

NINDS/NICHD-NCMRR NeuroRehab CDE Project Quality of Life Subgroup Summary

The subgroup began their selection process with a review of the assigned existing NINDS CDE subdomains. NCMRR revised the subdomains based on feedback from the subgroup.

NeuroRehab v1.0 QoL Subdomains
Global Health-Related Quality of Life Outcome
Generic Health-Related Quality of Life
Multifactorial Patient Reported Burden of Disease
Disease-Specific Health-Related Quality of Life
Patient/Caregiver Health-Related Quality of Life

The subgroup noted the need for additional revisions and creation of new subdomains. These additional changes will be considered in future phases of the project.

The subgroup determined that their recommended instruments would only be within the NeuroRehab Supplemental – Highly Recommended (S-HR) classification, as not all NeuroRehab studies will use Quality of Life (QoL) measures.

The Chairs reviewed the list of assigned instruments to remove those that were applicable only to the pediatric population. The remaining instruments were then reviewed to determine if they measure health-related (HR) QoL. The list of measures that were determined to be relevant or potentially relevant to HR QoL in the adult population was divided among members for review in pairs.

Information from the Research Measures Database; PROQOLID; StrokEDGE/StrokEDGE II and SCIRE databases, and NINDS CDE NOCs were used to help inform the subgroup’s decisions on recommending instruments. Reviewer feedback was discussed during teleconference meetings. Members assigned a subdomain to each instrument and then determined the top three S-HR measures for the Global HR QoL Outcome and Generic HR QoL and the top S-HR measure for each disorder for the Disease-Specific HR QoL Subdomain.

Measures that are exclusively for use in the pediatric population were removed from consideration, as there is a separate Infant Pediatrics subgroup. The subgroup’s Disease-Specific HR QoL subdomain includes recommendations for QoL measures in specific populations. The Generic HR QoL subdomain includes general, non-disease specific measures. The Global HR QoL Outcome subdomain includes overall evaluations like global ratings of health or change.

Summary of Recommendations

Subdomain	Instrument
Global HR QoL Outcome	PROMIS Item Bank v1.2 - Global Health
	Quality of Life in Neurological Disorders (Neuro-QOL)
Generic HR QoL	PROMIS-29 Profile
	Short Form 36-Item Health Survey (SF-36)
	World Health Organization Quality of Life Assessment (WHOQOL-BREF)
Disease-Specific HR QoL	HDQLIFE
	Headache Impact Test-6 (HIT-6)
	Myotonic Dystrophy Health Index (MDHI)
	Parkinson’s Disease Quality of Life Scale (PDQUALIF)
	Spinal Cord Injury - Quality of Life (SCI-QOL)
	Traumatic Brain Injury - Quality of Life (TBI-QOL)

Some QoL measure questions may not be acceptable for those who use mobility aids.

The subgroup did not identify any existing NINDS CDE instruments that could be categorized into the Multifactorial Patient Reported Burden of Disease or Patient /Caregiver HR QoL subdomains.

For the NeuroRehab v1.0 CDE recommendations, no new CDEs or subdomains may be created, and recommendations were limited to 3 S-HR measures per subdomain or 1 S-HR measure per disorder in the disease-specific subdomain. Additional measures or subdomains were categorized as gaps. Through their review, the subgroup noted the need for new subdomains and further revisions to existing ones. Some QoL NINDS CDE subdomains, like ‘Multifactorial Patient Reported Burden of Disease’ need a clear definition which will provide more specificity to the measures, benefitting CDE users.

The current recommendations focus on HR QoL. Future work should include broader measures of QoL. The subgroup noted the need for a Domain-Specific QoL subdomain and identified existing NINDS CDE instruments that could be included in this subdomain.

The subgroup identified the following gap areas in their review:

The following measures were identified as S-HR and were categorized into the Generic HR QoL and Disease-Specific HR QoL subdomains, but were not select as one of the top measures for these subdomains.

Subdomain	Instrument	Comment
Generic HR QoL	12-Item Short Form Health Survey (SF-12)	The measure seems outdated, although there is a lot of evidence about it. It may not be a measure of QoL. There might be a floor effect for it.
	Health Related Quality of Life-14 (HRQOL-14)	From the CDC, 14 questions, grouped into 3 modules. The 4-item Healthy Days module has been used in BRFSS. Focuses primarily on health and functional status -- raising questions about whether this is a QoL measure. May be outdated. Core module has been used in NHANES, so that provides comparative information.
	Short Form Health Survey-36 (SF-36) walk-wheel Modification for Spinal Cord Injury	Replaces the word "walk" with "wheel" in 3 questions of the SF-36. Aimed to address floor effect with SF-36.
Disease-Specific HR QoL	Migraine Specific Quality of Life Questionnaire (MsQoL v2.1)	Focus is specific to migraine. Addresses factors of role function, role function preventive, degrees to which performance of daily activities is prevented by migraine and emotional function.
	Parkinson's Disease Quality of Life Questionnaire (PDQL)	
	Qualiveen	Disease-specific QoL for individuals with SCI who have urinary disorders

The following measures were identified as S-HR but would be categorized into the Domain-Specific QoL subdomain which is a gap area for NeuroRehab v1.0.

