

## Stroke Outcome Measures: Current Issues and Development of a New Measure

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## Background

- A stroke is often associated with distressing and disabling sequelae. Stroke not only impacts the physical function, but also emotion, memory and thinking, communication, and quality of life.

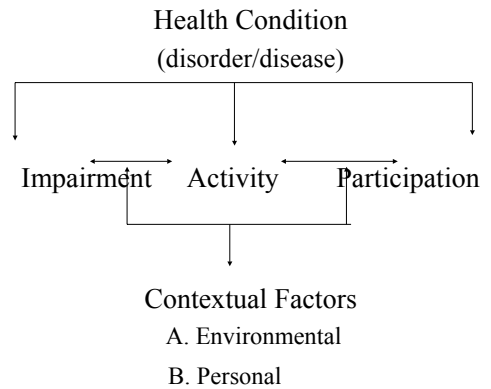
## Background

- Among those who are deemed recovered, the long-term disability resulting from stroke remains misunderstood and underestimated.

## Measuring Outcomes in Stroke is Difficult

- Stroke is heterogeneous
  - Type
  - Symptoms
  - Severity
  - Impact
- Natural history of recovery
- Survivors have a high probability of achieving independence in ADLs

- Conceptual model of disability



## RECOVERY..From What Perspective?

- Physiological
  - Neural reorganization
  - Synergistic Organization of Movements
- Behavioral
  - Impairments - motor, sensory, cognitive
  - Activities - walk, feed self, dress self, community mobility
  - Participation - Return to work, return to social roles

## RECOVERY...From Whose Perspective?

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>• Physician           <ul style="list-style-type: none"> <li>– Patient survival, independent in basic ADL's</li> </ul> </li> <li>• Social Worker           <ul style="list-style-type: none"> <li>– Patient can go home</li> </ul> </li> <li>• Physical Therapist           <ul style="list-style-type: none"> <li>– Patient can walk</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• PRIVATE Insurance Company           <ul style="list-style-type: none"> <li>– Requires only a few home health visits</li> <li>– “No change in FIM Score”</li> </ul> </li> <li>• Patient and Family           <ul style="list-style-type: none"> <li>– “To be normal”</li> </ul> </li> </ul> |
|---|---|

“ I have to give the man credit, the man can run. He runs real funny. The kids in the neighborhood laugh at him, but he runs, you know, but if I could have thirty minutes of a normal conversation to carry on with him, if I could have him reach over and kiss me and say ‘I love you’, you know, if I could have that back, he has no emotion, as far as that goes anymore. He’ll cry, but if he cries it’s because he saw you cry, he’s not crying for himself, that’s all gone, all of that emotion is gone. He doesn’t know how to have that anymore. It’s some days I wish for five minutes of normal, just normal, just give me five minutes of something normal....”

## Background

- There is no consensus concerning the measures that best reflect stroke related disability

## Measures in 51 Studies (Phase II-III Acute Drug Trials Since 1980)

- 14 Impairment Measures (8 stroke measures)
  - Modified Mathew Scale
  - NIH Stroke Scale
- 11 Activity Measures
  - Barthel Index
  - Rankin Handicap Scale
- 1 Health Status / QOL Measure
  - SF-36
- 8 Self-developed measures

## Most Common Outcome Measures For Clinical Trials

- Barthel- basic activities of daily living
- Rankin- global outcome scale
  - 0- no symptoms, 1 no significant disability despite symptoms, 2 slight disability, able to carry out own affairs without assistance, 3 moderate disability, but able to walk without assistance, 4 moderate severe disability, needs assistance, 5, severe disability, bedridden

## Barthel Index - Cutpoints

## Rankin Scale - Cutpoints

## Most Common Outcome Measure in Rehabilitation

- Functional Independence Measure
  - Motor (13 items)
  - Social-Cognitive (5 items)
- 7 point ordinal scale ( Independence)

## Most Common Health Status Measure ( QOL)

- Short Form –36
- Self-Report Measure

## SF-36 Eight Domains Scoring ( 0-100)

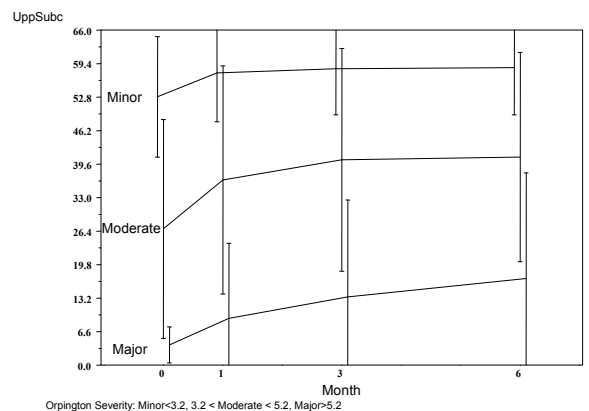
- physical functioning
- mental health
- social functioning
- physical role limitations
- emotional role limitations
- energy
- pain
- general perception of health

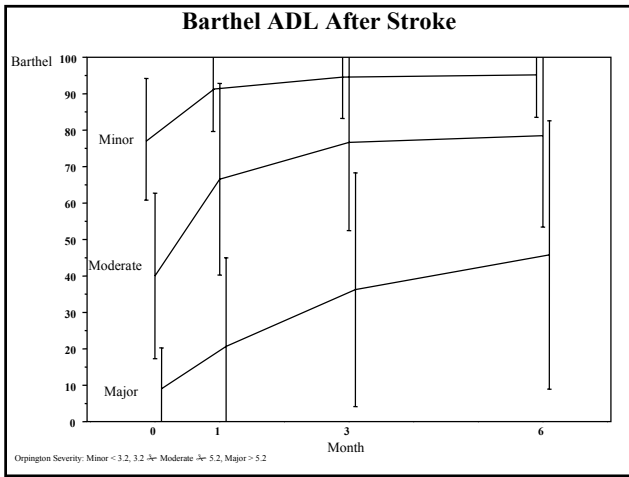
## Physical function- 10 items

- vigorous activities( running , lifting heavy objects),
- moderate activities ( moving a table pushing a vacuum cleaner),
- lifting or carrying objects,
- climbing stairs,
- bending kneeling or stooping,
- walking (a mile, several blocks, one block)
- bathing or dressing

Selection of outcomes measures requires understanding of stroke recovery

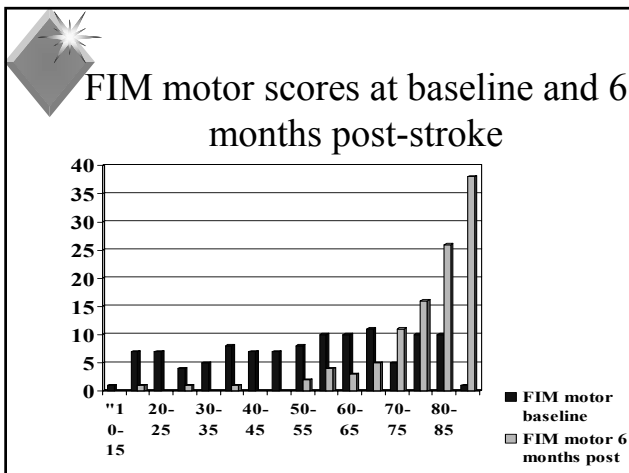
Plot of Means and 1 SD of UppSubc vs Orpington Prognostic Scale





## Limitations of the Barthel and FIM

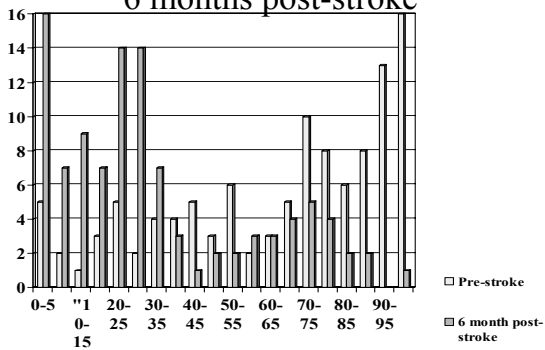
- Only measures basic activities of daily living
- Does not capture higher levels of physical function, IADL, or Quality of Life
- Has a ceiling effect in mild and moderate strokes
- Mild and moderate strokes have a high probability of achieving independence in ADLs



## FIM Motor

- 68% scored between 80 and 91

## SF-36 Physical Function-Baseline and 6 months post-stroke



## Sf-36

- 62% scored 30 OR LOWER

## Did the Patient Recover? Well It Depends

- Kansas City Stroke Study
- Prospective Cohort Study of 459 patients
- Baseline, 1 month, 3 months, 6 months

## KCSS Percentage Who Recovered At 3 Months

- NIH  $\leq 1$  45%
- Fugl-Meyer  $> 90$  37%
- Barthel  $> 90$  57%
- Rankin  $\leq 1$  24%
- Rankin  $\leq 2$  64%
- Women SF-36  $> 66$  24%
- Men Sf-36  $> 75$  28%

- Poor Selection of Stroke Outcome Measures Has Major Implications For:

- Clinical Trials of Stroke Therapies
- Monitoring Rehabilitation Outcomes
- Measuring the Impact of Stroke

## New Stroke Outcome Measures Are Needed

- Assess Outcomes Beyond Basic Activities of Daily Living
- Assess Significant Domains: Communication, Emotion, Memory and Thinking, Participation
- Assess Hand Function
- Do Not Suffer From High Rates of Ceiling Effects
- Consider Shifts in Disability States - Not simply Cure or No Cure, or Dependence or Independence
- Assess Quality of Life

## Development of a Stroke-Specific Outcomes Scale

Two Versions  
Stroke Impact Scale

## Characteristics of SIS

- Self-Report
- Difficulty

## Scoring

- Each Domain 0 to 100
- Transformed score  
–  $\frac{\text{Actual score} - \text{possible score}}{\text{range of score}} \times 100$

## Language Translations and Cultural Validation

- English
- French
- German
- Dutch
- Spanish
- Danish
- Swedish
- Norwegian
- Portuguese
- Italian

## Stroke Impact Scale: Version 3 59 Items and 8 Domains

- Communication
- Memory and Thinking
- Emotion
- Participation (Role Limitations)

## Domains of Stroke Impact Scale Version 3.0 - Physical Domains

- Strength (Upper and Lower Extremity)
- Hand Function
- ADL/IADL
- Mobility
- Physical (Combined)

## SIS-16

- Physical Function Items Only

## Stroke Impact Scale

- [www2.kumc.edu/coa](http://www2.kumc.edu/coa)

## Methods for Development

- Individual Interviews
- Focus Groups (Patient, Caregiver, Professional)
- Development of Version 1 and 2
- Psychometric Analysis-Rasch Analysis
- Revision
- Reduce items - Version 3.0 of SIS and SIS-16
- Evaluate reliability, validity, and sensitivity to change, and concordance between proxy and patient, and different modes of administration

## Reliability

- Internal Consistency
  - Cronbach's alpha for all domains ranged from .86 to .90, these alphas meet the standard (.90) for comparing the same patient across time
- Test Re-Test
  - Intra-class correlation coefficients ranged from .72-.92 except for emotion domain which was .567

## Concurrent validity

- Strength
  - NIH Motor .59
  - FM Motor .72
- Hand Function
  - FM Upper .81
- Mobility
  - FIM Motor .83
  - Barthel .82
  - SF-36 PFI .84
  - Duke Mobility .83
- ADL/IADL
  - FIM Motor .84
  - Barthel .82
  - Lawton IADL .82

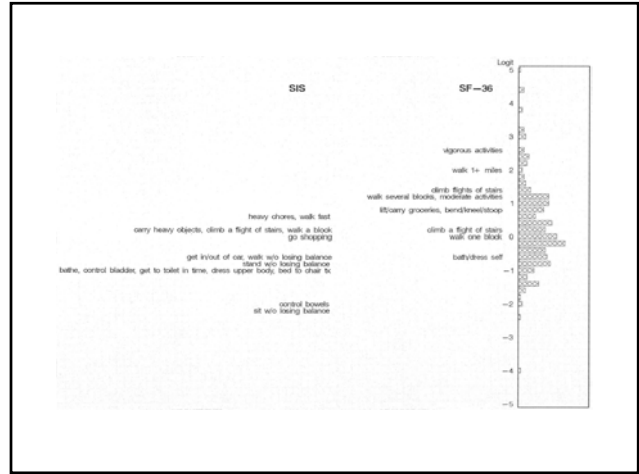
## Concurrent validity

- Memory
  - Mini Mental .58
- Emotion
  - GDS -.71
  - SF-36 MHI .74
- Communication
  - NIH Language -.44
  - FIM Soc/Cog .53
- Handicap
  - SF-36 Social .70

## Rasch Analysis

- Comparison of Range of ITEM Difficulty

Figure 1. Item Map for SIS-16 and Barthel



## Comparison of the SIS-16 vs the Barthel Index – A secondary analysis of the GAIN Americas Study

## Acknowledgement

- The Kansas Claude D. Pepper Older Americans Independence Center
- The GAIN Americas Randomized Stroke Trial - glycine antagonist neuroprotection trial

## Objective

- To compare the performance of the Barthel Index and the SIS-16, a subscale of the Stroke Impact Scale (SIS)

## Background

- The SIS-16 is a 16 item subscale derived from the 4 physical domains of the Stroke Impact Scale (SIS).
- The SIS-16 includes 7 ADL/IADL items, 8 mobility items, and 1 hand function item (see methods) and has a total score ranging from 0 to 100.

## Subjects

- Participated in the SIS sub-study of GAIN Americas Randomized Stroke Trial
- Had completed 3-month assessment of the SIS, Barthel Index, and Modified Rankin Scale

## Inclusion Criteria

- Aged 18 years or older
- Symptoms of acute stroke present at the time of study treatment
- Treatment can be initiated within 6 hours of symptom onset
- Limb weakness present
- Previously independent
- Written informed consent
- If female, must be of non-childbearing potential

## Exclusion Criteria

- Obtunded, totally unresponsive, flaccid, or areflexic
- Symptoms rapidly improving and likely to resolve within 24 hours
- Diagnosis or suspicion of subarachnoid hemorrhage
- Serious life threatening illness likely to lead to death within 3 months
- Symptoms consistent with severe congestive heart failure

## Methods

- The SIS was added as a secondary outcome measure in the Gain Americas trial after the trial was underway.
- For this analysis, SIS-16 scores were extracted from the SIS and compared to the Barthel Index.
- Both of these measures were performed at 90-days post stroke.

### Subject Characteristics

N = 621

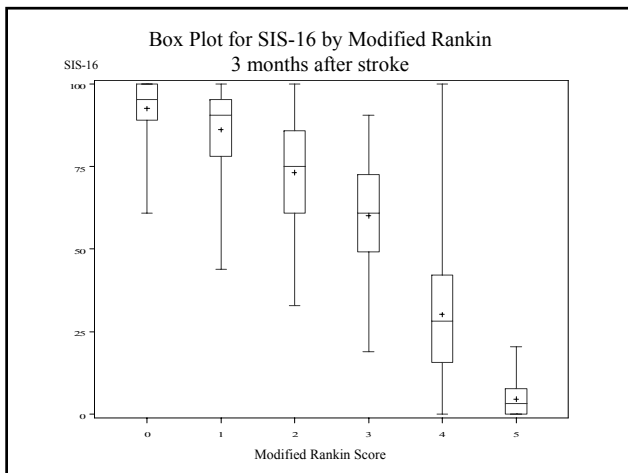
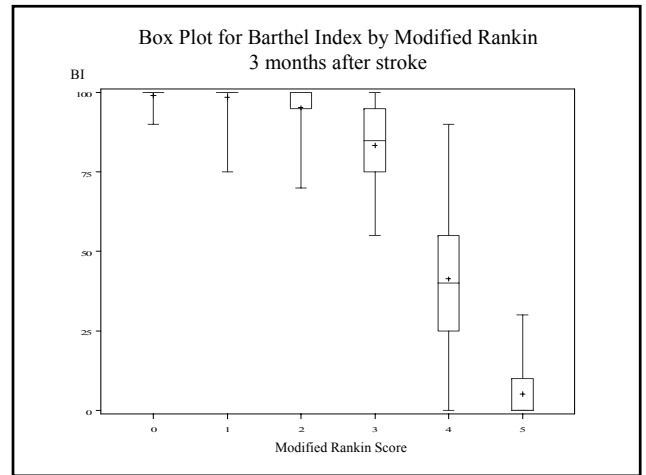
Male	56%
Age (yrs)	68 ± 12.4
Race	
White	84.2%
Black	7.3%
Asian	5.5%
Hispanic	2.3%
Other	.8%
Ischemic stroke	85.5%
Median baseline NIHSS	11
Median baseline Barthel	40

### Barthel Index at 3 months post stroke

Baseline NIHSS	N	Median	% Floor (BI = 0)	% Ceiling (BI = 100)
2 – 5	91	100	0	57%
6 – 13	304	95	1%	43%
≥ 14	226	60	11%	23%

## SIS-16 at 3 Months Post Stroke

Baseline NIHSS	N	Median	% Floor (SIS-16 = 0)	% Ceiling (SIS-16 = 100)
2 – 5	91	80	1%	12%
6 – 13	304	72	1%	6%
≥ 14	226	45	6%	4%



## Conclusions

- Compared with the Barthel Index, the SIS-16 has an excellent distribution with a very low ceiling effect for minor stroke patients and a very low floor effect for major strokes.
- The SIS-16 significantly discriminates among MRS 0-1, 2, 3,4, and 5, but the Barthel Index only discriminates significantly among 0-2, 3,4, and 5.
- The SIS-16 may be better able to capture residual stroke disability than the Barthel Index.

Does the SIS 3.0 pick up change across time?

### SIS Change Scores from 1 to 3 months

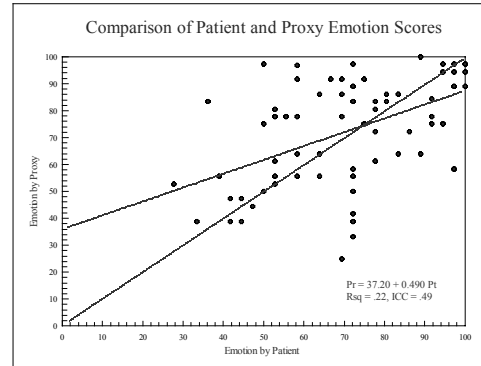
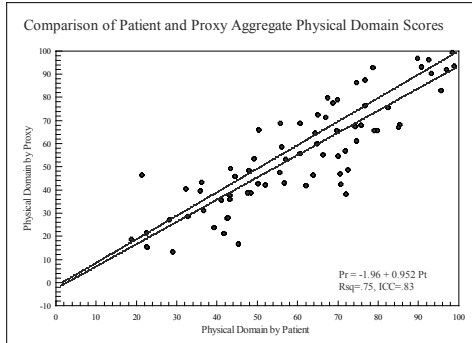
Variable	N	Mean	Std Dev	T value	Pr >  t
Strength	636	5.51	18.57	7.49	<.0001
Memory	634	3.76	20.00	4.74	<.0001
Emotion	626	.85	18.44	1.16	0.2475
Comm	630	4.82	18.45	6.52	<.0001
ADL/IADL	632	9.65	19.05	12.73	<.0001
Mobility	631	11.55	20.59	14.09	<.0001
Hand	632	7.92	24.36	8.17	<.0001
Part	629	12.64	25.82	12.28	<.0001
Physical	632	10.54	17.26	15.34	<.0001

### But Not ALL Patients Can Complete the SIS

- By 3 months approximately 85% could complete SIS In GAIN Americas Study

### Proxy-Patient Assessment - Preliminary Analysis

- 287 patient/proxy pairs
- 3 month assessments



## Summary

Evaluating Stroke Recovery is Complex

Self-Report Measurement Is Valid and  
Reliable in Most Stroke Survivors

Measures Must Assess Meaningful Domains  
and a Wide Range of Function

## Development of a Computerized Adaptive Measure of Disability Based on the ICF

9<sup>th</sup> North American Collaborating Center

Conference on ICF

June 17, 2003, St. Louis Missouri

Craig Velozo, Bradford Barrett, Sandra Piantieri, Katherine Byers,  
Jamie Pomeranz, Leigh Lehman, Ying-Chih Wang & David Gray



## Conclusions

Computerized Adaptive Testing Offers:

- Efficiency: 6-10 questions per construct
- Precision: high correlations of measures derived from 6-10 question-CAT with measures derived from taking entire test of 100 or more questions
- Testing anywhere in the world via the web
- Real-time results