

What domains of the International Classification of Functioning, Disability and Health are covered by the most commonly used measurement instruments in traumatic brain injury research?

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ABSTRACT

Objective: To identify the most frequently used outcome measurement instruments reported in clinical studies on TBI and to provide a content comparison in the framework of the International Classification of Functioning, Disability and Health (ICF).

Patients and methods: A systematic literature review of clinical studies in TBI was performed using Medline, EMBASE and PsychINFO. The items of the measurement instruments present in more than 20% of the studies were linked to the ICF language.

Results: 193 papers fulfilled the eligibility criteria. The frequency analysis identified six instruments: Functional Independence Measure (50%), Glasgow Outcome Scale (34%), Disability Rating Scale (32%), Wechsler Adult Intelligence Scale (29%), Trail Making Test (26%) and Community Integration Questionnaire (22%). The analysed instruments focus on different aspects of *body functions* (especially DRS, WAIS and TMT) and aspects of *activities and participation* in life (especially CIQ and FIM). Inter-researcher agreement for the ICF linking process was 0.83.

Conclusions: Translating the items of different measurement instruments into the ICF language provides a practical tool to facilitate content comparisons among different outcome measures. The comparison can assist clinical researchers to integrate information acquired from different studies and different tools.

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1. Introduction

Traumatic brain injury (TBI) is a frequently occurring condition and a common cause of death and disability. Approximately 7.8 million persons live in Europe with some level of disability caused by TBI [1,2]. Impairment, activity limitations and participation restrictions are ubiquitous and very important consequences of moderate and severe TBI [3–5].

The interest in TBI rehabilitation has increased during the last decade partly as a result of the increased awareness of disability which is, for example reflected in the 2005 WHO resolution on disability, including prevention management and rehabilitation [6–8]. Rehabilitation in patients with TBI has not only a beneficial effect on improving patient quality of life, but also shortens the length of stay in acute care hospitals and diminishes other health care costs.

Measurement of physical and cognitive changes and the description of patient problems in relevant life areas are essential aspects of rehabilitation settings in order to identify, quantify and plan interventions [9,10]. The use of measurement instruments offers the clinical researcher a practical, validated and standardized way to assess the nature and degree of a person's functional disability but they can also be applied to a great variety of purposes in clinical, research, management and policy settings.

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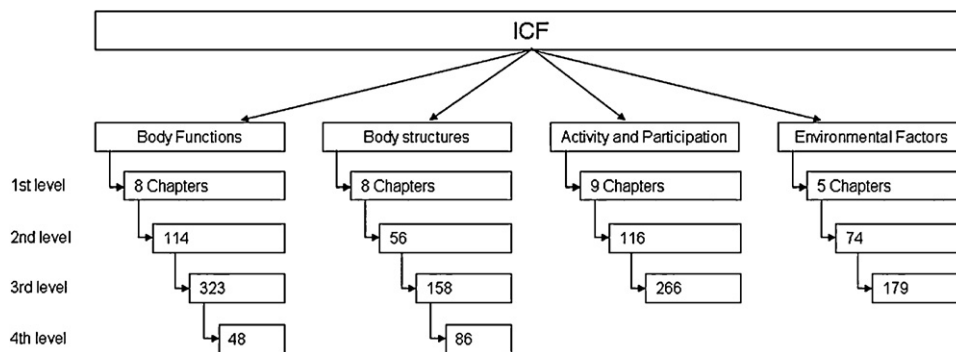


Fig. 1. Description of the ICF nested structure.

Commonly utilized TBI outcome instruments vary in scope and mode of measurement. Some instruments focus in impairments of neurological or cognitive functions whereas others focus on activity restrictions and others in the participation in society [11].

Therefore this little standardization in the use of these instruments and comparisons across studies or data from different centres and countries are difficult [12].

The World Health Organization (WHO) has adopted the International Classification of Functioning, Disability and Health (ICF) in 2001, as a universal reference framework for functioning and health. The ICF is based on a comprehensive bio-psycho-social model and has been designed as a common language for multi-professional cooperation [8,10,13–15]. The ICF is not a specific tool for assessment but a reference system that in healthcare settings reflects the findings of clinical assessments conducted by health professionals [9,16–18].

The ICF is a hierarchically organised taxonomy in a nested structure (see Fig. 1). The ICF components correspond to: *body functions* (b) that define physiological and psychological functions, *body structures* (s) that describe the anatomical parts of the body, and *activities and participation* (d) that comprises the full range of life areas, including the execution of a task, activities of daily life, interpersonal relationships, and community living. In addition to this, patient's functioning and disability are also influenced by contextual factors. *Environmental factors* (e) describe the physical, social and attitudinal environment in which people live and conduct their lives. *Personal factors* comprise individual features that are not part of the health condition, for example age, gender, race, habits, fitness or coping styles. In total, there are 1454 ICF categories, corresponding to 493 body functions, 310 body structures, 393 activities and participation and 258 environmental factors. Personal factors are not currently classified into detailed categories.

The objective of this study was to identify the most frequently used measures reported in TBI literature. A detailed content comparison to identify communalities and discrepancies of these aforementioned instruments was then made on the basis of the ICF to present their content in the neutral common framework recommended by the WHO.

2. Method

A systematic literature review was done in order to identify clinical studies on TBI. All the measures that were used in the studies were extracted and a frequency analysis was performed. For all those that were used in more than 20% of the studies, a content comparison was made on the basis of the ICF by two independent researchers [12,19–21].

2.1. Selection of studies

Three electronic databases were used for the search (Medline, EMBASE and PsycINFO) and searched for publications in the last five years using the keywords: “traumatic brain injury”; “brain injury”; “head trauma”; “outcome”; “measures”; “instrument”; “assessment”; “questionnaire”; “functioning”; “functional assessment”; “disability”; “quality of life”; and “evaluation”. (The exact terms and strategies varied across databases and can be retrieved from the corresponding author.)

Studies with patients over 18 years old who fulfilled a clinical diagnosis of TBI according to the definition established by the TBI Model System were included. This covered: randomized clinical trials, controlled clinical trials, observational studies and qualitative studies were the selected study designs.

Studies with exclusively laboratory parameters, genetic studies, animal experiments, letters, comments, editorials, systematic reviews and meta-analyses were excluded. In the case of multiple publications, the paper with the highest impact factor was included. All searches were limited to articles written in English.

2.2. Identification of measurement instruments

All measurement instruments used in the studies were then identified and the number of studies was documented in which each of them was used. The instruments that were used in more than 20% of the studies were further analysed.

2.3. Linkage to ICF nomenclature

The concepts contained in the items or tasks addressed in each of the measurement instruments, were then linked to the ICF categories according to standardized linking rules by Cieza et al. [22,23]

If an item contained more than one concept or if it was specified by examples, each of them was linked separately as is shown in the following example: “oriented: implies awareness of self and the environment. Patient able to tell you a) who he is; b) where he is; c) why he is there; d) year e) season, f) month, g) day...” The linking would lead to *orientation* (b114), *awareness* (b1644: insight), *orientation to oneself* (b1142: orientation to person), *orientation within the environment* (b1140: orientation to place), *orientation within time* (b1141: orientation to time).

The results of the linking are presented at the second level of the classification. If a concept was linked to a 3rd- or 4th-level ICF category, the corresponding 2nd-level category was reported.

Table 1

Representation of the 20 most frequent measurement instruments identified. The other 263 instruments have a frequency of less than 5%.

Measurement instrument	Occurrence frequency
Functional Independence Measure	50%
Glasgow Outcome Scale	34%
Disability Rating Scale	32%
Wechsler Adult Intelligence Scale III	29%
Trail Making Test (A & B)	26%
Community Integration Questionnaire	22%
Wisconsin Card Sorting Test	15%
Barthel Index	14%
Controlled Oral Word Association Test	14%
Galveston Orientation and Amnesia Test	13%
California Verbal Learning Test	12%
Rancho Los Amigos Level of Cognitive Functional Scale	12%
Mini Mental State Examination	10%
Stroop Color Word Test	10%
Beck Depression Inventory	9%
Functional Assessment Measure	9%
SF-36	8%
Sickness Impact Profile	7%

2.4. Interrater reliability

All steps of the review were done by two health professionals (SL, physician with specialization in PM&R and RL, statistician) who were trained at the ICF Research Branch, WHO FIC Collaborating Center at the Ludwig Maximilian University in Munich.

