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Oncology Section Task Force on Breast Cancer Outcomes: An Introduction to the EDGE Task Force and Clinical Measures of Upper Extremity Function

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ABSTRACT

With the proliferation of outcome measures in the literature, many of which lack documentation of sufficient psychometric properties to justify use, it is difficult to document patient change or demonstrate effectiveness of interventions. The goal of the Section on Research's EDGE (Evaluation Database to Guide Effectiveness) Task Force is to facilitate identification of valid and reliable tests and measures that reflect clinically important outcomes and are responsive to change for standard use across selected patient groups. This paper lays the groundwork for understanding the work of the Oncology Section's Breast Cancer EDGE Task Force on clinical measures of shoulder function including range of motion and muscle length, upper extremity function, and scapular position and movement, as reported in the 3 papers that follow.

INTRODUCTION

The importance of outcome measurements to assess effectiveness of interventions has long been recognized. The physical therapy profession has answered this need with the development of many such measures. A search of the term *outcomes measurement* in PubMed[1] yielded 12,138 hits. A search of the term *outcomes measurements in physical therapy* yielded 633 hits. As the variety of outcomes measurements proliferated, two concerns emerged. The first concern was over the quality of the measurements that led to an increased emphasis on ascertaining and documenting the psychometric properties of tests and measurements. In 1993, the American Physical Therapy Association (APTA) published the *Primer on Measurement: An Introductory Guide to Measurement Issues*[2] to educate researchers and clinicians alike on important considerations in development and use of tests and measures. Many journals now require that outcomes reported in submitted papers include information on references that support the psychometric properties and clinical utility of the measures.

The second concern in the proliferation of tests and measures is the variety and disparate nature of the tests and measures, even across similar outcomes. The desirability of reducing the number of tests and measures being used within certain domains and promoting select common or 'standard' measures became evident. Deyo et al[3] advocated for standardization in measurement of patient outcomes in order to:

- improve comparability of results among clinical studies;
- improve comparability of baseline patient characteristics among clinical studies;
- facilitate meta-analysis;
- facilitate cost-effectiveness analysis by creating an accepted metric for effectiveness;
- encourage more complete reporting of relevant outcomes;
- facilitate conduct of multicenter studies;
- facilitate design and review of manuscripts, publications, research proposals; and
- avoid 'reinventing the wheel.'

EDGE TASK FORCE BACKGROUND

In an effort to foster standardization of outcomes measurements in physical therapy, the APTA's Section on Research supported the formation of a task force led by Edelle Field-Fote, PT, PhD. The EDGE (Evaluation Database to Guide Effectiveness) Task Force brought together experts in evaluation of tests and measures and in examination-based classification of patients at APTA's Combined Sections Meeting in 2006. The group agreed that standardization of outcomes in a particular domain was a necessary step in the process of accumulating evidence on the effectiveness of a treatment approach in that domain. According to Field Fote et al,[4] "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." The EDGE Task Force goals were to:

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- establish a framework to facilitate the evaluation of outcome measures,
- assist stakeholder groups (ie, Section Research Chairs, SIGs, Specialty Councils) in evaluating outcome measures within their practice/content areas, and
- assist in promoting the use of a core set.

Using a literature and consensus-based iterative process, the EDGE Task Force developed a form for evaluation of a selected outcome measure. The purpose of the form was to provide criteria important in determining whether a measure is appropriate as a 'standardized' assessment tool and suitable for inclusion in a 'core set' in a particular clinical domain. Through use of the form, assessment of an outcome measure would be thorough and consistent among evaluators and across tools.

After completion of its assessment form, the EDGE Task Force expanded its membership to include representatives from the clinical sections of the APTA, with the goal of having the Sections carry the work forward to their particular areas of interest. The Neurology Section was the first Section to apply EDGE assessment to a practice area. The StrokEDGE Task Force led by Jane Sullivan, PT, DHS, and Genevieve Pinto-Zipp, PT, EdD, reviewed outcomes used in individuals who had a stroke. This Task Force also developed a 4-point ordinal scale to rank their recommendations for each outcome measure[5] (Table 1). StrokEDGE disseminated its recommendations through the Neurology Section Web site.[5]

As part of the ongoing progression of the EDGE Task Force work, the APTA's Oncology Section formed the Breast Cancer EDGE Task Force in 2010 under the leadership of Laura Gilchrist, PT, PhD. The working group employed a similar strategy to that of StrokEDGE, using the domains of the World Health Organization's International Classification of Functioning, Disability and Health (ICF).[6] The group agreed on 8 subdomains under Body Structure and Function and 11 subdomains under Activities and Participation that were appropriate to individuals who had been treated for breast cancer. The group also assessed the original EDGE assessment form and the StrokEDGE form.

Table 1. StrokeEDGE Rating Scale[1]

4	**Highly Recommend**	Highly recommended; the outcome measure has excellent psychometric properties and clinical utility.
3	**Recommend**	Recommended; the outcome measure has good psychometric properties and good clinical utility.
2	**Unable to Recommend at this time**	Unable to recommend at this time; there is insufficient information to support a recommendation of this outcome measure.
1	**Do not Recommend**	Not recommended. The outcome measure has poor psychometric properties and/or poor clinical utility.

[1] http://neuropt.org/go/healthcare-professionals/neurology-section-outcome-measures-recommendations

A few additional modifications were made to include criteria that were relevant to measurement tools that would be evaluated for use in the cancer population. The final CancerEDGE form approved for use by the group can be found in the Appendix.

The first practice area the Breast Cancer EDGE group chose was outcome measures relevant to shoulder and upper quarter function in individuals treated for breast cancer. Measurements of lymphedema were excluded because outcomes related to lymphedema were determined to be a separate subdomain. The Shoulder Subgroup is the first Oncology EDGE group to examine relevant outcome measures for the cancer population.

SHOULDER DYSFUNCTION ASSOCIATED WITH TREATMENT FOR BREAST CANCER

It is now widely acknowledged that various elements in the treatment for breast cancer can produce both early (less than one year) and late (greater than one year) adverse effects on shoulder function, including range of motion (ROM) strength deficits, and reported declines in quality of life. Furthermore, effects of treatment are considered to be multifactorial, including but not necessarily limited to type of surgery, degree of axillary node resection, radiation, prior shoulder problems, and age.[7-14] Such effects have been found after treatment when comparing pre-op to post-op values, when comparing involved to uninvolved sides, and when comparing those treated for breast cancer to an unaffected control group.[15-19] Documenting the incidence and magnitude of dysfunction or identifying treatment factors that increase the risk for dysfunction has been challenging because of the variety of assessment strategies used in different studies.

The absence of standardized measurements for shoulder dysfunction limits the ability to compare study findings across treatment factors and populations.[11,20] In their systematic review, Levangie and Drouin[17] looked at studies that compared several treatment factors, including chest wall radiation to more extensive radiation, and axillary node clearance to sentinel node biopsy. They found that the magnitudes of effect varied across studies dramatically from small (standardized effect sizes of ≤ 0.20 or odds ratios near 1.0) to substantial (standardized effect sizes well in excess of 0.80 or odds ratios of 2.0-3.0 or more). The variability in prevalence or magnitude of shoulder dysfunction may be attributed in part to the diversity of outcome measures and the variety of methods by which even similar outcomes were assessed and reported in the literature. Levangie and Drouin[17] noted that 10 of the 22 reviewed studies used patient self-report of loss of strength, ROM, or functional ability. Two other studies used simple observation of impairments such as ROM. In most of these studies, the data were then dichotomized into present or absent. Of the studies that measured ROM objectively, 7 reported actual ranges, while 5 dichotomized their findings based on losses of as little as 10° of motion.[17]

Shoulder impairments and functional limitations post-breast cancer treatment may not only affect function and quality of life, but may also increase the potential for subsequent pathology. Two studies using 3-dimensional motion analysis both came to

the conclusion that individuals treated for breast cancer were more likely to have internally rotated scapula.[15,21] An increase in scapular internal rotation may elevate the risk for impingement problems.[22] Yang et al[23] found that 7.1% of his breast cancer cohort had symptoms of rotator cuff disease at 12 months after surgery. If impairments and limitations that place a person treated for breast cancer at increased risk for later pathology can be identified, these impairments can be addressed with interventions targeted at interrupting the causal chain of events. Evidence does exist that physical therapy treatment can improve shoulder function in individuals treated for breast cancer.[24] We still do not have the tools, however, to demonstrate our ability to prevent dysfunction or future pathology through surveillance.

