

# An AmpEBR Update: REHABILITATION OUTCOME MEASUREMENT



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# Workshop Objectives

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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

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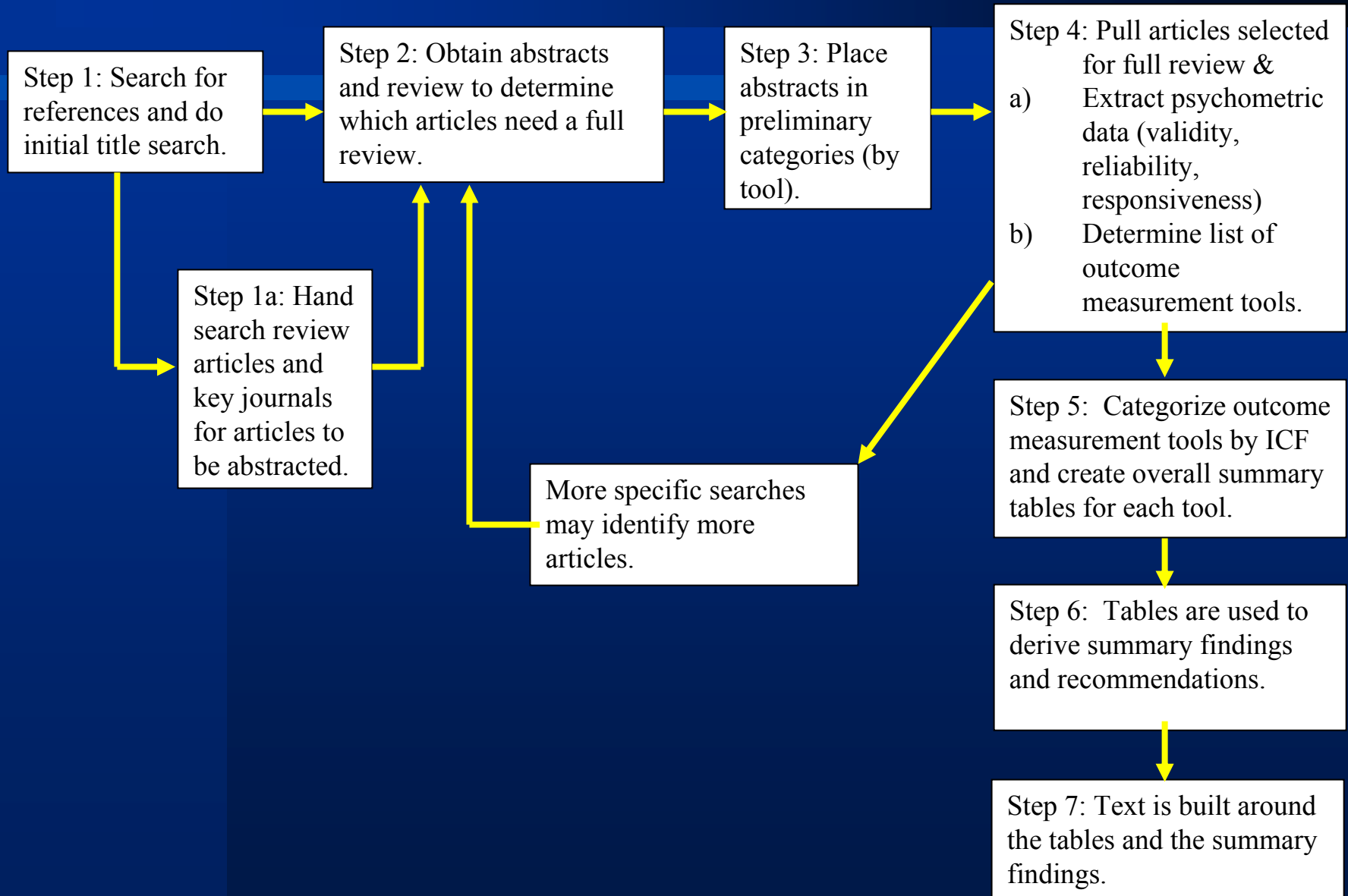
## 1. Outcome Measurement Tools

- 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) Psychoprosthetics. 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.

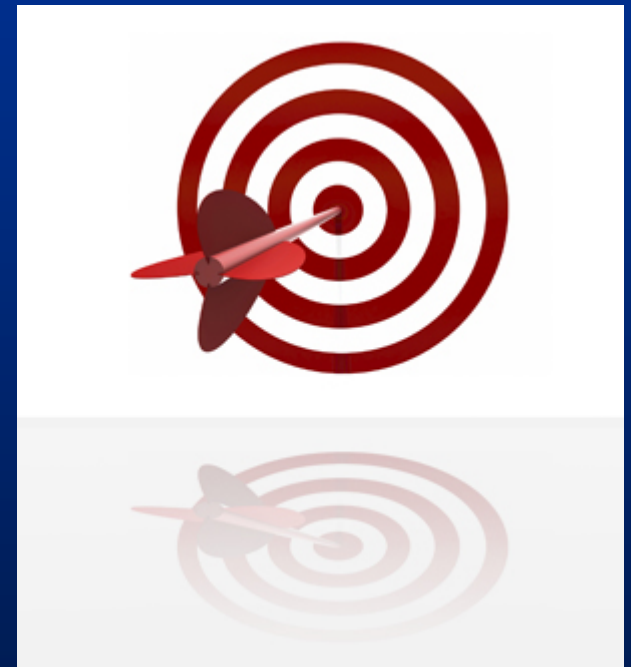
# Criteria for Overall Metric Findings of a Specific Instrument (Adapted from Johnson & Graves 2008)

- Extensively validated and widely used ..... +++++
- Content and metric reliability and validity shown ..... +++
- Minimal validity ..... ++
- Questionable or insufficient ..... +
- No formal validity/reliability information published ... 0

# Goal – Primary Objective

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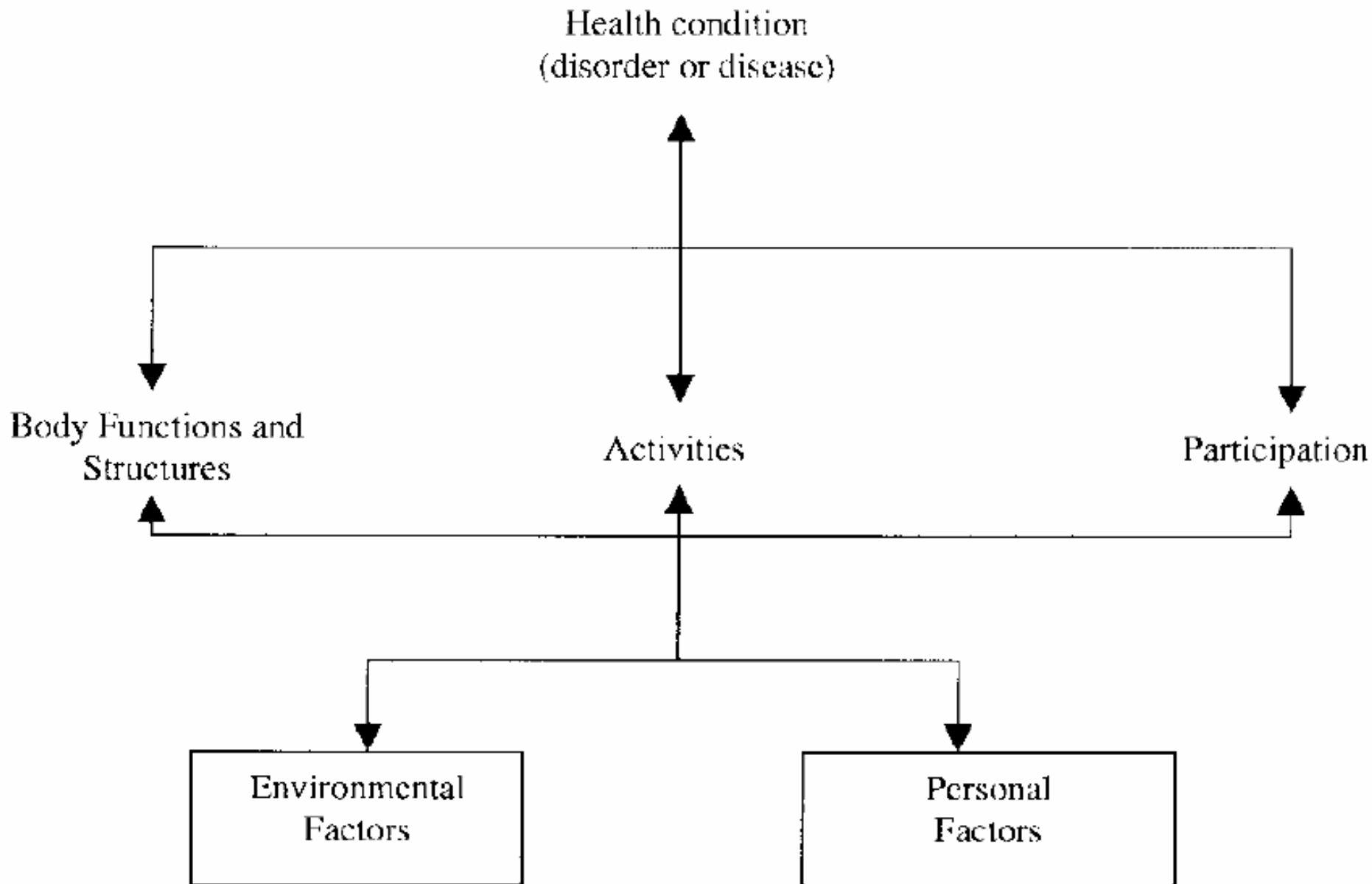
**A guide for the  
clinician to select the  
most appropriate  
outcome instrument**



# 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

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- 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

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- 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

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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 (VO<sub>2</sub> 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									Overall		
		Reliability			Validity			Responsiveness					
		IC	Intra	Inter	Conv	Conc	Pred	Ceiling Effect	Floor Effect	Resp			
SENSORY & PAIN	<u>Socket Comfort Score</u>											++	
	Hanspal / 2003			+++	++							+	
CARDIO-VASCULAR & RESPIRATORY	<u>One Leg Cycling Test</u>												++
	Chin / 2002								+				
	Chin / 1997			+++	+++								
	Currie / 1992				+++								
NMS & MOVEMENT	<u>Walking Speed</u>												++
	Boonstra / 1993			+++		++							
	<u>Postural Sway</u>												±
	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	Setting	Etiology	Level	n	Type of Data	# of Items	Item Response Range	Number of Studies		
									Reliability	Validity	Responsiveness
Walk Tests (Fixed Distance)	<u>TUG</u> Deathe / 2005[33]	OP	Vasc/Traum	TF-TT	93	Ratio	1	0 - ∞	1	5	1
	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+						
	Schoppen/1999[32]	OP	Vasc	TF-TT	329						

# 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	Ceiling 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

Inter = Inter-rater or Test-retest Reliability

Conv = Convergent Validity

Conc = Concurrent Validity

Pred = Predictive Validity

Resp = Responsiveness

# Guide to Selection of Activity Outcome Instruments for LEA

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



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

N. H. RYALL<sup>†\*</sup>, S. B. EYRES<sup>‡</sup>, V. C. NEUMANN<sup>†</sup>, B. B. BHAKTA<sup>‡</sup>  
and A. TENNANT<sup>‡</sup>

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<sup>‡</sup> Rheumatology and Rehabilitation Research Unit, Clarendon Road, Leeds, UK

# SIGAM Development

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Offer 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

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Harold Wood-Stanmore

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

# Modified HWS=SIGAM

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- 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)
  - $CV = \frac{WPSD}{Mean}$ 

1 SD	65x
2 SD	95x
- Weiss 2000: 470 patients with severe COPD but highly motivated
  - 2<sup>nd</sup> 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 3<sup>rd</sup> trial

# 6 MWT Interpretation

- Single Measurements of Functional Status

- Gibbons 2001 reference equation

$$\text{Predicted distance (m)} = 868 M - [\text{age} \times 2.9] - [\text{female} \times 74.1]$$

- Community Requirements?

- Menard-Rothe 1997

Ability to walk  $\geq 332\text{m}$  at 80m/min

- Expression of Change

- Absolute Value                      % Change                       $\Delta$  in the % of predicted value

- Clinically Meaningful Change

- Guyatt 1984, 1985, 1987 30-60m [15-18%]
- Redelmeira and Guyatt 1997

Stable severe COPD population

$$\text{MCID (perception)} = 54\text{m} [95\% \text{ CI} : 37-51\text{m}]$$

# 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