The Neuro-QoL item banks were created using advanced psychometric methods (Item Response Theory (IRT) and Computerized Adaptive Testing (CAT)). They were designed to be NIH CDEs for use in populations with neurological

disorders. The development team validated the scale in each of the target populations. Note that for individuals with SCI and TBI, optimized versions of this scale have been created utilizing large samples of individuals with SCI and TBI respectively as part of the SCI-QOL and TBI-QOL systems. The SCI-QOL and TBI-QOL version yields scores that are on the Neuro-QOL metric.

Instrument	HR QOL Measure?	General or Disease-Specific	Disease list (or 'All')	Comment
Neuro-QOL Adult Bank - Ability to Participate in SRA	Yes	Specific Diagnoses	Stroke, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis	It contains 45 items in the item bank and 8 items in the standard short form.
Neuro-QOL Adult Bank - Anxiety	Yes	Specific Diagnoses	Stroke, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis	It contains 21 items in the item bank and 8 items in the standard short form. It can be administered as a CAT or fixed form. The development team validated the scale with 200 individuals in the target population.
Neuro-QOL Adult Bank - Cognitive Function	Yes	Specific Diagnoses	Stroke, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis	It contains 28 items in the item bank and 8 items in the standard short form. It can be administered as a CAT.
Neuro-QOL Adult Bank - Depression	Yes	Specific Diagnoses	Stroke, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis	It contains 24 items in the item bank and 8 items in the standard short form. It can be administered as a CAT or fixed form.
Neuro-QOL Adult Bank - Fatigue	Yes	Specific Diagnoses	Stroke, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis	It contains 19 items in the item bank and 8 items in the standard short form. It can be administered as a CAT or fixed form.
Neuro-QOL Adult Bank - Lower Extremity Function	Yes	Specific Diagnoses	Stroke, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis	It contains 19 items in the item bank and 8 items in the standard short form. It can be administered as a CAT.
Neuro-QOL Adult Bank - Positive Affect and Well-Being	Yes	Specific Diagnoses	Stroke, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis	It contains 23 items in the item bank and 8 items in the standard short form. It can be administered as a CAT.
Neuro-QOL Adult Bank - Satisfaction with SRA	Yes	General (For All diseases)	Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis, Duchenne/Becker MD, Parkinson's Disease, Stroke	Additional psychometric evaluation has been conducted in specific diseases; the extent and level of evidence varies. It contains 45 items in the item bank and 8 items in the standard short form. It can be administered as a CAT. English and

Instrument	HR QoL Measure?	General or Disease-Specific	Disease list (or 'All')	Comment
				Spanish versions of short forms are freely available as administration-ready PDFs from Healthmeasures.net.
Neuro-QOL Adult Bank - Sleep Disturbance	Yes	General (For All diseases)	Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis, Duchenne/Becker MD, Parkinson's Disease, Stroke	The item bank contains 8 items in the item bank and is only available as an 8 items standard short form. English and Spanish versions of short forms are freely available as administration-ready PDFs from Healthmeasures.net.
Neuro-QOL Adult Bank - Stigma	Yes	General (For All diseases)	For All diseases	The item bank contains 24 items in the item bank and 8 items in the standard short form. It can be administered as a CAT. English and Spanish versions of short forms are freely available as administration-ready PDFs from Healthmeasures.net. Additional psychometric evaluation has been conducted in specific diseases; the extent and level of evidence varies.
Neuro-QOL Adult Bank - Upper Extremity	Yes	Specific Diagnoses	Stroke, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis	It contains 20 items in the item bank and 8 items in the standard short form. It can be administered as a CAT.
Patient-Reported Outcomes Measurement Information System (PROMIS)	Yes	General (For All diseases)	Stroke, Congenital Muscular Dystrophy (MD)	<p>GAP for other conditions; current CDE lists</p> <p>Supplemental: Traumatic Brain Injury (TBI), Amyotrophic Lateral Sclerosis (ALS), Chiari I Malformation (CM), Epilepsy, Friedreich's Ataxia (FA), Headache, Huntington's Disease (HD), Mitochondrial Disease (Mito), Multiple Sclerosis (MS), Myasthenia Gravis (MG), Neuromuscular Diseases (NMD), Duchenne/Becker Muscular Dystrophy (DMD/BMD), Spinal Muscular Atrophy (SMA), Parkinson's Disease (PD), Stroke, and Spinal Cord Injury (SCI), and Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH)</p> <p>Exploratory: Cerebral Palsy (CP) Myotonic Muscular Dystrophy (DM) and Facioscapulohumeral Muscular Dystrophy (FSHD) and Sport-Related Concussion (SRC)</p>

