Patient-reported outcomes – Challenges to world wide use

Joy C MacDermid PT PhD

2 major issues

- Lack of clinical use?
- Can we all agree on what to measure?

Reasons why we should use PROM

- The patients perspective of outcome is #1.
- Improved communication
- Compliments information we get from diagnostic tests and impairment measures.
- More predictive of outcomes like RTW, independent living than impairment measures
- Can support easier comparisons of data for quality improvement or research.

Systematic review

The experiences of professionals with using information from patient-reported outcome measures to improve the quality of healthcare: a systematic review of qualitative research

Maria B Boyce [1] , John P Browne [1] , Joanne Greenhalgh [2]

Correspondence to Maria Boyce, Department of Epidemiology and Public Health, University College Cork, Ireland; m.boyce@ucc.ie

Barriers SR 16 studies

- Correct infrastructure is not in place
- Disruptive to normal work routines.
- Interpretability

Perceived benefits and limitations of using patient-reported outcome measures in clinical practice with individual patients: a systematic review of qualitative studies

Review | Published: 27 September 2021

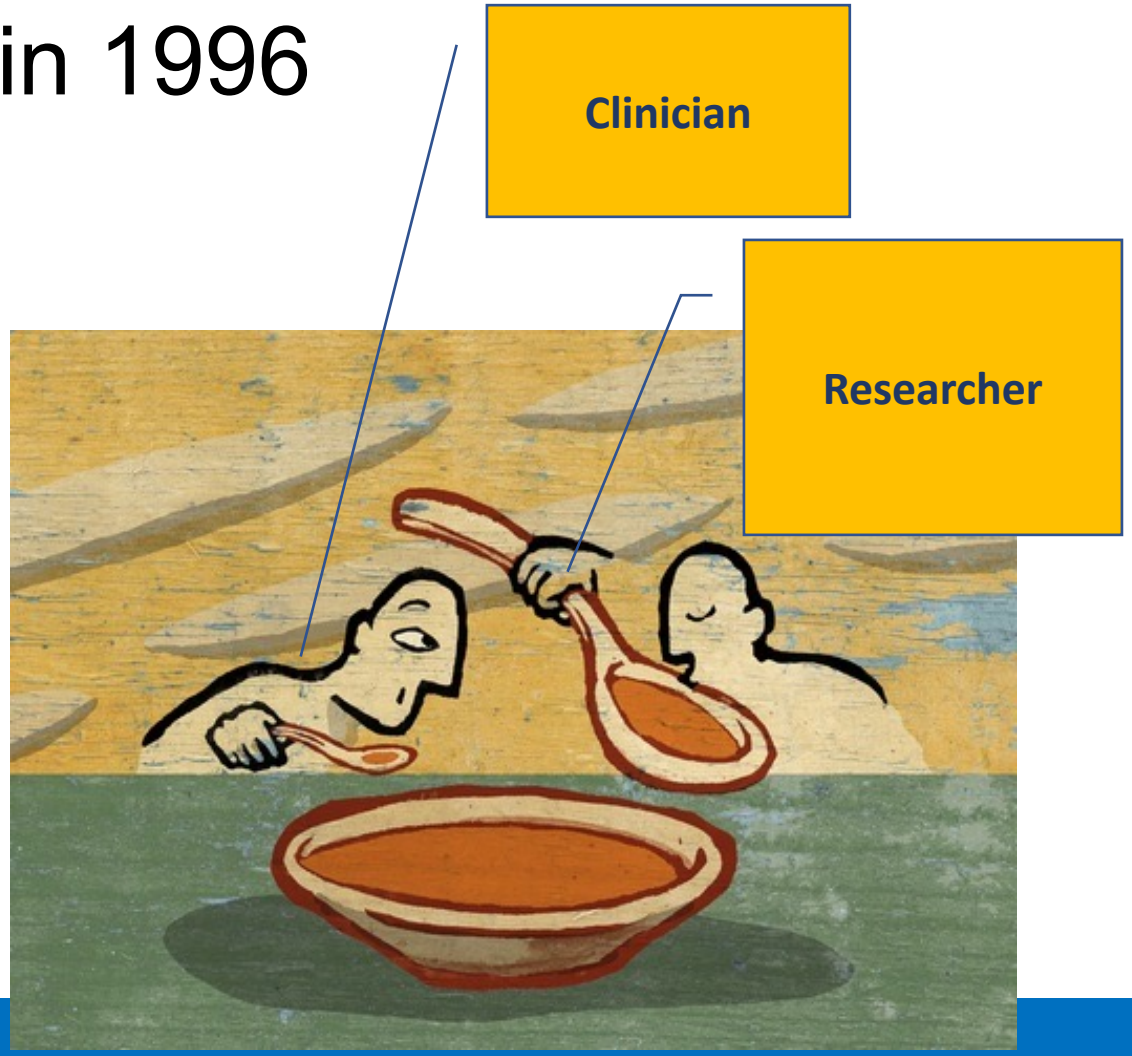
Volume 31, pages 1597–1620, (2022) Cite this article

Benefits – to patient care

- (1) promotes active patient involvement (enables goal setting and discussion of sensitive topics)
- (2) enhances the focus of consultations (prioritizes patient needs)
- (3) improves quality of care (enables tailored, holistic care and prompts action)
- (4) enables standardized monitoring of patient outcomes; and
- (5) enhances the patient–clinician relationship (provides reassurance).

Implementation has been slow

- PRWE and DASH published in 1996
- Use high in research
- In practice variable



Use: Nice or necessary?

