

# Common Data Elements for the NINDS Stroke Prevention/Intervention Research Programs

*Jeanne A. Teresi, Ed.D., Ph.D*

NINDS Stroke Prevention/Intervention Research Program (SPIRP)

in Health Disparities

Cross-SPIRPs Annual Meeting

July 13, 2015

Research Division, Hebrew Home at Riverdale;  
Columbia University Stroud Center and New York State Psychiatric  
Institute;

NYU/ Columbia University Center for Stroke Disparities Solutions (CSDS)

# Measurement Team

- **Mildred Ramirez, Ph.D:** Expert in translation methods, oversight of Spanish translations, measurement review for cultural bias
- **Stephanie Silver, MPH:** Measurement selection and item development
- **Katja Ocepek-Welikson, MPhil.,** Measurement statistics
- **Jian Kong, MS:** Biostatistician
- **Joseph P. Eimicke, MS:** Data Manager, psychometric analyses
  
- No conflicts of interest are reported.

# Common Core Measurement Projects

- Statistical Center for the Patient Reported Outcomes Measurement Information System (PROMIS)
- NIH Toobox
- NIA common core measures for dementia care

Common Data Elements: Subdomains	Common Data Elements: Recommended by NINDS	Common Data Elements: Measures Selected
Participant/Subject Characteristics	Demographics and Social Status	Demographics and Social Status

- Additional items of interest added:
  - Detailed ethnicity (e.g., Dominican, Puerto Rican, Jamaican)
  - Country of birth/ Parents country of birth
  - Length of time living in the US
- Issues with item wording:
  - While some items are worded as questions (e.g., “What is the highest grade level of school you have completed or the highest degree you have received?”), others are not, (e.g., “Current employment status”).
  - Double barreled items

Common Data Elements: Subdomains	Common Data Elements: Recommended by NINDS	Common Data Elements: Measures Selected
Participant/Subject History and Family History	Medical History – table to record history and 61 medically complex conditions items to ask	Medical History – Charlson Comorbidity Index

- Table to record body system
  - (e.g., respiratory, musculoskeletal); medical history term, start date, ongoing (y/n) end date.
  - 61 medically complex condition items to ask (e.g., hypercoagulable disorder).
- Potential issues
  - Complicated conditions to record for both the interviewer and participant
  - No scoring available

- Selected Charlson Comorbidity Index  
(over other measures, e.g., Elixhauser)
  - Scored index
  - Self-report version available
  - Extensive experience administering to elderly minority populations
  - Medical conditions not required for inclusion/exclusion- used as a time-varying covariate

Common Data Elements: Subdomains	Common Data Elements: Recommended by NINDS	Common Data Elements: Measures Selected
	Family History	Family History

- Suggested items were included
- Potential issues
  - There was some confusion/ambiguity about what ‘other’ types of disorders were relevant.
  - A physician RA noted that these are all clotting disorders and suggested that ‘other’ disorders should relate to clotting.

Common Data Elements: Subdomains	Common Data Elements: Recommended by NINDS	Common Data Elements: Measures Selected
Participant/Subject History and Family History	Behavioral History	Behavioral History

- As with the Demographic items, these items were not phrased as interviewer administered items. For example:
- **“Current tobacco use?** (Regular use of cigarettes, cigars, chewing tobacco or pipes within past year)”.
- Revised wording: **“Do you currently use tobacco, including cigarettes, cigars, chewing tobacco or pipes?”**
- If yes, follow up items include: **What type(s) of tobacco do you use?** If cigarettes: **What is the average number of cigarettes you smoke per day?** If hesitant or unsure the recommended choices are offered. Similarly, items about past use were developed.



Common Data Elements: Subdomains	Common Data Elements: Recommended by NINDS	Common Data Elements: Measures Selected
Prior Health Status	Prior Functional Status	Prior Functional Status

- In order to obtain a clear picture of ambulatory status prior to stroke, the recommended item

### **Ambulatory status\*:**

- Able to ambulate independently (no help from another person) w/ or w/o device
- With assistance (from person)
- Unable to ambulate
- Unknown

Reworded into question form and response options were expanded

# Updated ambulatory status item

**Now I want to ask about how you got around prior to your most recent stroke. Which of the following BEST describes how you got around? (Read choices)**

- 1 - Walked without help of any kind and without difficulty
- 2 - Walked without help of any kind but only with difficulty
- 3 - Walked with help of equipment and/or device (did not have help of another person)
- 4 - Walked with help of another person(s) (did not use equipment or a device)
- 5 - Walked with the help of another person(s) and equipment or a device

*If in wheelchair:*

- 6 - Wheeled without help of any kind
- 7 - Wheeled with the help of a device (electric or 1-arm drive AND did not have help of another person)
- 8 - Wheeled with the help of another person (did not use electric wheelchair or 1-arm drive)
- 9 - Wheeled with the help of another person and a device
- 10 - Was wheeled (did not participate)
- 11 - Was not wheeled (bedfast or chairfast)

Common Data Elements: Subdomains	Common Data Elements: Recommended by NINDS	Common Data Elements: Measures Selected
Treatment/Intervention Data: Drugs	Prior and Concomitant Medications- Table of individual medications & breakdown by drug classes	Prior and Concomitant Medications (Med Hx): Table items only

- Indication is not included as this is likely very difficult to collect from study participants.
- The 9 items related to drug classes (e.g., anticoagulants, diabetic medications) would be very difficult for non-physician based collection from participants
- We used an in-house program with dropdown menus created using FoxPro



Medication Information



01.15.2014

Study ID

Last Name

Visit No.

First Name

- 1..Baseline
- 2..First Follow-up
- 3..Second Follow-up
- 4..Third Follow-up
- 5..Fourth Follow-up
- 6..Fifth Follow-up

Search(Medication)

Interview Date (mm/dd/yy)

Medication No. 1  
 "Other(Specify\_\_\_\_\_)"  
 0.5 NORMAL SALINE  
 2-Octyl Cyanoacrylate  
 AA 5.5%/ELECTROLYTE-TPN SOLN  
 AA 8.5%/ELECTROLYTE-TPN SOLN

Med. Strength

Dose

Time of day AM  PM

Route PO  SQ

Units mg  units

Times /Day (77=PRN 99=MISSING)

Times/Week (optional)

Common Data Elements: Outcomes and Endpoints	Common Data Elements: Recommended Core/ Primary Measures	Common Data Elements: Measures Selected
Neurological Impairment	Neurological Impairment (NIH Stroke Scale)	None

- Sample item:

Best Gaze: evaluation includes a test of horizontal eye movements that requires testing voluntary or reflexive eye movements. Scoring directives are made for participants with isolated peripheral nerve paresis.

- While we intended to include this core/primary scale, it was determined by the research and clinical investigators that it was impossible for non-physician RAs to accurately administer this scale, thus we were unable to include it.

Common Data Elements: Outcomes and Endpoints	Common Data Elements: Recommended Core/ Primary Measures	Common Data Elements: Measures Selected
Activities of Daily Living/ Functional Status	Barthel Index, Modified Rankin Scale	Modified Rankin Scale & Barthel Index, PROMIS Physical Function 8 item short form (exploratory)

- Neither of the two core/ primary scales contain formal items to be administered by RAs to participants.
- In order to improve reliability of administration we reviewed the manuals and other item based scales developed based on these measures to create items for use in the projects.

# Original Modified Rankin Scale

Description	Score (select one)
No symptoms at all	<b>0</b>
No significant disability despite symptoms; able to carry out all usual duties and activities	<b>1</b>
Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance	<b>2</b>
Moderate disability; requiring some help, but able to walk without assistance	<b>3</b>
Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance	<b>4</b>
Severe disability; bedridden, incontinent and requiring constant nursing care and attention	<b>5</b>
Dead	<b>6</b>

# Barthel Index

## FEEDING

0 = unable

5 = needs help cutting, spreading butter, etc., or requires modified diet

10 = independent \_\_\_\_\_

## BATHING

0 = dependent

5 = independent (or in shower) \_\_\_\_\_

## GROOMING

0 = needs to help with personal care

5 = independent face/hair/teeth/shaving (implements provided) \_\_\_\_\_

## DRESSING

0 = dependent

5 = needs help but can do about half unaided

10 = independent (including buttons, zips, laces, etc.) \_\_\_\_\_

## BOWELS

0 = incontinent (or needs to be given enemas)

5 = occasional accident

10 = continent \_\_\_\_\_

## BLADDER

0 = incontinent/ catheterized, unable to manage

5 = occasional accident

10 = continent \_\_\_\_\_

## TOILET USE

0 = dependent

5 = needs some help, but can do something alone

10 = independent (on and off, dressing, wiping) \_\_\_\_

## TRANSFERS (BED TO CHAIR AND BACK)

0 = unable, no sitting balance

5 = major help (1 or 2 people, physical), can sit

10 = minor help (verbal or physical)

15 = independent \_\_\_\_\_

## MOBILITY (ON LEVEL SURFACES)

0 = immobile or < 50 yards

5 = wheelchair indep, including corners, > 50 yards

10 = walks w 1 person (verbal/physical) > 50 yards

15 = independent (but may use any aid) > 50 yards

## STAIRS

0 = unable

5 = needs help (verbal, physical, carrying aid)

10 = independent



# Potential Issues with Administration

- While there are training materials and rating guidelines for each of these measures, the original measures do not contain formal items
- This may lead to wide variability in administration and ratings

# Additional Sources Reviewed

## The Rankin Focused Assessment (RFA)

- contains specific section instructions
- Certain sections offer “Specific questions to ask”,
  - However, these items are not comprehensive or are multi-barrelled

Saver JL, Filip B, Hamilton S, Yanes A, Craig S, Cho M, Conwit R, Starkman S. Improving the reliability of stroke disability grading in clinical trials and clinical practice: the Rankin Focused Assessment. *Stroke* 2010;41:992-995.

# Sample of items used to rate as '5' per directions from the RFA

Rankin Focused Assessment	CSDS developed items
<p><b>“Is the person bedridden?”</b> The patient is unable to walk even with another person’s assistance. (If placed in a wheelchair, unable to self-propel effectively). May frequently be incontinent. Will usually require nearly constant care - someone needs to be available at nearly all times. Care may be provided by either a trained or untrained caregiver.</p>	<p>If you had to, could you get out of bed without the help of a person? (NO)</p> <p>During the past week, did you have to have someone around so you wouldn't fall, get hurt or have an accident, in general? (YES)</p> <p>Do you ever wheel by yourself? (NO)</p> <p>Are you able to propel yourself (in a wheelchair), if necessary? (NO)</p>

# Additional Sources Reviewed, cont'd

## Simplified Modified Rankin Scale (MRS).

- A five item scale is desirable in terms of administration time
  - However, we felt these items do not provide the level of detail required to adequately score the Modified Rankin Scale

Bruno A, Akinwuntan AE, Lin C, Close B, Davis K, Baute V et al. Simplified Modified Rankin Scale questionnaire: Reproducibility over the telephone and validation with quality of life. *Stroke* 2011;42:2276-2279.

# Additional Sources Reviewed, cont'd

## Structured Interview for the Modified Rankin Scale.

- This interview is similar to the Rankin Focused Assessment in style.
- Sample item for most severe rating: Constant Care: **Does the person require constant care?**
- While a definition of constant care is provided, it is not incorporated into the single item asked to rate.
- In addition, there is a place to indicate the need for constant care before stroke. Given our design, we are unable to rate abilities/ needs prior to stroke.

Available from: Lindsay Wilson, University of Stirling, Stirling FK9 4LA, UK & Asha Hareendran, Outcomes Research, Pfizer Ltd., Sandwich, CT13 9NJ, UK

# Comprehensive Function Components

Bed & chair assistance
Mobility/ Walking
Mobility/ Walking outside
Wheelchair inside
Wheelchair outside
Stairs
Eating/ dressing/ grooming/ bathing
Toileting/ Bladder/ Bowel function
Assistance to look after own affairs (meals and chores)
Managing Finances
Public transportation / Shopping
Usual duties and activities (Rankin score of 2)
Other Physical/medical conditions
Symptoms as a result of stroke (Rankin score of 1)

# Example of Developed Items and Scoring: Transfer

**1. During the past week, did you regularly use an object or device to help you get out of bed, e.g., end table, walker, side rail, trapeze?**

**2- Does anyone help you get in or out of bed? (Do they lift or help you in or out of bed?)**

(If no, skip to Q6)

If yes:

**3- How many people help you out of bed at the same time?**

(if 2 or more, code Barthel as 5)

**4- Do you help at all?**

(if 1 person helps and respondent provides assistance, code Barthel as 10; if 1 person helps and respondent does not provide assistance, code Barthel as 5)

# Example of Developed Items and Scoring: Transfer, cont'd

**5- If you had to, could you get out of bed without the help of a person?**  
(if no, code Rankin as 5)

**6- Are you able to sit in a chair without being propped up?**  
(if unable to sit in chair without being propped up, code Barthel as 0)  
(if can sit up, code Barthel as 5)

**7- During the past week, did you have to have someone around so that you wouldn't fall, get hurt or have an accident**  
**- while going from bed to chair?**  
**- in general?**  
(If yes to 'bed to chair'; code Barthel transfer as 10; If no, code Barthel as 15)  
(If yes to 'in general' code Rankin as 5)



# Benefits and Limitations of Structured Assessment

- Benefits
  - provides detailed, reliable information
  - easily administered by Research Assistants with variable levels of experience.
- Limitations
  - Administration time: According to Common Data Elements materials provided by NINDS, the time of administration for the MRS is five minutes and the Barthel Index is 5-10 minutes.
  - Based on our experience the combined measure designed by the CSDS takes approximately 20-30 minutes to administer

# Psychometric Properties

- Barthel

	Project 1 (n=33)	Project 2 (n=116)	Project 3 (n=234)
Cronbach's alpha		0.759	Not Applicable
McDonald's Omega Total	n too small	0.802	Not Applicable
Explained Common Variance		36.656	Not Applicable

- Modified Rankin Scale

	Project 1 (n=33)	Project 2 (n=116)	Project 3 (n=234)
Cronbach's alpha		0.799	N.A.
McDonald's Omega Total	n too small	Not calculated (n too small)	N.A.
Explained Common Variance		Not calculated	N.A.

# Psychometric Properties

- PROMIS Physical Function

	Project 1 (n=33)	Project 2 (n=116)	Project 3 (n=234)
Cronbach's alpha	0.944	0.909	0.911
McDonald's Omega Total		0.933	0.948
Explained Common Variance		61.715	63.723

Common Data Elements: Outcomes and Endpoints	Common Data Elements: Recommended Core/ Primary Measures	Common Data Elements: Measures Selected
Emotional Status	CES-D	PROMIS Depression 8-item Short Form

- While the CES-D was the recommended common core measure, based on the NIH goal of using PROMIS measures as Common Core, we chose to use the PROMIS short form depression scale
- The CES-D has been found to evidence differential item functioning (DIF) across ethnic groups

# PROMIS 8 item Short Form

- In the past seven days, how often have you felt:
  - Worthless?
  - Helpless?
  - Depressed?
  - Hopeless?
  - Like a failure?
  - Unhappy?
  - That you had nothing to look forward to?
  - That nothing could cheer you up?
- Response options:
  - “never”, “rarely”, “sometimes”, “often”, “always.”

# Psychometric Properties

- PROMIS Depression

	Project 1 (n=33)	Project 2 (n=116)	Project 3 (n=234)
Cronbach's alpha	0.914	0.927	Not Applicable
McDonald's Omega Total		0.954	Not Applicable
Explained Common Variance		66.804	Not Applicable

Common Data Elements: Outcomes and Endpoints	Common Data Elements: Recommended Core/ Primary Measures	Common Data Elements: Measures Selected
Cognitive Status	MoCA, Trail Making A & B	CAREDiag , BIMS

- While not a recommended common core measure, the Comprehensive Assessment and Referral Evaluation Diagnostic Scale (CAREDiag) has been found to be more culture fair than other batteries and has been studied using several advanced psychometric models, including analyses of its relationship to dementia diagnosis
- The Brief Interview for Mental Status (BIMS) is included in the OASIS home care intake assessment and thus was more appropriate for our project enrolling home care patients.

Common Data Elements: Outcomes and Endpoints	Common Data Elements: Recommended Core/ Primary Measures	Common Data Elements: Measures Selected
Quality of Life	EuroQol (EQ-5D)	EuroQol (EQ-5D)

- Core/primary scale used as recommended

Common Data Elements: Outcomes and Endpoints	Common Data Elements: Recommended Core/ Primary Measures	Common Data Elements: Measures Selected
Performance Measures	Walking Speed	None

- None used

Common Data Elements: Outcomes and Endpoints	Common Data Elements: Recommended Core/ Primary Measures	Common Data Elements: Measures Selected
Clinical Event End Points	(none)	Stroke Adjudication Worksheet (supplemental)

- Used as is for project that adjudicates stroke



# Spanish Translations of Primary/ Core Common Data Elements

- While the Euro-Qol and PROMIS measures are available in Spanish, the remaining measures required translation into Spanish
- As discussed several item wordings in English were modified for these projects, thus item wordings for these and additional measures required translation into Spanish
- Methods used were based on the NIH PROMIS translation methodology
- Potential issues-
  - Potential inconsistency in translation methods across SPIRPS
  - Potential inconsistency in translations across SPIRPS (for same language populations)

# Status of Recommended CDEs

## Recommended Common Data Elements

Demographics and Social Status

Medical History

Family History

Behavioral History

Prior Functional Status

Prior and Concomitant Meds

NIH Stroke Scale

Modified Rankin Scale

Barthel Index

PROMIS Physical Function Scale (exploratory)

CES-D

MoCA

Trail Making A&B

EuroQol (EQ-5D)

Walking Speed

Stroke Adjudication Worksheet  
(Supplemental/ Secondary)

## Used as presented

## Used with wording modifications

## Not used