

## Stroke Version 2.0 NINDS CDE Project

**Name of Stroke v2.0 Subgroup:** Outcomes and Endpoints

**Completed by:** Pam Duncan & Allen Heinemann

**Date:** March 7, 2020

Please answer the following questions below.

- 1. Approach for selection of elements** (*How did you go about drafting the recommendations and/or reviewing the current tools/instruments, and did you have any criteria for selection and classification?*)

Selected a committee of measurement experts with knowledge and experience in stroke research and clinical practice. This committee then reviewed all of the Outcome Measures included in the Stroke v1.0 (2010) Common Data Elements and subarachnoid hemorrhage CDEs. From this review we reviewed the literature for new measures not listed. We identified new measures or deleted old measures from prior CDEs or subarachnoid hemorrhage CDEs. This process was done by consensus and review by each member of the committee for assessment of reliability and validity, responsiveness to change, and utilization in stroke populations (either adult or pediatrics) and open access. Reviewed international consensus statements on stroke outcomes and speech and language to align as appropriate with our recommendations (Bushnell, et al., 2015; Kwakell et al., 2017; Moore, et al., 2018; Murphy, et al., 2015; Salinas, et al., 2015; Wallace, et al., 2018).

- 2. Differential application to types of Stroke** (*Do the instruments/elements you recommended differ between the types of Stroke?*)

No, our outcome measures were selected to be inclusive of the most common domains of impairments, functional performance, disability and quality of life – agnostic to stroke type.

- 3. Differential application to adult and pediatric and other subpopulations within Stroke patients** (*Do the instruments/elements you recommended differ between target populations within Stroke?*)

Yes

- 4. Summary of recommendations**

Instrument / Scale / CRF Name	Domain	Subdomain	Classification
Death CRF	Outcomes and Endpoints	Clinical Event End Points	<b>Core:</b> Vital Status <b>Exploratory:</b> Death location type; Death location other text <b>Supplemental:</b> all other CDEs on CRF
Home Time CRF	Outcomes and Endpoints	Quality of Life/Patient Report Outcomes	<b>Exploratory:</b> Home own relative time spent duration

<b>Instrument / Scale / CRF Name</b>	<b>Domain</b>	<b>Subdomain</b>	<b>Classification</b>
Return to Work CRF	Outcomes and Endpoints	Quality of Life/Patient Report Outcomes	<b>Supplemental:</b> all CDEs on CRF
6-Minute Walk Test	Outcomes and Endpoints	Performance Measures	Supplemental
Action Research Arm Test	Outcomes and Endpoints	Performance Measures	Supplemental
Animal Naming	Outcomes and Endpoints	Performance Measures	Supplemental
Assessment of Motor and Process Skills (AMPS)	Outcomes and Endpoints	Activities of Daily Living/Performance	Supplemental
Barthel Index	Outcomes and Endpoints	Activities of Daily Living/Performance	Supplemental
Bayley Scales of Infant Development (Bayley III, BSID)	Outcomes and Endpoints	Pediatric	Supplemental
Beck Anxiety Inventory (BAI) ©	Outcomes and Endpoints	Emotional Status	Supplemental
Beck Depression Inventory II (BDI-II) ©	Outcomes and Endpoints	Emotional Status	Supplemental
Berg Balance Scale (BBS)	Outcomes and Endpoints	Performance Measures	Supplemental
Boston Naming Test (BNT) - 30-item version	Outcomes and Endpoints	Cognitive Status	Supplemental-Highly Recommended
Brief Visuospatial Motor Test - Revised (BVMT-R)	Outcomes and Endpoints	Performance Measures	Supplemental
Canadian Occupational Performance Measure (COPM)	Outcomes and Endpoints	Quality of Life/Patient Report Outcomes	Supplemental
Center for Epidemiologic Studies-Depression Scale (CES-D)	Outcomes and Endpoints	Emotional Status	Supplemental
Color-Word Interference Test Delis-Kaplan Executive Function System (D-KEFS) ©	Outcomes and Endpoints	Cognitive Status	Supplemental
Controlled Oral Word Association Test (COWAT)	Outcomes and Endpoints	Performance Measures	Supplemental
Delis-Kaplan Executive Function System (D-KEFS)	Outcomes and Endpoints	Cognitive Status	Supplemental-Highly Recommended
EuroQoL-5 Dimension Questionnaire (EQ-5D)	Outcomes and Endpoints	Quality of Life/Patient Report Outcomes	Supplemental-Highly Recommended