The following measures were identified as not meeting the threshold for the S-HR classification.

Instrument	HR QoL?	General or Disease-Specific	Disease list (or 'All')	Comment
24-Hour Migraine Quality of Life Questionnaire (24-Hr-MQoLQ)	Yes	Specific Diagnoses		While it has been translated to 10 languages, and psychometric data are solid, there are few studies of the psychometric properties; in the literature cited it's been primarily as an outcome measure.
Assessment of Quality of Life (AQoL)	Yes	General (For All diseases)	For All diseases	Exploratory for CP only per CDE review. Pubmed search found new literature for stroke and MS. Seems to provide one score, but no evidence of unidimensionality found
EuroQoL-5 Dimension Questionnaire (EQ-5D)	Yes	General (For All diseases)	For All diseases	Current CDE S-HR for Stroke and Parkinson's Disease. Lower ratings for other conditions. Psychometric properties do not support use in NeuroRehab, does not capture disability, limited responsiveness to change, should be used for valuation studies only.
EuroQoL-VAS	Yes	General (For All diseases)	For All diseases	Supplemental for ALS & MS. Not appropriate use to measure QOL in any condition on its own.
Health Utilities Index (HUI)	Yes	General (For All diseases)		Feels a bit outdated. Question whether this reflects current understanding of health and QOL -- stigmatized views of disability. Linked to production of QALYS, which has embedded assumptions about how health relates to QOL that are controversial.
ICIQ-Lower Urinary Tract Symptoms Quality of Life	Yes	General (For All diseases)	Although it cuts across causes of urinary incontinence, the measure addresses QOL related specifically to urinary incontinence	Unclear how much psychometric testing has been done. There appear to be variants of this instrument, which have appeared over time. Therefore, it is difficult to assess its current status in terms of psychometric evaluation.
Individualized Neuromuscular Quality of Life Questionnaire (INQoL)	Yes	Specific Diagnoses	Facioscapulohumeral MD, Myotonic Dystrophy	Current CDE Supplemental, This instrument is listed on PROQOLID, which cites two publications (construction and validation). One additional reference for a Dutch translation.
International SCI Quality of Life Basic Data Set	Yes	Specific Diagnoses		Selected gap as a gap because while the psychometric properties of this 4 item (3 item in earlier versions) is intended to be brief and "basic". Its use will depend largely on context. If QOL was an outcome that is a focus of the work or there is a desire to understand in some depth, this would not be an ideal measure. But if the intent is to quickly gather very basic QOL data, this

Instrument	HR QoL?	General or Disease-Specific	Disease list (or 'All')	Comment
				would suffice for SCI. Not certain there is work on sensitivity to change.
Life Satisfaction Questionnaire (LISAT-9)	Yes	Specific Diagnoses	Spinal Cord Injury	Current CDE Supplemental for Spinal Cord Injury and lists 18 references but does not include literature since 2010. A PubMed search of "Life Satisfaction Questionnaire" OR "LISAT-9" retrieved 169 references, thus this instrument might be eligible for a higher rating but will require a literature review
McGill Quality of Life Questionnaire (MQOL)	Yes	General (For All diseases)	Amyotrophic Lateral Sclerosis, For All diseases	Current CDE supplemental for ALS. Developed for people with life-threatening diseases.
MOS Modified Social Support Survey (MSSS) Component of the Multiple Sclerosis Quality of Life Inventory (MSQLI)	Yes	Specific Diagnoses	Multiple Sclerosis	This measure is only for MS and therefore if the subgroup's preference is for measures covering more than 1 disease, this would not be recommended. If the subgroup is recommending disease-specific measures but only for use in that disease, then it seems to be a Gap measure. It was recommended as Supplemental for MS by NINDS CDE, so it doesn't seem appropriate to recommend it at a higher level for MS.
Multiple Sclerosis International Quality of Life Questionnaire (MusiQoL)	Yes	Specific Diagnoses	Multiple Sclerosis	This measure is only for MS and therefore if the subgroup's preference is for measures covering more than 1 disease, this would not be recommended. If we are recommending disease-specific measures but only for use in that disease, then it seems to be a Gap measure. It was recommended as Supplemental for MS by NINDS CDE, so it doesn't seem appropriate to recommend it at a higher level for MS.
Multiple Sclerosis Quality of Life Inventory (MSQLI)	Yes	Specific Diagnoses	Multiple Sclerosis	This measure is only for MS and therefore if the subgroup's preference is for measures covering more than 1 disease, this would not be recommended. If the subgroup is recommending disease-specific measures but only for use in that disease, then it seems to be a Gap measure. It was recommended as Supplemental for MS by NINDS CDE, so it doesn't seem appropriate to recommend it at a higher level for MS.
Multiple Sclerosis Quality of Life-54	Yes	Specific Diagnoses	Multiple Sclerosis	This measure is only for MS and therefore if the subgroup's preference is for measures

Instrument	HR QoL?	General or Disease-Specific	Disease list (or 'All')	Comment
Instrument (MSQOL-54)				covering more than 1 disease, this would not be recommended. If the subgroup is recommending disease-specific measures but only for use in that disease, then it seems to be a Gap measure. It was recommended as Supplemental for MS by NINDS CDE, so it doesn't seem appropriate to recommend it at a higher level for MS.
Myasthenia Gravis Quality of Life 15 (MG-QOL-15)	Yes	Specific Diagnoses	Myasthenia Gravis	Brief 15-item disease specific that is on par with the 60 item MGQOL.
Neuro-QOL Adult Bank - Communication	Yes	Specific Diagnoses	Stroke, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Epilepsy, Multiple Sclerosis	
NIH Toolbox - Emotional Battery General Satisfaction (Ages 18 and over) Item Bank	Yes	General (For All diseases)	For All diseases	Current CDE Supplemental for lots of conditions, Exploratory for others. Uses the same items as satisfaction with life. Item "If I could live my life over, I would change almost nothing" offensive to people with traumatic injury.
Quality of Life After Brain Injury (QOLIBRI)	Yes	Specific Diagnoses		One of the advantages of this measure is that it was developed cross-culturally; has solid psychometrics from what has been reported on the scale's website. Also in PubMed: https://pubmed.ncbi.nlm.nih.gov/20486801/
Quality of Life in Epilepsy Inventory-31 (QOLIE-31)	Yes	Specific Diagnoses		Many translations in other languages and developed cross culturally; unclear if this can be used digitally because of its use of some visual scales. Lots of refs in PROLOQID website though not certain if most of those are its use as an outcome vs. psychometric study. The psychometric information on PROLOQID suggests it's limited to its original development. Would have to look further for more recent psychometric work.
Quality of Life in Swallowing Disorders (SWAL-QOL)	Yes	Specific Diagnoses	Amyotrophic Lateral Sclerosis, Parkinson's Disease	QOL in swallowing disorders especially for neurodegenerative disorders (e.g. ALS, Parkinson's)
Quality of Life Index (QLI) - SCI Version	Yes	Specific Diagnoses	Spinal Cord Injury	

Instrument	HR QoL?	General or Disease-Specific	Disease list (or 'All')	Comment
Satisfaction with Life Scale	Yes	General (For All diseases)	For All diseases	Current CDE Supplemental for SCI, concussion and TBI. Appropriate for all conditions, but definite limitations in psychometric properties. Last item offensive to people with traumatic injuries (TBI, SCI, burns). If you choose to use, administer without the last item
Amyotrophic Lateral Sclerosis Assessment Questionnaire (ALSAQ-40)	Maybe	Specific Diagnoses	Amyotrophic Lateral Sclerosis	Measures subjective well-being of patients with ALS and MND
Belastungsfragebogen Parkinson kurzversion (BELA-P-k)	Maybe	Specific Diagnoses	Parkinson's Disease	Measures psychological and psychosocial problems in Parkinson's Disease and the need for help
Bell CFIDS Disability Scale	Maybe	Specific Diagnoses	Myalgic Encephalomyelitis/Chronic Fatigue Syndrome	Assesses functional ability in adult ME/CFS patients
Headache Disability Index	Yes	General (For All diseases)		Supplemental Highly Recommended for Chiari Malformation. Has been used extensively in studies examining rehabilitation interventions for multiple types of headache. Aside from initial reference, used in two outcome studies of people with Chiari Malformation. Little information on psychometrics aside from the initial development paper.
Headache Impact Questionnaire (HImQ)	Maybe	Specific Diagnoses	Headache	Either gap (Exploratory) or none, little information available except for the initial studies of reliability and validity. Hasn't been used in neurorehabilitation populations. Includes both assessments of severity and "disability". Exploratory for headache
Mental Fatigue Scale (MFS)	Maybe	General (For All diseases)		Exploratory. Currently Supplemental in ME/CFS. Developed for a neurologic population. Has been used in Stroke and TBI. Aims to measure fatigue, not quality of life
National Institutes of Health (NIH) Toolbox	Maybe	General (For All diseases)	Amyotrophic Lateral Sclerosis, Cerebral Palsy, Chiari I Malformation, Epilepsy, Friedreich's ataxia, Headache, Huntington's Disease,	Current CDE Supplemental for multiple conditions. However, more a neurobehavioral assessment rather than Quality of Life measure

Instrument	HR QoL?	General or Disease-Specific	Disease list (or 'All')	Comment
			Mitochondrial Disease, Multiple Sclerosis, Neuromuscular Diseases, Duchenne/Becker MD, Facioscapulohumeral MD, Congenital Muscular Dystrophy (MD), Myasthenia Gravis, Myotonic Dystrophy, Spinal Muscular Atrophy, Parkinson's Disease, Spinal Cord Injury, Stroke, Traumatic Brain Injury	
Parkinson's Impact Scale (PIMS)	Maybe	Specific Diagnoses	Parkinson's Disease	Current CDE Supplemental for Parkinson's Disease with 5 references from 1996-2008. A PubMed search of "Parkinson's Impact Scale" retrieved 10 results of which 5 were for other language versions, other instruments, or reports unrelated to validation evidence (e.g., systematic review).
Patient Reported Impact of Multiple Sclerosis (PRIMuS)	Maybe	Specific Diagnoses	Multiple Sclerosis	Current CDE is Supplemental for Multiple Sclerosis and lists 2 references. A PubMed search of "Patient Reported Impact of Multiple Sclerosis" retrieved no results. A PubMed search of "PRIMuS" AND multiple Sclerosis retrieved 10 results of which 4 appear to report on this instrument
Scales for Outcomes in Parkinson's Disease- Psychosocial (SCOPA-PS)	Maybe	Specific Diagnoses	Parkinson's Disease	Current CDE is Supplemental for Parkinson's Disease, and includes 4 references. PubMed search for "Scales for Outcomes in Parkinson's Disease-Psychosocial OR SCOPA-PS" retrieved 13 results of which 6 appear to report on this instrument
Sickness Impact Profile (SIP)	Maybe	Specific Diagnoses	Parkinson's Disease, Amyotrophic Lateral Sclerosis	Currently Supplemental for Parkinson's Disease, and Exploratory for Amyotrophic Lateral Sclerosis (ALS), Huntington's Disease (HD) and Myotonic Dystrophy (DM), with 4 references. Rehab Measures Database describes evidence for use of the 68-item SIP with Brain Injury, Stroke, Spinal Cord Injuries, and Non-Specific/Mixed populations. Rehab Measures Database also describes a 30-item Stroke-Adapted SIP with validation

Instrument	HR QoL?	General or Disease-Specific	Disease list (or 'All')	Comment
				evidence for acute and chronic stroke. Burden of the 68-item and original 136-item versions may make them unsuitable for most clinical and research applications.
Schedule for the Evaluation of Individual Quality of Life - Direct Weighting (SEIQoL-DW)	Yes	Specific Diagnoses	Amyotrophic Lateral Sclerosis, Parkinson's Disease, Parkinson's Disease, Amyotrophic Lateral Sclerosis	Current CDE Supplemental for Parkinson's Disease Exploratory for ALS
Schedule for the Evaluation of Individual Quality of Life (SEQOL)	Yes	Specific Diagnoses	Parkinson's Disease, Amyotrophic Lateral Sclerosis	Current CDE Supplemental for Parkinson's Disease Exploratory for ALS
Stroke and Aphasia Quality of Life-39 (SAQOL-39)	Yes	Specific Diagnoses	Stroke	Current CDE: Supplemental-Highly Recommended for aphasia due to stroke Limited available literature
Stroke Impact Scale (SIS)	Yes	Specific Diagnoses	Stroke	Current CDE Supplemental: Stroke Exploratory: Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH)
Stroke Specific Quality of Life Scale (SS-QOL)	Yes	Specific Diagnoses	Stroke	Current CDE Supplemental: Stroke Exploratory: Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH)