USING ADVANCED STATISTICAL TECHNIQUES TO DEVELOP AND UNDERSTAND OUTCOME MEASURES: WHAT CAN THEY DO AND WHY ARE THEY IMPORTANT

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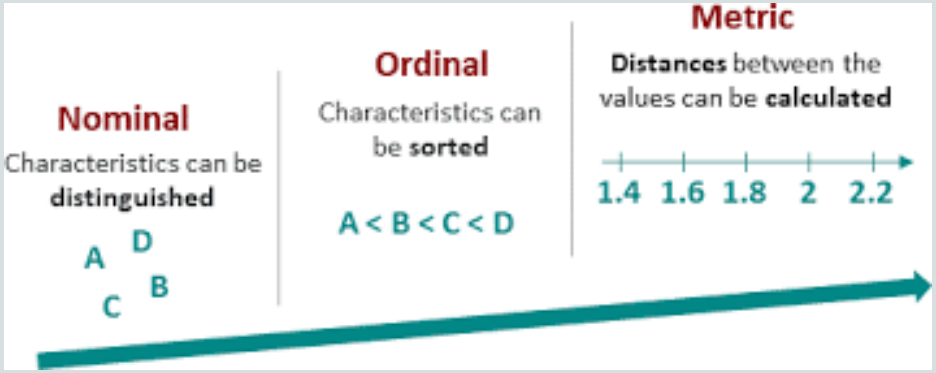
DISCLOSURES

No relevant disclosures

MEASUREMENT PROPERTIES



SCIM-SPINAL CORD INDEPENDENCE MEASURE

Version III, Sept 14, 2002

EXam 1 2 3 4 5 6

Self-Care DATE

1. Feeding (cutting, opening containers, pouring, bringing food to mouth, holding cup with fluid)
0. Needs parenteral, gastrostomy, or fully assisted oral feeding
1. Needs partial assistance for eating and/or drinking, or for wearing adaptive devices
2. Eats independently; needs adaptive devices or assistance only for cutting food and/or pouring and/or opening containers
3. Eats and drinks independently; does not require assistance or adaptive devices

2. Bathing (soaping, washing, drying body and head, manipulating water tap). **A-upper body; B-lower body**

A. 0. Requires total assistance
1. Requires partial assistance
2. Washes independently with adaptive devices or in a specific setting (e.g., bars, chair)
3. Washes independently; does not require **a**daptive **d**evices or **s**pecific **s**etting (not customary for healthy people) (adss)

B. 0. Requires total assistance
1. Requires partial assistance
2. Washes independently with **a**daptive **d**evices or in a **s**pecific **s**etting (adss)
3. Washes independently; does not require **a**daptive **d**evices (adss) or **s**pecific **s**etting

3. Dressing (clothes, shoes, permanent orthoses: dressing, wearing, undressing). **A-upper body; B-lower body**

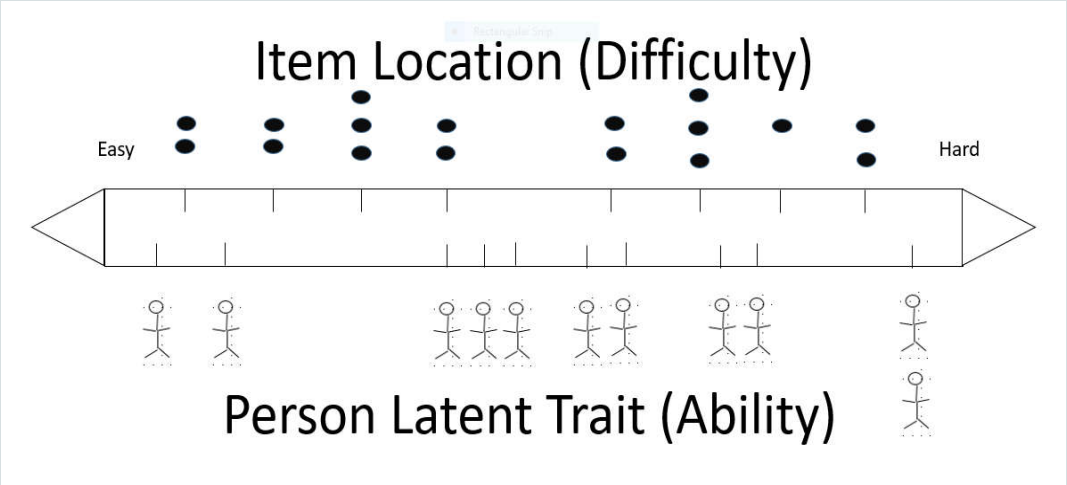
A. 0. Requires total assistance
1. Requires partial assistance with **c**lothes **w**ith**o**ut **b**uttons, **z**ippers or **l**aces (cwobzl)
2. Independent with cwobzl; requires **a**daptive **d**evices and/or **s**pecific **s**ettings (adss)
3. Independent with cwobzl; does not require adss; needs assistance or adss only for bzl
4. Dresses (any cloth) independently; does not require adaptive devices or specific setting

B. 0. Requires total assistance
1. Requires partial assistancewith **c**lothes **w**ith**o**ut **b**uttons, **z**ipps or **l**aces (cwobzl)
2. Independent with cwobzl; requires adaptive devices and/or specific settings (adss)
3. Independent with cwobzl without adss; needs assistance or adss only for bzl
4. Dresses (any cloth) independently; does not require adaptive devices or specific setting

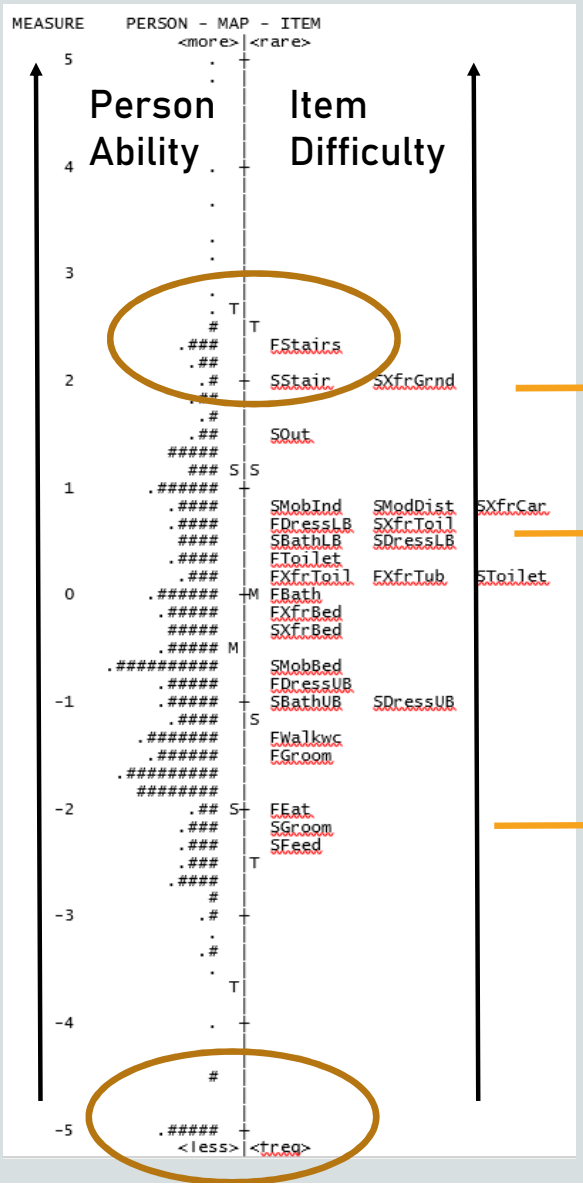
4. Grooming (washing hands and face, brushing teeth, combing hair, shaving, applying makeup)
0. Requires total assistance
1. Requires partial assistance
2. Grooms independently with adaptive devices
3. Grooms independently without adaptive devices **SUBTOTAL (0-20)**

Itzkovich al, 2017

RASCH ANALYSIS



- Linearized measure
- Co-calibrates items and persons
- Log odds of an individual person with X ability to achieve Y score
- Probabilities



Stairs
Ground transfers

Mobility/walking items
Dressing
Bathing

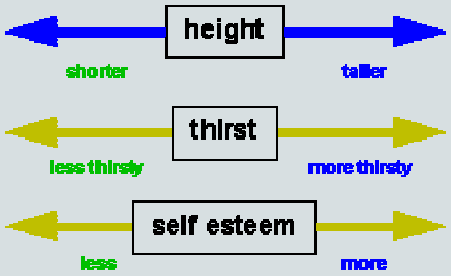
Grooming
Feeding

More difficult

Less difficult

RASCH ANALYSIS

- Assumes a unidimensional model
  - E.g. items measure the same thing



Motor items

Self- care
Mobility
Involuntary movement

Cognitive items

Functional Independence Measure
1) Eating
2) Grooming
3) Bathing
4) Upper body dressing
5) Lower body dressing
6) Toileting
7) Bladder management
8) Bowel management
9) Bed to chair transfer
10) Toilet transfer
11) Shower transfer
12) Locomotion
13) Stairs
14) Cognitive comprehension
15) Expression
16) Social interaction
17) Problem solving
18) Memory

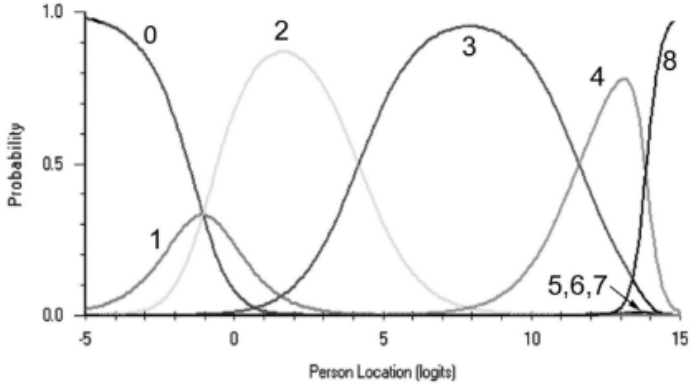
RASCH ANALYSIS

- Items (fit)
  - Do items “fit” the model?
  - Are items redundant?
- Scores
  - Are scores “ordered”?
  - Are all scores “used”?

Reed et al, 2017

a

SCIM score	Mobility Indoors (SCIM Item #12)
0	Requires total assistance
1	Needs electric wheelchair or partial assistance to operate manual wheelchair
2	Moves independently in manual wheelchair
3	Requires supervision while walking (with or without devices)
4	Walks with a walking frame or crutches (swing)
5	Walks with crutches or two canes (reciprocal walking)
6	Walks with one cane
7	Needs leg orthosis only
8	Walks without walking aids



RASCH ANALYSIS - USES

- Understanding of existing measures
  - Rasch analysis of SCIM III

a

SCIM score	Mobility Indoors (SCIM Item #12)
0	Requires total assistance
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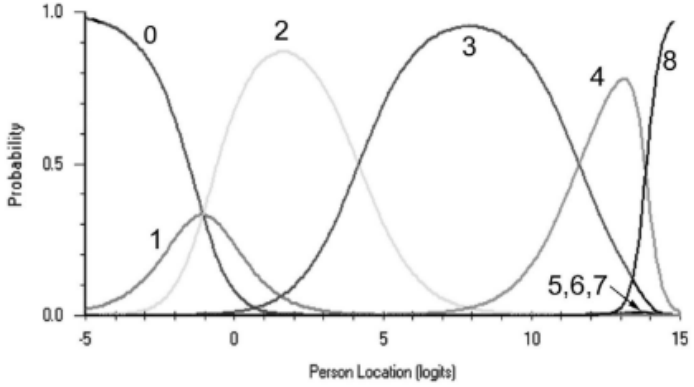

Catz et al, 2007
Reed et al, 2017

RASCH ANALYSIS - USES

- Measurement development
  - Develop measure
  - Assess in group of people
  - Refine measure
    - Eliminate redundant items
    - Gaps
    - Scoring
    - Balance with clinical utility

a

SCIM score	Mobility Indoors (SCIM Item #12)
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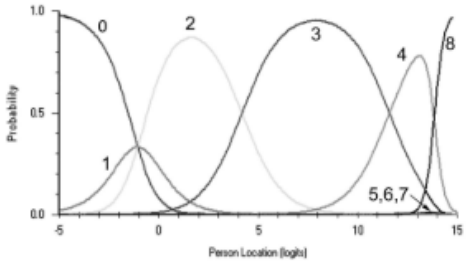
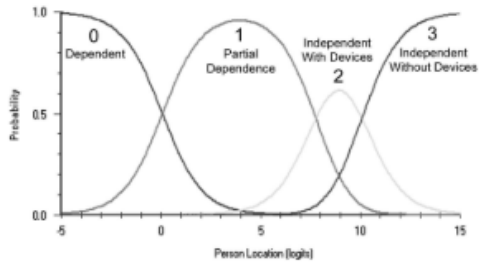
7	Needs leg orthosis only
8	Walks without walking aids



b

SCIM score	Mobility Indoors (SCIM Item #12)	Re-score
0	Requires total assistance	0
1	Needs electric wheelchair or partial assistance to operate manual wheelchair	0
2	Moves independently in manual wheelchair	1
3	Requires supervision while walking (with or without devices)	1
4	Walks with a walking frame or crutches (swing)	2
5	Walks with crutches or two canes (reciprocal walking)	2
6	Walks with one cane	2
7	Needs leg orthosis only	3
8	Walks without walking aids	3

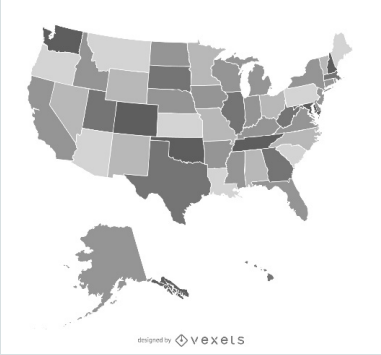


Reed et al, 2017

FUNCTIONAL OUTCOME MEASURES

Activities of Daily Living Clinical Outcome Assessments

Functional Independence Measure



Spinal Cord Independence Measure, version III

Neurological and functional recovery after thoracic spinal cord injury

Brian A. Lee[1], Benjamin E. Leiby[2], Ralph J. Marino[3]

[1]Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, PA, USA, [2]Department of Pharmacology and Experimental Therapeutics, Thomas Jefferson University, Philadelphia, PA, USA, [3]Department of Rehabilitation Medicine, Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, PA, USA

Characterization of neurological recovery following traumatic sensorimotor complete thoracic spinal cord injury

J Zariffa[1], JLK Kramer[1], JW Fawcett[2], DP Lammertse[3], AR Blight[4], J Guest[5], L Jones[6], S Burns[7], M Schubert[8,9], M Bolliger[8,9], A Curt[8,9] and JD Steeves[1]

[1]ICORD, University of British Columbia and Vancouver Coastal Health Research Institute, Vancouver, British Columbia, Canada; [2]Cambridge University Centre for Brain Repair, Robinson Way, Cambridge, UK; [3]Craig Hospital, Englewood, CO, USA; [4]Acorda Therapeutics, Hawthorne, NY, USA; [5]Neurological Surgery and the Miami Project to Cure Paralysis, Miami FL, USA; [6]Geron Corporation, Menlo Park, CA, USA; [7]VA Puget Sound Health Care System, Seattle, WA, USA; [8]Spinal Cord Injury Center, Balgrist University Hospital, Zurich, Switzerland and [9]European Multicenter Study about Spinal Cord Injury (EM-SCI) Study Group

GENERIC FUNCTION IN HUMANS

Activities of daily living

Phase III clinical trials:

How an individual feels, functions, survives

Must be clinically meaningful

OBJECTIVE

Create and validate a crosswalk for voluntary motor function

Functional Independence Measure

Generic assessment

11 voluntary motor items

7 levels of scoring

Spinal Cord Independence Measure III

Spinal cord specific measure

16 voluntary motor items

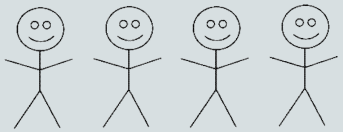
2-7 levels of scoring

SPECIFIC AIMS

- Create FIM/SCIM III crosswalks using three different methods
- Validate FIM/SCIM III crosswalks for all three methods in a separate dataset
- Identify the optimal method

METHODS

Study Design: Common Person



FIM and SCIM III voluntary musculoskeletal movement items

Single data point

Collected within 7 days

Development Dataset

SWISS
n = 662

Validation Datasets

Canadian
n = 133

ORIGINAL ARTICLE

United States (US) multi-center study to assess the validity and reliability of the Spinal Cord Independence Measure (SCIM III)

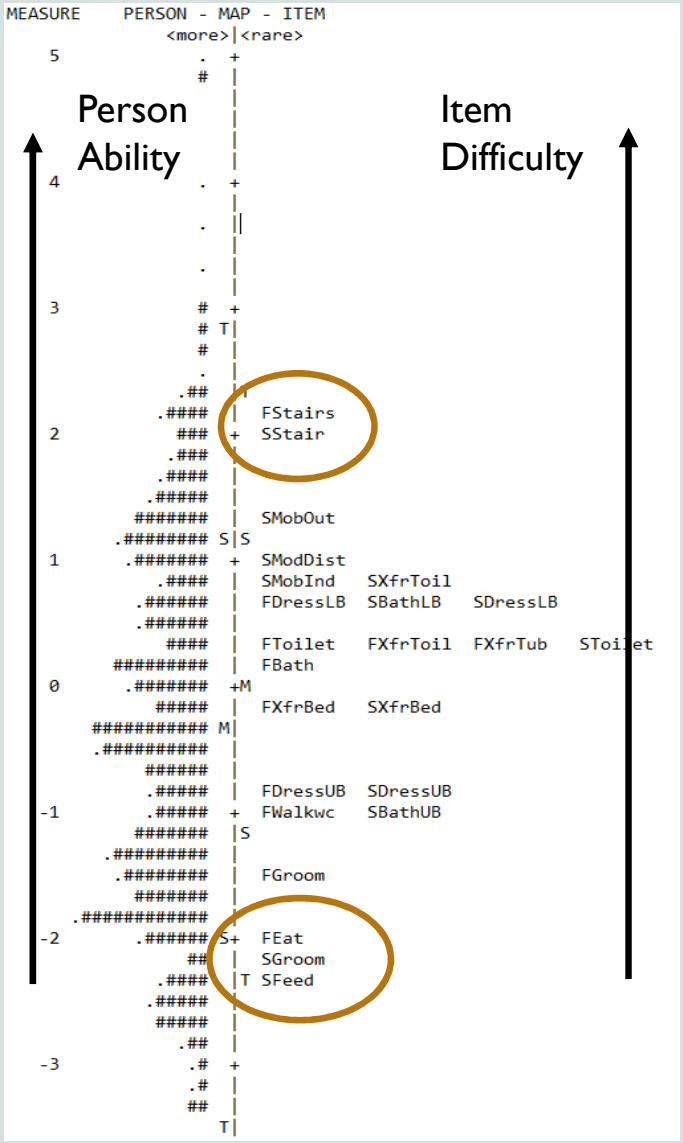
KD Anderson[1], ME Acuff[2], BG Arp[2], D Backus[3], S Chun[4], K Fisher[5], JE Fjerstad[6], DE Graves[7], K Greenwald[8], SL Groah[9], SJ Harkema[10], JA Horton III[8], M-N Huang[11], M Jennings[4], KS Kelley[12], SM Kessler[13], S Kirshblum[14], S Koltenuk[14], M Linke[15], I Ljungberg[9], J Nagy[16], L Nicolini[17], MJ Roach[16], S Salles[18], WM Scelza[19], MS Read[17], RK Reeves[13], MD Scott[11], KE Tansey[3], JL Theis[6], CZ Tolfo[10], M Whitney[19], CD Williams[15], CM Winter[12] and JM Zanca[20]

US
n = 119

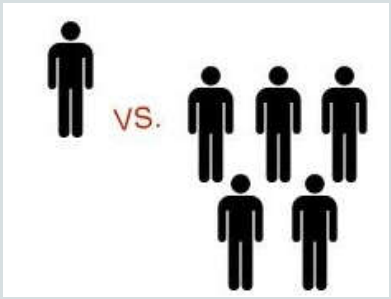
RESULTS: RASCH COCALIBRATION

FIM and SCIM III items are co-calibrated on a linear, common scale

FIM and SCIM III are "matched" based on item difficulty



CROSSWALK



Group and individual level

- ✓ Correlation coefficient > 0.866
- ✓ Point differences

FIM of 56
=
SCIM III score of 32

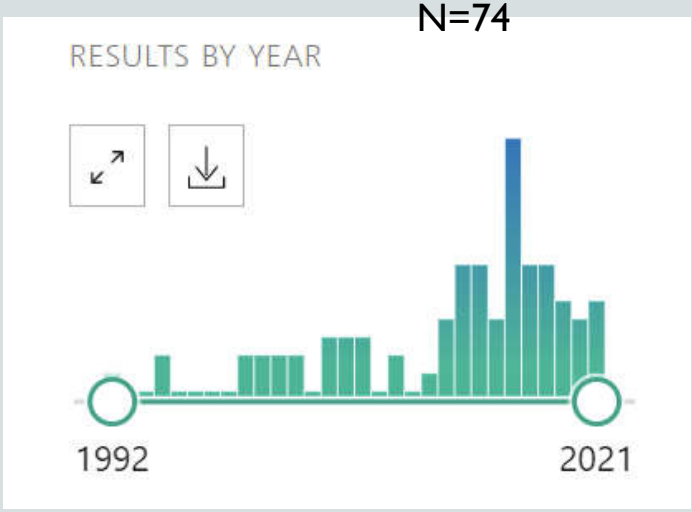
(voluntary motor score)

FIM raw scores	Rasch SCIM conversion		FIM raw scores	Equiperentile SCIM conversion
11	1		48	26
12	2		49	27
13	3		50	28
14	4		51	28.5
15	5		52	29
16	6		53	30
17	6		54	31
18	7		55	31.5
19	8		56	32
20	8		57	33
21	9		58	34
22	9		59	35
23	10		60	36
24	11		61	37
25	11		62	38
26	12		63	39
27	12.5		64	41
28	13		65	43
29	14		66	44
30	15		67	46

TAKE HOME POINTS

- In most cases, use of advanced statistical techniques for outcome measure development is warranted and desirable
- Have seen an increase in use of advanced techniques in human outcome measures in recent years
- Rarely used in animal outcome measures
  - E.g. Basso, Beattie, Bresnahan scale (BBB) locomotor rating scale– 21 points
- Can these techniques be used to further understand similarities and differences in animal and human outcome measures?

N=74



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- Susie Charlifue, PhD, Craig Hospital
- Chair: Heather Haugen, PhD, University of Colorado

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QUESTIONS?