The degree of agreement between the two health professionals was calculated by means of the kappa statistic. The values of kappa generally range from 0 to 1, in which 1 means perfect agreement.

3. Results

The electronic search identified 1089 articles. An abstract check yielded 274 articles which were fully read. Finally, 193 articles fulfilled the eligibility criteria.

Two hundred eighty three (283) different instruments were identified in the studies. Out of these, six instruments were used in more than 20% of the studies and their content were linked to the ICF. Functional Independence Measure (FIM, 50%), Glasgow Outcome Scale (GOS, 34%), Disability Rating Scale (DRS, 32%), Wechsler

Adult Intelligence Scale (WAIS, 29%), Trail Making Test (TMT 26%) and Community Integration Questionnaire (CIQ, 22%). The Glasgow Coma Scale was found to be named in the papers in a 33% but [24] is not truly an outcome measure as it measures impairment. It can be used as an outcome measure in a very acute phase to measure the effects of a treatment or neurosurgery but basically defines the severity of the TBI [25] (see Table 1).

The Functional Independence Measure (FIM) is an 18 item scale assessing different aspects of independent performance in life areas such as feeding, grooming, toileting, self-care, transfers, locomotion, as well as cognitive items for communication, memory, problem solving and social interaction [26]. The advantage of this tool is that it has shown the ability to detect changes in a rehabilitation setting but the usefulness is limited by a ceiling effect after discharge [27].

The Glasgow Outcome Scale (GOS) is the widest method for classifying outcome in TBI patients. It includes 5 items and is a brief descriptive outcome scale to describe a general assessment of functioning. It is used more frequently in clinical practice than an extended interview version of the GOS that has been reported recently [28].

The Disability Rating Scale (DRS) is a 30 point measure consisting of eight items assessing different areas of functioning such as eye opening, verbalization, feeding, toileting and grooming, dependence on others and employability [29]. It was originally developed to assess individuals with TBI during the recovery phase. However, there are some recommendations towards the use of the GOS in controlled trial setting [30].

The Community Integration Questionnaire (CIQ) is a 15 item scale designed to measure return to social and community life after TBI and it is most appropriate to quantify TBI outcome at participatory (handicap) level [31].

Cognitive deficits are often overlooked as outcome tools for TBI patients, but studies have shown that tests of orientation, verbal memory and processing speed are the most consistent predictors from a neuropsychological assessment [32].

The Trail Making Test (TMT) is a neuropsychological test with two parts to provide information on visual attention, scanning, speed of processing, mental flexibility and performance [33]. The Wechsler Adult Intelligence Scale (WAIS) consists of a battery of tests that examines cognitive abilities, both verbal and visual-spatial [34–36]

Table 2a

Content comparison of outcome measures based on the ICF linking for body functions ($n = 20$).

ICF code	Explanation	CIQ	DRS	FIM	GOS	TMT (A&B)	WAIS	Total
b110	Consciousness functions		xxx		x			2
b114	Orientation functions		xxx					1
b117	Intellectual functions				x			1
b126	Temperament and personality functions	x						1
b140	Attention functions		x			x		2
b144	Memory functions			x				1
b156	Perceptual functions		x					1
b160	Thought functions						x	1
b164	High level cognitive functions	x	xxx			x	x	4
b215	Functions of structures adjoining the eye		xxx					1
b280	Sensation of pain		xxx					1
b310	Voice functions		x					1
b320	Articulation functions		x					1
b330	Fluency and rhythm of speech functions		x					1
b510	Ingestion functions			xxx				1
b525	Defecation functions			x				1
b730	Muscle power functions		x					1
b750	Motor reflex functions		x					1
b755	Involuntary movement reaction functions		x					1
b760	Control of voluntary movement functions		x					1
Total		2	14	3	2	2	2	

x: 1 or 2 items included, xxx: 3 or more items included.

Table 2bContent comparison of outcome measures based on the ICF linking for activities and participation ($n = 36$).

ICF code	Explanation	CIQ	DRS	FIM	GOS	TMT (A&B)	WAIS	Total
d1	Learning and applying knowledge			x				1
d175	Solving problems			x				1
d310	Communicating with receiving spoken messages		x	x				2
d315	Communicating with receiving nonverbal messages		x	x				2
d330	Speaking		x	x				2
d335	Producing nonverbal messages			x				1
d410	Changing basic body position			xxx				1
d420	Transferring oneself			xxx				1
d450	Walking			x				1
d455	Moving around			xxx				1
d465	Moving around using equipment			x				1
d470	Using transportation	x						1
d510	Washing oneself		x	x				2
d520	Caring for body parts		xxx	xxx				2
d530	Toileting		x	x x				1
d540	Dressing			x x				0
d550	Eating		x	xxx				2
d560	Drinking		x	xxx				2
d598	Self-care		x					1
d620	Acquisition of goods and services	xxx		x				2
d630	Preparing meals	x						1
d640	Doing housework	x						1
d660	Assisting others	x						1
d710	Basic interpersonal interactions			x				1
d750	Informal social relationships	x						1
d760	Family relationships	x						1
d825	Vocational training	x			x			2
d830	Higher education	x			x			2
d840	Apprenticeship	x						1
d845	Acquiring, keeping and terminating a job	x			x			2
d850	Remunerative employment	xxx	xxx		x			3
d860	Basic economic transactions	x						1
d865	Complex economic transactions	x						1
d870	Economic self-sufficiency	x						1
d910	Community life	x			x			2
d920	Recreation and leisure	x						1
Total		17	10	17	5	0	0	

x: 1 or 2 items included, xxx: 3 or more items included.

3.1. Linkage to ICF nomenclature

The items of the six identified instruments were linked to 212 different ICF categories.

Tables 2a–2c summarize the 2nd level ICF categories that were covered by the different instruments.

The majority of the concepts referred to activities and participation ($n = 154$, 73%). Another 51 concepts were linked to the component *body functions* (24%), and only 3% were related to contextual *environmental factors*. No items in the instruments were linked to the assessment of *body structures*.

As expected, the identified measurement instruments focus on different aspects of rehabilitation after TBI: FIM and the CIQ focus predominantly on *activities and participation* in life; whereas, the other instruments put relatively stronger emphasis on the assessment *body functions*.

TMT and WAIS are neuropsychological tests and are confined to the assessment of attention, thought and cognitive functions (b140, b160, b164). However, they do not directly cover activities in life such as learning, applying knowledge and solving problems (d1, d175).

CIQ is a measure for social integration and covers activities and participation in life that are more closely connected to social integration, but not other aspects of functioning and disability.

DRS and FIM assess functional outcome with a wider focus to guide the rehabilitation process. They are the only instruments to cover speaking (b310–b330, d310–d335), food intake (b510–b525, d550–d560) and self-care (d520–d540). While the DRS is the only

instrument to cover pain (b280), the FIM is the only one to cover patient mobility (d410–d465).

3.2. Interrater reliability

The results of the kappa statistic showed a 0.83 index of agreement for both reviewers with a bootstrapped confidence interval at the second level categories between 0.77 and 0.83.

4. Discussion

This study provides a content comparison among outcome measurement instruments in TBI. With the help of the ICF classification as a reference and the ICF linking rules as a practical guideline, the items in the different instruments were translated into a universal and neutral language on functioning and disability. As the statement made by Scarponi et al. [39], the ICF is a flexible instrument for monitoring outcome and defining goals for rehabilitation. Therefore, this study not only provided new insights into the nature of the included instruments, but also provided TBI researchers with a new procedure to facilitate content comparisons among outcome measurement instruments. The ICF adequately covered the items of the instruments and should therefore be a useful frame of reference in the care and rehabilitation of patients with TBI. Similar experiences with the linkage of instruments to the ICF have been reported in other conditions such as stroke [11,16,21].

A systematic literature review identified instruments that had been frequently applied and published. The analysed instruments

Table 2cContent comparison of outcome measures based on the ICF linking for contextual environmental factors that influence the rehabilitation process ($n = 4$).

ICF code	Explanation	CIQ	DRS	FIM	GOS	TMT (A&B)	WAIS	Total
e115	Products and technology for personal use in daily living		x					1
e120	Products and technology for personal indoor and outdoor mobility and transportation		x					1
e320	Friends	x						1
e340	Personal care providers and personal assistants		xxx					1
Total		1	3	0	0	0	0	

x: 1 or 2 items included, xxx: 3 or more items included.

match up with those recommended by different groups to be used in clinical trials for TBI [24,25,37,38]. The linking of the items in the instruments into the ICF gave us more detailed insights into the content covered by each of the instruments. Most of them were related to the measurement of cognitive impairment and the ability to perform activities rather than addressing functioning from a comprehensive rehabilitation perspective.

Most of the items in the instruments were related to the ICF component of *Activities and Participation*, these findings were consistent with the study of Koskinen et al. [11]. The interest in rehabilitation for this domain of the ICF relies on the fact that activities and participation are the areas in which the rehabilitation team can sustain the efforts for treatment [40–42]. The analysed instruments cover key issues such as impairments in solving problems, applying knowledge, communication, mobility, self-care and major life areas were covered but they differed in the subcategory coverage and their approach to assess their activity and participation status. Domains 4 (mobility) and 5 (self-care) were covered in great detail; especially, the categories d410 *changing basic body position* ($n = 14$), d420 *transferring oneself* ($n = 8$), d510 *washing oneself* ($n = 11$), d520 *caring for body parts* ($n = 12$), d530 *toileting* ($n = 13$), d540 *dressing* ($n = 12$). The majority of these concepts were covered by the FIM in third and fourth levels indicating a greater specification of the items measured. While the FIM covers many aspects of communication (d3), mobility (d4) and self care (d5), the CIQ is focused on domestic life (d6), interpersonal interactions and relationships (d7), work, employment and economic life (d8) and community, recreational aspects of life (d9).

The majority of ICF categories on *Body functions* relate to domain 1 (mental functions) and domain 7 (neuromusculoskeletal and movement related functions). The content comparison of the scales showed that the areas covered by the instruments have little overlap. The category b164 *higher level cognitive functions* was the only ICF category that was represented in four instruments, while all others were represented in just one or two of the selected instruments.

Within *body functions*, cardiovascular, haematological, immunological, respiratory, metabolic, endocrine and genitourinary functions were not addressed in the selected instruments on TBI, as expected. This is especially interesting for genitourinary functions, because – from a clinical perspective – incontinence and reproductive problems are relevant problems in the rehabilitation process. The category d530 (toileting) and its subcategories d5300 (regulating urination) and d5301 (regulating defecation) are addressed in the FIM indirectly referring to genitourinary functions. The aforementioned categories are related to the movement functions regarding coordinating and managing urination such as indicating the need to use the restroom, getting into the proper position and manipulating clothing than the function itself (incontinence, urge, reflux, etc.).

Aspects of contextual *environmental factors*, that may also influence the rehabilitation process, are only covered in a limited number of items and only by 2/6 of the analysed instruments: CIQ and DRS. However, in the development of the ICF Core Sets for other

neurological conditions such as stroke, this component was widely represented [43].

Even though environmental factors cannot qualify as an outcome measure, its implication as barriers of facilitators can indeed affect the overall outcome. Previous studies named some environmental factors such as the use of drugs, walking aids, family support, social security systems and health care as factors influencing the overall outcome of patients in a specific health condition [44–46]. Through the application of the ICF and this linking procedure, it was possible to study the heterogeneity of the most frequently applied instruments in TBI clinical trials. Studies like this provide a useful tool to gather more detailed information on the instruments and to prevent research gaps or major redundancies in the data collection process. Nevertheless such studies can never substitute for individual and thorough study of the instruments before selecting the appropriate instrument.

The ICF offers a framework for a comprehensive understanding of the aforementioned components of health and is being increasingly used in clinical practice as well as research. It focuses on “what” to measure and not “how” to measure. The ICF and instruments attempting to operationalize the ICF such as the core sets do not and will not substitute for any of the currently utilized measures [19]. Instead they provide a useful tool to determine “what” is being measured within the currently available instruments. ICF core sets aim to help in selecting which is the best instrument for a specific purpose. Furthermore ICF Core Sets will help in designing new measuring instruments to address aspects of the individual with a particular pathology that have not been previously addressed (e.g., the lack of focus on environmental factors within the currently available measuring instruments) [47].

5. Conclusions

There is no universally accepted outcome measurement instrument that incorporates the full spectrum of problems in functioning that are associated with TBI. The assessment of the patient's problems is of vital importance for planning intervention management, outcome evaluation and service provision. