

D.M. Miller¹, C.J. D.E. Victorson², Nowinski², A. Peterman³, D. Cella²¹Cleveland Clinic Foundation, Cleveland, OH; ²Evanston Northwestern Health Care, Evanston, IL; ³University of North Carolina, Charlotte, NCWorld Congress on Treatment and
Research in Multiple Sclerosis
Montreal, September 2008
Supported by the HHS-N256-2004-236-03-C

Background

Neuro-QOL is a five year project funded by the National Institute for Neurological Disorders and Stroke to develop a psychometrically robust and clinically relevant HRQL measurement system for major neurological conditions using item response theory and computer adaptive testing. The project is conducted in 2 phases. Phase 1 includes 1) Defining criteria for acceptance by neurology researchers, 2) Selecting 5 adult and 2 pediatric conditions for field testing, 3) Selecting domains and sub-domains to generate generic item banks and disease targeted scales, 4) Creating item pools for generic and targeted scales and 5) Translation into Spanish. Phase 2 involves field-testing the Neuro-QOL instrument and create/test item bank derived generic short forms and disease targeted scales.

Objective

Describe the rationale for including multiple sclerosis in the first phase of this project as a key neurological condition for which item banks and scales are developed and tested.

Rationale For Including Multiple Sclerosis

- Literature review summarized major neurological disorders and their concomitant impact on health-related quality of life (HRQL). MS was identified as a targeted condition with likely onset in early or middle age.
- Individual interviews with 44 experts who nominated 5 neurological disorders for which they felt it was important to measure HRQL.

Table 1.
Disorders Selected by Expert Interviewees (N=44)

Stroke	35	Spinal Cord Injury	12
Multiple Sclerosis	33	ALS	10
Parkinson's Disease	27	CNS Tumor	7
Epilepsy/Seizures	24	Pain Disorders	5
AD/Dementias	17	Neurodegenerative	5
Traumatic Brain Injury	16	Sleep Disorders	4
Migraine	13	Neuropathies	4

- A consensus panel of 13 renowned Neurology experts was convened to select 5 adult and 2 pediatric neurological conditions to be the focus of subsequent HRQL development activities. First, the panelists were asked to agree on a set of criteria that would guide their disease selections.

Selection Criteria

- Prevalence of the disease/disorder
- Magnitude of the disease's impact on the individual
- Existence of promising current or new treatments
- Multiple domains affected
- Chronic nature of the disease/possibility of seeing HRQL change

Table 2.
Adult and Pediatric Diseases Selected by Consensus Panel

ADULT		PEDIATRIC	
Stroke	13	Epilepsy	9
Multiple Sclerosis	12	Muscular Dystrophy	7
Parkinson's Disease	11	Cerebral Palsy	4
Alzheimer's Disease	10		
Migraine Headache	7		
Spinal Cord Injury	6		
Epilepsy	5		
Traumatic Brain Injury	1		

- Consultation was also made with the American Academy of Neurology Practice Committee.

- FINAL RECOMMENDATIONS:** After completing the process outlined above and discussions with the NINDS, the Neuro-QOL Executive Committee finalized the list of adult and pediatric conditions.

Table 3.
Final Recommendations

ADULT CONDITIONS	PEDIATRIC CONDITIONS
Stroke	Epilepsy
Multiple Sclerosis	Muscular Dystrophy
Parkinson's Disease	
Epilepsy	
Neuromuscular Disorders/ALS	

Summary of Rationale for Disease Selection

ADULT

Stroke

Literature review, Expert Interviews, Consensus Panel, AAN

Multiple Sclerosis

Literature review, Expert Interviews, Consensus Panel, AAN

Parkinson's Disease

Literature review, Expert Interviews, Consensus Panel, AAN

Epilepsy

Investigators' recommendation: some support from each consultant group. Provides opportunity to study one condition across the life span

ALS

Literature review and desire by NINDS to include a neuromuscular condition with prominent HRQL impact

PEDIATRIC CONDITIONS

Epilepsy

Literature review, Expert Interviews, Consensus Panel, AAN

Muscular Dystrophies

Literature review, Consensus Panel, NIH input

Step 2, Phase 1.

The following generic banks and disease-specific scales will be tested during the next phase of the project

Generic Item Banks

Mental Health: Emotion

- Depression
- Anxiety/Fear
- Stigma
- Positive psychological function

Mental Health: Cognition

- Perceived cognitive function
- Applied cognitive function

Social Health

- Role performance
- Role satisfaction

Physical Health

- Mobility and ambulation
- Fine motor and upper extremity function

Targeted Scales

Developed and Tested

- Weakness/Fatigue
- Sleep disturbance
- Personality/behavioral change

Developed but not tested in this study

- Sexual function
- Bowel and bladder function

Fatigue Items

(Will be tested during Phase 2)

In the past seven days

- I needed help doing my usual activities because of my fatigue
- I had to limit my social activities because I was tired
- I needed to sleep during the day
- I had trouble starting things because I was to tired
- I had trouble finishing things because I was to tired
- I was too tired to do my household chores
- I was too tired to leave the house
- I was too tired to take a short walk
- I was too tired to eat
- I was frustrated by being too tired to do the things I wanted to do
- I felt exhausted
- I felt tired
- I felt fatigued
- I felt weak all over
- I needed help doing my usual activities because of weakness
- I had to limit my social activities because I was physically weak
- I had enough physical strength to do the things I wanted to do
- I had to force myself to get up and do things because I was physically too weak

Response set

- 1 = Never
- 2 = Rarely
- 3 = Sometimes
- 4 = Often
- 5 = Always

Conclusion

The Phase 1 process confirmed that the general neurology community recognizes the significant HRQL impact of MS and its treatments.

The inclusion of MS in the Neuro-QOL development process will assure that MS researchers and clinicians will have a robust means of assessing how the disease and its treatments effect persons with MS