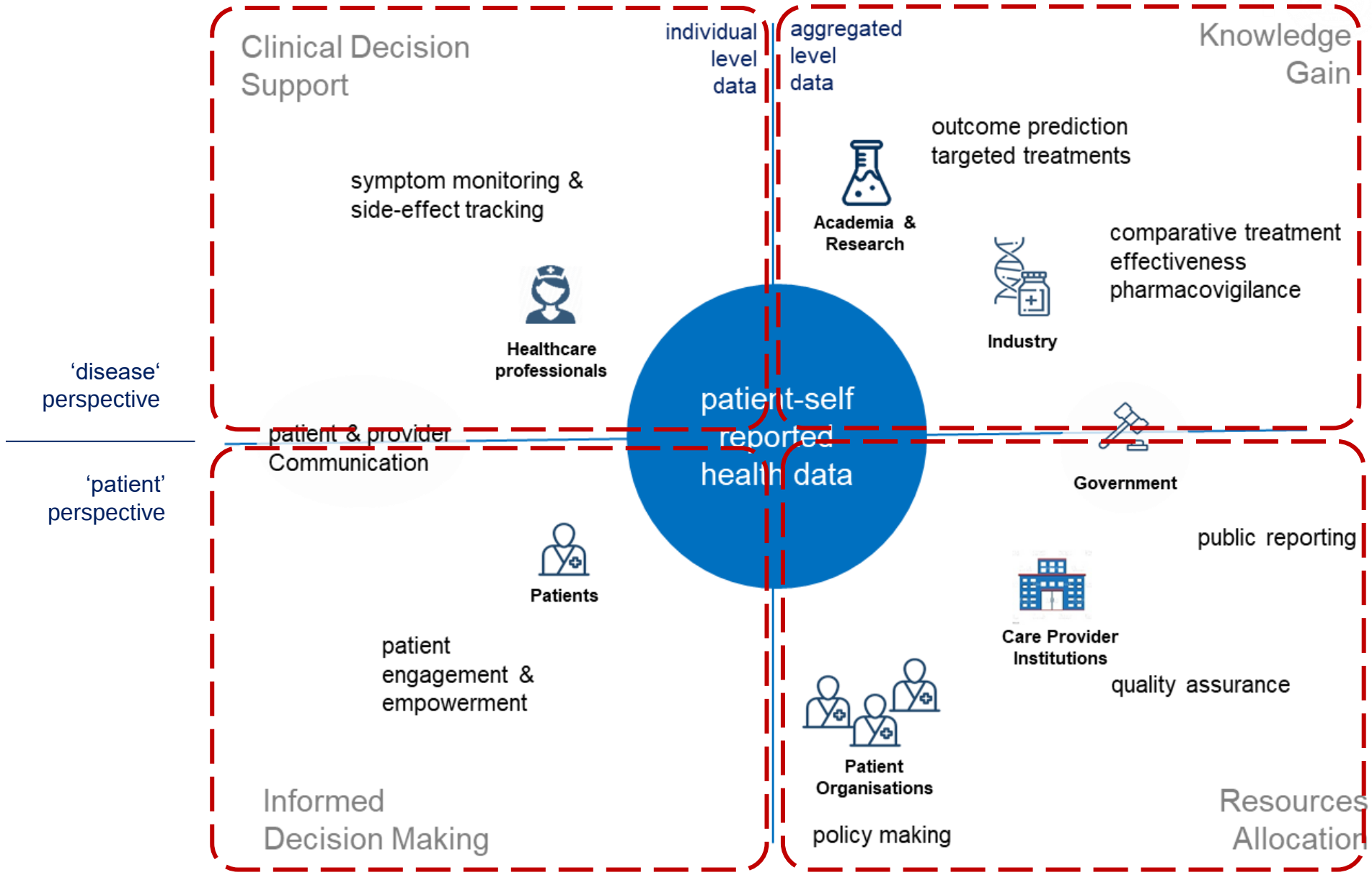


Treatment Goals German Law
SGB V §35

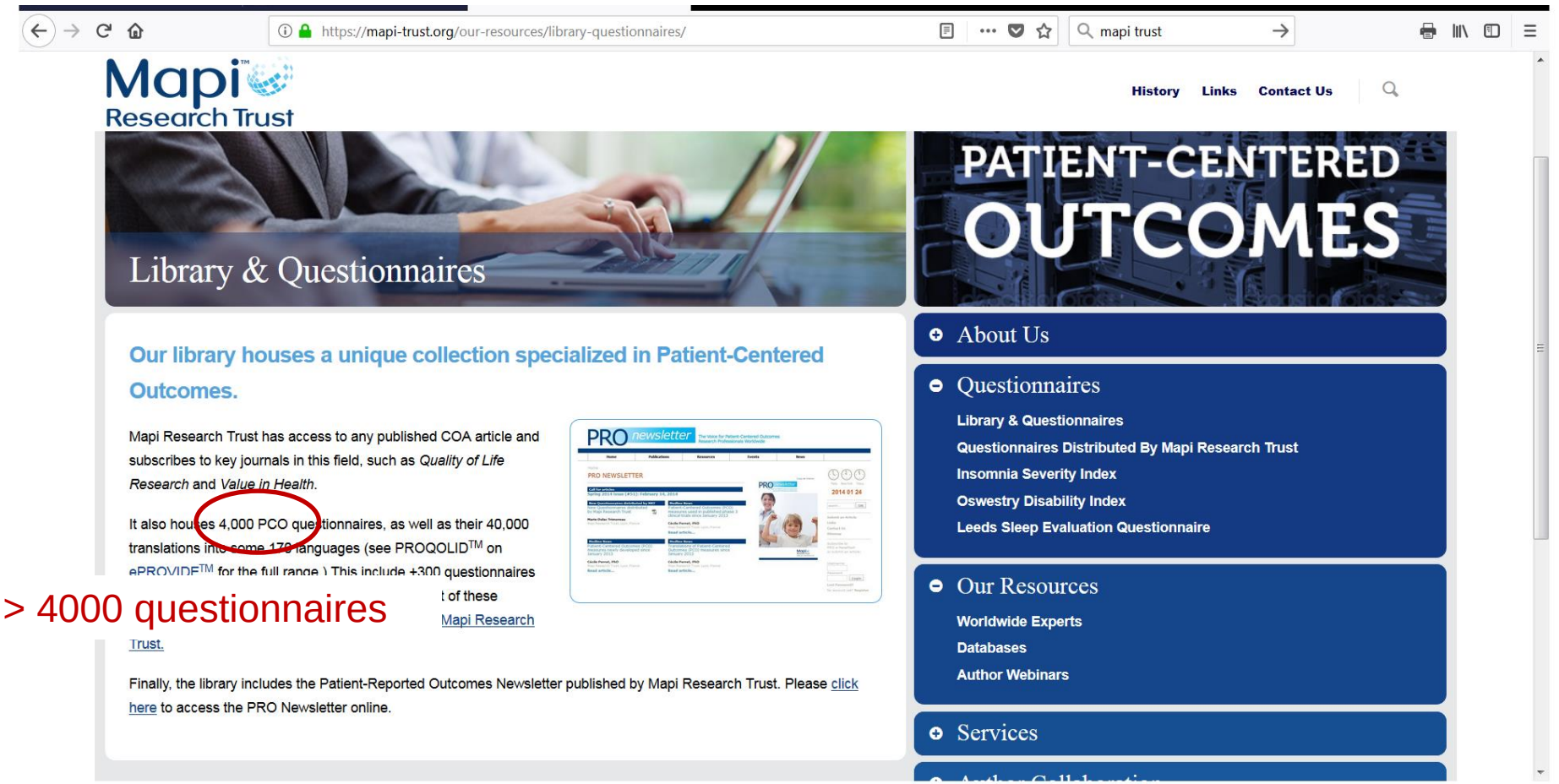

Patient-Centered Care
Challenges
Individualized Medicine
Disease-oriented Medicine
Biological Disposition
Genes
Psychological Disposition
Coping, Personal Goals, Conflicts, Structure
Biologisch
Social Disposition
Working Conditions
Family Situation
Culture
Mortality
Morbidity
Quality of Life


Challenges
Disposition
Biological
Psychological
Social
functional
health status
Functionality
behavior
psychological
neurological
immunological
hormonal
cellular
structural
organ damage
Disease
Mortality
Morbidity
Quality of Life
Patient-
Reported
Health Status

WHO ARE THE **STAKEHOLDERS** ?


Clinical Decision Support
individual level data
aggregated level data
Knowledge Gain
symptom monitoring & side-effect tracking
outcome prediction targeted treatments
Academia & Research
comparative treatment effectiveness pharmacovigilance
Industry
Healthcare professionals
'disease' perspective
patient-self reported health data
patient & provider Communication
'patient' perspective
Government
public reporting
Patients
Care Provider Institutions
patient engagement & empowerment
quality assurance
Patient Organisations
policy making
Informed Decision Making
Resources Allocation

Reality



> 4000 questionnaires

almost al of them are made for scientific use ….

WHAT ARE THE **CHALLENGES** ?

Challenges

I Construct Definition

II Precision

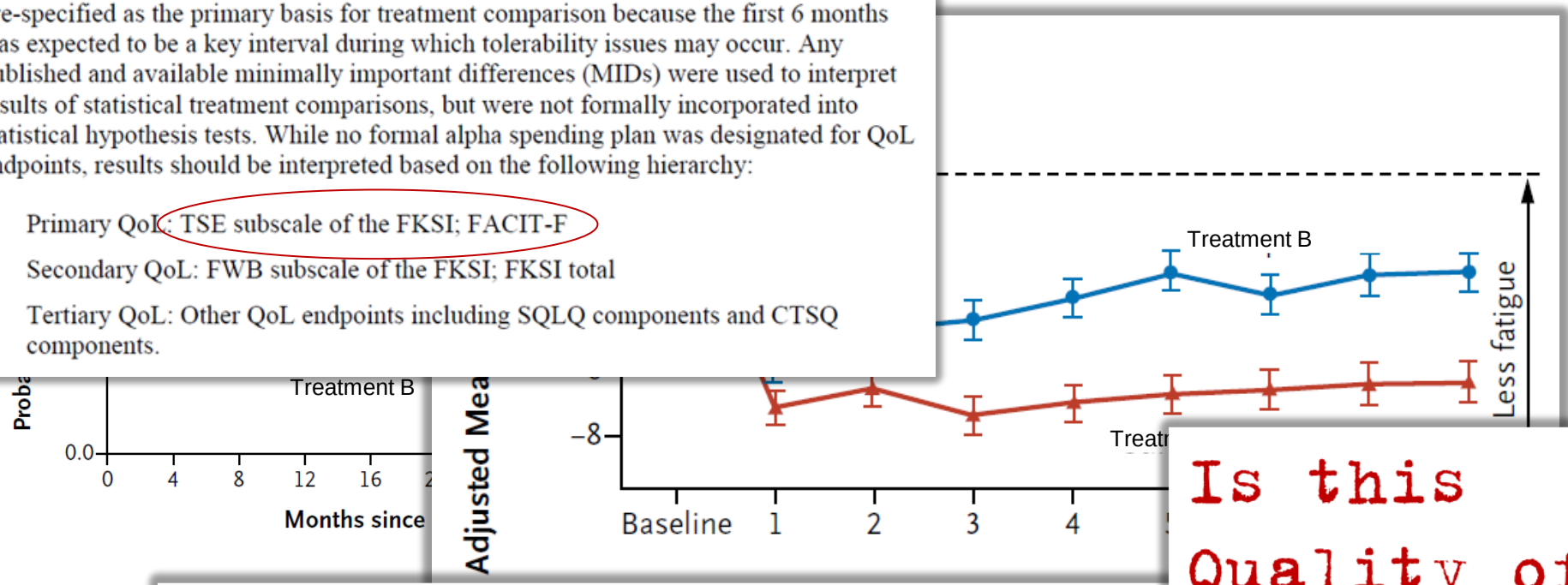
III Standardization

Example

4.8.7. Health Outcomes Study Protocol

Health-Related Quality of Life changes in mean scores over time were analyzed with a repeated measures analysis of covariance. The results from Cycles 1-4 were pre-specified as the primary basis for treatment comparison because the first 6 months was expected to be a key interval during which tolerability issues may occur. Any published and available minimally important differences (MIDs) were used to interpret results of statistical treatment comparisons, but were not formally incorporated into statistical hypothesis tests. While no formal alpha spending plan was designated for QoL endpoints, results should be interpreted based on the following hierarchy:

- Primary QoL: TSE subscale of the FKSI; FACIT-F
- Secondary QoL: FWB subscale of the FKSI; FKSI total
- Tertiary QoL: Other QoL endpoints including SQLQ components and CTSQ components.



Is this Quality of Life?

CONCLUSIONS The NEW ENGLAND JOURNAL of M

Treatment A and *Treatment B* have similar efficacy, but the safety and quality-of-life profiles favor *Treatment B*

2013

Specific vs Generic

FACIT Fatigue

		Not at all	A little bit	Some-what	Quite a bit	Very much
HI7	I feel fatigued	0	1	2	3	4
HI12	I feel weak all over	0	1	2	3	4
An1	I feel listless ("washed out")	0	1	2	3	4
An2	I feel tired	0	1	2	3	4
An3	I have trouble starting things because I am tired	0	1	2	3	4
An4	I have trouble finishing things because I am tired	0	1	2	3	4

health domain
'latent trait'

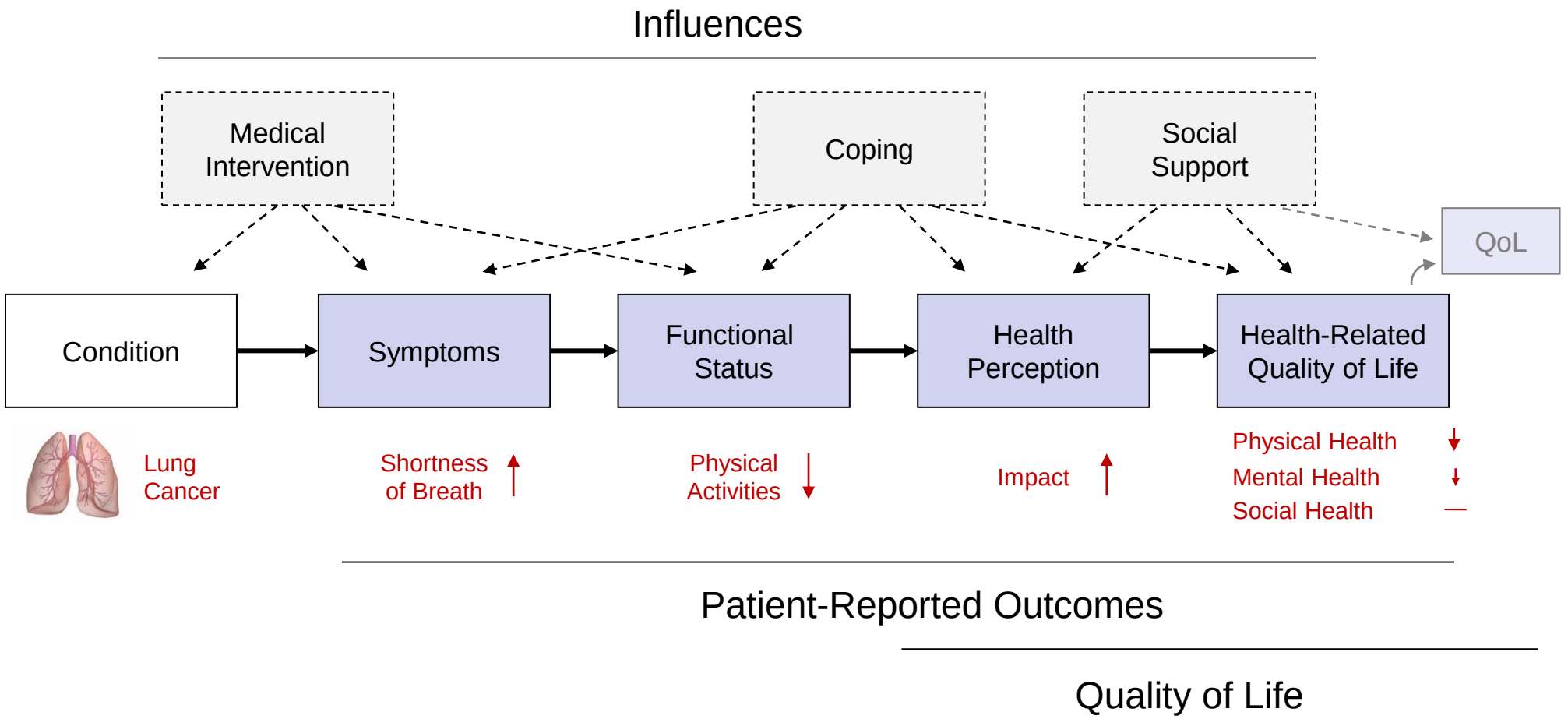
FKSI-TSE scale

		Not at all	A little bit	Some-what	Quite a bit	Very much
E						
	GP2 I have nausea	0	1	2	3	4
T	B5 I am bothered by hair loss	0	1	2	3	4
S	C3 I have control of my bowels	0	1	2	3	4
E	C5 I have diarrhea (diarrhoea)	0	1	2	3	4
	Cx6 I am bothered by constipation	0	1	2	3	4
	NTX 1 I have numbness or tingling in my hands	0	1	2	3	4
	NTX 10 I have pain in my hands or feet when I am exposed to cold temperatures	0	1	2	3	4
	GP5 I am bothered by side effects of treatment	0	1	2	3	4

compilation of distinct aspects
'composite score'

both are **NOT** Quality of Life !!

Conceptional Model



Wilson & Cleary JAMA 1995/2005

Challenges

I Construct Definition

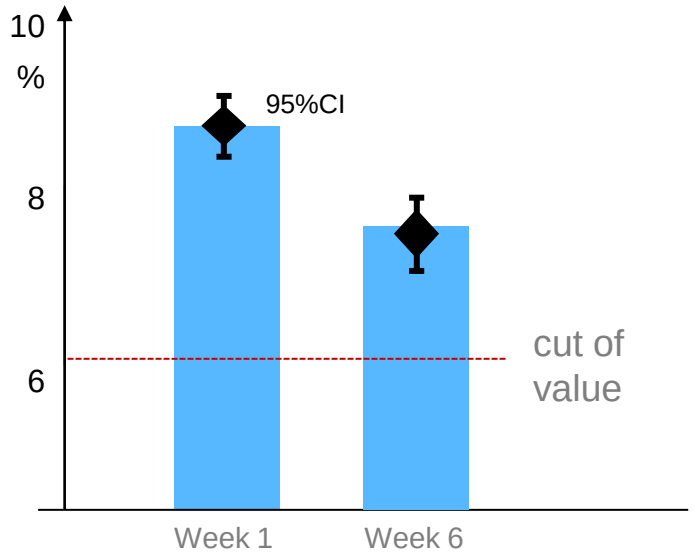
II Precision

III Standardization

Precision in Comparison

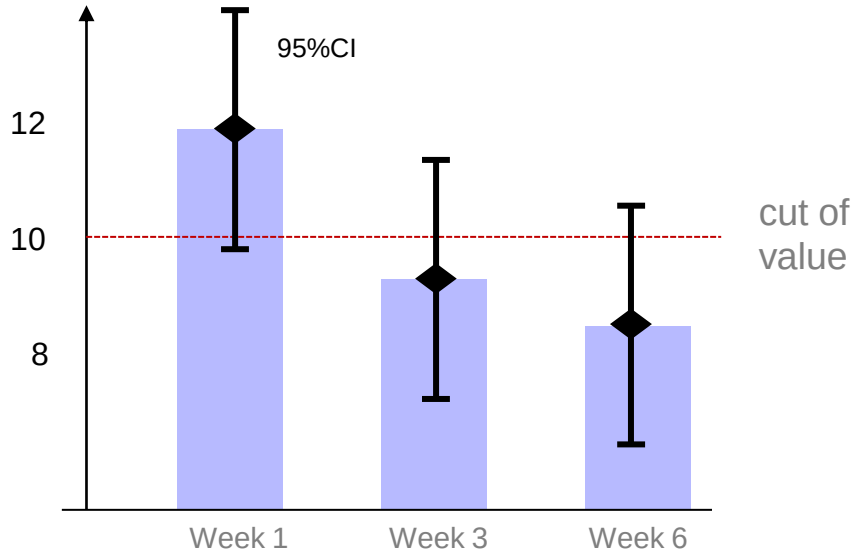
for clinical practice

HbA1c



HPCL Method (IFCC)

Depression



Hospital Anxiety and Depression Scale

Little et al. Clinical Chemistry 2011

Challenges

I Construct Definition

II Precision

III Standardization

Cornerstone Study

1985-1989

The Medical Outcomes Study

An Application of Methods for Monitoring the Results of Medical Care

Alvin R. Tarlov, MD; John E. Ware, Jr, PhD; Sheldon Greenfield, MD; Eugene C. Nelson, DSc; Edward Perrin, PhD; Michael Zubkoff, PhD

JAMA

Abstract

The Medical Outcomes Study was designed to (1) determine whether variations in patient outcomes are explained by differences in system of care, clinician specialty, and clinicians' technical and interpersonal styles and (2) develop more practical tools for the routine monitoring of patient outcomes in medical practice. Outcomes included clinical e... perceptions of their general... 523) were randomly sample... Calif. In the cross-sectional ... sample of these patients (n... selected for the longitudina... periodically reported outcor... Study staff performed physical examinations and laboratory tests. Results will be reported serially, primarily in THE JOURNAL.

(*JAMA*. 1989;262:925-930)

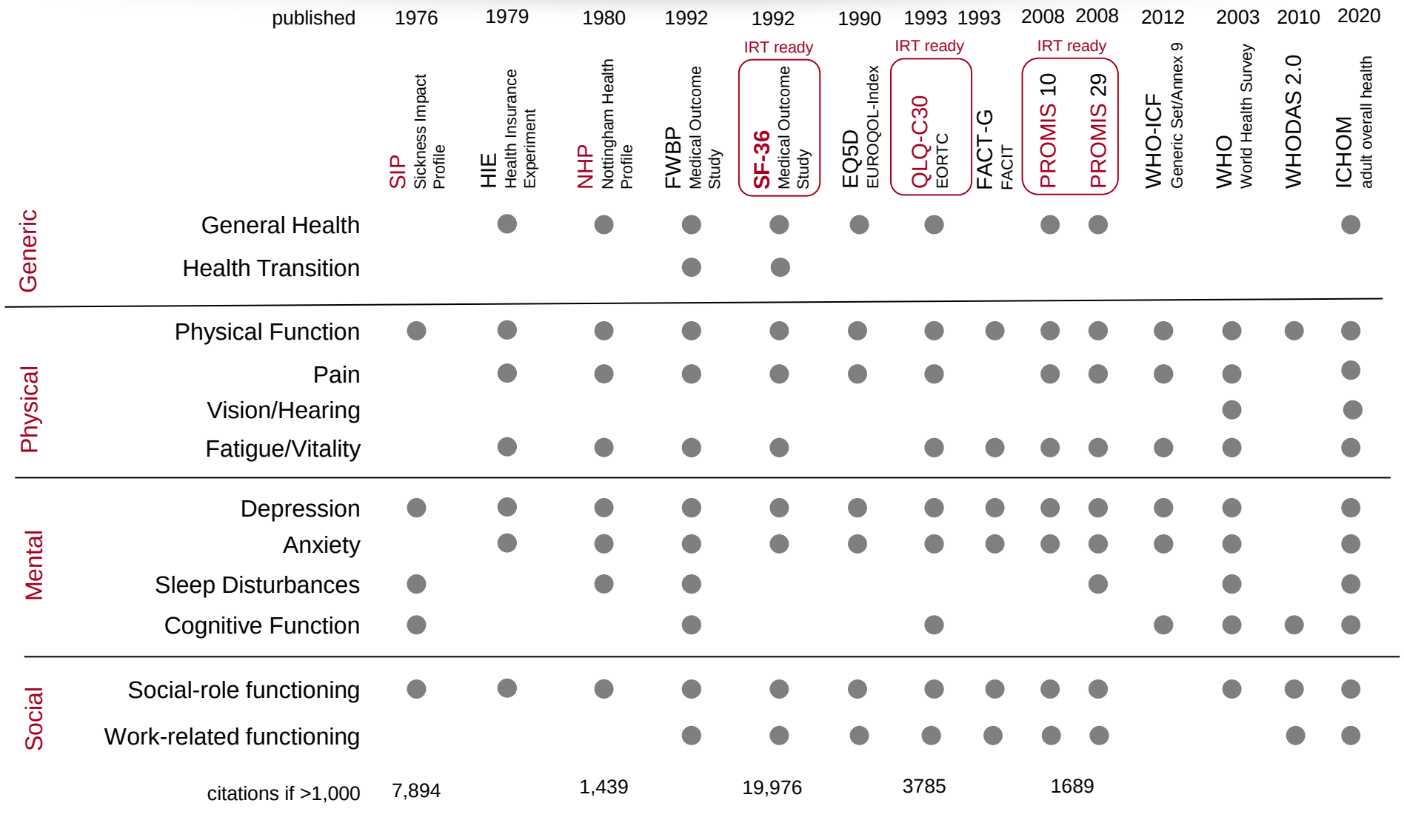
Can patient's outcomes be explained by differences in the

different reimbursement systems, health care provider characteristics, or interpersonal style ?

22,462 patients with chronic conditions cross-sectional subsample of n=2,349 with a two-year follow-up

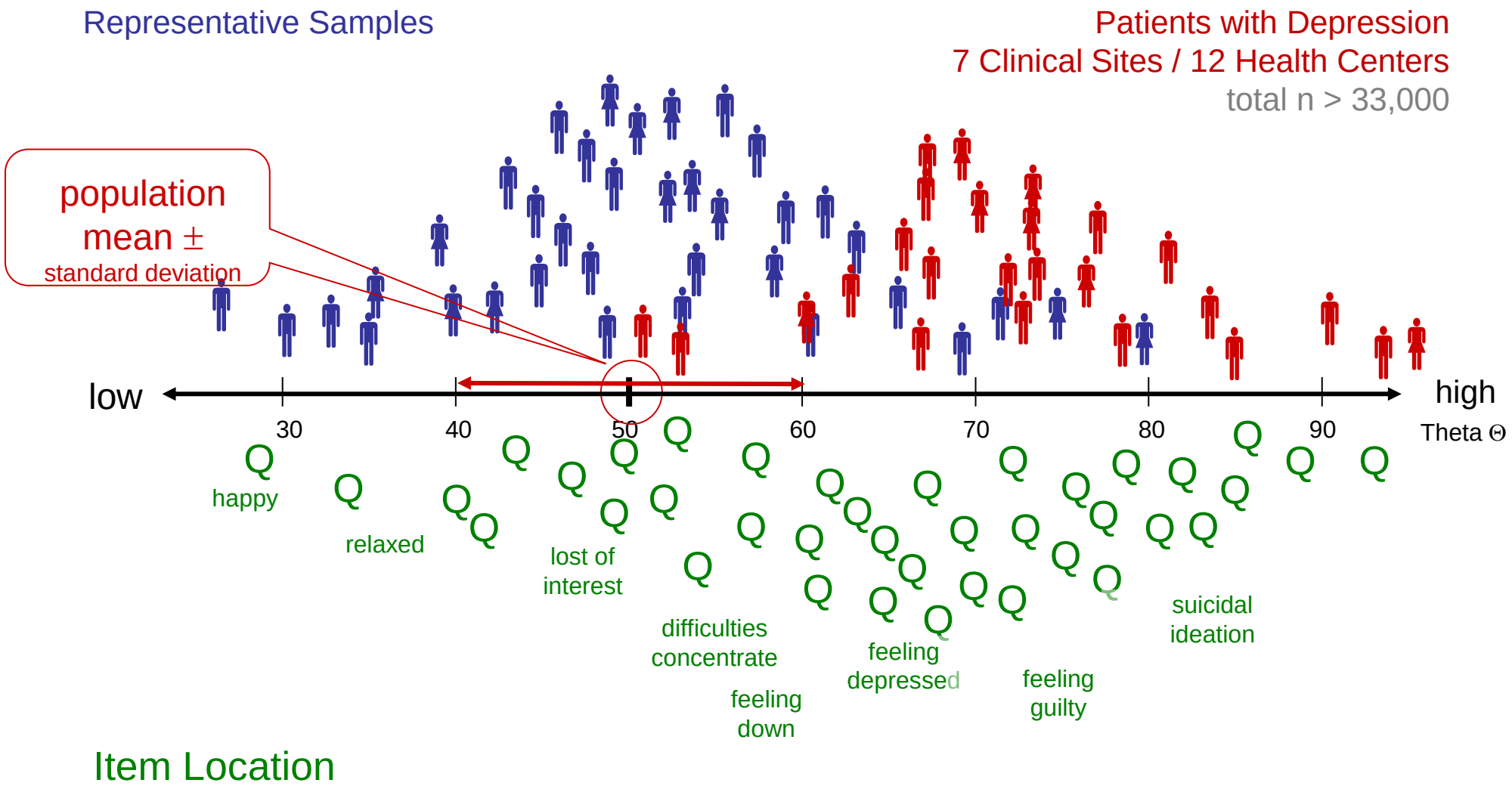
diabetes,
hypertension,
coronary heart disease
depression

Health Status Assessments



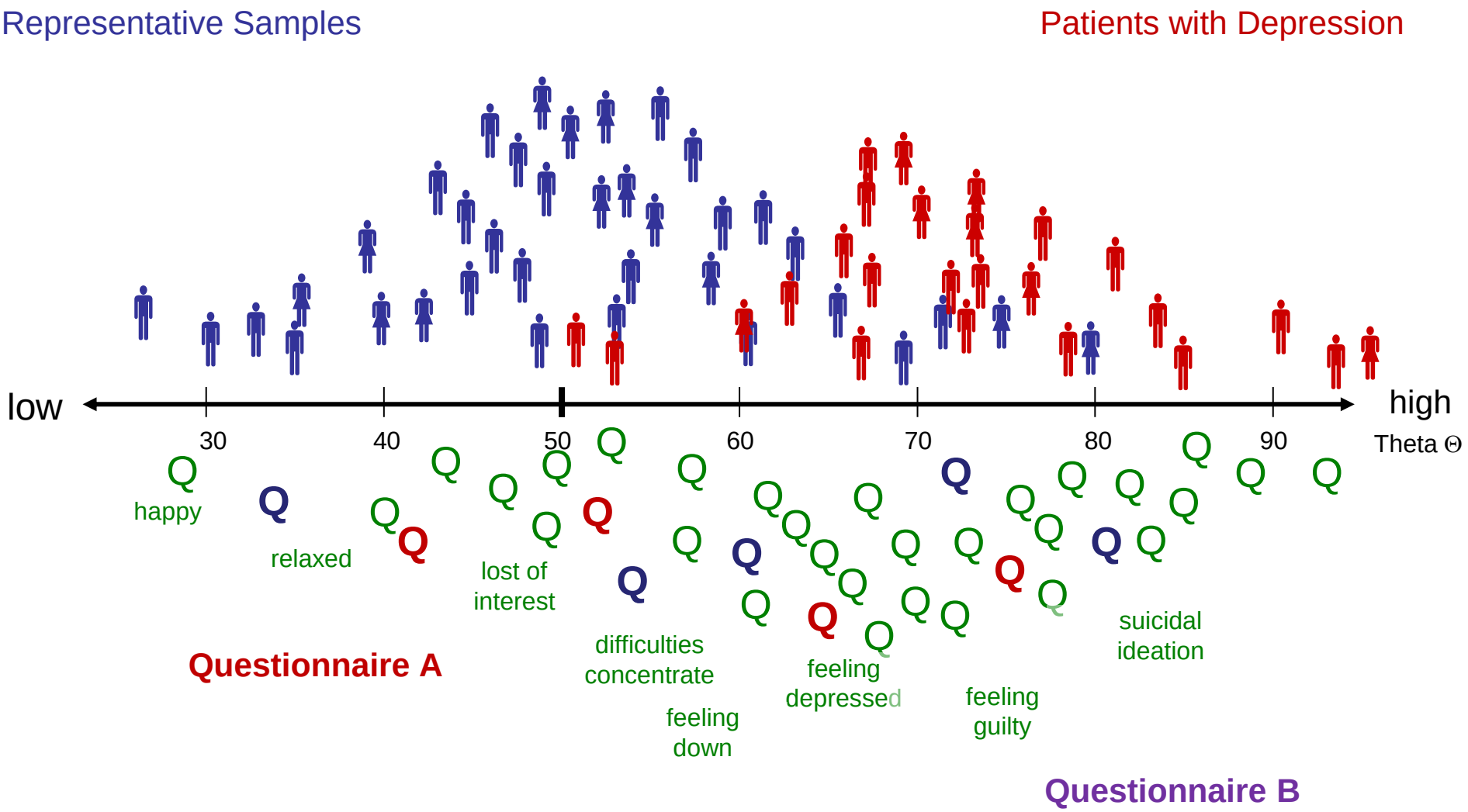
IS THERE **HOPE** ?

Item Bank - Depression



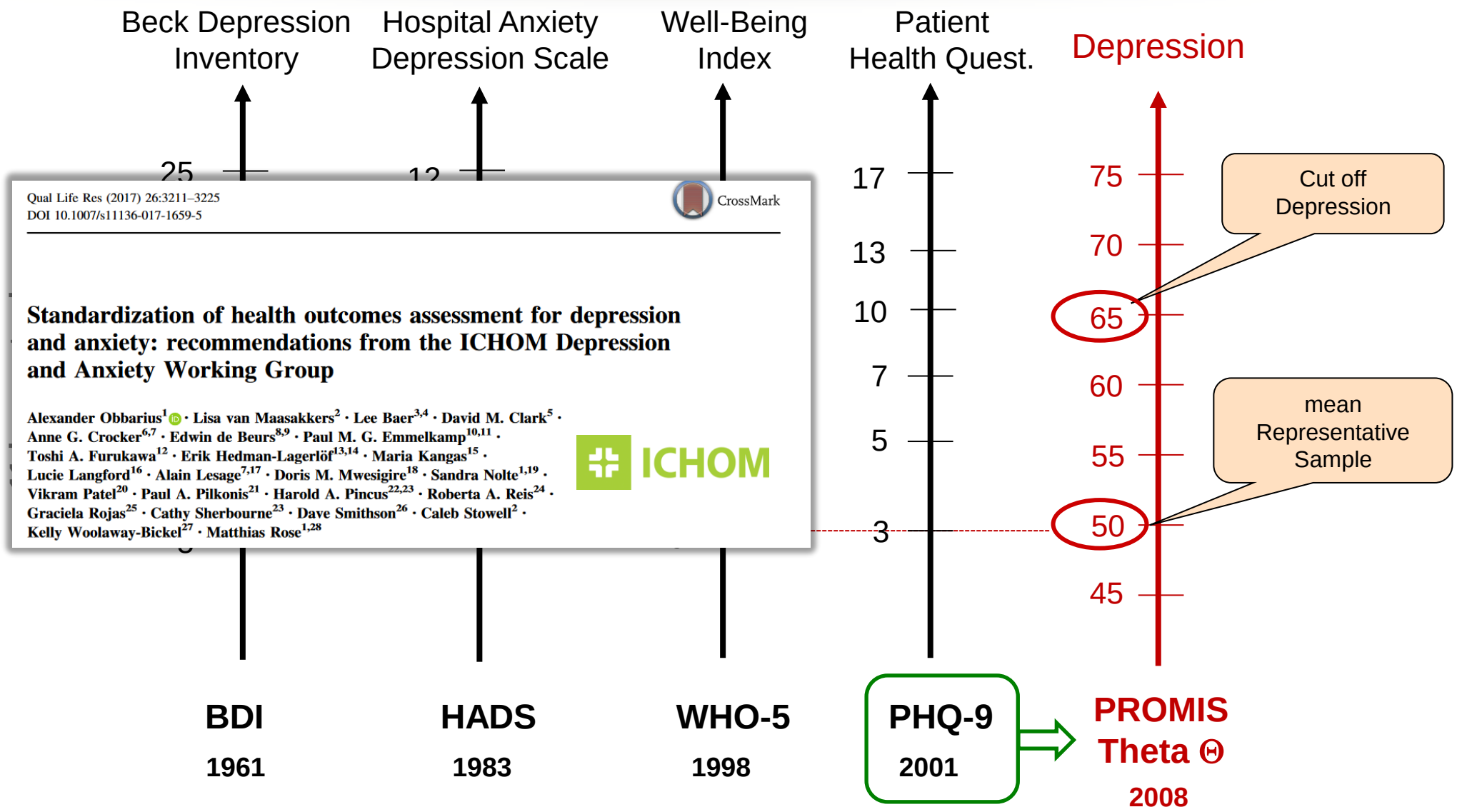
Wahl et al. J Clin Epi 2014

Item Bank - Depression



Wahl et al. J Clin Epi 2014

Common Metric



Qual Life Res (2017) 26:3211–3225
DOI 10.1007/s11136-017-1659-5

CrossMark

Standardization of health outcomes assessment for depression and anxiety: recommendations from the ICHOM Depression and Anxiety Working Group

Alexander Obbarius[1] · Lisa van Maasakkers[2] · Lee Baer[3,4] · David M. Clark[5] · Anne G. Crocker[6,7] · Edwin de Beurs[8,9] · Paul M. G. Emmelkamp[10,11] · Toshi A. Furukawa[12] · Erik Hedman-Lagerlöf[13,14] · Maria Kangas[15] · Lucie Langford[16] · Alain Lesage[7,17] · Doris M. Mwesigire[18] · Sandra Nolte[1,19] · Vikram Patel[20] · Paul A. Pilkonis[21] · Harold A. Pincus[22,23] · Roberta A. Reis[24] · Graciela Rojas[25] · Cathy Sherbourne[23] · Dave Smithson[26] · Caleb Stowell[2] · Kelly Woolaway-Bickel[27] · Matthias Rose[1,28]

ICHOM

Standardized Metric

Mercury

1953

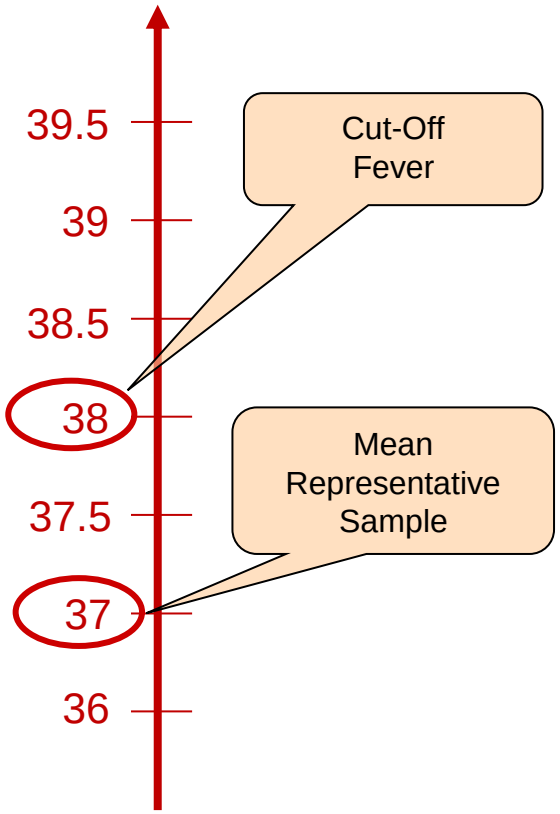
Quartz

1982

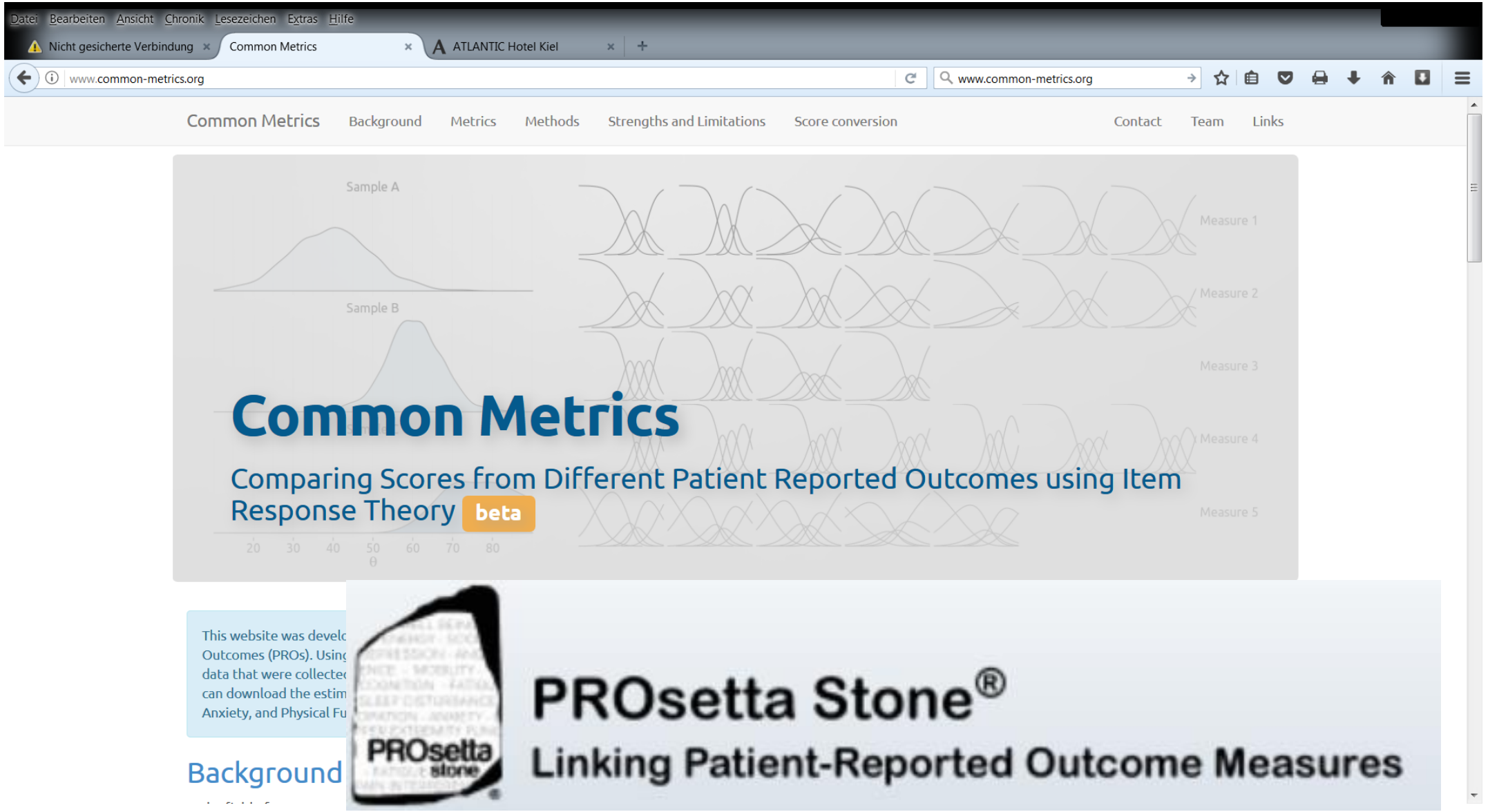
Infrared

2005

Temperature



Celsius ϴ



Fischer & Rose, BMC Med Res Methods 2016

Common Metric

Research article

Open Access

Hip disability and osteoarthritis outcome score (HOOS) – validity and responsiveness in total hip replacement

Anna K Nilsdotter*[1,2], L Stefan Lohmander[1], Maria Klässbo[3] and Ewa M Roos[1,2]

Address: [1]Department of Orthopedics, Lund University Hospital, Sweden, [2]Spenshult Hospital for Rheumatic Diseases, Halmstad, Sweden and [3]Department of Physiotherapy, Säffle Hospital and Neurotec Department Division of Physiotherapy, Karolinska Institute, Sweden

Email: Anna K Nilsdotter* - Anna.Nilsdotter@Spenshult.se; L Stefan Lohmander - Stefan.Lohmander@ort.lu.se; Maria Klässbo - maria.klassbo@liv.se; Ewa M Roos - Ewa.Roos@ort.lu.se

* Corresponding author

RESEARCH ARTICLE

Linking Hip Disability and Osteoarthritis Outcome Score-Physical Function Short Form and PROMIS Physical Function

Heng, Marilyn MD, MPH, FRCSC; Stern, Brocha Z. PhD, MOT; Tang, Xiaodan PhD; Schalet, Benjamin D. PhD; Collins, Austin K. BA; Chen, Antonia F. MD, MBA; Bedair, Hany S. MD; O'Brien, Todd M. MD, MBA; Sisodia, Rachel C. MD; Franklin, Patricia D. MD, MPH, MBA; Cella, David PhD

Author Information

RESEARCH: RESEARCH ARTICLE

Linking the KOOS-PS to PROMIS Physical Function in Knee Patients Evaluated for Surgery

Tang, Xiaodan PhD; Schalet, Benjamin D. PhD; Heng, Marilyn MD, MPH; Lange, Jeffrey K. MD; Bedair, Hany S. MD; O'Brien, Todd M. MD, MBA; Sisodia, Rachel C. MD; Franklin, Patricia D. MD, MPH, MBA; Cella, David PhD

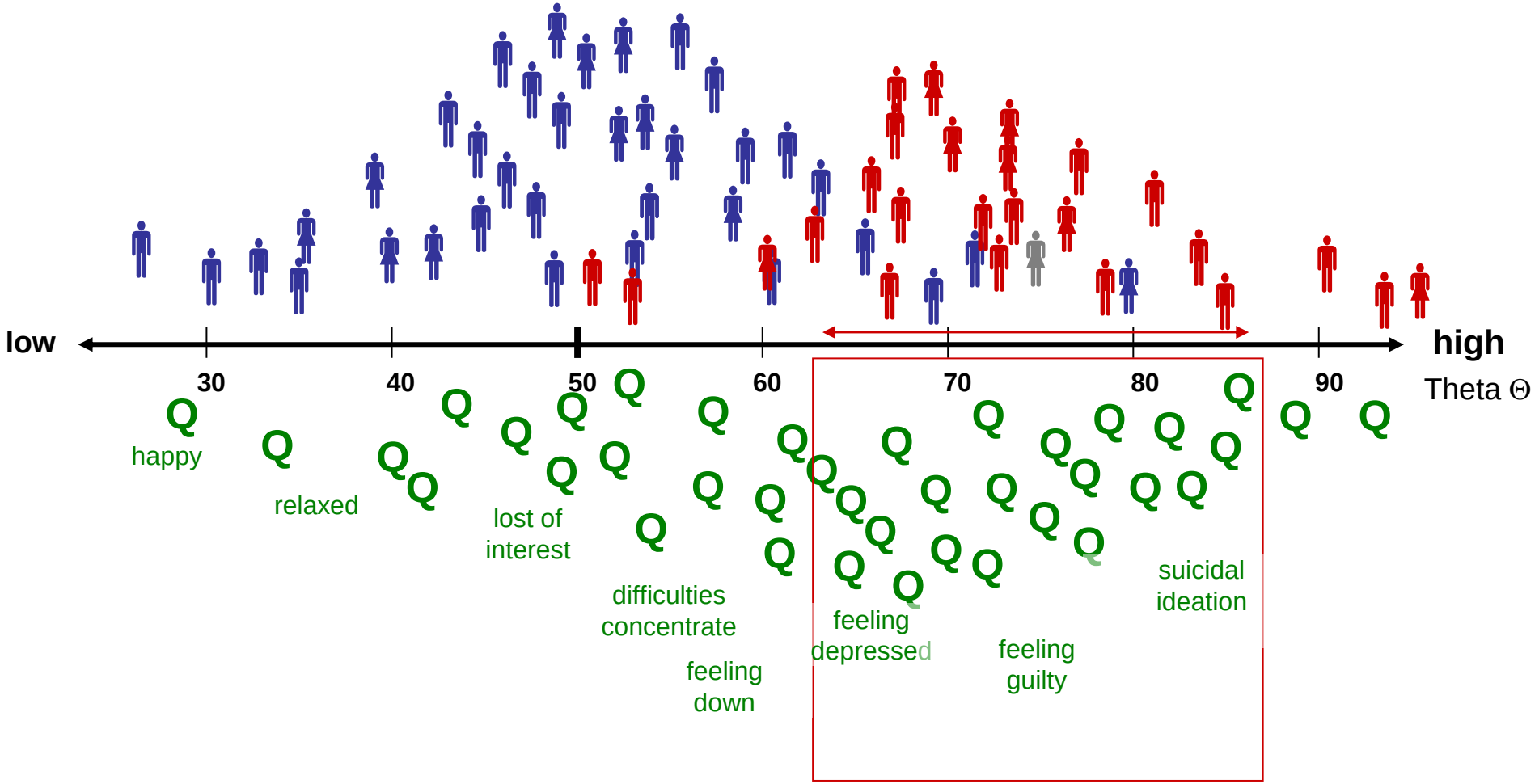
Author Information

Table 1: The 40 HOOS items arranged in the five subscales Pain, Symptoms, Activities of Daily Living, Sport and Recreation Function and Hip Related Quality of Life. The corresponding WOMAC item numbers and KOOS item numbers are declared as well as SRM (standardized response mean) and mean relevance of each question. * these items were constructed by one of the authors (MK)

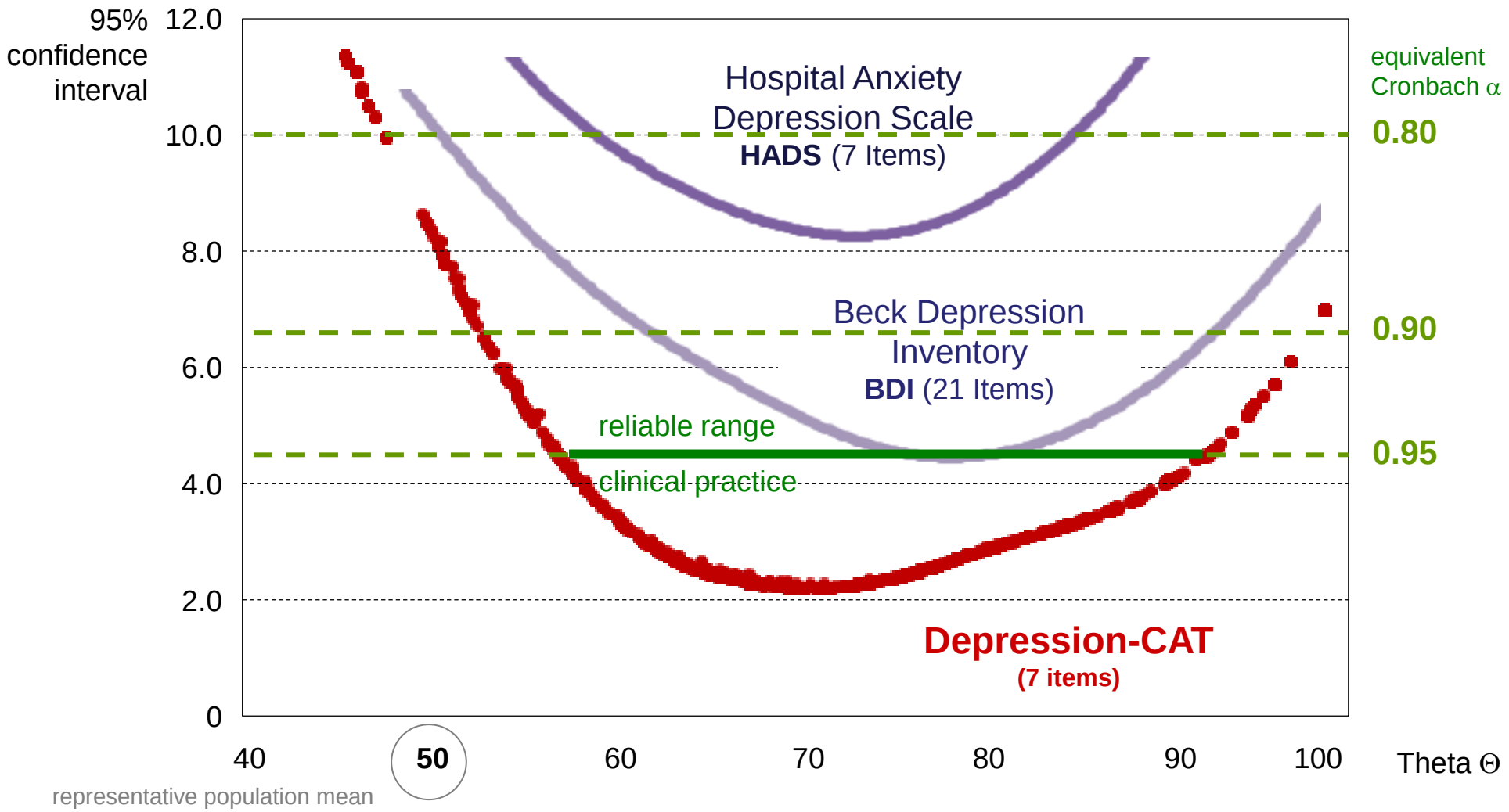
HOOS Item nr	HOOS 2.0	Mean Relevance	SRM	WOMAC item, nr	KOOS Item, nr
	Pain				
P1	How often do you experience hip pain?	2.6	1.7		P1
P3	Pain straightening hip fully?	3.0	1.8		P3
P4	Pain bending hip fully?	2.3	1.8		P4
P5	Walking on a flat surface?	2.7	1.4	P1	P5
P6	Going up or down stairs?	2.0	1.6	P2	P6
P7	At night while in bed?	2.7	1.5	P3	P7
P8	Sitting or lying?	2.7	1.2	P4	P8
P9	Standing upright?	2.3	1.2	P5	P9
P11	Walking on hard surface, ex. Asphalt, concrete?	2.3	1.6		*
P12	Walking on uneven ground?	3.0	1.5		
	Symptoms				
S2	Do you feel grinding, hear clicking or any other type of noise when your hip moves?	2.2	1.0		S2
S6	Severity of stiffness after first wakening in the morning?	2.5	1.1	S1	S6
S7	Severity of stiffness after sitting/lying/resting later in the day?	2.7	1.2	S2	S7
S10	Difficulty spreading your legs?	1.7	1.4		*
S11	Difficulty walking with long strides?	2.3	1.3		*
	ADL				
A1	Descending stairs?	2.3	1.5	A1	A1
A2	Ascending stairs?	2.3	1.5	A2	A2
A3	Rising from sitting?	2.7	1.3	A3	A3
A4	Standing?	2.3	1.5	A4	A4
A5	Bending to floor/pick up an object?	2.3	1.2	A5	A5
A6	Walking on flat surface?	2.0	1.2	A6	A6
A7	Getting in/out of car?	2.7	1.5	A7	A7
A8	Going shopping?	2.0	1.3	A8	A8
A9	Putting on socks/stockings?	2.7	1.2	A9	A9
A10	Rising from bed?	2.3	1.1	A10	A10
A11	Taking off socks/stockings?	2.0	0.9	A11	A11
A12	Lying in bed?	2.0	1.3	A12	A12
A13	Getting in/out of bath/shower?	1.3	0.9	A13	A13
A14	Sitting?	1.7	1.1	A14	A14
A15	Getting on/off toilet?	1.7	1.3	A15	A15
A16	With heavy domestic duties?	2.3	1.2	A16	A16
A17	With light domestic duties?	2.0	1.0	A17	A17
	Sport/Recreation				
SP1	Difficulty squatting?	2.7	1.0		SP1
SP2	Difficulty running?	3.0	0.8		SP2
SP4	Difficulty twisting/pivoting on loaded leg?	2.7	1.5		SP4
SP6	Difficulty walking on uneven ground?	2.3	1.1		*
	Hip Related QOL				
Q1	How often are you aware of your hip problems?	3.0	1.3		Q1
Q2	Have you modified your lifestyle to avoid potentially damaging activities to your hip?	3.0	1.0		Q2
Q3	How much are you troubled with lack of confidence in your hip?	2.7	1.3		Q3
Q4	In general, how much difficulty do you have with your hip?	2.7	1.7		Q4

Computer Adaptive Test

individually tailored test



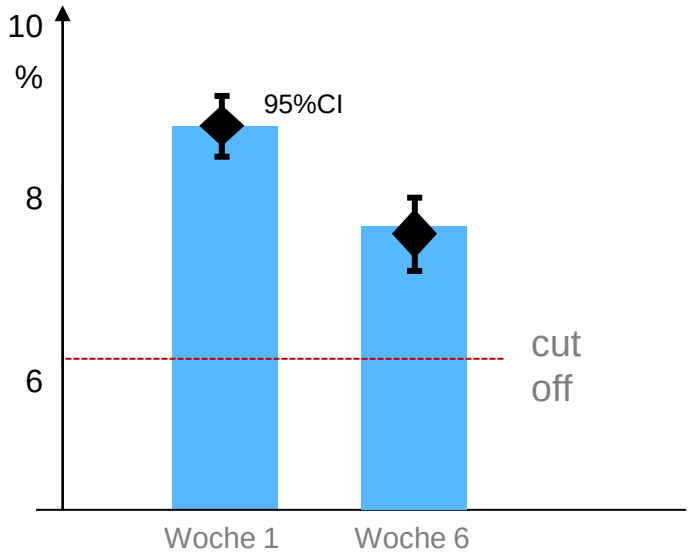
Individually Tailored Tools



Wahl et al. J Clin Epi 2014

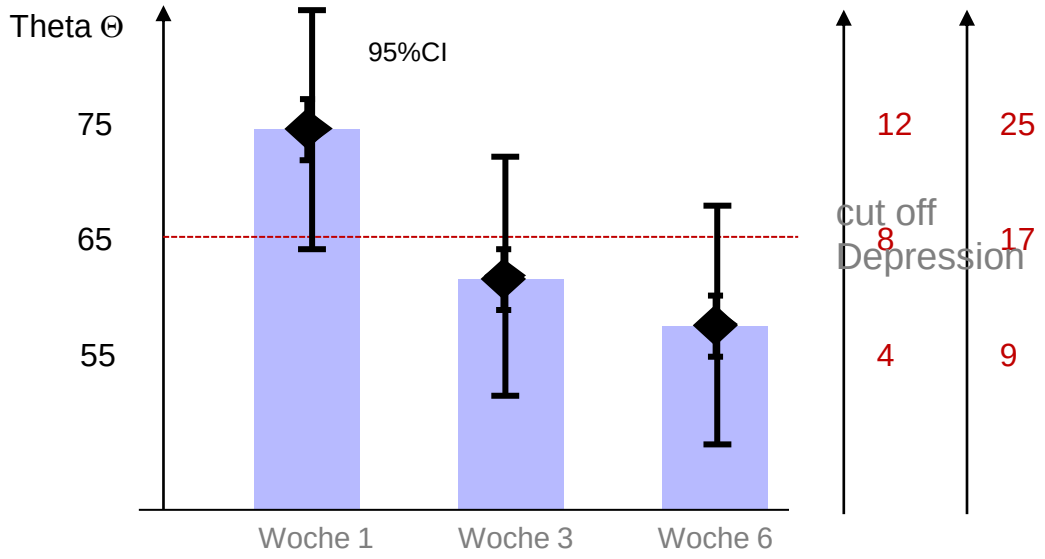
PRO Meeting Clinical Standards

HbA1c



HPCL Method (IFCC)

Depression



Standard tool (HADS)

HADS BDI

BEST **PRACTICE** ?

U.S. – Patient-Centered Research Funding

U.S. Funding Institutions for Patient-Centered Research

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

Digital Healthcare Research

Informing Improvement in Care Quality, Safety, and Efficiency

Current Digital Healthcare Research Priorities

- Care Transitions
- Clinical Decision Support
- Consumer-focused Digital Healthcare
- Patient-Reported Outcomes

US department of health and human services

Consumer-focused Digital Healthcare

Increasingly, innovative computer and information systems are being developed to help people manage health concerns, monitor important indicators of their health, and communicate with their caregivers. AHRQ supports research to determine how these patient-facing technologies can best improve the quality and effectiveness of care.

Patient-Reported Outcomes

While patient-reported outcomes (PROs) offer a complementary perspective to that of clinician assessments, and may provide greater insights into health status, function, symptom burden, adherence, health behaviors, and quality of life, many electronic health record systems do not collect PRO data in structured or standardized ways that can allow for their use. AHRQ currently funds research on how to collect and use PROs using digital methods, as well as to scale and spread existing digital models that currently incorporate PROs.

seit 2011

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

FY 2018 Awards Funding Commitment *(Awards Approved)* — **TOTAL:** $308 Million

83.2%	6.8%	5.2%	4.8%
$256 Million RESEARCH	$21 Million DISSEMINATION AND IMPLEMENTATION	$16 Million RESEARCH INFRASTRUCTURE	$15 Million ENGAGEMENT

$250m/Jahr

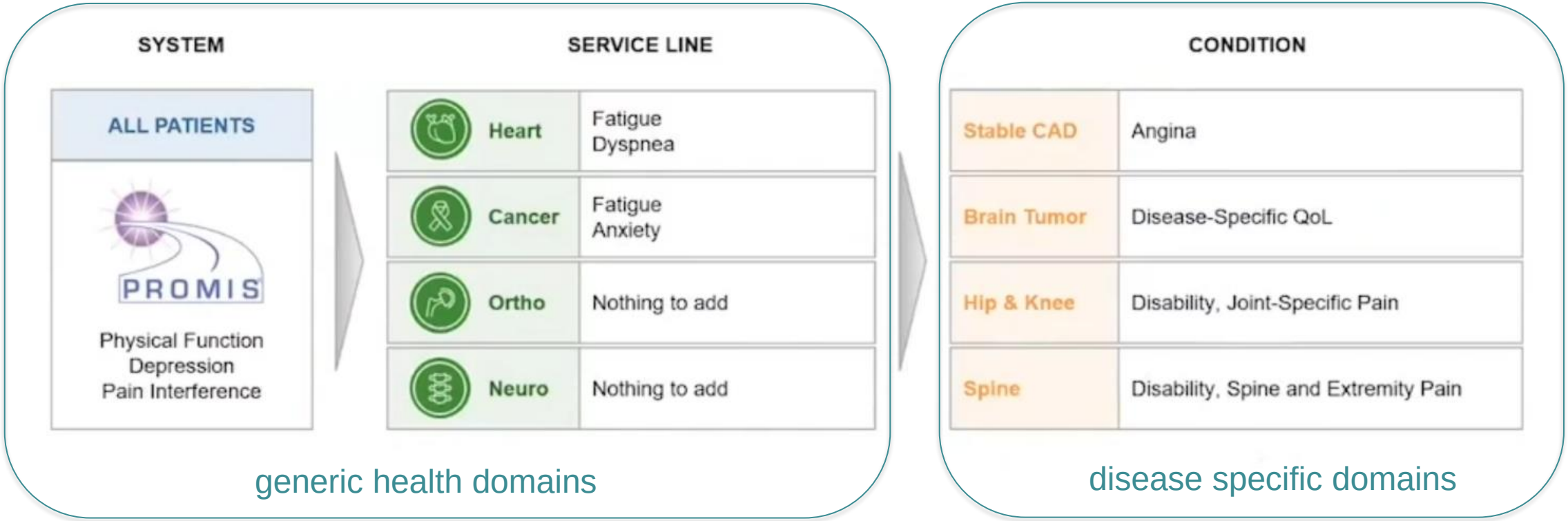
https://digital.ahrq.gov/ahrq-funded-projects/current-priorities/patient-reported-outcomes?page=1

U.S. – PRO Implementation

51 HOSPITALS

5m UNIQUE PATIENTS SERVED

Providence St. Joseph Health



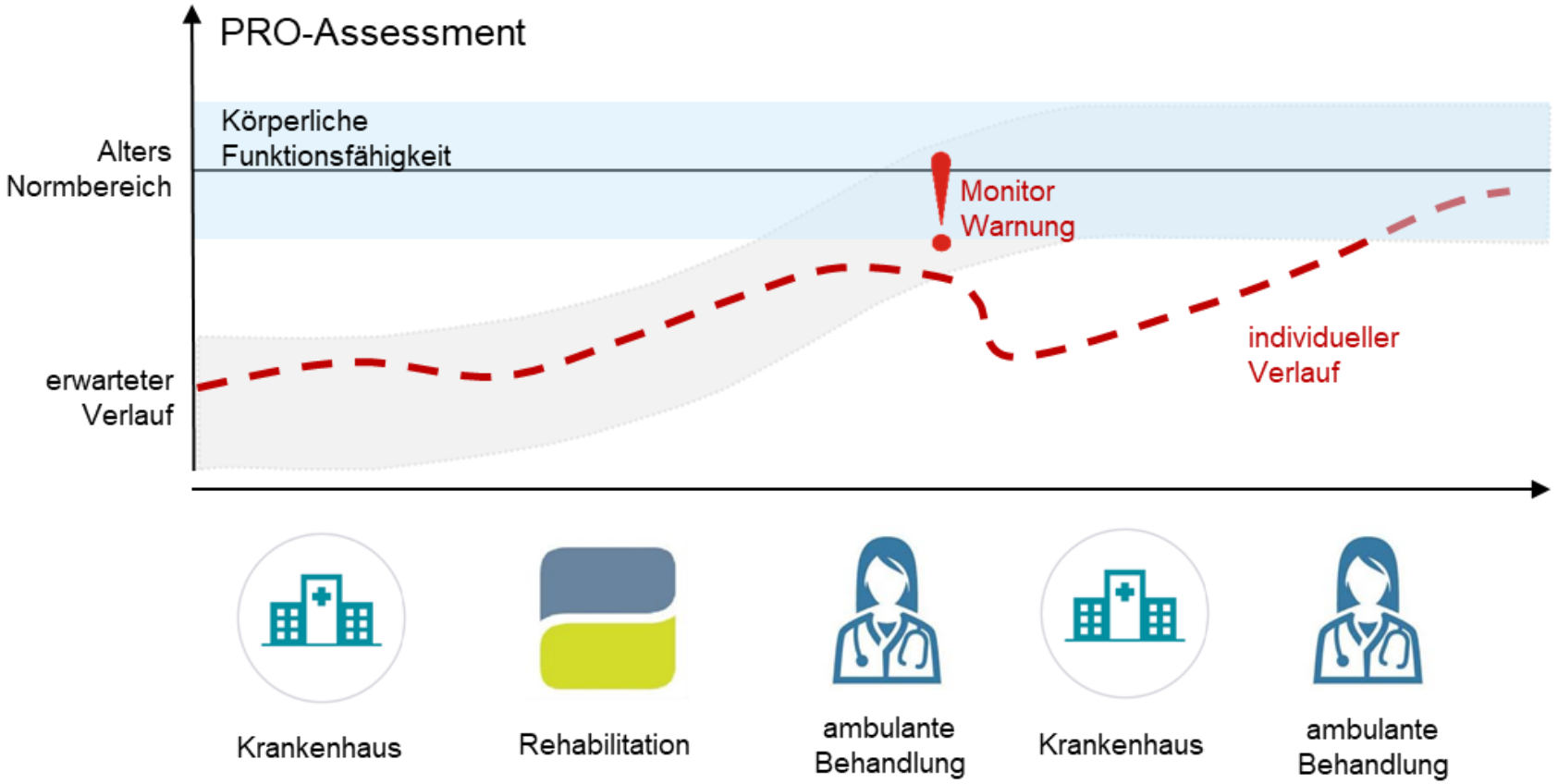
www.common-metrics.org

slide presented by J. Lippa, Providence

NEAR **FUTURE** ?

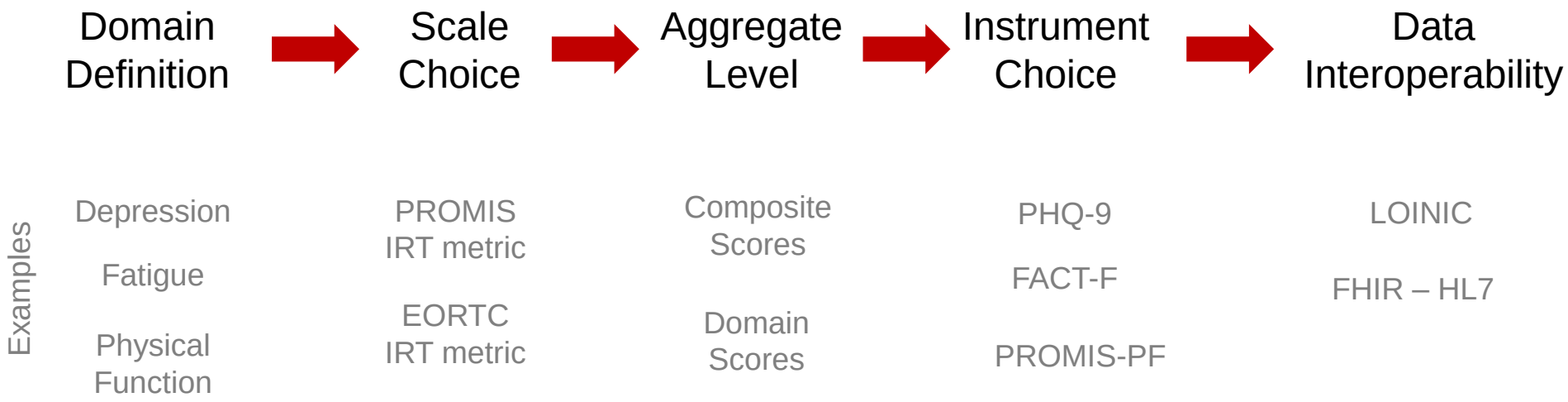
Patient Journey

Beispiel
TEP



PRO-Standardization Process

From Instrument- to Construct Oriented Measurement



Conceptual Model

Patient Perspective

self-reported health

ICHOM Disease Perspective

	Obesity	Low Back Pain	Diabetes mellitus	Coronary Artery Disease	Heart Failure	Chronic Kidney Disease	Colo-rectal Cancer	Hip-Knee Replacement	Depression	Dementia
Physical Functioning	↓	↓		↓↓	↓↓↓	↓↓	↓	↓	↓	
Shortness of Breath					↑↑↑	↑				
Pain	(↑)	↑↑		↑			(↑)	↑↑		
Fatigue			↑		↑↑	↑↑	↑↑		↑	
Depression	(↑)	(↑)	(↑)		↑		↑		↓↓↓	
Cognitive Function						(↓)			↓	↓↓
Social Role Participation	(↓)			(↓)	↓	↓			↓↓	↓↓↓

modern metric

instrument independent

disease specific

treatment knowledge …

time to recovery …

previous treatment

side effects

context specific

blood flow

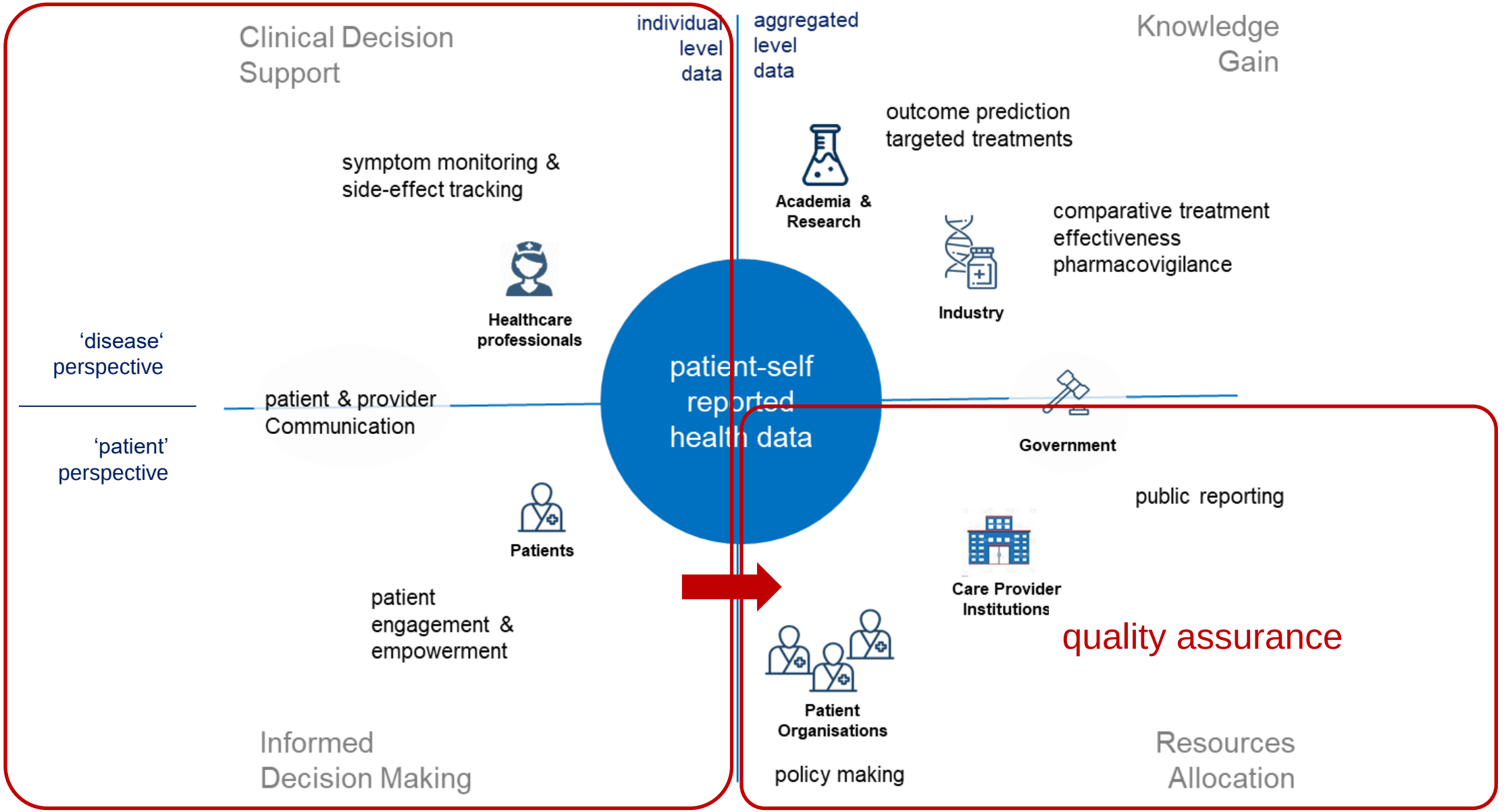
work ability

return to work

sick leave days

standard tools

sociodemographic facts


Clinical Decision Support
individual level data
aggregated level data
Knowledge Gain
outcome prediction
targeted treatments
symptom monitoring &
side-effect tracking
Academia & Research
comparative treatment
effectiveness
pharmacovigilance
Healthcare professionals
Industry
'disease' perspective
patient & provider Communication
patient-self reported health data
Government
'patient' perspective
public reporting
Patients
Care Provider Institutions
patient engagement & empowerment
quality assurance
Patient Organisations
policy making
Informed Decision Making
Resources Allocation

CONCLUSION

Conclusion

1. Modern psychometric methods make PRO assessments more similar to biomedical markers
2. Agreeing on the essential health domains will allow to standardize PRO assessments
3. Next steps are to make it happen in real …

"I dreamed I was being chased by a giant standardized test."

Thank you.

Wirbel: PROMIS, ODI, COMI, PROMIS Pain (validation)

Ortho Knie: PROMIS, KOOS, (IKDC, Lysholm für spezifischere Knieerkrankungen) – hier wird sicher nochmal was vom PF dazukommen

Ortho Hüfte: PROMIS, HOOS – hier wird sicher nochmal was vom PF dazukommen

AO – Studie: PROMIS Physical Function SF Custom AO14 (14)
PROMIS Upper Extremity SF Custom AO8 (8)
PROMIS Depression SF 1.0 6a (6)
PROMIS Anxiety SF v1.0 6a (6)
PROMIS Pain Interference (8)
PROMIS Ability to Participate in Social Roles SF v2.0 4a
PROMIS Global (10)
Numerical Rating Scale Pain (1)
Patient Activation Measure PAM-10 (10)
Pain Self-Efficacy Questionnaire PSEQ-2 (2)
RUSH/RUST score (provider does)
Quick-DASH (11)
HOOS-12 (12)
KOOS-12 (12)
FAAM (21) - only daily living will be used (no sport subscale)