<b>Instrument / Scale / CRF Name</b>	<b>Domain</b>	<b>Subdomain</b>	<b>Classification</b>
Fugl-Meyer Assessment	Outcomes and Endpoints	Performance Measures	Supplemental-Highly Recommended
Functional Independence Measure	Outcomes and Endpoints	Activities of Daily Living/Performance	Supplemental
Generalized Anxiety Disorder (GAD-7)	Outcomes and Endpoints	Emotional Status	Exploratory
Glasgow Outcome Scale (GOS)	Outcomes and Endpoints	Activities of Daily Living/Performance	Supplemental
Glasgow Outcome Scale Extended (GOSE)	Outcomes and Endpoints	Activities of Daily Living/Performance	Supplemental
Grooved Pegboard Test ©	Outcomes and Endpoints	Performance Measures	Supplemental
Hopkins Verbal Learning Test - Revised (HVLt-R)	Outcomes and Endpoints	Cognitive Status	Supplemental
Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE)	Outcomes and Endpoints	Cognitive Status	Supplemental
King's Outcome Scale for Childhood Head Injury (KOSCHI)	Outcomes and Endpoints	Pediatric	Exploratory
Modified Rankin Scale (mRS)	Outcomes and Endpoints	Activities of Daily Living/Performance	Supplemental-Highly Recommended
Montreal Cognitive Assessment (MoCA)	Outcomes and Endpoints	Cognitive Status	Supplemental-Highly Recommended
Motor Evaluation Scale for Upper Extremity in Stroke Patients (MESUPES)	Outcomes and Endpoints	Performance Measures	Supplemental
National Institutes of Health (NIH) Toolbox	NIH Resources	NIH Resources	Supplemental
Neuropsychiatric Inventory Questionnaire (NPI-Q)	Outcomes and Endpoints	Emotional Status	Exploratory
NIH Stroke Scale (NIHSS)	Assessment and Examinations	Physical/Neurological Examination	Supplemental-Highly Recommended
Patient Health Questionnaire - 9 (PHQ-9) Depression Scale ©	Outcomes and Endpoints	Emotional Status	Supplemental-Highly Recommended
Patient-Reported Outcomes Measurement Information System (PROMIS)	NIH Resources	NIH Resources	Supplemental-Highly Recommended
Patient-Reported Outcomes Measurement Information System (PROMIS)-Physical Function Assessments	NIH Resources	NIH Resources	Supplemental

<b>Instrument / Scale / CRF Name</b>	<b>Domain</b>	<b>Subdomain</b>	<b>Classification</b>
Pediatric Modified Rankin Scale (mRS)	Outcomes and Endpoints	Pediatric	Exploratory
Pediatric Quality of Life Inventory (PedsQL 4.0)	Outcomes and Endpoints	Pediatric	Supplemental
Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) - Child Version (Children Aged 2 Year and Older)	Outcomes and Endpoints	Pediatric	Supplemental-Highly Recommended
Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) - Infant Version (Infants Term Birth to Two Years)	Outcomes and Endpoints	Pediatric	Supplemental-Highly Recommended
Pediatric Stroke Recurrence and Recovery Questionnaire (RRQ)	Outcomes and Endpoints	Pediatric	Supplemental
Perceived Efficacy and Goal Setting System (PEGS)	Outcomes and Endpoints	Pediatric	Supplemental
PROMIS-10/PROMIS v1.2 – Global Health	Outcomes and Endpoints	Quality of Life/Patient Report Outcomes	Supplemental-Highly Recommended
PROMIS-29	Outcomes and Endpoints	Quality of Life/Patient Report Outcomes	Supplemental-Highly Recommended
PTSD Checklist - Civilian (PCL-C) ©	Outcomes and Endpoints	Emotional Status	Exploratory
Quality of Life in Neurological Disorders (Neuro-QOL)	NIH Resources	NIH Resources	Supplemental-Highly Recommended
Questionnaire for Verifying Stroke-Free Status (QVSFS)	Outcomes and Endpoints	Clinical Event End Points	Supplemental-Highly Recommended
Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)	Outcomes and Endpoints	Cognitive Status	Supplemental
Rey Auditory Verbal Learning Test [RAVLT] ©	Outcomes and Endpoints	Cognitive Status	Supplemental
Rey-Osterrieth Complex Figure Test (ROCF)	Outcomes and Endpoints	Cognitive Status	Supplemental
Short Form 36-Item Health Survey (SF-36)	Outcomes and Endpoints	Quality of Life/Patient Report Outcomes	Supplemental

Instrument / Scale / CRF Name	Domain	Subdomain	Classification
Similarities Subtest of the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV)	Outcomes and Endpoints	Cognitive Status	Exploratory
Six-Item Screener (SIS)	Outcomes and Endpoints	Cognitive Status	Supplemental
Stroke Adjudication Form	Outcomes and Endpoints	Clinical Event End Points	Supplemental
Stroke and Aphasia Quality of Life-39 (SAQOL-39)	Outcomes and Endpoints	Quality of Life/Patient Reported Outcomes	Supplemental-Highly Recommended
Stroke Impact Scale (SIS)	Outcomes and Endpoints	Quality of Life/Patient Report Outcomes	Supplemental
Stroke Specific Quality of Life Scale (SS-QOL)	Outcomes and Endpoints	Quality of Life/Patient Report Outcomes	Supplemental
Stroop Test	Outcomes and Endpoints	Cognitive Status	Supplemental
Telephone Interview for Cognitive Status (TICS)	Outcomes and Endpoints	Cognitive Status	Supplemental
Token Test	Outcomes and Endpoints	Performance Measures	Supplemental
Trail Making Test (TMT), Delis-Kaplan Executive Function System (D-KEFS)	Outcomes and Endpoints	Cognitive Status	Supplemental
Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P)	Outcomes and Endpoints	Quality of Life/Patient Reported Outcomes	Exploratory
Walking Speed	Outcomes and Endpoints	Performance Measures	Supplemental-Highly Recommended
Wechsler Adult Intelligence Scale - Fourth Edition (WAIS-IV)	Outcomes and Endpoints	Cognitive Status	Supplemental
Western Aphasia Battery-Revised (WAB-R)	Outcomes and Endpoints	Cognitive Status	Supplemental-Highly Recommended

**5. Comparison to other Stroke standards** *(Are there any notable similarities/differences in the CDE recommendations as compared with other standards?)*

The subgroup is not aware of other stroke standards.

**6. Issues unique to Stroke** *(Were there any issues encountered when developing the CDE standards which are unique to Stroke or which highlight a unique concern about Stroke data collection?)*

Stroke can result in sensory, motor, and cognitive limitations, not unlike traumatic brain injury, but distinct from spinal cord injury and some other neurological disorders which tend to have a narrower range of limitations. Test selection must consider the likelihood that respondents will be able to comprehend instructions and produce a scoreable response.

**7. Unmet needs; unanswered questions** (*What unmet need / unanswered questions were identified via the CDE process in Stroke? What areas are in need of further research and development?*)

Research on environmental factors that influence stroke outcomes is nascent, as is true for other areas of neurological rehabilitation. We have relatively good coverage of body structure and function, activity and participation components of the ICF, in contrast.