ONCOLOGY SECTION TASK FORCE ON BREAST CANCER OUTCOMES: CLINICAL MEASURES OF UPPER EXTREMITY FUNCTION

The evidence to date indicates that individuals treated for breast cancer may experience upper extremity functional limitations 12 months or more after treatment,[17] that long-term shoulder/arm problems in this population are significantly associated with poor quality of life,[18] that shoulder limitations may lead to pathology over time,[23] and that these sequelae might be modified with physical therapy surveillance and intervention.[24] To truly understand how and when to intervene and what interventions are effective in preventing or resolving shoulder dysfunction in the breast cancer population, valid and reliable measures must be available for the purposes described by Deyo et al.[3]

The Shoulder Subgroup of the Breast Cancer EDGE Task Force was charged with reviewing the literature and assessing clinical measures of the upper extremity. The group divided relevant outcomes into 3 categories: scapular measures (body structure and function), shoulder/glenohumeral measures (body structure and function), and upper extremity function (activity/participation measures). Three working groups were formed, each taking one of the 3 categories of clinical measures. After completing preliminary work, the group determined that a modification of the StrokEDGE 4-point recommendation scale was warranted. Many tests and measurements thought to be potentially appropriate for use in the breast cancer population were designed for other patient populations. Because there was concern that tests and measures might behave differently in the breast cancer population, the recommendation scale was revised to reflect whether psychometric properties for a measure had been obtained or used in studies with individuals treated for breast cancer (Table 2).

Table 2. Breast Cancer EDGE Rating Scale

4	**Highly Recommend**	Highly recommended; the outcome has good psychometric properties and good clinical utility; the measure has been used in research on individuals with or post breast cancer.
3	**Recommend**	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.
2A	**Unable to Recommend at this time**	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.
2B	**Unable to Recommend at this time**	Unable to recommend at this time; there is insufficient information to support a recommendation of this outcome measure; no published evidence that the measure has been applied to research on individuals with or post breast cancer.
1	**Do not Recommend**	Poor psychometrics &/or poor clinical utility (time, equipment, cost, etc.).

At the Combined Sections Meeting in 2012, the Breast Cancer EDGE Task Force's subgroup on Clinical Measures of Upper Extremity Function presented its findings. The presenters asked *Rehabilitation Oncology* for the opportunity to also present their findings to the entire Oncology Section. The goal of publishing these papers is to disseminate the EDGE recommendations on measures that can or should be used for individuals treated for breast cancer. Each paper also includes existing measures that require validation or further validation in the breast cancer population, as well as identification of areas where clinically relevant measures of upper extremity are still quite inadequate. Until valid, reliable, and clinically useful measures of upper extremity function are both available and in widespread use in those treated for breast cancer, we will be challenged in our ability to definitively demonstrate the effects of breast cancer on function and quality of life, as well as to justify the need for routine surveillance and periodic intervention in this population.

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(Cancer EDGE Task Force Outcome Measure Rating Form follows on page 10.)

CANCER EDGE TASK FORCE OUTCOME MEASURE RATING FORM
(Adapted from Neurology Section EDGE form)

Instrument name:	
Reviewer:	
ICF Domain (check all that apply): _____body function/structure _____ activity _____participation	
Type of measure: _____ performance-based _____self-report	
Languages available:	
Population developed in:	
Validated populations:	
Instrument properties	
Reliability (test-retest, intra-rater, inter-rater)	
Validity (concurrent, criterion-related, predictive)	
Ceiling/ floor effects	
Sensitivity to change (responsiveness, MCID, MDC)	
Reference Values for Interpretation	
Instrument use	
Equipment required	
Time to complete	
How is the instrument scored? (eg, total score, subscales, etc.)	
Level of client participation required (proxy participation?)	
Effect of Training (if applicable)	

Is this tool appropriate for individual patient decision-making? Yes _____ No _____
(available MDC, MCID, Likelihood ratios?)
Comments:

Availability:

Score Sheets: _____ Public Domain _____Available but copyrighted _____Unavailable

Instructions: _____ Public Domain _____Available but copyrighted _____Unavailable

Computer-based or Web-based scoring available: ____ yes _____ no

Purchase price:

Purchase Contact Info:

Assessment of Overall Usefulness (Primary Reviewer):

Secondary Reviewer Comments:

Overall Task Force Agreement with Recommendations:

Reference List: