An AmpEBR Update:
REHABILITATION OUTCOME MEASUREMENT

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Workshop Objectives

1. To appreciate the range of available outcome measurement tools for amputation rehabilitation in the context of the ICF
2. To understand considerations when selecting specific tools
    - Metric and clinimetric properties
3. To define next steps for obtaining national consensus on outcome measurement.

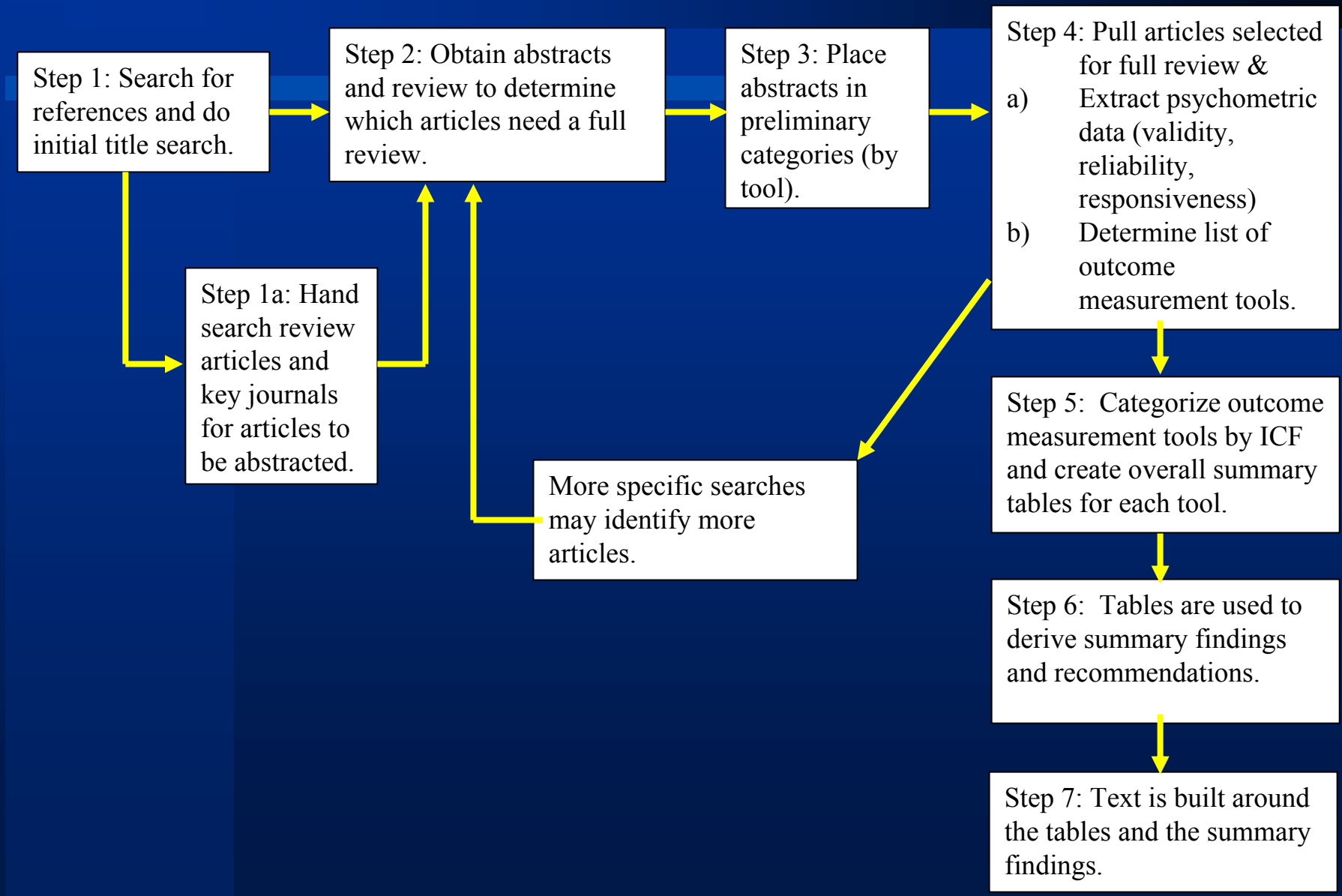
AMPEBR UPDATE: Outcome Measurement - OUTLINE -

- Objectives, Methods, Current status
- AMP EBR – consensus, criteria and standards (Barry Deathe)
- ICF: Body Structure/Fn Measures (Jackie Hebert)
- ICF: Activity Measures (Barry Deathe)
  - SIGAM mobility grades
  - Guidelines and Gaps: Using ATS statement on 6 MWT as an example

AmpEBR – Overall Objectives

1. Outcome Measurement Tools
    - A guide for the clinician for selection of appropriate outcome tools.
2. Review of Rehabilitation Practice and Patient Outcomes
    - A guide for the evaluation and development of programs and services.
    - A vehicle for setting the research agenda.

Outcome Measurement Tools - Methods



AmpEBR - Chapters

Main Chapters	
Outcome Tools Psychometrics	Rehabilitation Treatment
Knowledge Transfer	Rehabilitation Outcomes
Psychological Issues & Status	Prosthetic Analysis
Quality of Life	Exercise & Fitness
Epidemiology	Sport & Recreation
Amputation - Prevention	Pediatrics
Amputation - Surgery	Upper Limb Amputation
Amputation - Wound Healing	Vocational Rehabilitation
Amputation - Complications	
Amputation - Pain	

Outcome Measurement Tools – Current Status

- 1. Outcome Measurement Tools Classified as Body Structure/Fn (ICF)
  - Hebert JS, Wolfe DL, Deathe AB, Miller WC, Devlin M, Pallaveshi L. Outcome measures in amputation rehabilitation: ICF body functions. Disability and Rehabilitation, (In press 2009).
- 2. Outcome Measurement Tools Classified as Activity (ICF)
  - Deathe AB, Wolfe DL, Devlin M, Hebert JS, Miller WC, Pallaveshi L. Selection of outcome measures in lower extremity amputation rehabilitation: ICF activity. Disability and Rehabilitation, (In press 2009).
- 3. Tools to Assess Psychological Adjustment to Lower Limb Amputation
  - Wolfe DL, Hebert JS, Miller WC, Deathe AB, Devlin M, Pallaveshi L. Psychological adjustment to lower limb amputation: An evaluation of outcome measurement tools In: Gallaher P, Desmond D, Maclachlan M (Eds) Pychoprosthetics. Guildford, UK: Springer UK, 2007.

No Consensus on Outcomes or Outcome Instruments

The Status of Outcome Measurement in Amputee Rehabilitation in Canada

Barry Deathe, MD, William C. Miller, PhD, OT, Mark Speechley, PhD

ABSTRACT: Deathe B, Miller WC, Speechley M. The status of outcome measurement in amputee rehabilitation in Canada. Arch Phys Med Rehabil 2002;83:912-8.

Conclusion: A diverse selection of program- and patient related outcome measures were used by Canadian amputee centers. Outcomes could be better compared if all centers used similar outcome measures.

Factors in the Process to Achieve Consensus

1. Clinical Sensibility
   a) Clarify purpose for which data will be used
   b) Agree on the classification of health status
   c) Clarify context
      - ICF modifiers
        - Personal
        - Environmental
2. Instrument metrics
   a) Stability
   b) Validity
   c) Responsiveness

Evaluation Criteria: Health Technology Assessment (HTA)

1. **Appropriateness**
2. **Reliability**
3. **Validity**
4. **Responsiveness**
5. **Precision**
6. **Interpretability**
7. **Acceptability**
8. **Feasibility**

Fitzpatrick et al. Health Technology Assessment 1998 Vol. 2, No.14.

Criteria for Overall Metric Findings of a Specific Instrument
(Adapted from Johnson & Graves 2008)

- Extensively validated and widely used …… ++++
- Content and metric reliability and validity shown …… +++
- Minimal validity …… ++
- Questionable or insufficient ……... +
- No formal validity/reliability information published … o

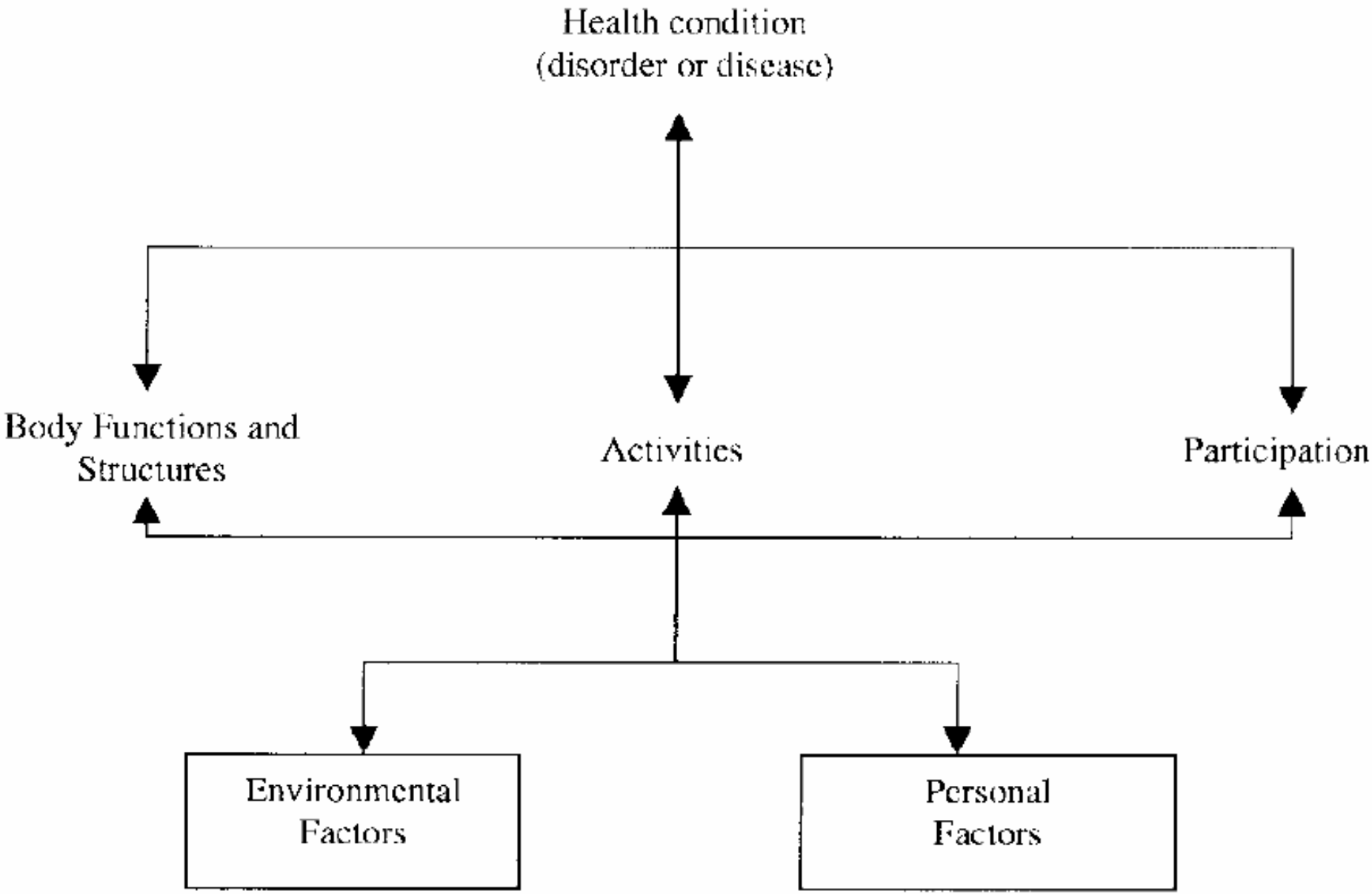
Goal – Primary Objective

A guide for the clinician to select the most appropriate outcome instrument

AmpEBR – Outcome Measure Selection

- 49 Individual Outcome Measures Extracted
- Classified according to domain that majority of items fit into
- Only those outcome measures that had been specifically studied in LL amputees
- Only those with reported psychometrics (reliability, validity, responsiveness)

International Classification of Functioning, Disability and Health (ICF) – Components, Modifiers and Interactions



Body Function & Structures

- **Physiological functions** of body systems including psychological
- **Structures** are anatomical parts or regions of their bodies and their components.
- **Impairments** are problems in body function or structure.

Activity

- **The execution of a task by an individual.**
- **Limitations in activity are defined as difficulty an individual might experience in completing a given activity.**

Participation

- **Involvement of an individual in a life situation.**
- **Restrictions to participation describe difficulties experienced by the individual in a life situation or role.**

Results: Body Function

- **Systematic review: any instruments with reported reliability, validity, or responsiveness in lower limb amputation**
- **16 instruments identified**
- **Classified into one of 4 subcategories of the ICF Body Function category**

Body Function - Subcategories

1. Mental functions
2. Sensory functions and pain
3. Functions of the cardiovascular, haematological, immunological and respiratory systems
4. Neuromusculoskeletal and movement-related functions

1. Mental Function (12 scales)

- Activity-Specific Balance Confidence Scale (ABC)
- Attitudes to Artificial Limbs Questionnaire (AALQ) [1]
- Body Image Questionnaire (BIQ) [1]
- Amputee Body Image Scale (ABIS) [3]
- Engagement in everyday activities involving revealing the body (EEARB) [1]
- Amputation-Related Body Image Scale (ARBIS) [1]
- Multidimensional Body-Self Relations Questionnaire (MBSRQ)
- Beck Depression Inventory (BDI) [3]
- Center for Epidemiological Studies - Depression Scale (CES-D) [5]
- General Health Questionnaire (GHQ-28) [3]
- Geriatric Depression Survey (GDS) [2]
- Hospital Anxiety and Depression Scale (HADS) [3]

Grouping of Mental Function Scales

- **Balance confidence**
  - **ABC scale**
- **Body image**
  - **AALQ, BIQ, ABIS, EEABR, D-EEABR, ARBIS, MBSRQ**
- **Depression/emotional status**
  - **BDI, CES-D, GDS, HADS, GHQ**

Other Body Function Domains

2. SENSORY FUNCTION AND PAIN

- **Socket Comfort Score (SCS) [1]**

3. CARDIOVASCULAR AND RESPIRATORY

- **One leg cycling test (VO2 max, AT) [3]**

4. NEUROMUSCULOSKELETAL AND MOVEMENT

- **Walking speed [1]**
- **Postural sway [3]**

Results: Mental Function

- Balance
  - ABC (Activities Balance Confidence)
    - Self rating of fear of falling during day to day activities; use in outpatients
    - Easy to administer
    - Excellent validity and reliability
    - Correlates with social participation
  - CLINICAL: Recommended for use to assess outcomes and as a proxy for participation
  - RESEARCH: Needs evaluation of responsiveness

Results: Mental Function

- Body Image Scales:
  - ABIS: (Amputee Body Image Scale)
    - Most psychometric testing
    - Self perception of body image (feelings)
    - Correlates with other measures of psychological well being
    - Excellent validity
  - RESEARCH: more study on reliability and responsiveness
  - CLINICAL: good potential for clinical use

Results: Mental Function

- **Depression/Emotional Status**
  - **CES-D (**Center for Epidemiological Studies - Depression Scale)
    - **Validity well demonstrated; may over report depressive symptoms (some questions related to physical effort)**
  - **GHQ-28** (General Health Questionnaire)
    - **good sensitivity and specificity**
    - **Recommended for use for screening for depression**

Results: Sensory and Pain

- **Socket Comfort Score (SCS)**
  - **Perceived comfort in a prosthetic socket (numerical rating)**
  - **Excellent reliability**
  - **Some responsiveness to prosthetic intervention**
  - **Easy to use and implement**
  - **CLINICAL: Very specific purpose**

Results: Cardio-Resp Function

- **One leg cycling ergometry**
  - **Measure AT and VO2 max**
  - **Need specialized equipment and trained personnel**
  - **RESEARCH applications (exercise capacity major factor with rehabilitation)**
  - **CLINICAL: Potential use as a predictor tool or to define exercise capacity**

Results: NM and movement

- **Walking speed**
  - **Instrumented motion analysis**
  - **Equipment may affect results**
  - **Other walking tests reviewed under "Activity"**
- **Postural Sway**
  - **Dynamic balance assessment tools**
  - **Limited access (equipment and trained personnel)**

Summary of Results – Metric Properties

Clinical Category	Instrument / Author / Year	Quality of Metric Property									
		Reliability			Validity			Responsiveness			Over-all
		IC	Intra	Inter	Conv	Conc	Pred	Ceiling Effect	Floor Effect	Resp	
SENSORY & PAIN	Socket Comfort Score										++
	Hanspal / 2003			+++	++					+	
CARDIO-VASCULAR & RESPIR-ATORY	One Leg Cycling Test										++
	Chin / 2002						+				
	Chin / 1997			+++	+++						
	Currie /1992				+++						
NMS & MOVEMENT	Walking Speed										++
	Boonstra / 1993			+++		++					
	Postural Sway										±
	Buckley / 2002					+++					
	Hermodsson / 1994					++					
	Isakov / 1992					++				+	

IC = Internal Consistency
Intra = Intra-rater Reliability
Inter = Inter-rater or Test-retest Reliability
Conv = Convergent Validity
Conc = Concurrent Validity
Pred = Predictive Validity
Resp = Responsiveness

Body Function: Summary

- **Adequate Psychometrics:**
  - **ABC (balance confidence)**
  - **ABIS (body image)**
  - **Depression Screen (GHS/CESD)**
  - **SCS (socket comfort score)**
- **More study on responsiveness needed for all measures**

ICF: Activity

- **The execution of a task by an individual.**
- **Limitations in activity are defined as difficulty an individual might experience in completing a given activity.**

Clinical Classification of ICF Activity Outcome Instruments

A. Walk Tests

1. Fixed Distance

i. Timed Up and Go (TUG)

ii. ‘L’ Test

iii. 10 Metre Walk

2. Fixed Time

i. 2 Minute Walk Test

B. Mobility Grades

1. SIGAM

Clinical Classification of ICF Activity Outcome Instruments (cont)

C. Indices (summary scores)

1. Generic

i. ADLs

a. Barthel Index

b. Functional Independence Measure (FIM)

ii. Mobility

a. Clinical Outcome Variables Scale (COVS)

b. Rivermead Mobility Index (RMI)

c. Wheelchair Skills Test (WST)

2. Amputation Specific

i. Day's Amputee Activity Score (AAS)

ii. Houghton Score

iii. Locomotor Index (LCI)

iv. Prosthetic Evaluation Questionnaire – Mobility Scale (PEQ-MS)

v. Questionnaire for Persons with a Transfemoral Amputation (Q-TFA)

vi. Child Amputee Prosthetic Project-Functional Status Inventory (CAPP-FSI)

vii. Amputee Mobility Predictor (AMP)

Results - TUG Test Summary

Clinical Category	Instrument Author / Year	Set-ting	Etiology	Level	n	Type of Data	# of Items	Item Res-ponse Range	Number of Studies		
									Relia-bility	Valid-ity	Respons-iveness
Walk Tests (Fixed Distance)	TUG					Ratio	1	0 - ∞	1	5	1
	Deathe / 2005[33]	OP	Vasc/Traum	TF-TT	93						
	Miller / 2004[87]	OP	Vasc/Traum	TF-TT	84						
	Miller / 2003[88]	OP	VascTraum	TF-TT	50						
	Miller / 2001[62]	OP	Vasc/Other	TF-TT	55+						
					329						
	Schoppen/1999[32]	OP	Vasc	TF-TT	32						

Results – Metric Properties of TUG Test

Clinical Category	Instrument Author / Year	Quality of Metric Property									Overall Metric Findings
		Reliability			Validity			Responsiveness			
		IC	Intra	Inter	Conv	Conc	Pred	Ceil-ing Effects	Floor Effects	Resp	
Walk Tests (Fixed Distance)	TUG										++
	Deathe / 2005[33]				+++			+			
	Miller / 2004[87]						++				
	Miller / 2003[88]						+++				
	Miller / 2001[62]				+++						
	Schoppen/1999[32]		+++	+++			++				

IC = Internal Consistency
Intra = Intra-rater Reliability
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Conv = Convergent Validity
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Resp = Responsiveness

Guide to Selection of Activity Outcome Instruments for LEA

Outcome Measures & Categories	Intended Use		Activity Limitation		Context?		
	Why?		What?		Who?	Where?	How?
	Health Status	Δ in Health Status	Capacity (Can Do)	Perform (Does Do)	Fit / Frail	Clinic	Mode of Admin
Walk Tests							
F ixed Distance							
TUG	X		X		X	X	Observational
L-Test	X		X		X	X	Observational
10 m	X	X	X		X	X	Observational
Fixed Time							
2 minute	X		X		X		Observational
Mobility Grades							
SIGAM	**X**	**X**		**X**	**X**	**X**	**Questionnaire**
Indices (Summary)							
Generic – ADL's							
FIM	X		X		X	X	Interview
Generic – Mobility							
COVS	X		X		X		Observational
RMI	X	X		X	X	X	Observational
WST	X	X	X		X	X	Observ. / Self report
Amputee Specific							
AAS	X			X	X		Interview
Houghton	X	X		X	X	X	Questionnaire
LCI-5	X		X		X	X	Questionnaire
PEQ-MS	X		X		X	X	Questionnaire
Q-TFA	X		X	X	X		Questionnaire
AMP	X		X		X	X	Observation
CAPP	X			X	X		Proxy report

SIGAM Mobility Grades

- Special Interest Group of Amputee Medicine
  British Society of Rehabilitation Medicine

DISABILITY AND REHABILITATION, 2003; VOL. 25, NO. 15, 833–844

Taylor & Francis
healthsciences

The SIGAM mobility grades: a new population-specific measure for lower limb amputees

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SIGAM Development

Hoffer Criteria for any classification/categorical scheme

- self explanatory
- made sense and had meaning to: a) patients, b) health care professionals, c) society
- natural hierarchy of mutually exclusive categories

SIGAM Development

Harold Wood-Stanmore

1. Cosmetic
2. Therapeutic
3. Indoor
4. Outdoor with walking aids
5. Independent
6. Normal

Modified HWS=SIGAM

- observer based to self report questionnaire
- benchmark distance of 50 meters
- algorithm for questionnaire inconsistencies

SIGAM Psychometrics

- Gardiner 2002 - inter-observer reliability [multi centre studies]
- Ryall 2003 - reliability validity responsiveness
- Rommers 2008 - inter-observer reliability (rollator walker added)
- Viosca 2005 - compares within stroke population - 3 category classification vs the 6 category instrument

SIGAM Mobility Grades

A. Limb wearing or use of cosmetic limb only

B. Therapeutic wearer wears the prosthesis only for transfers, to assist nursing, walking with the physical aid of another during therapy.

C. Walks on level ground only <, 50 meters, with or without the use of walking aids: a = frame, b = crutches/ sticks , c = crutch/stick

D. Walks on level ground only and in good weather, more than 50 meters, with or without the use of walking aids: a = frame, b = crutches/sticks, c=crutch/stick

E. Walks more than 50 meters. Independent walking aids except occasionally for confidence or to improve confidence in adverse terrain or weather.

F. Normal or near normal gait.

Refer to Rydall [2003] for the algorithm and self-report questionnaire.

Guidelines and Gaps Using ATS Statement as an Example – (Crapo 2002)

- Purpose and Scope
- Background
- Indications and Limitations
- Contraindications
- Safety Issues
- Technical Aspects of 6 MWT
- Required Equipment
- Patient Preparation
- Measurement Protocol
- Quality Assurance
- Interpretation
- References

6 MWT Reproducibility (Stability)

- Sources of variability
- Guyatt 1984 Encouragement significantly increases distance walked
- Guyatt 1985: Coefficient of variation 0.05 (WPSD = 22.5m)
  - CV = WPSD / Mean — 1 SD 65x; 2 SD 95x
- Weiss 2000: 470 patients with severe COPD but highly motivated
  - 2nd day test ↑ 66 feet (20m) = 5.8% higher
- Kervio 2003: measurement error in healthy elderly in community
  - 20m
- Lin 2008: 3 within day trials in transtibial amputees (N=13)
  - learning effect → T1=545m, T2=554m, T3=570m
  - T3-T1 = 25m difference = 4.6% higher in 3rd trial

6 MWT Interpretation

- Single Measurements of Functional Status
  - Gibbons 2001 reference equation

    Predicted distance (m) = 868 M – [age x 2.9] – [female x 74.1]
- Community Requirements?
  - Menard-Rothe 1997

    Ability to walk ≥ 332m at 80m/min
- Expression of Change
  - Absolute Value % Change Δ in the % of predicted value
- Clinically Meaningful Change
  - Guyatt 1984, 1985, 1987 30-60m [15-18%]
  - Redelmeira and Guyatt 1997

    Stable severe COPD population

    MCID (perception) = 54m [95% CI : 37-51m]

CONCLUSIONS – Related to Workshop Objectives

1. Considerations for Outcome Measurement Tool Selection
   - Purpose for which data will be used
   - Classification Scheme (ICF)
   - Context
     - Personal and Environmental
   - Metrics and Pragmatics
2. Achieving Consensus
   - Review Literature
   - Convene Consensus Group
   - Use ATS statement as template

Handouts

- Body Function
  - List of OMs and Results from BF&S paper
- Activity
  - Table VI ICF activities paper
  - SIGAM Classification System, Questionnaire, Algorithm (Ryall et al. 2003)
  - ATS statement article
  - Test instructions per Parkwood Hospital with respect to walk tests