Oncology Section EDGE Task Force on Breast Cancer Outcomes: Clinical Measures of Chemotherapy Induced Peripheral Neuropathy, Balance, and Functional Mobility

Speakers:
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CSM February 2015

Disclosure
All members on “Oncology Section EDGE Task Force on Breast Cancer Outcomes: Subcommittees on Chemotherapy Induced Peripheral Neuropathy, Balance, and Functional Mobility” declare no relevant financial relationship.

Session Objectives
1. Briefly describe the most common impairments of body structure and activity limitations in individuals treated for related to breast cancer, including those which contribute to balance and functional mobility limitations.
2. Identify selected assessment techniques and outcome measures that can appropriately be used for individuals with limitations in functional mobility and balance, as well as chemotherapy-induced peripheral neuropathy following treatment for breast cancer.
3. Recognize the role of sound psychometric properties of outcomes measures to monitor patient status and demonstrate intervention effectiveness in survivors of breast cancer.
4. Discuss the relative merits of presented outcome tools based on psychometric properties, clinical utility, administration issues, and limitations.

Introduction

History of Evaluation Database to Guide Effectiveness (EDGE)
EDGE Task Force of the Section on Research, CSM 2006

In her 2005 McMillan Lecture, Dr. Rebecca Craik endorsed a three-pronged approach to competency that is comprised of: 1) classifying patients in meaningful ways, 2) standardizing our interventions, and 3) agreeing on the best outcome measures.

“The bottom line is that evidence of intervention effectiveness depends on, among other things, common use of valid and reliable tests/measures that reflect clinically important outcomes and are responsive to change.”

Neurology Section - Initial group to develop a database for their specialty practice

EDGE Purpose
- Standardize outcome measures
- To support/refute effectiveness of intervention strategies
- Determine outcome measures which are
  - Reflective of important outcomes
  - Valid
  - Reliable
  - Responsive to change
EDGE Goals
1. Establish a framework to facilitate the evaluation of outcome measures
2. Assist stakeholder groups in evaluating outcome measures reflective of specialty practice
3. Assist in promoting the use of a core set

EDGE Form (Attachment)
- Developed by consensus of experts to assess outcome measures
- Completed on each test/measure evaluated

EDGE Taskforce Outcome Measure Rating Form

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<td>Recommended; the outcome measure has good psychometric properties and good clinical utility; no published evidence that the measure has been applied to research on individuals with or post breast cancer.</td>
<td>Unable to recommend at this time; there is insufficient information to support a recommendation of this outcome measure; the measure has been used in research on individuals with or post breast cancer.</td>
<td>Poor psychometrics &amp;/or poor clinical utility (time, equipment, cost, etc.).</td>
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Oncology Breast Cancer EDGE Work to Date
- Shoulder function: Scapular assessment; ROM and Muscle Length; Self-reported Functional Scales for the Shoulder (Presented at CSM ‘12 – Chicago, Rehabil Onc, Vol. 33:1)
- Pain; Fatigue; Lymphedema (CSM ’13 – San Diego, Rehabil Onc, Vol 34:1)
- Muscle Strength and Endurance, Cardiorespiratory Endurance, Quality of Life (CSM’14 – Rehabil Onc, 34:4, 35:1)
- Functional Mobility, Balance, Neuropathy (CSM’15--Indianapolis, Rehabil Onc,2015-16)

Oncology Head and Neck Cancer EDGE Work to Date
- Neck function and Shoulder Function (Rehabil Onc, 34: 3)

Oncology Prostate Cancer EDGE Work to Date
- CSM 2015 - Indianapolis, Rehabil Onc,2015-16

Future work in Prostate Cancer:
- CSM 2016 - Pain, Balance, Lymphedema measures
- Cardiovascular Function, Body composition, personal cares, recreation, employment, sleeping, neuropathy, gait

Future work - Other cancers
- Pediatric
- Head and Neck
- Colo-rectal: CSM 2016 - Muscle Strength and Endurance, other measures
- Lung (potentially in collaboration with Cardiopulmonary Section)

Future work -
- Web-based repository of outcome measure information
Breast Cancer

Lifetime risk of developing breast cancer is 1 in 8 (12%); it is the most commonly diagnosed cancer in women after breast cancer.

- >232,670 women diagnosed in 2014
- Near 90% survival rate
- In 2011, nearly 3 million people were living after breast cancer (US figures)

Treatment for breast cancer results in immediate and long term side effects:

- Surgery: limited motion, declines in strength and muscular endurance, pain, lymphedema
- Chemotherapy: neuropathy, cardiac toxicity and cardiovascular changes, fatigue
- Radiation: fatigue, limited mobility, fatigue

Physical function scores reported by breast cancer survivors decline the greatest immediately following surgical treatment for breast cancer, but remain below baseline 6-104 weeks after treatment.

Treatments and side effects result in functional mobility challenges, ranging from neuropathy and balance impairment to overall functional mobility declines. Ultimately, these deficits can result in disability.

Accurate ongoing assessment is crucial to deliver physical therapy interventions, including balance and functional mobility retraining, to mitigate the negative effects of treatment.
Oncology Section Task Force on Breast Cancer Outcomes: 
Chemotherapy Induced Peripheral Neuropathy (CIPN)

CSM February 2015

Presented by: Elizabeth Hile, PT, PhD, NCS, CLT
Subcommittee members: Laura Gilchrist PT, PhD
Pamela Levangie PT, DSc, FAPTA
Kathryn Ryans, PT, DPT

Introduction to CIPN

- Drug-dependent & Dose-dependent
- Synergistic effects of combination therapies
- Transcends cancer type/site – chemotherapy drug or drug combination is more relevant
- Typical clinical presentation
  - Sensory
  - Motor
  - Autonomic
- May or may not be painful
- Reasons for increased clinical & research attention
- CIPN in breast cancer – drugs, prevalence, presentation

Search Strategy: Search for Measures to Include in Review

EDGE taskforce members established a list of measures by supplementing those found in two recently published reviews of neuropathy assessment tools (Griffiths, Cavaletti) with database searches using the terms and limits specified below, and finally their own clinical knowledge of existing tools and manuscripts as oncology clinicians and researchers.

<table>
<thead>
<tr>
<th>Databases and Sites Searched</th>
<th>Search Terms/Strings (MeSH and keyword)</th>
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<tr>
<td>Pubmed/Medline</td>
<td>chemotherapy, neuropathy, neurotoxicity</td>
<td>English articles Human Year*: 2007 or newer</td>
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<td>CINAHL</td>
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*Year was selected to capture publications since the existing systematic reviews.

Inclusion Criteria for Articles

- Adults
- English language
- Clinically feasible methods
- Measures neuropathy burden (signs/symptoms)
Exclusion Criteria for Articles

- Animal studies
- Conditions other than cancer
- Not adult
- Measures of pain or general quality of life (as primary focus)

Results of Database Searches:

2497 Articles Identified in Database Searches (2442 PubMed; 55 additional in CINAHL)

25 CIPN Measures Identified; 14 Excluded as Below

11 CIPN Measures Reviewed and Scored

Inclusion Criteria for Measures:

- Validation in adult cancer population using chemo agent related to those used in breast cancer
- English language
- Clinically feasible assessment methods
- Measures neuropathy burden (signs/ symptoms)
- At least one paper reporting development or psychometric properties

Exclusion Criteria for Measures:

- Requires invasive techniques, or other measures of nerve function not appropriate for administration in a PT clinic setting (e.g. axonal excitability studies, Total Neuropathy Score, TNSr)
- Primary focus other than neuropathy (eg: MD Anderson Symptom Inventory)
- Primary focus on neuropathic pain

Once a list of measures was generated, each primary reviewer searched for all validation articles, or other articles with clinical relevance. The secondary reviewer was responsible for verifying comprehensiveness of the search before addressing the accuracy of the primary review.
Final List of Measures Reviewed by EDGE CIPN Taskforce

- Chemotherapy-Induced Peripheral Neuropathy Assessment Tool (CIPNAT)
- Rasch-built Overall Disability Scale for Patients with Chemotherapy-Induced Peripheral Neuropathy (CIPN-R-ODS or R-ODS)
- European Organization for Research and Treatment in Cancer (EORTC) CIPN-20
- Functional Assessment of Cancer Therapy/Gynecologic Oncology Group Neurotoxicity Subscale (FACT/GOG-NTx)
- Functional Assessment of Cancer Therapy/Gynecologic Oncology Group Taxane Subscale (FACT/GOG-Taxane)
- Patient Neurotoxicity Questionnaire (PNQ)
- Peripheral Neuropathy Scale (PNS)
- Scale for Chemotherapy-Induced Neurotoxicity (SCIN)
- Modified Total Neuropathy Score (mTNS)
- Total Neuropathy Score, clinical version (TNSc)
- 5-item Reduced Total Neuropathy Score (TNSr 5-item)

Results of Review by Measure:

Chemotherapy-Induced Peripheral Neuropathy Assessment Tool (CIPNAT)

- Brief Description: A survey with 36 items addressing symptom experience and 14 items evaluating interference with activities
- Approximately 15 minutes to complete
- The symptom scale has a range of scores from 0-279, with higher scores indicating greater severity. The interference scale has a range of possible scores from 0-140 with higher scores indicating worse function
- Copyrighted

Clinical Utility: Pencil and paper survey with complex scoring

Psychometric Properties

- Reliability
  - Test-retest: Total score: r=0.93; Symptoms: r=0.89; Interference: r=0.93 (P<0.001 for each) (Toftthagen 2011)
- Validity: completed in patients receiving paclitaxel, docetaxel, oxaliplatin, or cisplatin
  - Content validity: Reviewed by 5 clinical experts
  - Convergent validity with FACT/GOC-NTx r=0.83 (P<.001) (Toftthagen 2011)
    Total scores, Symptom and Interference subscores were statistically different than those of cancer patients on non-neurotoxic chemotherapy (t-tests, P<0.001) (Toftthagen 2011)
- Responsiveness: responsive to change (Toftthagen, 2011) but no MDC or MCID reported

Final Analysis - CIPNAT

- Major points in final rating: No normative data available and no ability to determine important change for individual patients. Clinical utility is hampered by complex scoring.
- Rating = 2A
Rasch-built Overall Disability Scale for Patients with Chemotherapy-Induced Peripheral Neuropathy (CIPN-R-ODS)

- A 28 item survey
- Currently the scale is still under development. The questions and scoring strategy is available in the publication (Binda, 2013)

Clinical Utility: Unclear

Psychometric Properties

- Reliability:
  - Test-retest: Acceptable test-retest reliability findings were obtained, since items' hierarchy and patients' location were mainly located within the 95% CI. (Binda, 2013)

- Validity:
  - Validated using Rasch analytic techniques, "with PSI value of 0.92 indicating excellent internal reliability". (Binda, 2013)
  - Compared to NCI-CTC motor and sensory subsets and to PI-NRS (pain intensity numeric rating scale) using Rasch analyses. (Binda, 2013)

- Responsiveness: Not completed

Final Analysis – CIPN-R-ODS

- Major points in final rating: The CIPN-R-ODS is a scale under development. Currently it is unclear how scores should be interpreted.
- Rating = 2A


European Organization for Research and Treatment in Cancer (EORTC) CIPN-20

- Brief Description: 20 item survey assessing symptoms and function: 9 sensory items; 8 motor items; 3 autonomic items. Measured in Likert scale format
- 8-10 minutes to complete
- Higher scores indicate worse neuropathy
- Available free for academic or non-commercial use from EORTC website

Clinical Utility: Survey with straightforward scoring
Psychometric Properties

• Reliability
  – Test-retest: acceptable reliability for all three subscales: sensory (r = 0.836), motor (r = 0.844), and for the autonomic submodules (r = 0.726). (Cavaletti, 2013)

• Validity
  – Content Validity determined by relevance, comprehensiveness, and importance of each item, as rated by clinicians and patients. (Postma, 2005)
  – Concurrent Validity: Moderate correlations were found between QLQ-CIPN20 and Brief Pain Inventory pain severity items (r = 0.30–0.57, p <= .0001). (Lavoie Smith, 2013)
  – Mean scores for all QLQ-CIPN20 scales were significantly higher (worse) (P = 0.0001) in patients who had received neurotoxic chemotherapy when compared to scores from those who had not. (Lavoie Smith, 2013)

• Responsiveness:
  – Sensory and motor scales exhibited moderate-high responsiveness to change (Cohen’s d = 0.82 and 0.48, respectively) (Lavoie Smith, 2013)

Final Analysis – EORTC CIPN-20

• Major points in final rating: While the content and contrasting groups validity for the EORTC CIPN-20 is promising, the concurrent validity needs to be strengthened. Further investigation is needed before being useful for individual clinical decision-making.

• Rating = 2A


Functional Assessment of Cancer Therapy/Gynecologic Oncology Group Neurotoxicity Subscale (FACT/GOG-NTx)

• Brief Description: 11 item self-report subscale covering sensory, motor, and hearing neuropathy along with dysfunction associated with chemotherapy induced neuropathy.

• Ntx subscale scores range from 0 = no neuropathy to 44 = most extreme neuropathy

• Note: Several studies seem to invert the scoring for the 11-item Ntx

• Available at www.FACIT.org. Free for clinical use but registration is required.

Clinical Utility: Brief survey taking about 5 minutes to complete.
Psychometric Properties

• Reliability
  – Research on the Ntx provided a number of examples where proposed constructs for the Ntx have supported the ability of the Ntx to discriminate between patient groups treated with neurotoxic versus non-neuotoxic chemotherapy, between groups treated with chemotherapies expected to differ in neurotoxic effects, or the responsiveness of the Ntx to increases in peripheral neuropathy with increased cumulative doses of neurotoxic therapies. In instances of substantiated validity, reasonable reliability can be cautiously assumed. If the test was not reliable, the increased variability created by measurement error would make it difficult to find statistically significant differences between groups or over time. (Huang 2007; Cella 2003)

• Validity
  – Discriminate validity has been evaluated in multiple studies. The measure differentiates between patients on neurotoxic chemotherapy and chemotherapy naïve groups (Calhoon 2003) as well as patients on chemotherapy believed to be less neurotoxic (Huang 2007; Shimozuma 2012)
  – Concurrent validity: Ntx scores correlated significantly (-0.39 to -0.64) to most of the objective measures of peripheral neuropathy (Calhoon 2003)

• Responsiveness
  – Multiple studies have demonstrated responsiveness to change (Huang 2007; Cella 2003)
  – Cella et al (2003) reported an SEM of 2.8 points for the Ntx. They then defined a decline (greater CIPN) of 3 points on the Ntx to be "significant" and as the criterion for "emerging neurotoxicity".

Final Analysis – FACT/GOG-Ntx

• Major points in final rating: There is ample evidence to indicate that the Ntx subscale is a valid scale able to document worsening CIPN over time with continued administration of platinums and taxanes, including in patients with breast cancer.
• Rating = 4


**Functional Assessment of Cancer Therapy/Gynecologic Oncology Group Taxane Subscale (FACT/GOG-Taxane)**

- Brief Description: The FACT/GOG-Taxane is a set of 5 questions designed to be used in addition to the FACT/GOG-Ntx to fully describe the experience of patients on taxane treatment. The additional questions explore, bloating, swelling, pain in fingertips, and skin and nails.
- Time to complete: minutes
- Available at [www.FACIT.org](http://www.FACIT.org). Free for clinical use but registration is required.

**Clinical Utility:** Brief survey taking about 5-7 minutes to complete when administered with the FACT/GOG-Ntx

**Psychometric Properties**

- Reliability
  - Not reported
- Validity
  - Internal consistency: Cronbach's alpha: 0.84-0.88 across baseline, week 5 and week 11 administrations. (Cella 2003)
- Responsiveness
  - The Taxane subscale (11 item Ntx plus 5 additional Taxane items) showed statistically significant declines in scores (increased CIPN) from baseline to 12 weeks (P<0.0001), with standardized effect sizes of 0.37 at 6 weeks and 0.91 (taxane) at 12 weeks. (Cella 2003)

**Final Analysis – FACT/GOG-Taxane**

- Major points in final rating: There is evidence that the Taxane subscale is a valid scale able to document worsening symptoms (including CIPN) over time with continued administration of taxanes. However, it is not clear how or if the additional 5 Taxane-specific items added to the Ntx subscale increases psychometrics and understanding of neurotoxicity.
- Rating = 2A


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**Patient Neurotoxicity Questionnaire (PNQ)**

- Brief Description: 2 item self-report measure. One question on sensory symptoms scored as A (absent) through E (severity sufficient to prevent ADLs) and one on motor symptoms using same scoring system. Also asks that patients identifying symptoms as D or E (interfering or precluding ADLs) identify which ADLs from a list.
- Time to complete: Minimal
- Lower scores indicate less neuropathy and less interference with function
- Availability: Copyrighted

**Clinical Utility:** Simple to use and score
Psychometric Properties

- Reliability
  - Not yet published
- Validity
  - Concurrent Validity: Spearman correlation for PNQ sensory and motor scores with Ntx were $r = 0.66$ and $r = 0.51$ respectively (Shimozuma 2009)
  - Discriminant Validity: PNQ sensory score in a sample of breast cancer patients were able to identify groups with more or less neurotoxic treatment.
- Responsiveness
  - PNQ’s sensory and motor scores showed statistically significant worsening as number of taxane treatments increased. (Shimozuma 2009)

Final Analysis - PNQ

- Major points in final rating: This is a simple and promising measure of neuropathy’s interference with function, but reliability testing needs to be completed.
- Rating = 2A


Peripheral Neuropathy Scale (PNS)

- Brief Description: 9 item survey (5 hand items and 4 foot items), PN symptoms rated on frequency of from 1 (not at all) to 4 (very much), ranging from 9-36 with higher indicating worse symptoms. (Almadrones 2004) An older 8 item version also exists. (Ostchega 1988)
- Time to complete: A few minutes
- Availability: Public domain

Clinical Utility: This is scale is intended to be used as a subscale along with questions on general and specific mobility, initially developed as a phone interview.

Psychometric Properties

- Reliability
  - Test-retest: Not yet completed
- Validity
  - Content validity: 2 patients with PN and 2 senior physicians familiar with PN reviewed the questions (Ostchega 1988)
  - Construct validity: 8 item scale correlated with time since end of treatment: $r= -0.48$ (p<0.05) (Ostchega 1988)
- Responsiveness
  - Hand subscale and foot subscale showed significant differences from T1 to T2 (P<0.05) using Signed Rank test. However, the median score changes from T1 to T2 were 0-2 pts) (Almadrones 2004)
Final Analysis - PNS
• Major points in final rating: This scale has 2 versions with limited psychometric properties testing for each version. This measure has not been tested in the breast cancer population.
• Rating = 2B


Scale for Chemotherapy-Induced Neurotoxicity (SCIN)
• Brief Description: 6-item survey developed from the EORTC QLQ-C30 testicular cancer-specific module, with subscales designed to capture 3 aspects of the cisplatin symptom experience: paresthesias, Raynaud’s, and ototoxicity
• Approximately 5 minutes to complete
• Item response scale of 0-3 yields total score of 0-18, higher scores indicate greater severity.
• Public domain

Clinical Utility: Very brief pencil and paper survey with simple scoring

Psychometric Properties
• Reliability: Test-retest not available
• Validity: completed in testicular cancer survivors who received cisplatin
  – Internal consistency = 0.72 (Cronbach’s alpha)
  – Content validity: 3 subscales supported by Principle Component Analysis
  – Convergent validity:
    • Hearing item correlated with audiometrics r=0.63 (P<.0001) (Oldenburg 2006)
    • Residual serum platinum levels correlated with SCIN total ($X^2$ trend, P≤0.007) and 5/6 subscales ($X^2$ trend, P=0.001-0.033) (Sprauten 2012)
  – Discriminant validity:
    • Distinguished chemo group from radiation (p=0.028) and surgery groups (p=0.002), and the latter two did not differ from each other; ‘high-dose’ exposed from ‘low-dose’ exposed survivors on paresthesia, Raynauds, ototoxicity (p=0.039, 0.023, 0.004). chemo from no-chemo groups (AUC 0.61; 95% CI: 0.56-0.65). (Oldenburg 2006)
    • Serum platinum levels associated with SCIN total scores, hand/foot paresthesias, and tinnitus (ORs; 95% CIs reported) (Sprauten 2012)
• Responsiveness: Distinguished groups based on chemo dose received (as above), but no within-group change analyses, no MDC or MCID reported

Final Analysis - SCIN
• Major points in final rating: No test-retest reliability, normative, or responsiveness data available for individual patient decision-making. Tool was designed to capture cisplatin
effects and has good convergent and discriminant validity in testicular cancer survivors, but cisplatin is not commonly used in breast cancer.

- Rating = 2B


Modified Total Neuropathy Score (mTNS)

- Brief Description: Modified from the original Total Neuropathy Score (TNS) by removal of neurophysiologic testing items. mTNS includes report of symptoms (sensory and motor), and clinical examination of pin sensibility, vibratory threshold (biothesiometer), strength (manual testing) and deep tendon reflexes.
- Completion time = 10 min
- Item response scale of 0-4 for 6 items yields total score range 0-24, higher scores indicate more severe neuropathy
- Public domain

Clinical Utility: Reasonable completion time, most items are already included in PT evaluation of neuropathy, with the exception of a biothesiometer for quantification of vibratory threshold.

Psychometric Properties

- Reliability: Not available specifically for the mTNS
- Validity: conducted in variety of cancers including breast, and with taxane, platinum, thalidomide, or vinca-alkaloid chemotherapy exposure
  - Convergent validity
    - Correlates with full TNS (r=0.99, p<0.001), SOT (r=-0.638, p 0.002), TUG (0.654 p=0.002), and FACT-Taxane subscale (-0.691, p=0.001) (Wampler 2006), however other authors found no correlation with TUG or Berg. (Vasquez 2014)
  - Discriminant validity
    - Total scores distinguished taxane-exposed breast cancer survivors from matched healthy controls (p<0.001) (Wampler 2006)
    - mTNS did not correlate with FACT-G (Vasquez 2014)
- Responsiveness:
  - No MCD, MCID available
  - From validation of full TNS: Of 20 patients, % who developed abnormal findings (≥1 point) on TNS items over chemo course = 90% DTR, 81% vibration threshold (VT), 86% distal weakness; and VT elevations correlated with cumulative taxol dose (r=0.62). (Chaudhry 1994); Vibration and DTR items predicted final CIPN severity. (Cavaletti 2004)
  - Other: Note that the mTNS did not correlate with Pain Quality Assessment Scale ratings. (Wampler 2006)
Final Analysis - mTNS

- Major points in final rating: While used in breast cancer survivors and having limited control group 'normative' data, there are insufficient reliability or responsiveness data to recommend for individual patient decision-making. Of note, validation findings do support exclusion of the neurophysiologic testing items. (Wampler 2006)
- Rating = 2A


Total Neuropathy Score, clinical version (TNSc)

- Brief Description: Modified from the original Total Neuropathy Score (TNS) by removal of neurophysiologic testing items and quantitative (biothesiometer) assessment of vibratory threshold. TNSc includes report of symptoms (sensory, motor, autonomic), and clinical examination of pin sensibility, vibratory threshold (Rydel-Seiffer semi-quantitative 128 Hz tuning fork), strength (manual testing) and deep tendon reflexes.
- Completion time = 10 min
- Item response scale of 0-4 for 7 items yields total score range 0-28, higher scores indicate more severe neuropathy
- Public domain

Clinical Utility: Enhanced by removal of biothesiometer quantitative testing item for vibratory threshold.

Psychometric Properties

- Reliability
  - Inter-rater reliability: 0.85
  - Test-retest/intra-rater reliability: 0.86-0.87 (Cavaletti 2013)
- Validity: tested in taxane, platinum, thalidomide, vinca alkaloid chemotherapies
  - Face validity: Consensus meeting of experts, literature review (Cavaletti 2013)
  - Convergent validity
    - Correlates with NCI-CTC 2.0 sensory and motor, ECOG sensory and motor ($r = 0.36-0.80$) (Cavaletti 2006, 2007, 2013)
  - Discriminant validity
- Responsiveness: Appears more sensitive than CTC2.0 in detecting mild sensory changes (Cavaletti 2013); no MCD, MCID available.
Final Analysis - TNSc

- Major points in final rating: Compared to the mTNS, the TNSc is supported as reliable, and has greater clinical feasibility. Further validation is needed, however, as the use of NCI-CTC and ECOG scales as gold standards is questioned. Also lacking are responsiveness data to support clinical use for individual decision-making.
- Rating = 2A


5-item Reduced Total Neuropathy Score (TNSr 5-item)

- Brief Description: Modified from the original Total Neuropathy Score (TNS) by removal of neurophysiologic testing items and quantitative (biothesiometer) vibratory threshold, and also the collapse of symptom report to a single item. In addition to a clinical examination of pin sensibility, vibratory sensibility (standard 128 Hz tuning fork), strength (manual testing) and deep tendon reflexes, the TNSr 5-item includes a rating of sensory symptom extension (equals the worst score out of the tingling, numbness, and neuropathic pain extension subcomponents).
- Completion time = 5-10 min
- Item response scale of 0-4 for 5 items yields total score range 0-20, higher scores indicate more severe neuropathy
- Public domain

Clinical Utility: Enhanced by substitution of a standard 128 Hz tuning fork for the original Rydel-Seiffer semi-quantitative tuning fork and biothesiometer quantitative testing of vibratory threshold.

Psychometric Properties

- Reliability: Not available
- Validity: Not available
- Responsiveness – in taxane or platinum-based chemotherapy for a variety of solid tumor cancers including breast
  - Floor effect concerns for strength item (Lavoie Smith 2010)
  - No MCD, MCID available

Final Analysis – TNSr 5-item

- Major points in final rating: Only an initial description is available for this measure, so it cannot be recommended at this time. Of note: Similar to mTNS findings, all TNSr short
form items (exception is neuropathic pain extension item) load on a distinct factor compared to the Neuropathic Pain Scale. (Lavoie Smith 2010)
• Rating = 2A


Summary of Final Recommendations for Clinical Measures of CIPN

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<th>Highly Recommend (4)</th>
<th>Recommend (3)</th>
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<th>Unable to Recommend (2B)</th>
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<td>CIPNAT</td>
<td>PNS</td>
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Oncology Section Task Force on Breast Cancer Outcomes: Balance and Falls Measures

CSM February 2015

Presented by: Min H. Huang, PT, PhD, NCS
Subcommittee members: Jennifer Blackwood, PT, PhD, GCS
Earlaine Croarkin, PT, MPT, NCS
Meredith Wampler-Kuhn, PT, DPTSc
Lucinda (Cindy) Pfalzer, PT, PhD, FACSM, FAPTA
Genevieve Colon, SPT, BS

Session Outline
• Balance impairments in BC survivors
• Search strategies for evidence
• Selection and rating of outcome measures
• Recommendations of outcome measures
• Future direction

What is Balance (Postural Stability)?
• “ability to orient the body in space, maintain an upright posture under both static and dynamic conditions, and move and walk without falling”
• “ability to respond to internal and external disturbance, to realign body segments, as well as to protect oneself from falling is essential and inherent in everyday tasks”

Impairment Contributing to Balance Problems in Breast Cancer Survivors
• Medications increase fall risks
  – pain medications for surgery or radiation
  – psychotropic/sedative hypnotics for depression, anxiety, and sleep disturbances associated with cancer and chemotherapy
  – > 4 medications
• Aromatase inhibitors
  – cause osteoporosis, myalgia, arthralgia
• Lymphedema in 10-50% BC survivors
  – impact on postural alignment/biomechanics
• Radiation side effects
  – cause integumentary changes, loss of appetite, fatigue
• Chemotherapy side effects
  – nausea, vomiting, myelosuppression, ocular toxicity during chemotherapy
  – ovarian failure causes rapid bone loss within 6 months: fracture risks correlate with fall risks in BC survivors
  – cardiac toxicity (doxorubicin, epirubicin, herceptin) onset immediately after treatment, or months to years later
  – cognitive impairments: some reported the incidence in about 20%-30% patients while others did not find any evidence of cognitive changes
  – sensory/motor neuropathy: motor symptoms were found to strongly correlate with fall risks
Balance Impairment in Breast Cancer – Acute Phase

- Wampler et al. 2007
  - BC survivors within 30 days of final taxane infusion
  - Age 30-60 years
  - Compared to controls, BC survivors had worse performance in clinical outcome measures of balance and sensory organization test (SOT)
  - Differences in the SOT scores between controls and BC survivors were most evident in conditions where the vision was either occluded or altered. In these conditions, the patients had to rely on somatosensory or vestibular input for postural stability

<table>
<thead>
<tr>
<th>Measure</th>
<th>BC mean (SD)</th>
<th>Control mean (SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fullerton Advanced Balance Scale (0-40)</td>
<td>33.90 (3.46)</td>
<td>36.48 (2.13)</td>
<td>0.008</td>
</tr>
<tr>
<td>Tug (seconds)</td>
<td>6.69 (0.99)</td>
<td>5.85 (0.86)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Outcome Measures Selected for Balance

- ABC (Activity-specific Balance Confidence)
- BBS (Berg Balance Scale)
- BESTest (Balance Evaluation Systems Test)
- CTSIB/mCTSIB Clinical Test of Sensory Organization and Balance/Modified Clinical Test of Sensory Organization and Balance
- SOT (Sensory Organization Test)
- DGI (Dynamic Gait Index)
- Functional Reach
- Gait speed
- Romberg/Sharpened Romberg
- Sit to stand
- SPPB (Short Physical Performance Battery)
- TUG (Timed Up and Go)
Search Strategy

<table>
<thead>
<tr>
<th>Databases and Sites Searched</th>
<th>Search Terms/Strings (MeSH and keyword)</th>
<th>Limits Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Google Scholar</td>
<td>• Breast cancer</td>
<td>• English</td>
</tr>
<tr>
<td>• Ovid</td>
<td>• Breast neoplasms</td>
<td>• January 1,</td>
</tr>
<tr>
<td>• Pubmed/Medline</td>
<td>• Psychometrics</td>
<td>1995 July 31,</td>
</tr>
<tr>
<td>• CINAHL</td>
<td>• Balance</td>
<td>2014</td>
</tr>
<tr>
<td>• Cochrane Review</td>
<td>• Name of measure (e.g. ABC)</td>
<td></td>
</tr>
<tr>
<td>• PEDro</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Web of Science</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Inclusion Criteria

• Balance measures/methods
• Adults, preferably female (human subjects)
• English language
• Published in 1995 to July 31st 2014
• Clinically feasible methods
• Psychometric properties reported

Exclusion Criteria

• Non-clinical measures of balance
• Physical function or mobility measures
  – e.g. Rivermead mobility index, physical performance test

Consensu Selection of Articles

Initial search of articles = 683

Final articles included for initial review = 82

Articles not meeting criteria = 46

Articles reviewed for testing methods = 36

Each outcome measure was reviewed independently and rated by 2 reviewers

A 3rd reviewer was assigned to obtain consensus if necessary
Highly Recommend (Rating of “4”)
- None available

Recommended (Rating of “3”)

<table>
<thead>
<tr>
<th>Outcome Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fullertson Advanced Balance Scale (FABS)</td>
</tr>
<tr>
<td>Timed Up and Go (TUG)</td>
</tr>
</tbody>
</table>

Unable to Recommend (Rating of “2A”)

<table>
<thead>
<tr>
<th>Outcome Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities Specific Balance Confidence Scale (ABC)</td>
</tr>
<tr>
<td>Balance Evaluation Systems Test (BESTest)</td>
</tr>
<tr>
<td>Berg Balance Scale (BBS)</td>
</tr>
<tr>
<td>Functional Reach</td>
</tr>
<tr>
<td>Repeated Sit to Stand/30-second Sit to Stand/10 Times Sit to Stand/5 Times Sit to Stand</td>
</tr>
<tr>
<td>Short Physical Performance Battery</td>
</tr>
</tbody>
</table>

Unable to Recommend (2B) & Do Not Recommend (1)

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Test of Sensory Interaction and Balance (CTSIB)/Modified Clinical Test of Sensory Interaction (mCTSIB)</td>
<td>2B</td>
</tr>
<tr>
<td>Dizziness Handicap Inventory (DHI)</td>
<td>2B</td>
</tr>
<tr>
<td>Dynamic Gait Index (DGI)</td>
<td>2B</td>
</tr>
<tr>
<td>Gait Speed</td>
<td>2B</td>
</tr>
<tr>
<td>Romberg/Sharpened Romberg</td>
<td>2B</td>
</tr>
<tr>
<td>Tinetti Performance Oriented Mobility Assessment (POMA)</td>
<td>2B</td>
</tr>
<tr>
<td>Sensory Organization Test (SOT)</td>
<td>1</td>
</tr>
</tbody>
</table>

Fullertson Advanced Balance Scale (FABS) - Summary
- Performance-based measure
- Static/dynamic balance with various sensory conditions
- Designed for high-functioning active older adults
- 10 activities
- 40 points max possible
- Each item scored on a 5 point scale (0-4)
- Higher scores are better
- Time to Administer = 0-12 minutes
- Cost is free
- Cut-off score for fall risks $\leq 25/40$ Points
- Assessment Form
- Administration Instruction
  http://hhd.fullerton.edu/csa/documents/FABScaleTestAdministrationInstructions.pdf
Directions for Performance
1. Stand with feet together and eyes closed
2. Reach forward to retrieve an object (pencil) held at shoulder height with outstretched arm
3. Turn 360 degrees in right and left directions
4. Step up onto and over a 6-inch bench
5. Tandem walk
6. Stand on one leg
7. Stand on foam with eyes closed
8. Two-footed jump for distance
9. Walk with head turns
10. Reactive postural control

Clinical Utility
• Rating Score = 3 (recommended)
• Good clinical utility
• Equipment is clinically feasible
• Staff training is minimal
• Quick (10-12 min) and easy to use
• Psychometric properties have been reported in BC survivors

Psychometric Properties
• Excellent reliability
  – Inter-rater reliability (ICC= 0.98)
  – Test-retest/intra-rater reliability (ICC= 0.92)
• Adequate construct validity
  – Correlation with SOT composite score (r= 0.581)
  – Correlation with COP velocity
    • Eyes open/head straight (r= -0.581)
    • Eyes open/head back (r= -0.541)
    • Eyes closed/head straight (r= -0.523)
    • Eyes closed/head back (r= -0.496)

Final Analysis - Fullerton Advanced Balance Scale (FABS)
• No studies yielded a rating of 4
• 1 study with methodology designed specifically for breast cancer survivors
• No psychometric data on criterion validity, cutoff scores for fall risks, MDC, MCID, SEM in BC survivors
• Good clinical utility
• Rating = 3 recommended

Timed Up and Go (TUG)
• Patients wear regular footwear for testing
• Can use a walking aid (be consistent)
• Allow one practice trial
• Time to administer < 3 minutes
• Cut-off score for fall risks
  ≥13.5 sec in community-dwelling older adults
  >12 sec CDC STEADI tool kit
• Instruction available at
Directions for Performance

- Begin by having the patient sit back in a standard arm chair and identify a line 3 meters (10 feet) away on the floor
- When I say “Go,” I want you to……
  - Stand up from the chair
  - Walk to the line on the floor at your normal pace
  - Turn
  - Walk back to the chair at your normal pace
  - Sit down again
- On the word “Go” begin timing. Stop timing after patient has sat back down.

Clinical Utility

- Rating Score = 3 (recommended)
- Good clinical utility
- Equipment is clinically feasible
- Staff training is minimal
- Quick (<3 min) and easy to use
- Psychometric properties have been reported in BC survivors

Psychometric Properties

- High reliability
  - ICC=0.88
- Adequate construct validity
  - Correlation with COP velocity
    - Eyes open/head back (r=0.549)
    - Eyes closed/head straight (r=0.498)
    - Eyes closed/head back (r=-0.474)

Timed Up and Go (TUG)

- No studies yielded a rating of 4
- 1 study with methodology designed specifically for breast cancer survivors
- No psychometric data on validity, cutoff scores for fall risks, MDC, MCID, SEM in BC survivors
- Good clinical utility
- Rating = 3 recommended

Directions for Further Research in Assessment Tools for Balance

- More studies on reliability, validity, and responsiveness to determine intervention effectiveness
- Cutoff scores to assess fall risks
- Self-report outcome measures
- Tools for specific practice settings, e.g. acute, inpatient, community/outpatient
- Changes in balance through various stages of survivorship
- Interplay between factors such as cancer treatments, cancer stages, comorbidity, age, previous functional level, and balance

Acknowledgements

- This project was supported by the Physical Therapy Department, the University of Michigan-Flint to MH, JB and GC.
- Oncology Section of APTA.
<table>
<thead>
<tr>
<th>Measure</th>
<th>Equipment Needed</th>
<th>Cost</th>
<th>Ease of Use</th>
<th>Scoring/Interpretation</th>
<th>Normative Data</th>
<th>Study Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fullerton Advanced Balance Scale (FABS)</td>
<td>Yes</td>
<td>Free</td>
<td>High</td>
<td>Easy</td>
<td>No</td>
<td>Community-dwelling older adults Breast cancer survivors post chemotherapy</td>
</tr>
<tr>
<td>Timed Up &amp; Go (TUG)</td>
<td>No</td>
<td>Free</td>
<td>High</td>
<td>Easy</td>
<td>Yes</td>
<td>Community-dwelling older adults Parkinson’s disease Spinal cord injury Vestibular disorders</td>
</tr>
<tr>
<td>Balance Evaluation Systems Test (BESTest)</td>
<td>Yes</td>
<td>Free*</td>
<td>Moderate</td>
<td>Easy</td>
<td>No</td>
<td>Adults with mixed neurologic diagnoses Older adults Older cancer survivors with mixed diagnoses Parkinson’s disease Stroke</td>
</tr>
<tr>
<td>Berg Balance Scale (BBS)</td>
<td>No</td>
<td>Free</td>
<td>High</td>
<td>Easy</td>
<td>Yes</td>
<td>Community-dwelling older adults Institutionalized older adults Parkinson’s disease/Parkinsonism</td>
</tr>
<tr>
<td>Five Time Sit to Stand (FTSTS)</td>
<td>No</td>
<td>Free</td>
<td>High</td>
<td>Easy</td>
<td>Yes</td>
<td>Community-dwelling older adults Parkinson’s disease Stroke Vestibular disorders</td>
</tr>
<tr>
<td>Functional Reach</td>
<td>Yes</td>
<td>Free</td>
<td>High</td>
<td>Easy</td>
<td>Yes</td>
<td>Parkinson’s disease Stroke Vestibular disorders</td>
</tr>
<tr>
<td>Short Physical Performance Battery (SPPB)</td>
<td>Yes</td>
<td>Free</td>
<td>High</td>
<td>Easy</td>
<td>No</td>
<td>Older adults</td>
</tr>
</tbody>
</table>

*Free but copyrighted, training DVD is $200
Table 2. EDGE Task Force Ratings and Clinical Utility of the Balance Measures for Breast Cancer Survivors.

<table>
<thead>
<tr>
<th>Measure</th>
<th>EDGE Rating</th>
<th>Clinical Utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities Specific Balance Confidence Scale (ABC)</td>
<td>2A</td>
<td>Self-administer or interview. Time efficient. No equipment needed. Free. Good clinical utility.</td>
</tr>
<tr>
<td>Balance Evaluation Systems Test (BESTest)</td>
<td>2A</td>
<td>Good psychometric properties. 20-30 min to administer. May not distinguish fallers from non-fallers in older cancer survivors.</td>
</tr>
<tr>
<td>Berg Balance Scale (BBS)</td>
<td>2A</td>
<td>No training required. Good psychometric properties, normative data available. Free. Good clinical utility.</td>
</tr>
<tr>
<td>Short Physical Performance Battery (SPPB)</td>
<td>2A</td>
<td>Good psychometric properties established in older adults but not in cancer survivors. Free.</td>
</tr>
</tbody>
</table>
Table 3. Psychometric Properties of Balance Test/Measure with a Rating of 3.

<table>
<thead>
<tr>
<th>Test/Measure</th>
<th>Timed Up and Go (TUG)</th>
<th>Fullerton Advanced Balance Scale (FABS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-rater reliability</td>
<td>Not established</td>
<td>In breast cancer survivors post chemotherapy (Wampler 2007)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– Excellent (ICC=0.92)</td>
</tr>
<tr>
<td>Inter-rater reliability</td>
<td>Not established</td>
<td>In breast cancer survivors post chemotherapy (Wampler 2007)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– Excellent (ICC=0.98)</td>
</tr>
<tr>
<td>Test-retest reliability</td>
<td>Not established</td>
<td>In breast cancer survivors post chemotherapy (Wampler 2007)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– Excellent (ICC=0.92)</td>
</tr>
<tr>
<td>SEM</td>
<td>Not established</td>
<td>Not established</td>
</tr>
<tr>
<td>MDC/MCID</td>
<td>Not established</td>
<td>Not established</td>
</tr>
<tr>
<td>Validity</td>
<td>In breast cancer survivors post chemotherapy</td>
<td>In breast cancer survivors post chemotherapy (Wampler 2007)</td>
</tr>
<tr>
<td></td>
<td>(Wampler 2007)</td>
<td>– Moderate correlation with SOT ($r = -0.48$)</td>
</tr>
<tr>
<td></td>
<td>In older adults with a diagnosis of breast,</td>
<td>– Moderate correlation with COP velocity</td>
</tr>
<tr>
<td></td>
<td>lung, or colorectal carcinoma, or lymphoma</td>
<td>(Hurria 2007)</td>
</tr>
<tr>
<td></td>
<td>(Hurria 2007)</td>
<td>– Poor correlation with measures of physical functioning ($r &lt; 0.07$)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– Poor correlation with the number of falls in the last 6 months ($r = 0.28$)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– Moderate correlation with SOT ($r = -0.58$)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– Moderate correlation with COP velocity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>($r = -0.581$ for Eyes open/ head straight)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>($r = -0.541$ for Eyes open/ head back)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>($r = -0.523$ for Eyes closed/ head straight)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>($r = -0.496$ for Eyes closed/ head back)</td>
</tr>
</tbody>
</table>

Abbreviations: ICC, intraclass correlation coefficient; $r$, Pearson’s Coefficient Correlation; SEM, standard error of measurement; MDC, minimal detectable change; MCID, minimal clinical important difference.
Oncology Section Task Force on Breast Cancer Outcomes:  
Functional Mobility  

CSM February 2015  

Presented by: Claire Davies, PT, PhD, CLT, LANA  
Subcommittee members: Mary I. Fisher, PT, PhD, OCS, CLT  
Cindy Pfalzer, PT, PhD  
Jeannette Lee, PT, PhD  
Genevieve Colon, SPT  
Hannah Geyer, SPT  

Operational Definition:  
Activities enabling an individual to move about their environment in order to perform ADLs and participate in life situations.  

Functional Mobility Measures:  
- Sub-committee utilized multiple databases and literature to derive a list of 27 measures.  
- These measures were then researched, and some were removed from analysis secondary to a lack of literature available.  
- Remaining tests were grouped into 4 categories:  

1. Walk Tests  
   a. 6 minute walk test  
   b. 12 minute walk test  
   c. 10 meter walk  
   d. 2 Minute Walk Test  
   e. Timed 25 Foot Walk  
   f. Timed Up & Go (Cognitive and Manual)  
   g. High-level Mobility Assessment Tool (HiMAT)  
   h. Short Performance Physical Battery  
   i. Physical Performance Battery for Patients with Cancer  
   j. 5 times sit to stand  

2. ADL functional Tests  
   a. Assessment of Life Habits  
   b. Canadian Occupational Performance Measure  
   c. Barthel Index  
   d. Functional Independence Measure/ Functional Self-assessment  

3. Upper Extremity functional movement tests  
   a. Action Research Arm Test  
   b. Activity Measure for Post Acute Care  
   c. Arm Motor Ability Test  
   d. Six Minute Arm Test (6-MAT)  
   e. Wolf Motor Function Scale
4. Self-Report – community participation
   a. Impact on Participation and Autonomy Questionnaire (IPAQ)
   b. Life Satisfaction Questionnaire (LISAT-9)
   c. Functional Status Examination
   d. Modified Rankin Scale
   e. Participation Objective, Participation Subjective (POPS)
   f. Participation Survey of Mobility Limited people (PSM)

Search Strategy

<table>
<thead>
<tr>
<th>Databases and Sites Searched</th>
<th>Search Terms/Strings (hits with potential for review)</th>
<th>Limits Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Google Scholar</td>
<td>• Breast cancer</td>
<td>English articles</td>
</tr>
<tr>
<td>• Ovid</td>
<td>• Breast neoplasm</td>
<td>Year: 1995 or newer</td>
</tr>
<tr>
<td>• Pubmed/Medline</td>
<td>• Functional mobility</td>
<td></td>
</tr>
<tr>
<td>• CINAHIL</td>
<td>• Walk tests</td>
<td></td>
</tr>
<tr>
<td>• Sports Discus</td>
<td>• ADL/activities of daily living assessment</td>
<td></td>
</tr>
<tr>
<td>• Web of Science</td>
<td>• Transfers</td>
<td></td>
</tr>
<tr>
<td>• Cochrane Review</td>
<td>• Physical Performance</td>
<td></td>
</tr>
<tr>
<td>• PEDro</td>
<td>• Psychometric properties</td>
<td></td>
</tr>
<tr>
<td>• Academic Search</td>
<td>• Clinimetrics</td>
<td></td>
</tr>
<tr>
<td>• Individual searches on identified tools (for example, 2 min walk test, Timed Up and Go, etc).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Inclusion Criteria

- Adults, preferably female (human subjects)
- English language
- Clinically feasible methods
- Meets operational definition
- Patient focused/centered measure
- Psychometric properties reported

Exclusion Criteria

- Non-clinical measures of functional mobility
- Fine motor/dexterity functional tests
- Balance and falls measures
- Tests of sensation/sensory motor function
- Assessments of the environment for functional purposes (rather than the individual)
## Assessment of Usefulness of Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Intra-rater Reliability (ICC)</th>
<th>Inter-rater Reliability (ICC)</th>
<th>Test /Re-Test Reliability (ICC)</th>
<th>Responsive-ness to Change</th>
<th>Validity</th>
<th>Clinical Utility</th>
<th>EDGE Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Walk Tests</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **2 Minute Walk Test** | Inter-trial ICC: Rater A: 0.94<sup>17</sup> Rater B: 0.96<sup>17</sup>  
                   | r = 0.85<sup>5</sup>  
                   | r = 0.83 (0.71-0.90) | r = 0.85  
                   | r = 0.97  
                   | ICC = 0.96<sup>17</sup>  | Inter-occasion ICC: Rater A: 0.94  
                   | Rater B: 0.95  
                   | 0.94 | Absolute reliability for the 2MWT was calculated as the SEM and estimated to be ≤ 6.3m<sup>17</sup>  
                   | SEM: 48.5<sup>18</sup> | 2MWT and 6MWT: r=0.892<sup>17</sup>  
                   | 2MTW and 12MWT: r=.864<sup>17</sup>  
                   | 2MWT and TUG: r=0.87<sup>17</sup>  
                   | 2MWT and BBS: r=0.88<sup>17</sup>  
                   | MWT and 6MWT: r=0.93<sup>17</sup> | 2MWT and 6MWT: r=0.96<sup>10</sup>  
                   | 2MWT and EDSS: r= -0.61<sup>10</sup>  
                   | 2MWT and MSWS-12: r=-0.72<sup>10</sup>  
                   | 2MWT and MFIS physical sub-index: r = 0.31<sup>10</sup> | Quick and easy to administer. Free.  
<pre><code>               | Good psychometric properties and but unable to locate evidence that test has been applied to individuals with breast cancer. | 3 |
</code></pre>
<table>
<thead>
<tr>
<th>Measure</th>
<th>Intra-rater Reliability (ICC)</th>
<th>Inter-rater Reliability (ICC)</th>
<th>Test /Re-Test Reliability (ICC)</th>
<th>Responsive-ness to Change</th>
<th>Validity</th>
<th>Clinical Utility</th>
<th>EDGE Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6 minute walk test</strong></td>
<td>SCI: ICC = 0.99⁸</td>
<td>Stroke: ICC = 0.99</td>
<td>Cancer pop: ICC = 0.93 (0.86-0.97)¹</td>
<td>Measured by SRM scores was 1.52²</td>
<td>Distance correlated with exercise capacity r=0.67, maximum workload r=0.70, perceived physical function (r= 0.55); age (r=-0.52).¹</td>
<td>Good psychometrics has been used in cancer patients, easy to administer and free. Good clinical utility.</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Stroke: ICC = 0.78, acute stroke²</td>
<td></td>
<td></td>
<td></td>
<td>Healthy elderly r=0.57 to 0.88⁹</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cancer: ICC = 0.78, stroke²</td>
<td></td>
<td></td>
<td>10 mwt (r=-.95)¹⁰</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>TUG (r=-0.88)¹⁰</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Walking index for SCI (r=0.60)¹⁰</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Stroke ² 2 min walk test r=0.99⁷</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 min. walk test r=0.994⁷</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Chronic stroke TUG r = -0.89¹¹</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10m fast gait r=0.94¹¹</td>
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<td></td>
<td>10m comfortable gait r=0.84¹¹</td>
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<td></td>
<td>Divergent validity Cancer Not correlated significantly with overall quality of life (EORTC QLQ-C30)</td>
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<td>Measure</td>
<td>Intra-rater Reliability (ICC)</td>
<td>Inter-rater Reliability (ICC)</td>
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<tr>
<td>Walk Tests – cont.</td>
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<tr>
<td><strong>12 minute walk test</strong></td>
<td>$r = 0.71$ (p &lt; 0.0003)²</td>
<td>$r = 0.68$ (p &lt; 0.0007)²</td>
<td>Measured by standardized response mean (SRM) scores was, $1.90$ (F = 24.24, p &lt; 0.001)²</td>
<td></td>
<td></td>
<td>Easy to administer, may have limited utility in the clinic with lower functioning patients due to the time it takes to complete.</td>
<td>3</td>
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<tr>
<td><strong>10 meter walk</strong></td>
<td>ICC = 0.823 with 95% CI 0.565 to 0.934¹⁴</td>
<td>Healthy adults: (ICC = 0.980)¹⁵</td>
<td>Healthy Adults: for comfortable gait speed ($r = 0.75-0.90$)¹² for comfortable and fastest gait speeds ($r = 0.93-0.91$)¹³</td>
<td>Geriatrics Small meaningful change $= 0.05m/s¹⁷$ Substantial meaningful change $= 0.13 m/s¹⁷$ Predictive validity Multiple Sclerosis: $r = (0.35 - 0.87)$¹⁶ Correlation with dependence in instrumental activities of daily living: $r = 0.76¹⁶$ Correlation with Barthel Index: $r = 0.78¹⁶$ Chronic Stroke: correlation between comfortable gait speed and TUG: ICC = -0.84, and 6MWT: ICC = 0.89¹¹ Correlation between fast gait speed and TUG: ICC = -.91 And 6MWT = ICC = 0.95</td>
<td></td>
<td>Inexpensive, easy to administer, no psychometrics for cancer patients. Good clinical utility.</td>
<td>3</td>
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<tr>
<td>Measure</td>
<td>Intra-rater Reliability (ICC)</td>
<td>Inter-rater Reliability (ICC)</td>
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<tr>
<td>Walk Tests – cont.</td>
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<tr>
<td>Timed 25 Foot Walk</td>
<td>r = 0.88&lt;sup&gt;20&lt;/sup&gt;</td>
<td></td>
<td>MS pop: r = 0.942&lt;sup&gt;20&lt;/sup&gt;</td>
<td></td>
<td>Construct validity: Correlation with Expanded Disability Status Scale (r=0.69)&lt;sup&gt;20&lt;/sup&gt;</td>
<td>Correlation with timed 100 foot walk (r=0.92)&lt;sup&gt;20&lt;/sup&gt; Correlation with walking distance for both MS patients with limited ambulation (r=0.71)&lt;sup&gt;20&lt;/sup&gt;, and patients with restricted ambulation (r=0.68)&lt;sup&gt;20&lt;/sup&gt;</td>
<td>Limited reliability and validity available, easy to administer, free. Developed for MS, no psychometrics established for cancer cohort.</td>
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<td></td>
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<td>Health controls: r = 0.884&lt;sup&gt;20&lt;/sup&gt;</td>
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<tr>
<td>Timed Up &amp; Go (Cognitive &amp; Manual)</td>
<td></td>
<td></td>
<td>r = 0.90&lt;sup&gt;14&lt;/sup&gt;</td>
<td></td>
<td>TUG and 2MWT &amp; FIM at admission: r=0.59&lt;sup&gt;13&lt;/sup&gt; TUG and 2MWT &amp; FIM at discharge: r=0.42 and r=0.47&lt;sup&gt;13&lt;/sup&gt; 2MWT and TUG at admission: r=0.81&lt;sup&gt;13&lt;/sup&gt; 2MWT and Tug at discharge: r=0.68, p&lt;0.001</td>
<td>Easy to administer clinically, no training required, time efficient, free. Good clinical utility.</td>
<td>4</td>
</tr>
<tr>
<td>imed Up &amp; Go – cont.</td>
<td>TUG and falls within 1 year: r=0.85</td>
<td>TUG and falls within 3 months: r=0.85</td>
<td>TUG and falls since cancer diagnosis: r=0.74</td>
<td>TUG and Simmonds Performance Status Battery: r=0.85</td>
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<tr>
<td><strong>High-level Mobility Assessment Tool (HiMAT)</strong></td>
<td>Chronic TBI: r = 0.99(^{23}) Healthy pop (ages 18-25): r= 0.99(^{24})</td>
<td>Chronic TBI: r= 0.99(^{21}) r= 0.99(^{23})</td>
<td>MDC: -2 to +4 points (95% CI)(^{23})</td>
<td>Pearson Separation Index: 0.91(^{24}) Cronbach alpha= 0.93(^{24}) Internal consistency Chronic TBI Cronbach alpha = 0.97(^{23}) 8 item version = 0.96(^{23})</td>
<td></td>
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<tr>
<td><strong>Short Performance Physical Battery (SPPB)</strong></td>
<td>ICC = 0.88 - 0.92(^{26,27}) ICC &gt;0.90(^{27})</td>
<td>ICC &gt;0.90(^{27}) r= 0.82(^{27}) ICC: Summary : r =88-.92(^{28}) Balance: r = .70 -.8222(^{8}) Gait: r = .80-.89(^{28}) Chair Stands: r = .76 -.90(^{28})</td>
<td>SPPB score of 4-6 points had relative risk of 4.2 to develop ADL disability over 4 year period vs. those who scored 10-12 points.(^{30}) SPPB score of 7-9 points had RR of 1.6</td>
<td>Good psychometrics but not established in prostate cancer populations. Free.</td>
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</table>

\(^{1}\) Good psychometric properties for populations other than cancer. Free. Items tested may not be applicable to BC population.
| Short Performance Physical Battery (SPPB) - continued | ICC: Summary = .87\(^{30}\) Balance = .64\(^{30}\) Gait = .92\(^{30}\) Chair Stands = .75\(^{30}\) ICC: Summary = .83 - .89\(^{29}\) Balance = .55 - .75\(^{29}\) Gait = .75 - .90\(^{29}\) Chair Stands = .73 - .78\(^{29}\) | Responsive to change following exercise-based intervention and following medical event.\(^{28}\) | | |
|---|---|---|---|
| Physical Performance Battery for Patients with Cancer | r=0.98 and 0.99\(^{12}\) | r= 0.69-0.99\(^{13}\) | Healthy pop:\(^{31}\) Correlation with Forward Reach: r = -0.26 to -0.05 Sit to Stand: r =-0.13 to 0.28 50’ walk: r = 0.08-0.31 6 MWT: r = 0.01-0.35 Cancer pop:\(^{33}\) Correlation with Forward Reach: r = -0.33 to 0.21 Sit to Stand: r =-0.44 to 0.59 50’ walk: r = 0.03-0.16 6 MWT: r = 0.23-0.45 | Specifically developed for cancer cohort, easy to administer. Free. May not be time efficient for use in the clinic but has been used in prostate cancer population. | 3 |
| **Physical Performance Battery for Patients with Cancer - continued** |  |  | **Convergent/ discriminant validity**
Correlations between performance measures and pain ($r=0.03-0.35$)

Correlations between self-report of function and performance measures ($r=0.25$ to $0.51$)

Correlations between fatigue and performance measures ($r=0.14 - 0.45$)

Correlation between fatigue and 6 min. walk $r=0.45$

**Construct validity**
correlations between tests of upper limb function ($r=0.3$ to 0.85)$^{34}$

Large body movement tests (sit to stand, walk tests) stronger correlations$^{34}$ |  |  |
<table>
<thead>
<tr>
<th>Measure</th>
<th>Intra-rater Reliability (ICC)</th>
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<tbody>
<tr>
<td><strong>Walk Tests</strong></td>
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<td>5 times sit to stand</td>
<td>PD: ICC=0.99&lt;sup&gt;39&lt;/sup&gt;</td>
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<td></td>
<td>LBP: ICC = 0.99&lt;sup&gt;38&lt;/sup&gt;</td>
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<td></td>
<td>CVA: ICC = 0.99&lt;sup&gt;41&lt;/sup&gt;</td>
<td>Community dwelling elderly</td>
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<td>r= 0.82&lt;sup&gt;35&lt;/sup&gt;</td>
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<td></td>
<td></td>
<td>r= 0.89&lt;sup&gt;36&lt;/sup&gt;</td>
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<td>r= 0.957&lt;sup&gt;37&lt;/sup&gt;</td>
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<td></td>
<td>PD: r= 0.99&lt;sup&gt;39&lt;/sup&gt;</td>
<td>LBP: r= 0.99&lt;sup&gt;38&lt;/sup&gt;</td>
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<td></td>
<td>CVA: r= 0.99&lt;sup&gt;25&lt;/sup&gt;</td>
<td>OA: r=0.96&lt;sup&gt;40&lt;/sup&gt;</td>
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<td></td>
<td>PD : With PASE r=-0.38&lt;sup&gt;39&lt;/sup&gt;</td>
<td>With PDQ-mobility r=0.58&lt;sup&gt;39&lt;/sup&gt;</td>
<td>With ABC r=0.54&lt;sup&gt;39&lt;/sup&gt;</td>
<td>With Mini-BEST r=0.71&lt;sup&gt;39&lt;/sup&gt;</td>
<td>With quads MVIC r=-0.33&lt;sup&gt;39&lt;/sup&gt;</td>
<td>With 6mwt r=0.6&lt;sup&gt;39&lt;/sup&gt;</td>
<td>Easy to administer, no training required, time efficient and free. Normative data available. Good clinical utility.</td>
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<td></td>
<td>LBP: With 5 min. walk test r=-0.78&lt;sup&gt;38&lt;/sup&gt;</td>
<td>50 foot walk r=0.87&lt;sup&gt;38&lt;/sup&gt;</td>
<td>Repeated trunk flexion r=0.64&lt;sup&gt;38&lt;/sup&gt;</td>
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<tr>
<td><strong>Activities of Daily Living Functional Tests</strong></td>
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<tr>
<td><strong>Barthel Index</strong></td>
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<td></td>
<td>Parkinson’s Pop:</td>
<td>Internal Consistency: 0.69</td>
<td>Concurrent validity with Parkinson’s Disease Questionnaire : ADL’s r=0.60 Mobility r=0.49</td>
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<td>Not used in cancer population; only adequate psychometrics reported.</td>
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Copyright Fisher, Hile, Huang, Davies, 2015
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<tr>
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<th>Clinical Utility</th>
<th>EDGE Rating</th>
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<tr>
<td>Activities of Daily Living Functional Tests - cont</td>
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<td><strong>Functional Independence Measure (FIM)</strong></td>
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<tr>
<td></td>
<td>ICC = 0.95</td>
<td>ICC = 0.90</td>
<td>ICC = 0.80</td>
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<td></td>
<td><em>(Ottenbacher 1996)</em></td>
<td><em>(Pollak 1996)</em></td>
<td><em>(Hobart 2001)</em></td>
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<td><strong>Assessment of Life Habits (LIFE-H)</strong></td>
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<td></td>
<td>CVA: ICC=0.89</td>
<td>SCI Pop: ICC=0.89</td>
<td>SCI Pop: ICC=0.89</td>
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<td><em>(Derosiers 2004)</em></td>
<td><em>(Noreau 2002)</em></td>
<td><em>(Noreau 2002)</em></td>
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<td>Older Adults: ICC=0.74-0.83</td>
<td><em>(Fougeyrollas 1998)</em></td>
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<td></td>
<td></td>
<td>ICC=0.84</td>
<td><em>(Poulin2009)</em></td>
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**Internal Consistency:**
- General Rehab Pop:
  - Cronbach’s alpha =0.93-0.95 *(Dodds 1993)*
- SCI:
  - Cronbach’s alpha =0.91-0.92
- Concurrent Validity with Barthel:
  - SCI:
    - r=0.92-0.94 *(Hsueh 2002)*

**Convergent Validity:**
- Craig Handicap Assessment and Reporting Technique:
  - SCI:
    - r=0.14-0.76
- Convergent Validity with Community Integration Questionnaire:
  - SCI:
    - R=0.54-0.75 *(Noreau 2002)*

Cost to purchase; 30-45 minutes to complete. Validated in multiple populations including elderly, orthopedic, general rehab.

Good psychometrics but clinical utility lower. Marked degree of difficulty scoring, takes time to complete.

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<tr>
<th>Measure</th>
<th>Intra-rater Reliability (ICC)</th>
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<tbody>
<tr>
<td>Canadian Occupational Performance Measure</td>
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<td>Spearman’s r=0.88-0.89</td>
<td>Convergent Validity: 0.88-0.89</td>
<td>Limited but good psychometric properties; fee to use. No evidence for use in cancer.</td>
<td>2B</td>
</tr>
</tbody>
</table>

### Upper Extremity Functional Tests

#### Action Research Arm Test

<table>
<thead>
<tr>
<th>Subparts ICC: 51</th>
<th>Chronic Stroke: 50 Subparts ICC:</th>
<th>Stroke, MS, TBI: 52 Subparts ICC:</th>
<th>Chronic Stroke: 50 Subparts ICC:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grasp = 0.98</td>
<td>Grasp = 0.949</td>
<td>Grasp = 0.99</td>
<td>Grasp = 0.99</td>
</tr>
<tr>
<td>Grip = 0.97</td>
<td>Grip = 0.947</td>
<td>Grip = 0.99</td>
<td>Grip = 0.99</td>
</tr>
<tr>
<td>Pinch = 0.99</td>
<td>Pinch = 0.894</td>
<td>Pinch = 0.99</td>
<td>Pinch = 0.99</td>
</tr>
<tr>
<td>Gross Movt. = 0.93</td>
<td>Gross Movt. = 0.976</td>
<td>Gross Movt. = 0.98</td>
<td>Gross Movt. = 0.98</td>
</tr>
<tr>
<td>Total Score = 0.99</td>
<td>Total Score = 0.965</td>
<td>Total Score = 0.98</td>
<td>Total Score = 0.98</td>
</tr>
<tr>
<td>Acute Stroke: 53</td>
<td>Chronic Stroke: 50 ICC =0.92</td>
<td>Chronic Stroke: 50 ICC =0.995</td>
<td>Chronic Stroke: 50</td>
</tr>
<tr>
<td>Chronic Stroke: 51</td>
<td>Subparts ICC:</td>
<td>Subparts ICC:</td>
<td>Subparts ICC:</td>
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<tr>
<td>Grasp = 0.99</td>
<td>Grasp = 0.99</td>
<td>Grasp = 0.99</td>
<td>Grasp = 0.99</td>
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<tr>
<td>Grip = 0.99</td>
<td>Grip = 0.99</td>
<td>Grip = 0.99</td>
<td>Grip = 0.99</td>
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<tr>
<td>Pinch = 0.99</td>
<td>Pinch = 0.99</td>
<td>Pinch = 0.99</td>
<td>Pinch = 0.99</td>
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<tr>
<td>Gross Movt. = 0.98</td>
<td>Gross Movt. = 0.98</td>
<td>Gross Movt. = 0.98</td>
<td>Gross Movt. = 0.98</td>
</tr>
<tr>
<td>Total Score = 0.99</td>
<td>Total Score = 0.99</td>
<td>Total Score = 0.99</td>
<td>Total Score = 0.99</td>
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**Concurrent validity**

Stroke: 50,55 corr with upper limb subtest of Fugl-Meyer (r=0.91-0.94) Correlated with the upper extremity part of Motor Assessment Scale (r=0.96) Correlated with the Motoricity Index arm subscale (r=0.87)

**Divergent validity** 52 negatively related to Ashworth scale, not related to Modified Barthel Index

**Construct validity** 52 Stroke, MS, TBI: Fugl-Meyer Motor = 0.925 Box and Block = 0.951

Observation upper limb function test. Not tested or used in cancer population, or chronic illness population (rather neurological population). Takes several pieces of equipment to administer. 2B
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Activity Measure for Post Acute Care</strong></td>
<td>Andres Post Acute Care: Daily Activity: ICC = 0.90 Mobility: ICC = 0.80 Applied cognition: ICC 0.68</td>
<td>Andres Post Acute Care: Daily Activity: ICC = 0.96 Mobility: ICC = 0.97 Applied cognition: ICC 0.91</td>
<td>MDC AMPAC Computer version (Jette) basic mobility = 4.28 Daily activity = 3.7 Applied cognitive = 5.55 MID AMPAC CAT – 2 points (Cheville) in late stage lung cancer Small SRM between 3 diagnostic groups (ortho, neuro, complex medical) -0.02 to 0.10 (Coster)</td>
<td>Internal consistency Cronbach alpha 0.92-0.94 total, 0.90-0.95 for specific diagnostic groups (Haley 2004) Content Validity Factor analysis: 3 factors account for 72% variance Convergent Validity Hip Fractures SF-36: r = .84 Gait speed: r= 65 6 MWT: r = .67 Predictive validity Score declines (2, 5, and 10 points) in AMPAC associated with worst pain, average pain, and fatigue (Cheville) New brain mets associated with AMPAC score declines of 5 and 10 points (Cheville)</td>
<td>Can utilize CAT version to reduce number of items. Based on WHO ICF model; intended for any post-acute patient. Has been used in cancer, but not breast cancer.</td>
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<tr>
<td><strong>Upper Extremity Functional Tests</strong> - continued</td>
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<tr>
<td><strong>Arm Motor Ability Test</strong></td>
<td>ICC = 0.95-0.99[^43]</td>
<td>ICC = 0.93-0.99[^43]</td>
<td>MDC</td>
<td>Concurrent validity</td>
<td></td>
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<td></td>
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<td>subacute stroke, mild to moderate deficits, AMAT able to detect change occurring as a result of passage of 1 vs. 2 weeks (no number given) (Kopp)</td>
<td>with Motoricity Index Arm – r = 0.45-0.61[^43] (Kopp)</td>
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<td>With Fugl-Meyer – r = 0.92-0.94[^44] (Chae)</td>
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<tr>
<td><strong>6-Minute Arm Test</strong></td>
<td>HR = ICC 0.90[^42] &amp; VO₂ = ICC 0.81[^42]</td>
<td>HR = 19.68 &amp; VO₂ = 4.48</td>
<td>SCI Pop MDC.[^42]</td>
<td>Convergent Validity[^42]</td>
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<td>VO₂ Peak to VO₂: r = 0.92</td>
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<td>Power output to VO₂ Peak:</td>
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<td></td>
<td></td>
<td>r = 0.73</td>
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<td></td>
<td></td>
<td>HR to VO₂ Peak: r = 0.63</td>
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<tr>
<td><strong>Wolf Motor Function Test</strong></td>
<td>Chronic stroke[^56-58] ICC = 0.93 for functional ability; 0.99 for performance tests ICC = 0.99 ICC = 0.97</td>
<td>Chronic TBI[^59] ICC = 0.89-97 (self-report and objective measures) Chronic stroke[^56] ICC=0.95 for Functional Ability. ICC = 0.90 for performance tests MDC Chronic Stroke[^60] Average for timed items – 0.7 sec Average for Functional Ability Scale 0.1 points MCID Acute stroke[^54] MCID (Functional Ability): 1.0 points or</td>
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<td></td>
<td>MDC</td>
<td>Concurrent validity</td>
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<td></td>
<td>Chronic stroke[^57-58] correlated with Fugl-Meyer r=-0.57 and -0.88</td>
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<td></td>
<td>Not tested or used in cancer population, or chronic illness population (rather neurological population).</td>
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</tbody>
</table>

[^43]: Kopp
[^44]: Chae
[^42]: Not tested or used in cancer population, or chronic illness population (rather neurological population).
<table>
<thead>
<tr>
<th>Test</th>
<th>ICC</th>
<th>SRM</th>
<th>MCID (time)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wolf Motor Function Test - Cont</td>
<td>0.97</td>
<td>17% change (Dominant Side Affected) 1.2 points or 20% change (Non-dominant Side Affected)</td>
<td>-19.0 seconds or 16% change (Dominant Side Affected)</td>
<td></td>
</tr>
<tr>
<td>Self-report Questionnaires/ Community Participation</td>
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</tr>
<tr>
<td>Impact on Participation and Autonomy Questionnaire (IPAQ)</td>
<td>0.56-0.90</td>
<td>SRM ranged from 0.1-0.3</td>
<td>30 minutes to complete</td>
<td></td>
</tr>
<tr>
<td>Life Satisfaction Questionnaire (LiSat-9)</td>
<td>Spearman’s r=0.63-0.89 Cronbach’s alpha = 0.75</td>
<td>Concurrent validity between all 3 life satisfaction instruments (Life Satisfaction questions (LS Questions), LiSat-9, and the Satisfaction With Life Scale (SWLS)) 0.59-0.60</td>
<td>10-30 minutes to complete; free</td>
<td></td>
</tr>
<tr>
<td>Functional Status Examination</td>
<td>Spearman’s r=0.80 <em>(Dikmen 2001)</em></td>
<td>Concurrent Sickness Impact Profile: r= 0.81 SF-36: r = -0.27-0.64 Glasgow Outcome Scale: r=0.75 <em>(Dikmen 2001)</em></td>
<td>6-30 minutes to complete. Free. Validated in TBI population; not recommended in cancer at this time.</td>
<td></td>
</tr>
<tr>
<td>Measure</td>
<td>Intra-rater Reliability (ICC)</td>
<td>Inter-rater Reliability (ICC)</td>
<td>Test /Re-Test Reliability (ICC)</td>
<td>Responsive-ness to Change</td>
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</tr>
<tr>
<td><strong>Self-report Questionnaires/ Community Participation - continued</strong></td>
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<tr>
<td>Modified Rankin Scale</td>
<td>Kappa = 0.25-0.95 (Quinn 2009)</td>
<td>Kappa = 0.56-0.57 (Quinn 2009)</td>
<td>Kappa = 0.81-0.95 (Banks 2007)</td>
<td></td>
</tr>
<tr>
<td>Participation Objective, Participation Subjective (POPS)</td>
<td></td>
<td>Traumatic Brain Injury ICC = 0.37-0.89</td>
<td></td>
<td>Construct validity in TBI: ICC 0.21-0.23</td>
</tr>
<tr>
<td>Participation Survey of Mobility Limited people (PARTS/M)</td>
<td>Cronbach’s alpha = 0.42-0.92 Pearson’s r = 0.71-0.91</td>
<td></td>
<td></td>
<td>Concurrent validity with Reintegration to Normal Living Scale: r=0.71</td>
</tr>
<tr>
<td>Reintegration to Normal Living/ life index</td>
<td>Cronbach’s alpha = 0.91</td>
<td></td>
<td></td>
<td>Concurrent validity with Spitzer QOL Index: r=0.72 Construct Validity with PARTS/M: r=0.70</td>
</tr>
</tbody>
</table>

Abbreviations: ICC, intraclass correlation coefficient; r, Pearson’s Coefficient Correlation; SEM, standard error of measurement; MDC, minimal detectable change; MCID, minimal clinical important difference.
### Summary of Recommendations

<table>
<thead>
<tr>
<th>Highly Recommended (4)</th>
<th>Recommended (3)</th>
<th>Unable to Recommend (2A/2B)</th>
<th>Do Not Recommend</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Minute Walk</td>
<td>12 Minute Walk</td>
<td>Timed 25 Foot Walk</td>
<td>Functional Status Exam</td>
</tr>
<tr>
<td>6 Minute Walk</td>
<td>10 Meter Walk</td>
<td>Barthel Index</td>
<td>Participation Objective, Participation Subjective</td>
</tr>
<tr>
<td>TUG</td>
<td>Hi-Level Mobility Assessment Tool</td>
<td>Canadian Occupational Performance Measure</td>
<td>Participation Survey of Mobility Limited People</td>
</tr>
<tr>
<td>5 Times Sit to Stand</td>
<td>Short Performance Physical Battery</td>
<td>Impact on Participation and Autonomy Questionnaire</td>
<td>6 Minute Arm Test</td>
</tr>
<tr>
<td></td>
<td>Physical Battery for Patients with Cancer</td>
<td>Life Satisfaction Questionnaire</td>
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<tr>
<td></td>
<td>Functional Independence Measure</td>
<td>Modified Rankin Scale</td>
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<tr>
<td></td>
<td>Assessment of Life Habits</td>
<td>Reintegration into Normal Living/Life Index</td>
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<tr>
<td></td>
<td>Activity Measure for Post-Acute Care</td>
<td>Arm Mobility Ability Test</td>
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<tr>
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<td></td>
<td>Wolf Motor Function Test</td>
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<td></td>
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<td>Action Research Arm Test</td>
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</tbody>
</table>
Selected References


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# Cancer EDGE Taskforce Outcome Measure Rating Form

(Adapted from Neurology Section EDGE form)

<table>
<thead>
<tr>
<th>Instrument name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reviewer:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICF Domain (check all that apply):</th>
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</thead>
<tbody>
<tr>
<td>_____ body function/structure  _____ activity  _____ participation</td>
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<table>
<thead>
<tr>
<th>Type of measure:</th>
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<tbody>
<tr>
<td>__ performance-based  _____ self-report</td>
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</table>

<table>
<thead>
<tr>
<th>Languages available:</th>
</tr>
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<tbody>
<tr>
<td>English</td>
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<table>
<thead>
<tr>
<th>Population developed in:</th>
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</table>

<table>
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<tr>
<th>Validated populations:</th>
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</table>

<table>
<thead>
<tr>
<th>Instrument properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliability (test-retest, intra-rater, inter-rater)</td>
</tr>
<tr>
<td>Results for the intra-tester reliability:</td>
</tr>
<tr>
<td>Validity (concurrent, criterion-related, predictive)</td>
</tr>
<tr>
<td>Ceiling/ floor effects</td>
</tr>
<tr>
<td>Sensitivity to change (responsiveness, MCID, MDC)</td>
</tr>
<tr>
<td>Reference Values for Interpretation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Instrument use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment required</td>
</tr>
<tr>
<td>Time to complete</td>
</tr>
<tr>
<td>How is the instrument scored? (e.g. total score, subscales, etc.)</td>
</tr>
<tr>
<td>Level of client participation required (proxy participation?)</td>
</tr>
<tr>
<td>Effect of Training (if applicable)</td>
</tr>
</tbody>
</table>
Is this tool appropriate for individual patient decision-making? Yes _____ No _____

(available MDC, MCID, Likelihood ratios?)

Comments:

<table>
<thead>
<tr>
<th>Availability:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score Sheets:</td>
</tr>
<tr>
<td>_____ Public Domain _____ Available but copyrighted _____ Unavailable</td>
</tr>
<tr>
<td>Instructions:</td>
</tr>
<tr>
<td>_____ Public Domain _____ Available but copyrighted _____ Unavailable</td>
</tr>
<tr>
<td>Computer-based or Web-based scoring available: _____ yes _____ no</td>
</tr>
</tbody>
</table>

Purchase price:

Purchase Contact Info:

| Assessment of Overall Usefulness (Primary Reviewer): |

| Secondary Reviewer Comments: |