



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

* Mortimer PS & Rockson SG. New developments in clinical aspects of lymphatic disease
J Clin Invest. March 2014; 124(3):915-921.

The Stages of Lymphedema



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

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

**International Society of Lymphology Executive Committee. *Lymphology* 2013;46:1-11.

Lymphedema Body Sites



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

Bosompra et al. *Patient Education and Counseling* 2002;47:155-63
Haid et al. *Breast Cancer Research and Treatment* 2002;73:31-6.

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

*Rockson SG. The Unique Biology of Lymphatic Edema, *Lymph Res Biol.* 2009;7(2):97-100

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

World Health Organization. *Towards a Common Language for Functioning, Disability and Health — ICF*, WHO/EIP/GPE/CAS/013 (2002), Geneva

Impact of ICF on Therapy Practice



- ◆ *Guide to Physical Therapist 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 questionnaires¹
 - Compare meaningful concepts from lymphedema research with those derived from patient questionnaires²
 - Describe functioning and disabilities of patients through interviews³
 - Determine relevant aspects of functioning, environmental, personal⁴
- ◆ Development of Core Sets of meaningful concepts to lymphedema patients

¹Coding of meaningful concepts in lymphoedema-specific questionnaires. *Disabil Rehabil* 2013;35:2105-12.

²Factors related to lymphoedema coded with the ICF. *J Lymphoedema* 2014;9(1):25-33

³Identification of relevant ICF categories in lymphoedema patients. *Acta Oncol.* 2015;early online 1-7.

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



Site	Short Title	Full Title	Author	Date
UL	FACT-B+4	Functional Assessment Cancer Therapy-BC-LE	Cella	2007
LL	FLQA-L	Freiberg Life Quality Assessment-Lymphedema	Augustin	2005
LL	GCLQ	Gynecologic Cancer Lymphedema Questionnaire	Carter	2010
UL	LBCQ	Lymphoedema and Breast Cancer Questionnaire	Armer	2003
LL, UL	LEL, UEL	Lower/Upper Extremity Lymphedema Index	Yamamoto	2011/13
LL, UL	LLIS	Lymphedema Life Impact Scale	Weiss	2013
UL	Lymph-ICF	Lymphoedema Functioning, Disability & Health	Devoogdt	2011
LL	Lymph-ICF-LL	Lymph-ICF for Lower Limb Lymphoedema	Devoogdt	2014
	LYMPH-Q		Massey	
UL, LL	LYMQOL	QOL Measure for Lymphedema of the limbs	Keeley	2004/10
UL	NQ	Norman Telephone Questionnaire	Norman	2001
UL	ULL-27	Upper Limb Lymphedema	Launois	2000
UL	WCLS	Wesley Clinic Lymphedema Scale	Mirola	1995

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.