Using PROMIS, Neuro-QOL, SCI-QOL, and TBI-QOL in Neurorehabilitation

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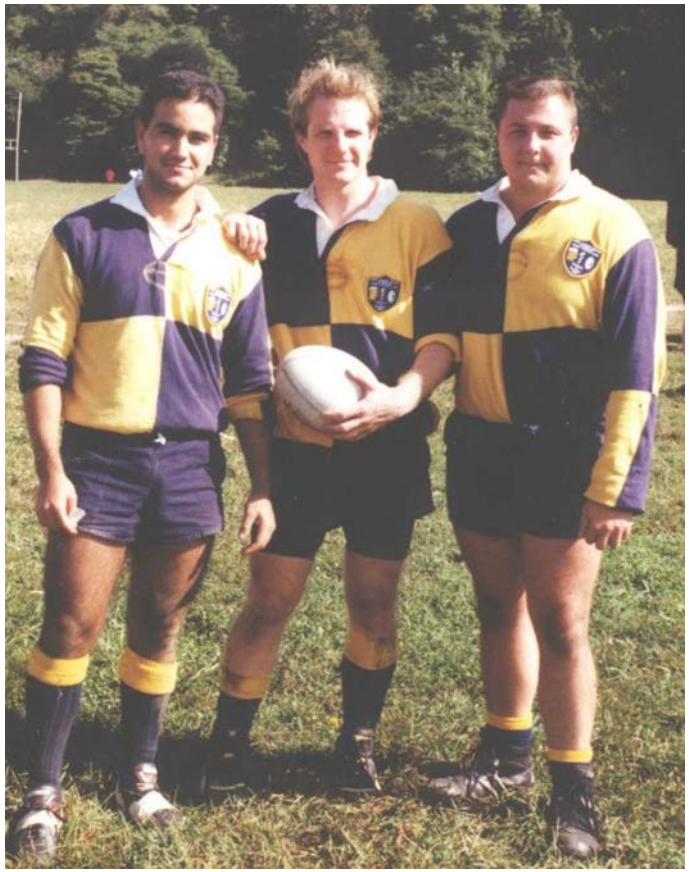
What is it like having a traumatic injury? (such as SCI or TBI)

- Sudden
- Unexpected



Traumatic Injury

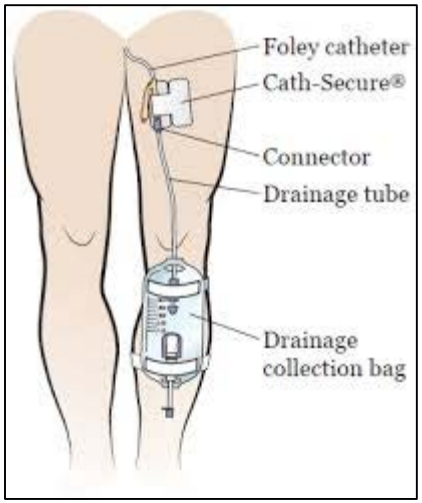
- DRAMATICALLY alters an individual's life

Potential for Life-long Impairment

- Physical Function/Mobility
- Secondary Medical Complications
  - *Bowel, Bladder, Pain, Pressure Ulcers, Respiratory*
- Cognition
  - *Executive Function, Memory, Communication*
- Social Participation
  - *Social roles, social activities, independence*

How does this affect HRQOL?

- How ***HASN'T*** it?
- Wide range of potential functional, medical, emotional, and social outcomes
- Some symptoms/limitations are more universal (e.g., depression, pain) while others are very disability-specific (e.g., bladder management difficulties, respiratory complications)



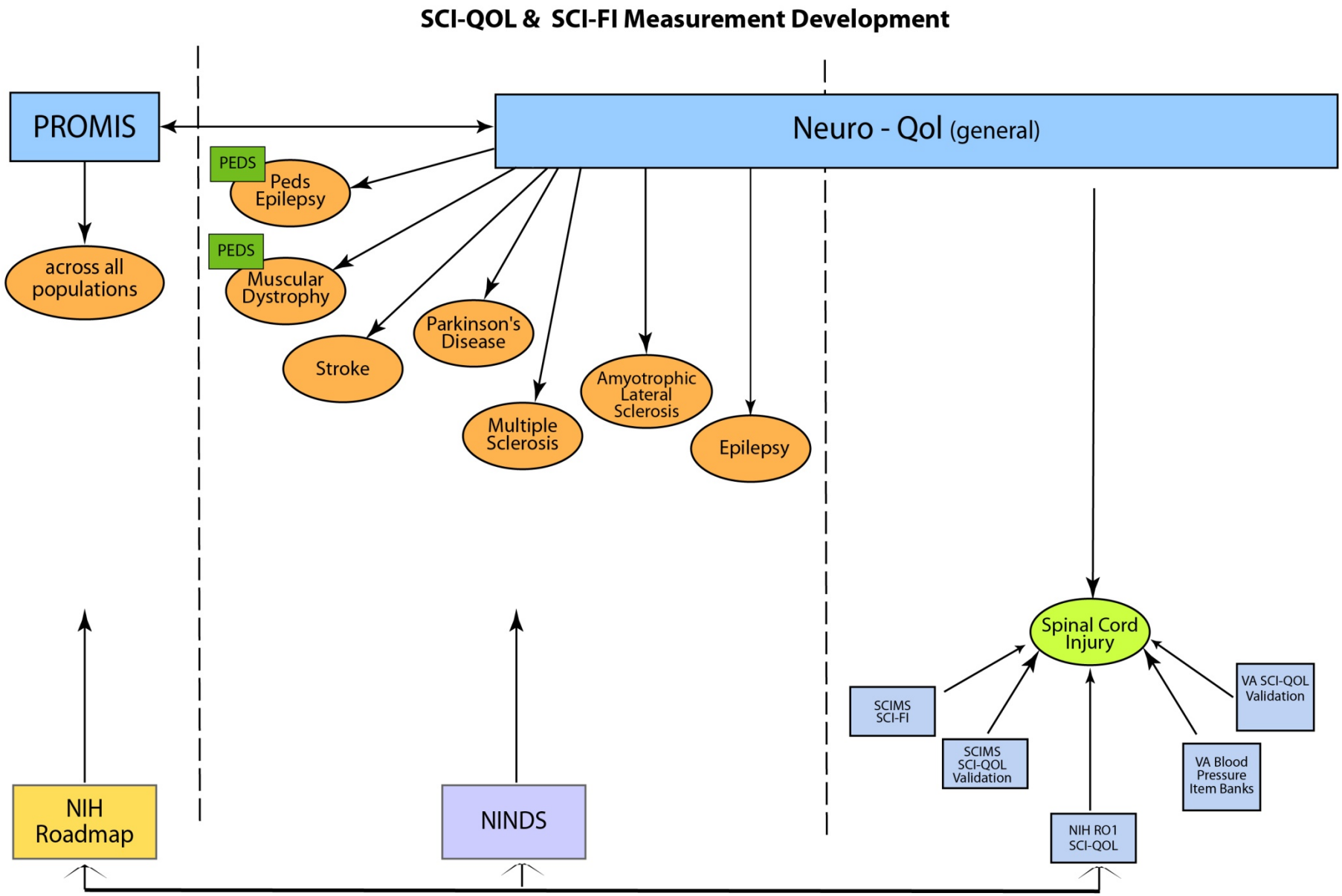
How to Measure PRO in Rehabilitation Populations?

- Some symptoms/limitations are more universal (e.g., depression, pain) while others are very disability-specific (e.g., bladder management difficulties, respiratory complications)

Extending the PROMIS® measurement system into SCI or TBI?

- Distinction between chronic illness and a sudden traumatic injury
- How is quality of life impacted?
- How should it be measured?

PROMIS/Neuro-QOL/SCI-FI/SCI-QOL



Use PROMIS for Individuals with Traumatic Injury?

- In 2000, Andresen & Meyers outlined some major caveats to using HRQOL measures for individuals with disabilities
- PROMIS has improved some of the issues through item banking:
  - CAT administration
    - Decreases likelihood of inappropriate or offensive items, e.g.:
      - SWLS item "If I could live my life over, I would change almost nothing…"
      - SF-36 item "Does your health now limit you in…climbing several flights of stairs?"
  - Customized SF administration
    - Researcher/clinician can select items to match functioning to sample

Use PROMIS for Individuals with Traumatic Injury?

- How do we further the use of PROMIS in a population of persons with severe conditions?
- Does PROMIS cover the appropriate domains?
  - Are there unique, highly salient aspects that aren't covered?
- Are PROMIS items appropriate for individuals with SCI or TBI?

- **Qualitative research to find out!**

SCI-QOL and TBI-QOL projects

- Started in 2006 (SCI) and 2007 (TBI)
- Partnership with Northwestern (including Drs. Cella, Gershon, Victorson, Nowinski, Choi, Lai)
- Partnership with SCI & TBI Model Systems

Focus Groups

- **SCI:**
  - 24 focus groups with 134 individuals with SCI
  - 4 focus groups with 42 clinicians

- **TBI:**
  - 7 focus groups with 33 individuals with TBI
  - 4 focus groups with 17 individuals who are caregivers or significant others of individuals with TBI
  - 2 focus groups with 15 clinicians

Unique Concepts

- So what domains are missing?
- Will PROMIS/NQ banks mean the same thing in SCI/TBI?
- Qualitative analysis steps:
  - Team-based codebook development (open & axial coding)
  - Two independent raters (selective coding)
  - Establish Inter-Rater Reliability
  - Coding Comparison & Reconciliation
  - Relative frequencies determined

Qualitative Analysis Results: SCI & TBI

- Some **PROMIS** *domains* are important:
  - Depression
  - Anxiety
  - Pain Interference
  - Ability to Participate in Social Roles & Activities
  - Satisfaction with Social Roles & Activities
  - Fatigue [TBI only]
  - Anger [TBI only]

TULSKY, D.S., KISALA, P.A., VICTORSON, D., TATE, D., HEINEMANN, A., AMTMANN, D., & CELLA, D. (2011). Developing a Contemporary Patient Reported Outcomes Measure for Spinal Cord Injury. Archives of Physical Medicine and Rehabilitation, 92 (10 Suppl 1):S44-S51. doi: 10.1016/j.apmr.2011.04.024. PubMed PMID: 21958922.

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Qualitative Analysis Results: SCI

- Some **PROMIS** *domains* are relevant but need modification:
  - Physical Function
    - Changing & Maintaining Body Position
    - Transferring (e.g., wheelchair to bed)
    - Bathing
    - Eating
    - Grooming
    - Toileting
    - Fine hand use (e.g., manipulating coins, phone buttons)
    - Wheelchair use (& maintenance)
    - Walking & Running

SCI-FI Item Development Process

Existing Items	124
AMPAC	25
NeuroQOL	37
PROMIS	33
PROMIS AT	6
Shriners	57

Literature → **Item Writing (k=619)**

Focus Groups → **Item Writing (k=619)**

Item Writing (k=619) → **Cognition Debriefing** → **Translatability Evaluation** → **Reading Level Analysis** → New SCI-FI Items, k=204 → **Field Testing (k=328)**

Existing Items → **Field Testing (k=328)**

Field Testing (k=328) → **Beginning Items**

Beginning Items										
Changing & Maintaining Body Position	Transferring	Walking & Running	Wheelchair Use	Bathing	Eating	Grooming	Toileting	Sexual Functioning	Fine Hand Use/ Manipulating Objects	Communica-tion Device Use

CFA: Confirm Models	Basic Mobility	Ambulation	Wheelchair Mobility	Self Care	Fine Motor	Subset 1 k=119; Subset 2 k=115

CFA: Confirm Unidimension-ality	Basic Mobility	Ambulation	Wheelchair Mobility	Self Care	Fine Motor	
	54	39	56	90	36	Final Items k=275

Some New Domains are Needed :

- Physical Function (SCI)
  - **Basic Mobility, Self Care, Fine Motor Function, Wheelchair Mobility, Ambulation**
- Physical/Medical Health
  - **Bladder Management Difficulties, Bowel Management Difficulties, Bladder Complications, Pressure Ulcers, Respiratory Complications***, Headache Pain
- Emotional Health:
  - Resilience, Grief/Loss, Self-esteem, **Psychological Trauma**
- Social Participation:
  - Independence, Asking for Help
- Cognition
  - Communication/Comprehension

**Items developed and tested but not calibrated*

Bold text indicates SCI-specific domains

Underlined text indicates TBI-specific domains

Optimizing Relevant Item Banks

- Add supplemental content to fill gaps in item hierarchy
  - SCI Basic Mobility
    - "Are you able to move your upper body while lying down in bed?"
  - SCI Anxiety
    - "I felt trapped in my own body."

Optimizing Relevant Item Banks

- Remove Clearly Inappropriate Items, e.g.:
  - PROMIS Pain Behavior Items
    - "Pain caused me to bend over while walking"
    - "When I was in pain I moved stiffly"
    - "When I was in pain I thrashed"
    - "When I was in pain I tried to stay very still"

Creating Supplemental Item Banks

- PROMIS instrument development standards, e.g.:
  - Literature Review
  - Content & Measurement Experts
  - Key Stakeholder Input – consumers, clinicians, caregivers
  - PROMIS item format
  - Qualitative Item Review (Expert Item Review & Cognitive Interviews)
  - Reading Level Review
  - Translatability Review

PROMIS®
Instrument Development and Validation
Scientific Standards
Version 2.0
(revised May 2013)

SCI-QOL/TBI-QOL Collaborators

- Boston University: Alan Jette, Mary Slavin, Pengsheng Ni
- University of Michigan: Denise Tate, Claire Kalpakjian, Marty Forchheimer
- Kessler Foundation: Steven Kirshblum, Trevor Dyson-Hudson, Denise Fyffe, Nancy Chiaravalloti
- Rehabilitation Institute of Chicago: Allen Heinemann
- Northwestern University: David Victorson, David Cella, Richard Gershon, Seung Choi, Jin-Shei Lai, Karon Cook
- TIRR: Mark Sherer, Angelle Sander
- Bronx VA: Ann Spungen
- Craig Hospital: Susan Charlifue, Gale Whiteneck
- University of Washington: Dagmar Amtmann, Charles Bombardier
- Mt. Sinai Medical School: Marcel Dijkers, Jeanne Zanca
- Shepherd Center: Jim Krause
- University of Miami: Elizabeth Felix
- University of Louisville: Dan Graves, Susan Harkema
- New York University: Tamara Bushnik
- Rehabilitation Institute of Michigan: Robin Hanks
- Santa Clara Valley Medical Center: Stephanie Kolokowsky-Hayner

SCI: Item Pools to Calibration Testing

Packet #	Domain	Included Item Pools	N
1	Physical Function	Basic Mobility, Self Care, Fine Motor Function, Wheelchair Mob., Ambulation	855
2	Physical-Medical	Bladder Mgmt. Diff., Bowel Mgmt. Diff, Bladder Complications, Pressure Ulcers, Pain Interference, Pain Behavior, Respiratory*	757
3	Emotional	Depression, Anxiety, PAWB, Stigma, Resilience, Grief/Loss, Self-esteem, Trauma	717
4	Social	Ability to Participate in SRA, Satisfaction with SRA, Independence, Sexual Function*	641

**Items developed and tested but not calibrated*

Packet 1: Physical Functioning Calibration Field Testing - Goals

- 750 cases (125 per site at 6 sites)

- **Balanced Sample will be Stratified by:**
  - Diagnosis (Paraplegia / Tetraplegia)
  - Severity (Complete / Incomplete)
  - Time Since Injury (<1 yr / 1 yr– 3 yrs / >3 yrs)

- Collect injury level / AIS scores for all participants

Physical Functioning: Packet 1
Calibration Field Testing - Results

	Total n = 854
Paraplegia	389
Tetraplegia	465
Complete	446
Incomplete	408
Incomplete Paraplegia	161
Incomplete Tetraplegia	247
Complete Paraplegia	228
Incomplete Tetraplegia	218
<1	264
1-3	237
3+	353

TBI: Item Pools to Calibration Testing

Packet #	Domain	Included Item Pools	N
1	Physical	Mobility, Upper Extremity, Fatigue, Pain Interference, Headache Pain	590
2	Emotional	PAWB, Depression, Anxiety, Stigma, Resilience, Grief/Loss, Self-Esteem	521
3	Cognitive + Anger/EBD	Cognition – General Concerns, Executive Function, Communication/Comprehension, Anger, Emotional & Behavioral Dyscontrol	569
4	Social	Ability to Participate in SRA, Satisfaction with SRA, Independence, Asking for Help, Sexual Function*	557

**Items developed and tested but not calibrated*

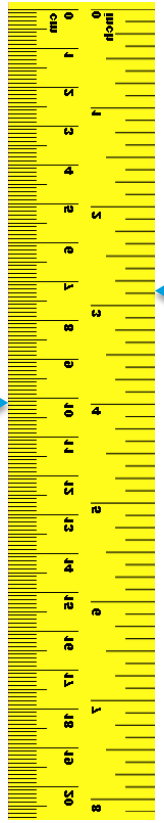
Analyses

- **Preliminary Analyses**
  - Internal consistency
  - Missing data
  - Item-total correlations
  - Sparse cells
  - Violations of motonicity
- **Dimensionality**
  - Factor loadings
  - Local item dependence (LID)
- **IRT parameter estimation and model fit**
  - Differential item functioning (DIF)

Preliminary Results

- SCI
  - 22 Item banks/scales
    - 4 from PROMIS
    - 4 from Neuro-QOL
- TBI
  - 20 Item banks/scales
    - 5 from PROMIS
    - 9 from Neuro-QOL

The Potential Problem



General Population
(Mean 50, SD 10)

Spinal Cord Injury
(Mean 50, SD 10)

= 77.9 Fahrenheit

(Multiply by 9, then divide by 5, then add 32)

Or push the button

Problem = Same score, different metric!

How to Preserve the PROMIS/Neuro-QOL Metric?

- Transform scores to original metric
  - Use of common, verbatim “anchor” items
  - STUIRT / Stocking-Lord methods used
    - “PROsetta Stone” methodology
    - In partnership with Northwestern
  - Linear transformation to PROMIS or NQ metric

SCI-QOL Bank	N	T-score Before Transformation		T-score After Transformation	
		Mean	S.D.	Mean	S.D.
Anxiety	716	49.69	9.60	50.75	9.12
Depression	716	48.59	9.29	50.66	9.62
Positive Affect and WB	717	51.15	9.61	54.47	7.92
Pain Behavior	757	49.94	9.60	53.50	9.30
Pain Interference	757	48.65	9.26	53.10	9.89
Stigma	611	49.84	9.66	53.18	6.69
Ability to Perform Social Roles and Activities	641	50.46	9.76	45.42	6.57
Social Role Satisfaction	641	50.72	9.77	45.44	5.59

T-Score: Mean = 50, SD = 10

Scores produced *directly* on PROMIS Metric

- SCI-QOL
  - Depression
  - Anxiety
  - Pain Interference
  - Pain Behavior
- TBI-QOL
  - Depression
  - Anxiety
  - Pain Interference
  - Fatigue
  - Anger

The same method has been used to place some item bank scores (e.g., PAWB, Stigma, Executive Function) directly on the **Neuro-QOL** metric

Scores produced on Neuro-QOL metric

- SCI-QOL
  - PAWB
  - Stigma
  - Ability to Participate
  - Satisfaction with SRA
- TBI-QOL
  - PAWB
  - Stigma
  - Ability to Participate
  - Satisfaction with SRA
  - Cognition: General Concerns
  - Executive Function
  - Emotional & Behavioral Dyscontrol
  - Mobility
  - Upper Extremity Fxn

New, Targeted Domains reference SCI/TBI

SCI-QOL

- Independence
- Grief/Loss
- Psychological Trauma
- Self-Esteem
- Resilience
- Bladder Complications
- Bowel Management Difficulties
- Bladder Management Difficulties
- Pressure Ulcers

TBI-QOL

- Independence
- Grief Loss
- Self-Esteem
- Resilience,
- Headache Pain
- Communication/ Comprehension

Final SCI-QOL v1.0

Table 5 Linkages with PROMIS and Neuro-QOL

Subdomain/Bank	# SCI-QOL Items	Linked to	# PROMIS Items	# Neuro-QOL Items	Reference Population
Bladder Management Difficulties	15	–	0	0	SCI
Bladder Complications	5	–	0	0	SCI
Bowel Management Difficulties	26	–	0	0	SCI
Pressure Ulcers	14	–	0	0	SCI
Pain Interference	7	PROMIS	18	0	General
Pain Behavior	4	PROMIS	3	0	General
Positive Affect & Well-being	5	Neuro-QOL	0	14	General
Depression	6	PROMIS	18	22	General
Anxiety	2	PROMIS	18	5	General
Stigma	5	Neuro-QOL	0	12	Neuro
Resilience	21	–	0	0	SCI
Grief/Loss	17	–	0	0	SCI
Self-Evaluation	19	–	0	3	SCI
Psychological Trauma	19	–	0	0	SCI
Ability to Participate in Social Roles & Activities	0	Neuro-QOL	0	19	General
Satisfaction with Social Roles & Activities	2	Neuro-QOL	3	14	General + Neuro
Independence/Autonomy	8	–	0	0	SCI
Ambulation	39	–	4	9	SCI
Basic Mobility	54	–	6	9	SCI
Fine Motor Function	36	–	9	6	SCI
Self Care	90	–	11	10	SCI
Wheelchair Mobility	56	–	0	0	SCI

Final TBI-QOL v1.0

TABLE 3 *Linkages with PROMIS and Neuro-QOL*[a]

Subdomain/Bank	No. TBI-QOL items	Linked to	No. PROMIS items	No. Neuro-QOL items	Reference population
Mobility	32	Neuro-QOL	9	**19**	General + Neuro
Upper Extremity	33	Neuro-QOL	17	**16**	General + Neuro
Fatigue	73	PROMIS	**67**	6	General
Pain Interference	40	PROMIS	**40**	0	General
Headache Pain	13	. . .	0	0	TBI
Positive Affect and Well-being	32	Neuro-QOL	0	**23**	General
Depression	28	PROMIS	**18**	22	General
Anxiety	28	PROMIS	**16**	20	General
Stigma	28	Neuro-QOL[b]	0	**23**	Neuro
Resilience	27	. . .	0	0	TBI
Grief/Loss	17	. . .	0	0	TBI
Self-Evaluation	13	. . .	0	0	TBI
Anger	35	PROMIS	**29**	0	General
Emotional and Behavioral Dyscontrol	26	Neuro-QOL	2	**16**	Neuro
Executive Function	37	Neuro-QOL	0	**11**	General + Neuro
Cognition—General Concerns	39	Neuro-QOL	0	**12**	General + Neuro
Communication/ Comprehension	31	. . .	0	5	TBI
Ability to Participate in Social Roles and Activities	45	Neuro-QOL	0	**43**	General
Satisfaction with Social Roles and Activities	41	Neuro-QOL	19	**39**	General
Independence	13	. . .	0	0	TBI

Options for Administration

- Each bank may be administered as:
  - Full bank
  - CAT
  - Fixed-length "Short form"
- Electronic Administration Options:
  - Assessment Center
  - NIH Toolbox App
  - REDCap*

*Contact SCI-QOL@udel.edu or TBI-QOL@udel.edu for access.

**SCI-QOL & TBI-QOL SF loading spreadsheets are currently available through SCI-QOL@udel.edu or TBI-QOL@udel.edu. All CATs & SFs expected to be added to REDCap library within the next year.

Barriers to Independent Self-Report

- Limited or no access to computer and/or internet
- Limited ability to interface with computer (e.g., for individuals with high tetraplegia)
- Cognitive difficulties impacting attention span

Administering PROMIS/SCI-QOL/TBI-QOL to Individuals with Disabilities

- Benefits of interview administration:
  - Does not require a person to access computer and/or internet
  - Does not require any hand or upper extremity functioning
  - Helps participants maintain attention to task (e.g., by redirecting)
  - Few to no missing data points
- Hard copy or electronic response cards used

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Research article

Overview of the Spinal Cord Injury – Quality of Life (SCI-QOL) measurement system

David S. Tulsky[1,2], Pamela A. Kisala[1], David Victorson[3], Denise G. Tate[4], Allen W. Heinemann[5,3], Susan Charlifue[6], Steve C. Kirshblum[7], Denise Fyffe[2,8], Richard Gershon[3], Ann M. Spungen[9], Charles H. Bombardier[10], Trevor A.

Research article

Methodology for the development and calibration of the SCI-QOL item banks

David S. Tulsky[1,2], Pamela A. Kisala[1], David Victorson[4], Seung W. Choi[3], Richard Gershon[4], Allen W. Heinemann[4,5], David Cella[4]

Research article

Measuring anxiety after spinal cord injury: Development and psychometric characteristics of the SCI-QOL Anxiety item bank and linkage with GAD-7

Pamela A. Kisala[1], David S. Tulsky[1,2], Claire Z. Kalpakjian[3], Allen W. Heinemann[4], Ryan T. Pohlig[1], Adam Carle[5], Seung W. Choi[6]

Research article

Measuring resilience after spinal cord injury: Development, validation and psychometric characteristics of the SCI-QOL Resilience item bank and short form

David Victorson[1], David S. Tulsky[2,3], Pamela A. Kisala[2], Claire Z. Kalpakjian[4], Brian Weiland[1], Seung W. Choi[5]

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Objective: To describe the development and psychometric properties of the Spinal Cord Injury - Quality of Life (SCI-QOL) Resilience item bank and short form.
Design: Using a mixed-methods design, we developed and tested a resilience item bank through the use of focus groups with individuals with SCI and clinicians with expertise in SCI, cognitive interviews, and item-response theory based analytic approaches, including tests of model fit and differential item functioning (DIF).
Setting: We tested a 32-item pool at several medical institutions across the United States, including the University of Michigan, Kessler Foundation, the Rehabilitation Institute of Chicago, the University of Washington, Craig Hospital and the James J. Peters/Bronx Department of Veterans Affairs medical center.
Participants: A total of 717 individuals with SCI completed the Resilience items.
Results: A unidimensional model was observed (CFI = 0.968; RMSEA = 0.074) and measurement precision was good (theta range between −3.1 and 0.9). Ten items were flagged for DIF, however, after examination of effect sizes we found this to be negligible with little practical impact on score estimates. The final calibrated item bank resulted in 21 retained items.
Conclusion: This study indicates that the SCI-QOL Resilience item bank represents a psychometrically robust measurement tool. Short form items are also suggested and computer adaptive tests are available.

Keywords: Patient outcomes assessment, Psychological resilience, Psychometrics, Quality of life, Spinal cord injuries

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OPEN

TBI-QOL: Development and Calibration of Item Banks to Measure Patient Reported Outcomes Following Traumatic Brain Injury

David S. Tulsky, PhD; Pamela A. Kisala, MA; David Victorson, PhD; Noelle Carlozzi, PhD; Tamara Bushnik, PhD; Mark Sherer, PhD; Seung W. Choi, PhD; Allen W. Heinemann, PhD; Nancy Chiaravalloti, PhD; Angelle M. Sander, PhD; Jeffrey Englander, MD; Robin Hanks, PhD; Stephanie Kolakowsky-Hayner, PhD; Elliot Roth, MD; Richard Gershon, PhD; Mitchell Rosenthal, PhD; David Cella, PhD

http://journals.lww.com/headtraumarehab/Fulltext/2016/01000/TBI_QOL___Development_and_Calibration_of_Item.6.aspx

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