FUNCTIONAL OUTCOMES MEASUREMENT

IN THE ABSENCE OF DISABILITY: THE LYMPHEDEMA EXAMPLE

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Motivation

- We are in the midst of a transformation of our healthcare system from “pay for service” to “pay for outcome”.
- “Service” is relatively easy to measure whereas measurement of “outcome” can be somewhat elusive.
- Therapy outcome has been mainly measured by improvement in musculoskeletal functional deficiency.
- Lymphedema is a medical problem involving the lymphatic, circulatory, immune and lipid systems which may or may not involve musculoskeletal functional deficiency.
- Outcome measures traditionally utilized by therapists do not have adequate sensitivity to measure lymphedema severity.
Approach to Lymphedema Functional Outcomes Measurement

◆ Background
  ▪ Lymphedema (LE) pathology and standard of treatment
  ▪ Medicare lymphedema treatment reimbursement

◆ Specific Problems
  ▪ Subjective & objective tools measure different aspects of LE
  ▪ No objective measurement methods for Stage 0 LE
  ▪ No objective measurement methods for Mid-line LE
  ▪ Few validated instruments for subjective measurement of LE

◆ Promising New Objective Measurement Techniques
◆ Promising New Subjective Measurement Instruments
Lymphedema Pathology

◆ Definition of Lymphedema (LE)
  ▪ “Edema is swelling due to faulty lymph drainage” or “Lymphedema results from a blockage in your lymphatic system” or “Lymphedema, also known as lymphatic obstruction”
  • Common definitions need to be brought up to current knowledge
  • Needs recognition of pre-clinical/pre-edema lymphedema

◆ Lymphedema Pathology
  ▪ Lymphedema is due to more than just a blockage of lymphatics*
    • Failure of initial lymphatic collectors
    • Aberrant lymphangion smooth muscle function
    • Faulty lymphatic valve function
    • Faulty neural control of lymphangion smooth muscle pumping
    • Genetic predisposition, abnormal development

# The Stages of Lymphedema

<table>
<thead>
<tr>
<th>Földi Stage and Description</th>
<th>MDACC Head &amp; Neck* Stage and Description</th>
<th>ISL** Stage and Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0</strong> Time between lymphatic trauma and onset of LE; No clinical symptoms; Histologically evident.</td>
<td><strong>0</strong> No clinical symptoms</td>
<td><strong>0</strong> Latent or sub-clinical; swelling not evident; subtle changes in tissue; subjective symptoms.</td>
</tr>
<tr>
<td>1a Clinical swelling with no pitting; moveable edema, no functional effects.</td>
<td>2 Clinical swelling; pitting edema; reduced limb swelling with elevation.</td>
<td><strong>1</strong> Early fluid accumulation subsides with elevation; pitting may occur.</td>
</tr>
<tr>
<td>1b Clinical swelling with reversible pitting; may be functional effects.</td>
<td><strong>2</strong> Hard swelling; does not recede with elevation.</td>
<td><strong>II</strong> Swelling rarely reduced with elevation; pitting; fat and fibrosis evident.</td>
</tr>
<tr>
<td>2 Hard swelling; does not recede with elevation.</td>
<td><strong>2</strong></td>
<td><strong>III</strong> Elephantiasis; Pitting can be absent; skin changes; fat, fibrosis, overgrowths</td>
</tr>
<tr>
<td><strong>3</strong> Clinical symptoms of elephantiasis.</td>
<td><strong>3</strong> Elephantiasis with tissue changes; rarely seen in head and neck.</td>
<td><strong>3</strong> Elephantiasis with tissue changes; rarely seen in head and neck.</td>
</tr>
</tbody>
</table>

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*Lewin JS, Hutcheson KA, Barringer DA & Smith BG. *SIG 13 Perspectives on Swallowing & Swallowing Disorders (Dysphagia).* June 2010;19:45-52.

## Lymphedema Body Sites

<table>
<thead>
<tr>
<th>SWELLING LOCATION</th>
<th>BOSOMPRA</th>
<th>HAID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Swelling</td>
<td>35.8</td>
<td>27.1</td>
</tr>
<tr>
<td>Side of Chest Wall</td>
<td>13.5</td>
<td></td>
</tr>
<tr>
<td>Front of Chest Wall</td>
<td>10.1</td>
<td></td>
</tr>
<tr>
<td>Remaining Breast Tissue</td>
<td>13.5</td>
<td></td>
</tr>
<tr>
<td>Back</td>
<td>10.1</td>
<td></td>
</tr>
<tr>
<td>Armpit</td>
<td>22.6</td>
<td></td>
</tr>
<tr>
<td>Shoulder/Upper Arm</td>
<td>18.2</td>
<td>20.7</td>
</tr>
<tr>
<td>Forearm</td>
<td>18.9</td>
<td>15.0</td>
</tr>
<tr>
<td>Wrist</td>
<td>12.8</td>
<td></td>
</tr>
<tr>
<td>Hand</td>
<td>13.5</td>
<td>12.1</td>
</tr>
<tr>
<td>Fingers</td>
<td>14.2</td>
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</table>


Lymphedema Treatment*

◆ Treatment Protocols
  ▪ Complex Decongestive Therapy
    • Manual Lymph Drainage by Specially-Trained Therapists
    • Compression (Bandage Systems, Garments, Devices)
    • Lymph Drainage Exercises
    • Skin Care
  ▪ Sequential Pneumatic Compression

◆ Multi-Phase Treatment Program
  ▪ Intensive Phase (Phase 1, Clinic)
  ▪ Maintenance Phase (Phase 2, Home)

* General agreement by specialty medical societies, clinics, professional organizations
Need for Early Treatment of LE

- Lymphedema is a chronic, progressive condition. If not treated it progresses to more severe states.
  - Lymph stasis is an inflammatory state
  - It is associated with immune traffic disruption, collagen deposition, and adipose accumulation*
- Early treatment requires early detection & measurement
  - Current methods of measurement are not adequate
- Early detection and treatment may prevent progression
  - Stout-Gergich (2008) off-the-shelf compression sleeves
  - Torres-Lacomba (2010) manual lymph drainage and exercises
  - Zimmermann (2012) MLD, exercise, breath therapy

General Medicare Coverage Policy

◆ Payment is made under Medicare for services or items that are “reasonable and necessary for
  ▪ the diagnosis or treatment of illness or injury OR
  ▪ to improve the functioning of a malformed body member.”¹

◆ “Coverage of skilled nursing care or therapy to perform a maintenance program does not turn on the presence or absence of a patient’s potential for improvement from the nursing care or therapy, but rather on the patient’s need for skilled care. Skilled care may be necessary to improve a patient’s current condition, to maintain the patient’s current condition, to prevent or slow further deterioration of the patient’s condition.”²

¹Social Security Act § 1862(a)(1)
²Medicare Benefit Policy Manual CMS IOM 100-02, Ch. 7, §20.1.1 (Rev. 179, 01/14/14)
Distinction Between Rehabilitation & Treatment of Illness and Injury

◆ Medical and Other Health Services include:
  ▪ physician’s services [Social Security Act § 1861(s)(1)];
  ▪ services and supplies … furnished as an incident to a physician’s professional service [Social Security Act § 1861(s)(2)(A)];
  ▪ outpatient physical therapy services and outpatient occupational therapy services.” [Social Security Act § 1861(s)(2)(D)].

◆ In defining the therapy annual cap §1833(g)(1) distinguishes:
  ▪ “physical therapy services … of such a type which are furnished by a physician or as incident to a physicians’ services…” and;
  ▪ “physical therapy services of the type described in section 1861(p) …”
Current Medicare Lymphedema Treatment Reimbursement

◆ Manual Lymph Drainage
  ▪ Primarily provided by PTs and OTs
  ▪ Governed by “rehabilitation” policies
  ▪ Subject to statutory limits
  ▪ Modified by *Jimmo v. Sebelius* settlement agreement

◆ Compression Bandages, Garments and Devices
  ▪ Material costs not covered
  ▪ Application of compression bandages bundled with MLD

◆ Patient Education
  ▪ Instruction covered for lymphatic drainage exercise program, simple lymph drainage, self bandaging and skin care

◆ Pneumatic Compression Devices
  ▪ Coverage criteria may not match patients’ medical requirements
Enter Functional Outcomes Reporting*

- Claims-based data collection started in 2013 to support the reforming of medical payment system for outpatient services.
- Functional limitation/outcome data collected each encounter
  - Non-payable G-Codes and Severity Modifiers collected
  - Basic Function-Related G-Code sets for current, goal and discharge:
    - Mobility; Changing & Maintaining Body Position; Carrying, Moving & Handling Objects; Self Care
  - “Other” G-Code sets for:
    - Functional limitation not falling into basic four functional categories;
    - Therapy services not intended to treat a functional limitation; or
    - When an overall, composite or other score from a functional assessment tool is used and it does not clearly represent a functional limitation defined by one of the basic four categories
  - Severity Modifiers collected for each encounter
    - CH – CN modifiers for 7 levels of impairment from 0 to 100%

*Medicare Claims Processing Manual, IOM Pub. 100-04 Chapter 5, § 10.6 Functional Reporting
International Classification of Functioning, Disability and Health

◆ What is the ICF?
  ▪ A classification of health and health-related domains
  ▪ Lists: Body Functions and Structure; Activity and Participation; Environment

◆ Functioning and Disability-Levels of Human Functioning
  ▪ Body or Body Part
  ▪ Whole Person (Physical and Mental)
  ▪ Whole Person in a Social Context

Impact of ICF on Therapy Practice

- Guide to Physical Practice Practice\(^1\) based on Nagi disablement model focusing on interrelationship of pathology, impairment, functional limitation, and disability\(^2\).
- The ICF model is, in contrast, a human functioning model, where human functioning and disability are described as a dynamic interaction between various health conditions and environmental and personal factors.
- ICF framework allows description of changes in the body, the whole person, ability to perform tasks, societal roles and the contextual environment.\(^2\)

\(^1\)Guide to Physical Therapist Practice, 2nd Ed. Phys Ther. 2001; 81:9-744
\(^2\)Bemis-Dougherty A. “Practice Matters: What is the ICF?”, PT Magazine. Feb 2009;17(1)
ICF Core Sets for Lymphedema

◆ Systematic research on the effects of lymphedema on patients
◆ Relating these meaningful concepts to the International Classification of Functioning, Disability and Health (ICF)
◆ Phases of investigation Peter B. Viehoff et al.
  ▪ Coding of meaningful concepts in lymphedema-specific questionnaires
  ▪ Compare meaningful concepts from lymphedema research with those derived from patient questionnaires
  ▪ Describe functioning and disabilities of patients through interviews
  ▪ Determine relevant aspects of functioning, environmental, personal
◆ Development of Core Sets of meaningful concepts to lymphedema patients

2Factors related to lymphoedema coded with the ICF. J Lymphoedema 2014;9(1):25-33
4Functioning in lymphoedema from the patients’ perspective using the ICF. Acta Oncol. 2015;54:411-21.
Objective Measurement of Lymphedema Severity

◆ Extremity Physical Properties
  ▪ Circumferential Measurement
  ▪ Volume Calculations using External Measurements
  ▪ Volume Measurement by Displaced Water

◆ Indirect Measurement of Skin Tissue Composition
  ▪ Bio-impedance Analysis/Spectrometry (BIA/BIS)
  ▪ Tissue Dielectric Constant (TDC)
  ▪ Dual-Energy X-Ray Absorptiometry (DXA or DEXA)

◆ Imaging and Measurement of Skin Thickness
  ▪ Ultrasound imaging
  ▪ MRI

◆ Measurement of Skin Elasticity/Tissue Compliance
  ▪ Ultrasound elastography
  ▪ Tonometry (mechanical, electrical, ultrasound)
Subjective Measurement of Functional Deficit

◆ Generic QOL measurement instruments
  ▪ AM-PAC, FOTO, OPTIMAL & NOMS suggested by CMS
  ▪ Patient-Specific Functional Scale (PSFS), SF-36, Nottingham Health Profile
◆ Specific measures of function & symptoms
  ▪ Berg Balance Score, Dynamic Gait Index, 6-Min Walk Test
  ▪ Functional Living Index-Cancer (FLIC)
  ▪ European Org. for Research and Treatment of Cancer (EORTC-QLQ C30)
  ▪ Disability of Arm, Shoulder and Hand (DASH)
  ▪ Upper Extremity Functional Index (UEFI)
  ▪ Lower Extremity Functional Index (LEFI)
  ▪ Lower Extremity Functional Scale (LEFS)
  ▪ Upper Limb Disability Questionnaire (ULDQ)
  ▪ Lower Limb Functional Index (ULFI)
  ▪ Vanderbilt Head & Neck Symptom Survey
  ▪ MD Anderson Symptom Inventory-Head and Neck
## Subjective Measurement of LE Severity

<table>
<thead>
<tr>
<th>Site</th>
<th>Short Title</th>
<th>Full Title</th>
<th>Author</th>
<th>Date</th>
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<td>FACT-B+4</td>
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<td>Freiberg Life Quality Assessment-Lymphedema</td>
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<td>Yamamoto</td>
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<td>QOL Measure for Lymphedema of the limbs</td>
<td>Keeley</td>
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<td>Norman Telephone Questionnaire</td>
<td>Norman</td>
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<td>ULL-27</td>
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<td>Launois</td>
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<td>UL</td>
<td>WCLS</td>
<td>Wesley Clinic Lymphedema Scale</td>
<td>Mirolo</td>
<td>1995</td>
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</tbody>
</table>
Conclusions

- Lymphedema is a complex, progressive, systemic medical condition.
- Early detection and treatment of lymphedema is essential to prevent up-staging and disability.
- Current treatment protocols involve manual therapies.
- Current physical therapy is based on a disability model, outcomes are expressed as improvement of function.
- There are few instruments in use to measure functioning of the lymphatic system and effectiveness of therapy.
- New measurement instruments are needed to measure early pre-clinical lymphedema at all body sites and which blend objective and subjective measures over all ICF domains.