Nice

- Good for profession
- Everyone expects me to do
- For research

Necessary

- Integrated in clinical decisions
  - In monitoring progress
  - Directing treatment
  - Communication with patients

We do what we think is necessary

Patient-specific activity scoring scheme (Point to one number):

0 1 2 3 4 5 6 7 8 9 10

Unable to perform activity

Able to perform activity at the same level as before injury or problem

(Date and Score)

Activity	Initial					
1.						
2.						
3.						
4.						
5.						
Additional						
Additional						

Total score = sum of the activity scores/number of activities
Minimum detectable change (90%CI) for average score = 2 points
Minimum detectable change (90%CI) for single activity score = 3 points

PSFS developed by: Stratford, P., Gill, C., Westaway, M., & Binkley, J. (1995). Assessing disability and change on individual patients: a report of a patient specific measure. Physiotherapy Canada, 47, 258-263.

Barriers to implementation

Patient/Measure Issues

- HEALTH LITERACY
- Cross-cultural translations
- Perceived use
- Targeting
  - Floor/Ceiling Effects
  - Relevancy

Clinician/Clinic

- Perceived utility
- Time
- Interpretability
- Infrastructure supports
- Access to measures
- Scoring Complexity

Uptake in research : strong

- ✓ Easier comparison of clinical data
- ✓ Multi-site research
- ➢ Easier meta-analysis

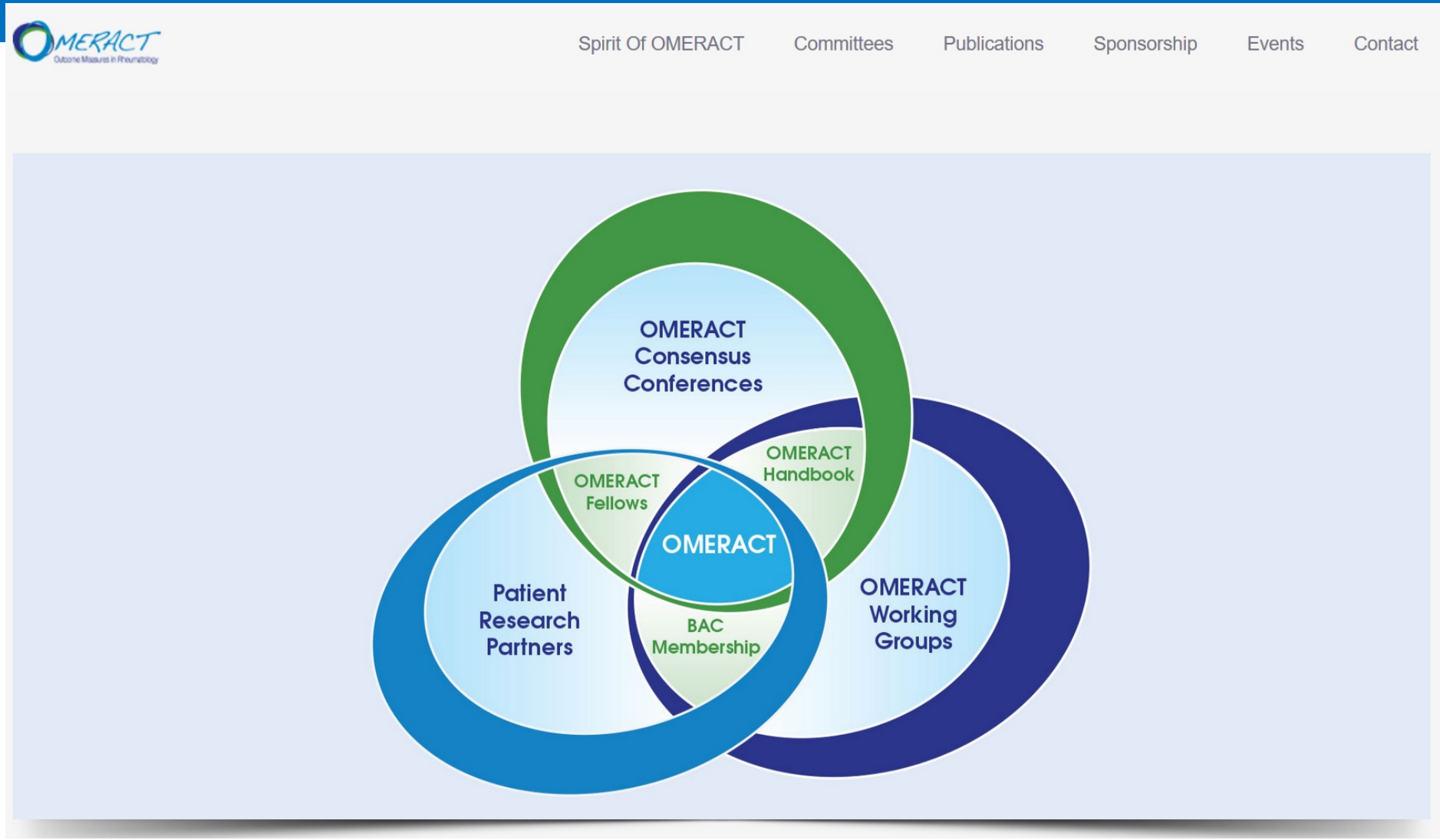
Research Trends

- Rasch model to achieve interval level scaling
- Cross-cultural translations
- New measures
- New methods of implementation
  - PROMIS CAT
  - Technology-enabled
- CONSENSUS on what to measure

Consensus process

- Agree on constructs that are important to measure
- Agree on measures
- Literature
  - Measurement properties
- User input
  - Patients
  - Clinicians
- Feasibility

OMERACT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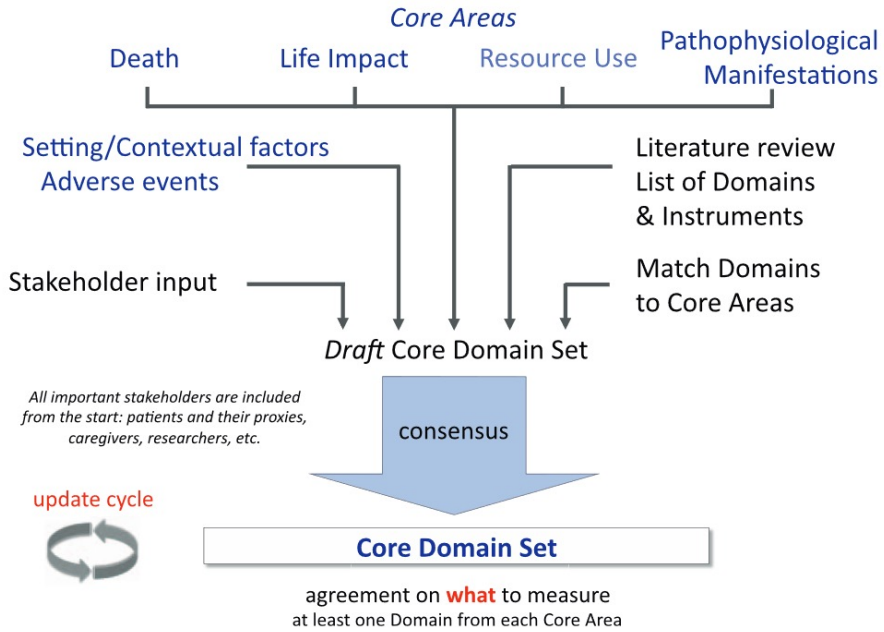
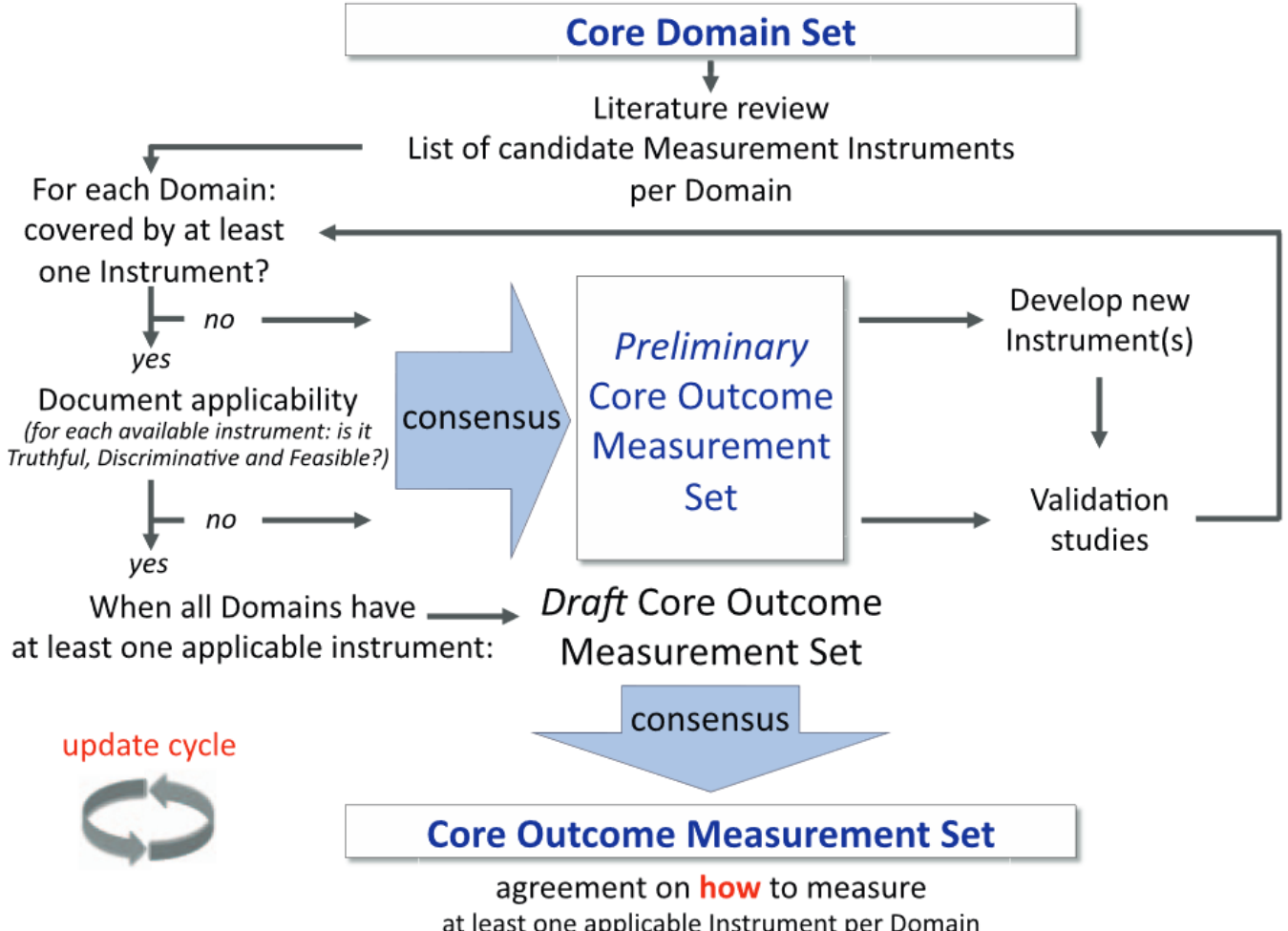
OMERACT domains and processes



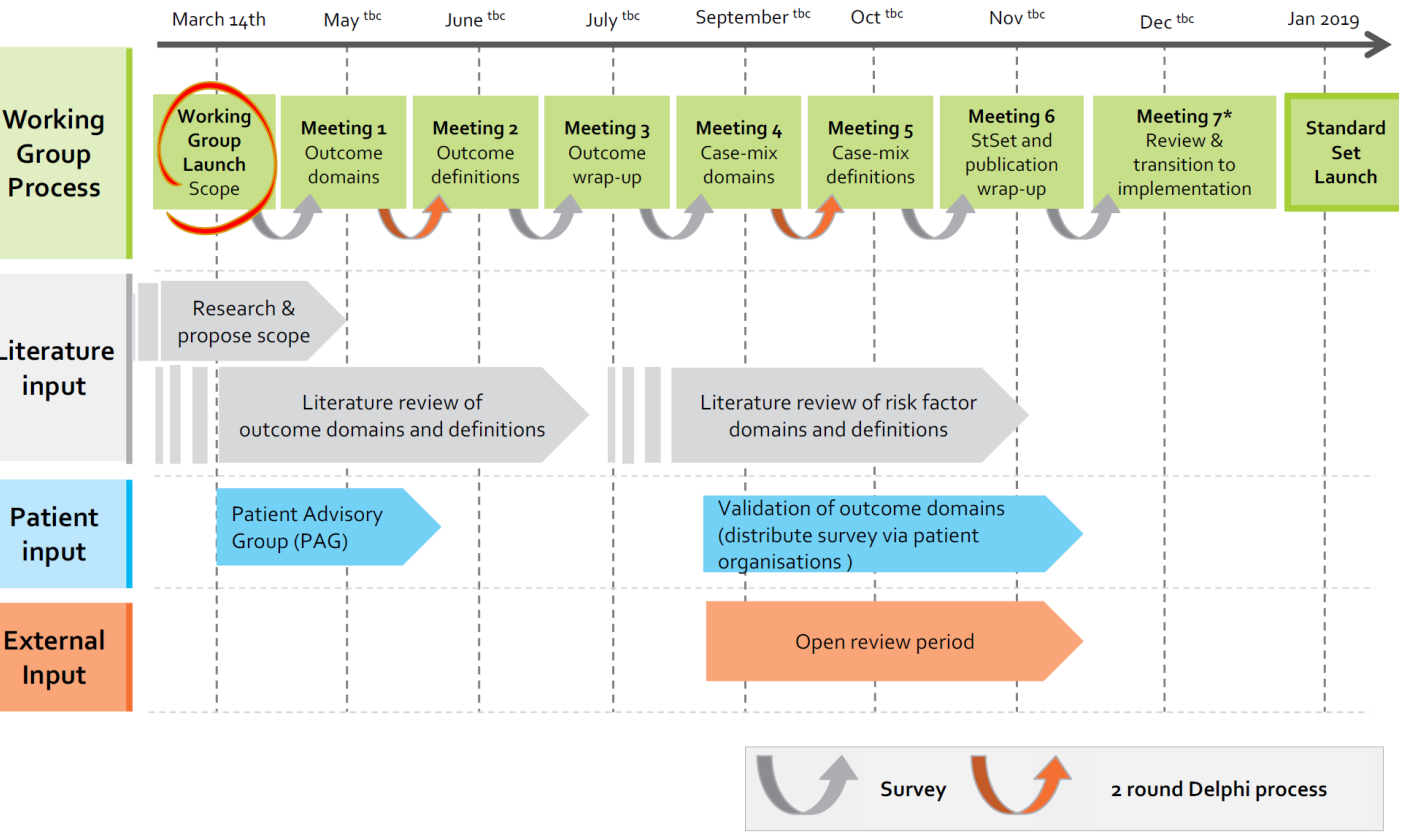


COMET

Core Outcome Measures in Effectiveness Trials

"A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care."

A Standard Set is defined through series of teleconference calls, supported by research and patient input



ICHOM

International Consortium for Health Outcomes Measurement

Hand and Wrist Conditions Working Group – Launch Call

EDITOR'S CHOICE

A Standard Set for Outcome Measurement in Patients With Hand and Wrist Conditions: Consensus by the International Consortium for Health Outcomes Measurement Hand and Wrist Working Group

Robbert M. Wouters, PhD,* Adedayo O. Jobi-Odeneye, MSc,† Alethse de la Torre, MD, PhD,† Andria Joseph, MSc,† the ICHOM Hand and Wrist Working Group, Steven E. R. Hovius, MD, PhD‡

ORIGINAL ARTICLE

Recommendations For Core Outcome Domain Set For Whiplash-Associated Disorders (CATWAD)

Kenneth Chen, BExSpSc (Hons),† Tonny Andersen, PhD,‡*
*Linda Carroll, PhD,§ Luke Connelly, PhD,†‖¶ Pierre Côté, PhD,#**††*
Michele Curatolo, PhD,‡‡ James Elliott, PhD,§§‖‖
Genevieve Grant, PhD,†¶¶ Gwendolen Jull, PhD,##
*Helge Kasch, PhD,***†††‡‡‡ Joy MacDermid, PhD,§§§‖‖‖*
Eva-Maj Malmström, PhD,¶¶¶### Annick Maujean, PhD,†*
*Samuel A. McLean, MD,**** Mandy Nielsen, PhD,††††*
Trudy Rebbeck, PhD,†‖‖ Anne Söderlund, PhD,‡‡‡‡
Joanna Sterling, M Psych, Julia Treleaven, PhD,##*
David M. Walton, PhD,§§§ Hans Westergren, PhD,¶¶¶###
and Michele Sterling, PhD†§§§§*

Research Paper
PAIN
International Research Consortium for Complex Regional Pain Syndrome

Recommendations for a first Core Outcome Measurement set for complex regional PAin syndrome Clinical sTudies (COMPACT)

Sharon Grieve[a,b,*], Roberto S.G.M. Perez[c], Frank Birklein[d], Florian Brunner[e], Stephen Bruehl[f], R. Norman Harden[g], Tara Packham[h], Francois Gobeil[i], Richard Haigh[j], Janet Holly[k], Astrid Terkelsen[l], Lindsay Davies[a], Jennifer Lewis[a,b], Ilona Thomassen[m], Robyn Connett[n], Tina Worth[o], Jean-Jacques Vatine[p,q], Candida S. McCabe[a,b]

DOMAIN	MEASURE
Pain	SF McGill Neuropathic scale PROMIS 29
Disease severity	CRPS Severity Scale
Participation	PROMIS 29 EQ-5D
Physical function	
Emotional and psychological functioning	PROMIS 29 Single item on suicidal ideation
Self-efficacy	Pain Self-Efficacy Questionnaire
Catastrophizing	Pain Catastrophizing Scale
Self-perception of change	GROC

5a. Development of Resources

INTRO TO NIH TOOLBOX

OBTAIN & ADMINISTER MEASURES

MEASURE DEVELOPMENT & RESEARCH

Next NIH Toolbox Training June 12-13 in Cambridge, MA

Learn more here

The NIH Toolbox® is a comprehensive set of neuro-behavioral measurements that quickly assess cognitive, emotional, sensory, and motor functions from the convenience of an iPad.

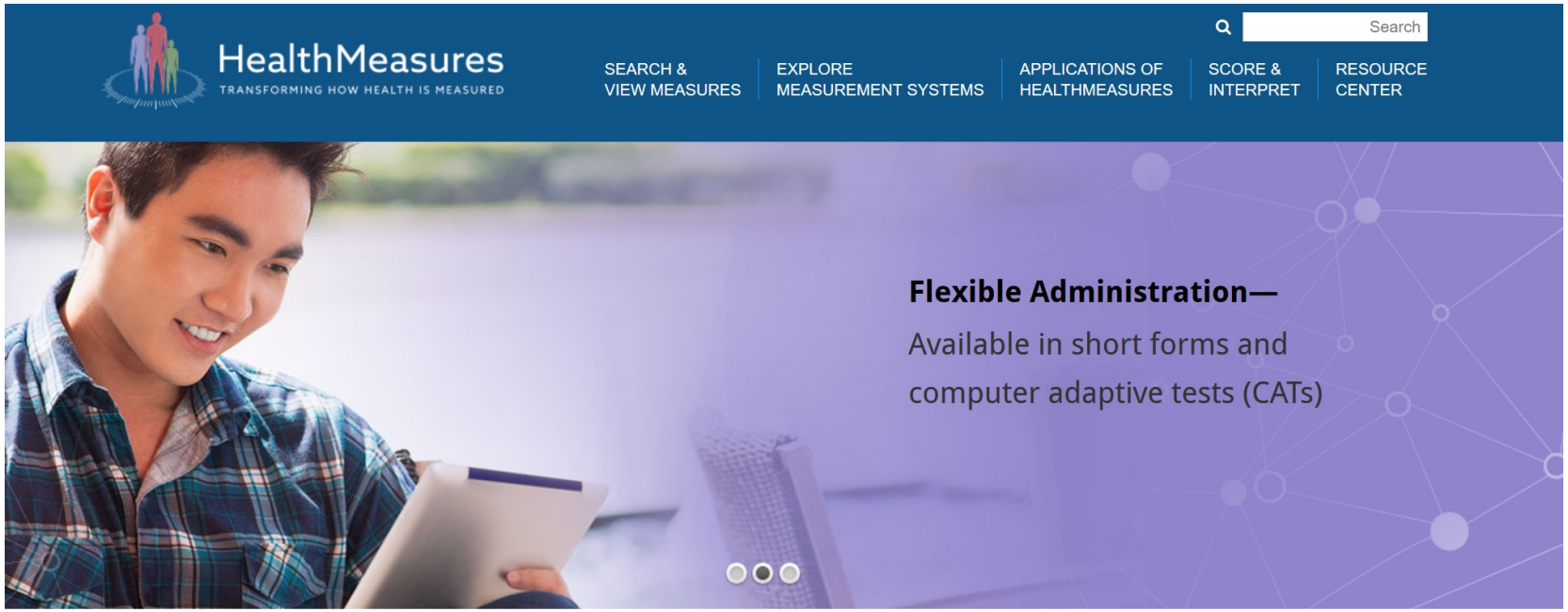
Why use NIH Toolbox?

- Developed and validated with state-of-the-science methodology to be psychometrically sound
- Based on a nationally representative sample to enable cross-measure comparisons
- Created to be well-suited for measuring outcomes in longitudinal studies
- Translations are available in Spanish and other languages
- To learn more about the NIH Toolbox measures and scores, view the **introductory brochure**

Get the NIH Toolbox iPad App at the iTunes Store

Get it on iTunes

PROMIS



PROMIS

Next PROMIS Training June 9 in Chicago

Learn more here

Table 3. ICF Hand$_A$ assessment set based on the Brief ICF Core Set for Hand Conditions.

Aspects of the Brief ICF Core Set for HC		(1) Screening
Body structures		
s120	Spinal cord and related structures (e.g. nerves)	Localization and nature of impairments in body structures is documented based on diagnostic imaging techniques, if required.
s730	Bones of forearm and hand	
s730	Joints of forearm and hand	
s730	Muscles and tendons of forearm and hand	
Body functions		
b152	Emotional functions	Depression (PHQ-2)[1], anxiety (GAD-2)[2] and standardized question to screen for post-traumatic stress disorder
b265	Touch functions	Ten Test[8]
b270	Sensory functions related to temperature and other stimuli	Two-point discrimination[10] Pin prick test[11] Cold-warm discrimination
b280	Sensation of pain	Numeric rating scale[14]
b710	Mobility of joint functions	Goniometry[15] Fingernail-table distance[16] Fingertip-to-palm distance[16]
b715	Stability of joint functions	Manual provocation testing (e.g. Piano-Key-Test[12])
b730	Muscle power functions	(Non-standardized grip test)[a]
b760	Control of voluntary movement functions	One standardized performance task (grasping/lifting and releasing a pen)
b810	Protective functions of the skin	Visual inspection
	Swelling[b]	Visual inspection
Activities and participation		
d230	Carrying out daily routine	One standardized question to screen for problems
d430	Lifting and carrying objects	One standardized performance task (lifting/carrying an objec from one place to another)
d440	Fine hand use	DASH[21] items 2, 3[c] Grasp, lift and release a paperclip
d445	Hand and arm use	Four standardized performance tasks (Pushing/pulling, reaching, throwing/catching, turning/twisting)
d5	Self-care	DASH[21] items 13, 14, 15
d6	Domestic life	DASH[21] items 4, 7, 8, 9

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Research Article | OMERACT 12 — International Consensus Conference on Outcome Measures in Rheumatology, Budapest, Hungary, May 7–11, 2014

Report from the OMERACT Hand Osteoarthritis Working Group: Set of Core Domains and Preliminary Set of Instruments for Use in Clinical Trials and Observational Studies

Margreet Kloppenburg, Pernille Bøyesen, A. Willemien Visser, Ida K. Haugen, Maarten Boers, Annelies Boonen, Philip G. Conaghan, Gillian A. Hawker, Tore K. Kvien, Robert Landewé, Till Uhlig, Wilma Smeets, Elsie Greibrokk and Désirée M. van der Heijde

The Journal of Rheumatology November 2015, 42 (11) 2190-2197; DOI: https://doi.org/10.3899/jrheum.141017

- Pain,
- physical function,
- patient global assessment,
- joint activity and
- hand strength.

Recommended Measures

Domains	Subdomains	Instruments	
		Settings	
		Clinical Trials of Symptom Modification	Clinical Trials of Structure Modification and Observational Studies
Pain		Pain VAS/NRS	Pain VAS/NRS
Physical function		FIHOA	FIHOA
Patient global assessment		Research	Research
Joint activity	Tender joints	Tender joint count	Tender joint count
	Soft swollen joints	Research	Research
Hand strength		Grip/pinch strength	Grip/pinch strength
HRQOL*		Research	Research
Structural damage	Radiographic damage		Kellgren-Lawrence or Verbruggen-Veys or Kallmann or OARSI
	Aesthetic damage*		Research
	Bony damage*		Research
	Deformity*		Research
Hand mobility*			Research

DOI 10.1007/s00402-013-1767-9

TRAUMA SURGERY

Recommendation for measuring clinical outcome in distal radius fractures: a core set of domains for standardized reporting in clinical practice and research

Summary – DRF outcomes for clinical practice consensus

- Pain
  - NRS or PRWE Pain Subscale
- Function
  - QuickDASH or PRWE
- Complications
- Participation- can be one question
- Secondary Impairments
  - Grip strength
  - Motion
  - Radiographic measures

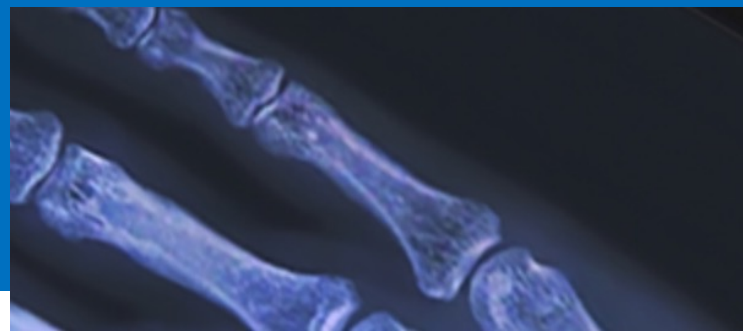
A Unified Approach to Outcomes Assessment for Distal Radius Fractures

Jennifer F. Waljee, MD,* Amy Ladd, MD,† Joy C. MacDermid, PhD,‡ Tamara D. Rozental, MD,§
Scott W. Wolfe, MD,|| Distal Radius Outcomes Consortium¶

- Pain
- Hand/Wrist/Elbow ROM and Bilateral Grip
- PRO- Function
- Complications
- Radiographs

TABLE 4. Summary Checklist Regarding Minimum Outcomes to Capture After DRFs

Outcome Domain		Assessment Parameters	
Performance measures	Hand, wrist, forearm, and elbow range of motion	Bilateral distal interphalangeal, proximal interphalangeal, and metacarpophalangeal joints, wrists, and elbow including passive and active range of motion through flexion and extension; wrist ulnar and radial deviation; forearm pronation and supination	Goniometer measurement at bedside or certified hand therapist assessment
	Bilateral hand grip strength	Bilateral hands	Dynamometer measurement at bedside or certified hand therapist assessment
Patient-reported outcomes	Disability and function	Activities of daily living; work performance; high-performance activities (music, sports, and art)	PRWE, *Quick*DASH, Brief MHQ, PROMIS upper-extremity, function
Pain		Character, intensity, frequency, interference	Visual analog or numeric pain rating scale, PRWE pain subscale, MHQ Pain subscale, PROMIS—Pain Interference
Complications	Occurrence of complications	Malunion, nonunion, tendinopathy, neuropathy, hardware failure, infection	Clinical record
	Reoperation	Unplanned reoperation within 1 y of injury	
	Unplanned readmission	Unplanned readmission to hospital after treatment	
Radiographs	Bony healing, alignment, collapse, and articular congruity as measured on plain radiographs including anteroposterior	Radial inclination, ulnar variance, volar tilt, radial height, articular congruency, hardware position and failure, bony union	Clinical record



BSSH The British Society for Surgery of the Hand

OUTCOME MEASURES

MEASUREMENT PROPERTIES OF PATIENT-REPORTED OUTCOME MEASURES IN THE SETTING OF ADULT PATIENTS WITH DISTAL RADIUS FRACTURES

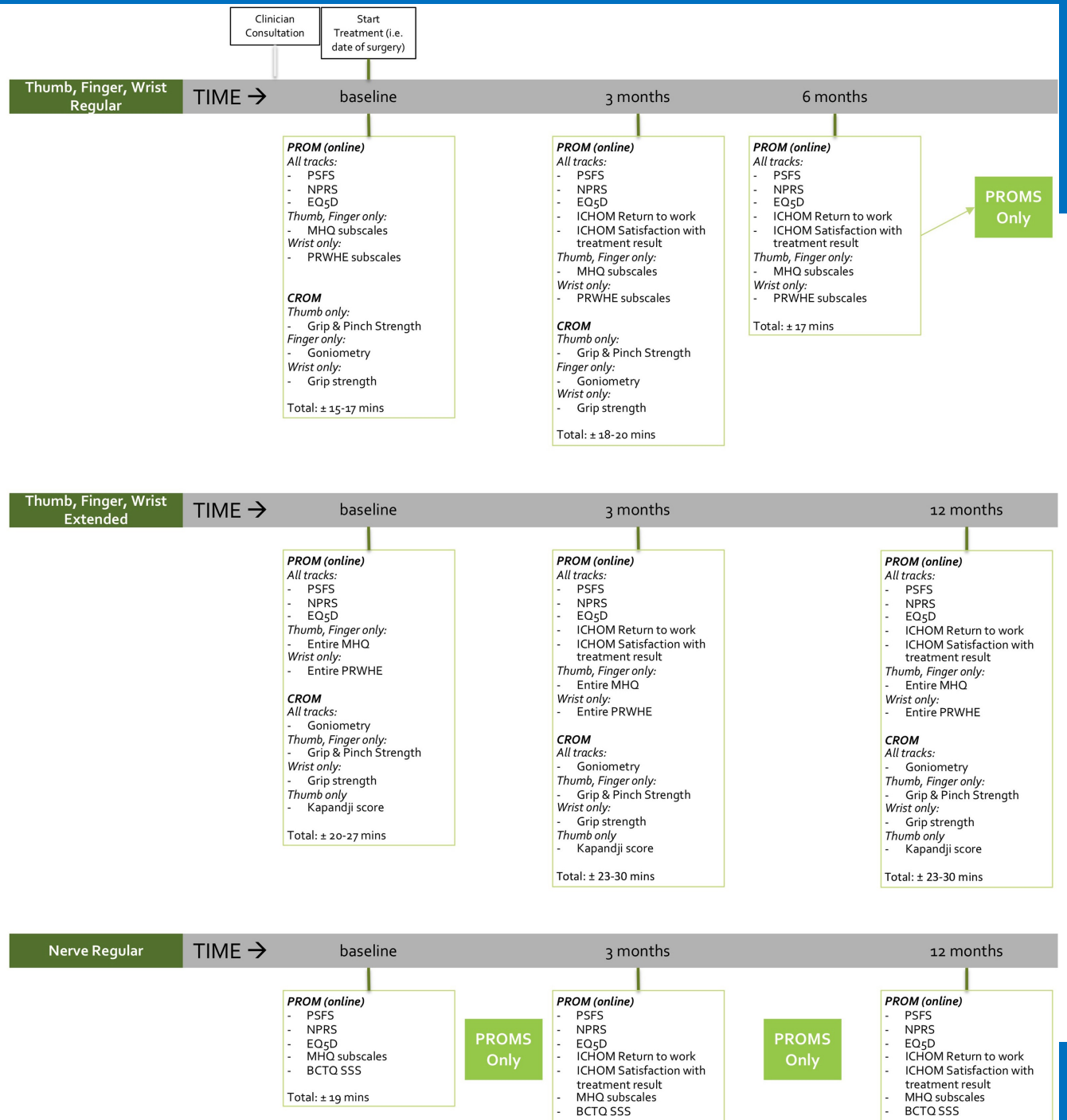
Introduction

Best Practice:

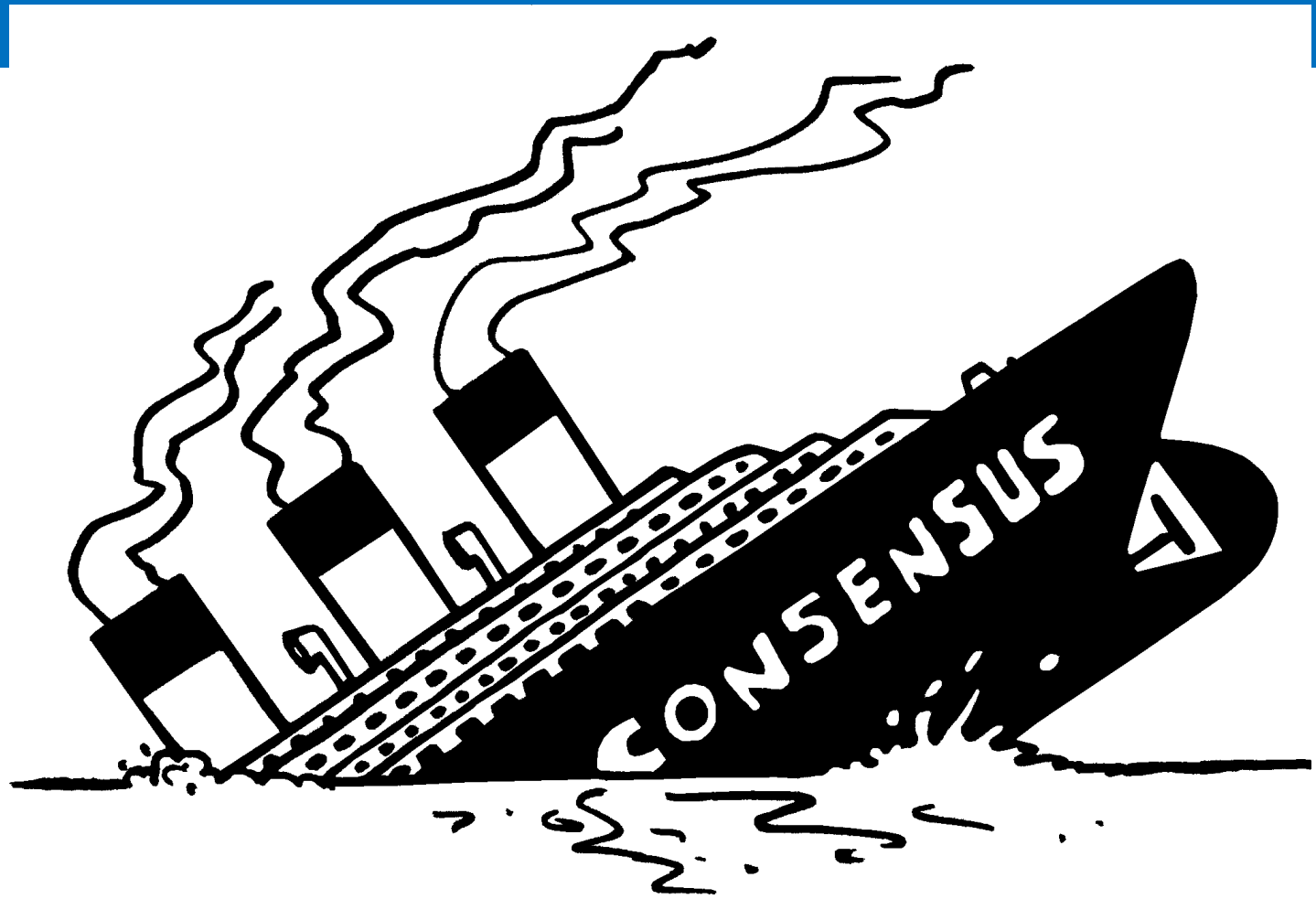
There is insufficient evidence to recommend the optimal PROM for capturing outcomes in studies of adult patients with DRFs. However, pending future research, an interim recommendation can be made for the use of either the PRWE or the DASH, based on available evidence for responsiveness in this setting.

ICHOM


Hand Function/ Activities of Daily Life
Pain
Health-related QOL
Satisfaction with Treatment Results
Return to Work
Complications
Revision
Range of Motion
Grip & Pinch Strength
Sensibility
Cold Intolerance
All Tracks
Track-specific


Clinician Consultation
Start Treatment (i.e. date of surgery)
Thumb, Finger, Wrist Regular
TIME →
baseline
3 months
6 months
PROM (online)
All tracks:
- PSFS
- NPRS
- EQ5D
Thumb, Finger only:
- MHQ subscales
Wrist only:
- PRWHE subscales
CROM
Thumb only:
- Grip & Pinch Strength
Finger only:
- Goniometry
Wrist only:
- Grip strength
Total: ± 15-17 mins
- ICHOM Return to work
- ICHOM Satisfaction with treatment result
Total: ± 18-20 mins
Total: ± 17 mins
PROMS Only
Thumb, Finger, Wrist Extended
12 months
- Entire MHQ
- Entire PRWHE
- Kapandji score
Total: ± 20-27 mins
Total: ± 23-30 mins
Nerve Regular
- BCTQ SSS
Total: ± 19 mins

Results of Consensus



Consensus processes valuable to identify core constructs

- Pain and function should be measured
  - PROM
  - Separately
- Use a validated PROM as a primary outcome

Research Issues

Ceiling effects and under use of impairment measures means higher level gains may be missed

Research centres have infrastructure to administer – others do not

loss of generalizability

Equity Issues

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5

Floor or ceiling effects

Patient-specific Functional Scale

Patient-specific activity scoring scheme (Point to one number):

0 1 2 3 4 5 6 7 8 9 10

Unable to perform activity

Able to perform activity at the same level as before injury or problem

(Date and Score)

Activity	Initial					
1.						
2.						
3.						
4.						
5.						
Additional						
Additional						

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PSFS developed by: Stratford, P., Gill, C., Westaway, M., & Binkley, J. (1995). Assessing disability and change on individual patients: a report of a patient specific measure. Physiotherapy Canada, 47, 258-263.

MSK Network Solutions

- Support development of a free or cheap infrastructure for core outcome measure assessment

MSK Network Project Progress

- Worked with EmPower to set scope of work
- Developed a core list of MSK outcome measures
- D Walton leading project on demographics collection
- Research project on clinicians perspectives of collecting data with the platform (Underway); testing useability

Next steps

Modify

Implement