## Outcome Domain:

Patient-Reported Outcomes (Future Multidimensional Tools)

### Domain Description and Relevance in TBI:

“No single measure to date can adequately capture the multiplicity of difficulties that people with TBI may face. This domain includes emerging large-scale measurement tools for patient-reported outcomes across several domains for generic medical populations, neurologic compromise, and TBI-related symptoms.” – Wilde et al 2010

Table CDE Classification by Type of TBI Study and Relevant Population for Recommended Patient-Reported Outcomes (Future Multidimensional Tools) Measures.

| Outcome Measure Name | Relevant TBI Population | Acute Hospitalized | Moderate/ Severe Rehabilitation | Concussion/ Mild TBI | Epidemiology |
| --- | --- | --- | --- | --- | --- |
| Neuro-QOL | Adult and Pediatric | Supplemental | Supplemental | Supplemental | Supplemental |
| Patient Reported Outcomes Measurement Information System (PROMIS) | Adult and Pediatric | Supplemental | Supplemental | Supplemental | Supplemental |
| TBI-QOL | Adult and Pediatric | Supplemental | Supplemental | Supplemental | Supplemental |

## Neuro-QOL

### DESCRIPTION

Contains 10 calibrated item banks with likert style items with several banks linked with PROMIS (e.g., anxiety, depression, stigma, positive psychological functioning, mobility, activities of daily living, satisfaction with social activities and roles, Social Roles, Applied and perceived cognitive functioning). Administered as short-forms to make keep assessments brief.

### PERMISSIBLE VALUES

T scores for all scales

### PROCEDURES

Patient reads Likert items on computer screen and responds. Computer scored. Administration time = < 5 minutes per subdomain (total time for short form across all domains is about 30 minutes).

### COMMENTS

General scale designed to be used in NINDS-sponsored clinical trials and other studies where cross-sample, cross-disease comparisons are desired. Has been tested in large samples of individuals from the general population and diverse neurologically impaired populations. However, has not been validated in TBI. Future plans are to develop a computer adaptive test (CAT).

### RATIONALE

Development funded by NINDS through a contract mechanism with the goal of utilizing in clinical trials research. Calibrated item banks offer advantages of obtaining reliable measurement across a wide spectrum of functioning with minimal items.

**REFERENCES**

See [Neuro-QOL Instrument Link](http://www.neuroqol.org/Pages/default.aspx)

## Patient Reported Outcomes Measurement Information System (PROMIS)

### DESCRIPTION

Version 1.0 contains 12 calibrated item banks with likert style items (e.g., anger, anxiety, depression, Fatigue, pain, physical function, satisfaction with social activities and roles, sleep/wake disturbance, and global health). Can be administered as a computer adaptive test or short-forms make assessment brief, yet reliable

### PERMISSIBLE VALUES

T scores for all scales

### PROCEDURES

Patient reads Likert items on computer screen and responds. Computer adapted version will select items with maximum discriminability and tailored to individual. Computer scored. Administration time is < 5 minutes per subdomain (total time for short form or CAT across all domains is about 30 minutes).

### COMMENTS

General scale designed to be used across multiple general medical populations for cross-sample comparisons. Has been tested in large samples of individuals from the general population and diverse medical populations. However, has not been validated in TBI.

### RATIONALE

Designed as part of the NIH Roadmap initiative for use in NIH sponsored clinical trials research. Calibrated item banks and CAT administration offer advantages of obtaining reliable measurement across a wide spectrum of functioning with minimal items.

### REFERENCES

see [NIH PROMIS Instruments Link](http://www.nihpromis.org/default.aspx)

## TBI-QOL

### DESCRIPTION

Contains 6 Neuro-QOL calibrated item banks along with targeted TBI item banks to enhance sensitivity and specificity of HRQL measurement in TBI population. Will be administered as short-forms and CAT to make keep assessments brief. The following scales are recommended:

* TBI-QOL Ability to Participate in Social Roles and Activities
* TBI-QOL Anger
* TBI-QOL Anxiety
* TBI-QOL Cognitive Health – Communication
* TBI-QOL Cognitive Health – Executive Functioning
* TBI-QOL Cognitive Health – General Concerns
* TBI-QOL Depression
* TBI-QOL Fatigue
* TBI-QOL Grief/Loss
* TBI-QOL Headache Pain
* TBI-QOL Independence
* TBI-QOL Mobility
* TBI-QOL Pain Interference
* TBI-QOL Positive Affect & Well-Being
* TBI-QOL Resilience
* TBI-QOL Satisfaction with Social Roles and Activities
* TBI-QOL Self-Evaluation
* TBI-QOL Stigma
* TBI-QOL Upper Extremity

### PERMISSIBLE VALUES

T scores for all scales

### PROCEDURE

Patient reads Likert items on computer screen and responds. Computer scored. Administration time is < 5 minutes per subdomain (total time for short form across all domains is about 30 minutes).

### COMMENTS

Being designed so that Neuro-QOL and PROMIS equivalency scores can be extracted to allow cross study comparisons. Specialized version of NINDS-sponsored Neuro-QOL for use in TBI clinical trials and other TBI studies. Is being field tested in a large sample of individuals with TBI (e.g., > 500). Future plans are to develop a computer adaptive test (CAT).

### RATIONALE

Will be a comprehensive TBI-specific outcome measure.

### REFERENCES

None available