

HRQL Measures in Chronic Pain Trials

Prof. Gerold Stucki, MD, MS

Department of Physical Medicine and Rehabilitation

ICF Research Branch, WHO FIC Germany

University of Munich

Task

- Identify the **generic or HRQL measures** best suited for chronic pain trials
- Examine the representation of the other 5 (specifically measured) core domains
 - **Function (physical, pain-related)?**
 - Pain
 - Mood
 - Patient global / satisfaction
 - Negative health states / adverse events

Selection of Measures

- Non-systematic search of HRQL measures used in pain trials
 - Pain conditions
 - and
 - Terms used for generic measures
 - Names of a number of generic measures
 - Head-to-head comparison

Identified Measures Profiles

- Spitzer's quality of life index **QLI**
- Sickness Impact Profile **SIP**
- Quality of Well-Being Index **QWB**
- WHOQOL-Bref
- WHO Disability Assessment Schedule II **WHODAS**
- Nottingham Health Profile **NHP**
- Medical Outcome Study Short Form 36 **SF-36**

Identified Measures Indices

- **SF-6D**
- European Quality of Life Instrument **EQ-5D**

Examination of Measures

- Use in chronic pain trials
 - Study examples
- Content comparison
 - Linkage based on the ICF
 - Compare to the ICF core set for chronic pain
- Feasibility
 - Instrument length
 - Missings
- Discriminative ability
 - Head-to-head comparisons



International Classification of Functioning, Disability and Health

ICF

ICF is WHO's framework for measuring health and disability at both individual and population levels

While the International Classification of Diseases classifies diseases as causes of death, ICF classifies health



**Dr. Gro Harlem Brundtland
Director General, WHO**

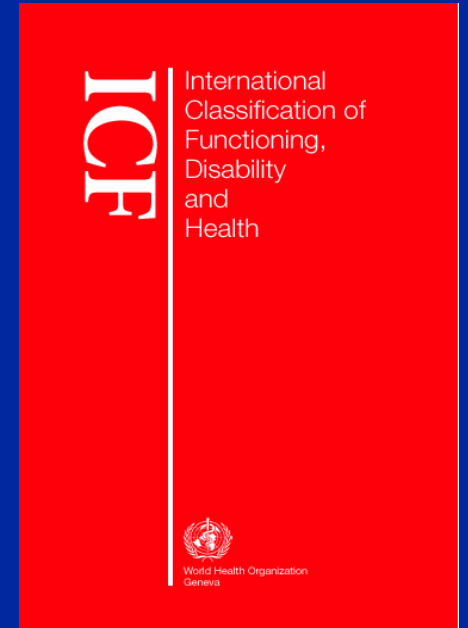




Linking



rules



Rule 1

Before one links health-status measures to the ICF categories, one should have acquired good knowledge of the conceptual and taxonomical fundamentals of the ICF, as well as of the chapters, domains, and categories of the detailed classification, including definitions.

Rule 2

Each item of a health-status measure should be linked to the most precise ICF category.

West Haven – Yale Multidimensional Pain Inventory

Item	Component	Chapter 1 st Level	2 nd Level	3 rd Level	4 th Level
4. Play cards or other games.	d	9	20	0	

d920

Recreation and leisure

d9200

Play

Engaging in games with rules or unstructured or unorganized games and spontaneous recreation, such as playing chess or cards or children's play

Rule 3

If a single item encompasses different constructs, the information in each concept should be linked.

Oswestry Low Back Pain Disability Questionnaire

Item	Component	Chapter 1st Level	2nd Level	3rd Level	4th Level
4. Section: <i>Walking</i>					
Pain doesn't prevent me from walking any distance.	b	2	80	1	3
	d	5	40		

Aberdeen Low Back Pain Scale

Item	Component	Chapter 1st Level	2nd Level	3rd Level	4th Level
I didn't lose any sleep, but I needed tablets.	b	1	34		
	e	1	10	1	

SF-36

ICF

*Does your health now limit
you in these activities?*

- | | |
|--|-------------------------|
| a) vigorous activities, such as running,
lifting heavy objects,
participating in strenuous sports | d4559
d4309
d9209 |
| b) moderate activities, such as, moving a table,
pushing a vacuum cleaner,
bowling or playing golf | d4459
d6409
d9209 |
| c) lifting or carrying groceries | d430 |
| d) climbing several flights of stairs | d4551 |
| e) climbing one flight of stairs | d4551 |
| f) bending, or
kneeling, stooping | d4105
d4102 |
| g) walking more than 1 mile | d4501 |
| h) walking several blocks | d4501 |
| i) walking one block | d4500 |
| j) bathing or
dressing yourself | d5101
d540 |

Linkage Results

Example Body Functions

- Energy and drive functions
 - Not in WHODAS, EQ-5D
- Sleep functions
 - Only in NHP, WHOQOLBREF
- Emotional functions
 - Covered by all (in detail SF-36, NHP)
- Pain
 - Not in WHODAS and QLI (in detail NHP)

Feasibility

- Disadvantage SIP and QWB
- Missings
 - High in EQ-5D
 - Lowest for the NHP
- SF-36 also performed well in the elderly

Discrimination

- SF-36 likely to be more responsive than the NHP and the SIP
 - Caveat: possible floor effect
- EQ-5D inconsistent performance

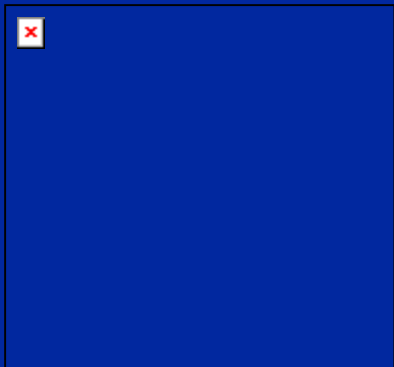
Recommendation

- SF-36 and NHP
 - Only NHP covers sleep; pain in more detail
 - SF-36 more responsive
 - SF-36 allows calculation of SF-6D
- EQ-5D or SF-6D
 - Options for economic evaluation
 - Caveat: limited evidence in pain patients

Option

- Define what to measure
 - ICF as the general reference framework
 - ICF Core Set for chronic pain trials
 - E.g. body functions: sleep, pain, energy and drive functions, emotional functions
- Provide up-dates on currently best suited HRQL measures
- Suggest the (additional) use of an operationalized ICF Core Set

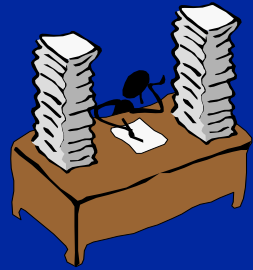
Thank you



**ICF Research Branch
WHO Collaborating Center for the Family of
Classifications, Germany
at the University of Munich**

**WHO
CAS Classification, Assessment Surveys**

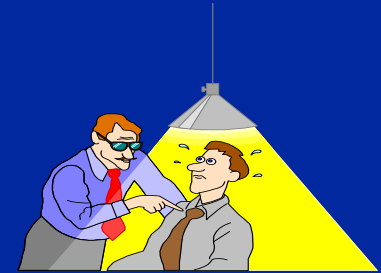
ICF Core Set Development



systematic review



empiric data collection (checklist)



Delphi - procedures

international consensus conferences

Core-Sets

intermediate data analysis

evaluation in clinical practice



Body Functions - Pain

b280 Sensation of pain

b152 Emotional functions

b130 Energy and drive functions

b147 Psychomotor functions

b134 Sleep functions

b455 Exercise tolerance functions

b730 Muscle power functions

b760 Control of voluntary movement functions

Body Structures - Pain

S770 Additional musculoskeletal structures related to movement

Activities & Participation - Pain

d230 Carrying out daily routine

d240 Handling stress and other psychological demands

d760 Family relationships

d850 Remunerative employment

d770 Intimate relationships

d450 Walking

d430 Lifting and carrying objects

d640 Doing housework

d920 Recreation and leisure

Environmental Factors - Pain

e310 Immediate family

e410 Individual attitudes of immediate family members

e355 Health professionals

e570 Social security services, systems and policies

e1101 Drugs

- **Condition-oriented Core-Sets**

- Lists of domains that are relevant to most patients with that condition
- Link to the world of the ICD

- **Generic Core-Set**

- Lists of domains relevant to most patients
- Comparability across conditions

ICF Core-Set Project Goal

- To develop evidence-based and internationally accepted lists of domains for patients with a specific condition
 - Comprehensive assessment
 - Multidisciplinary care
 - Minimum data set
 - Research, health reporting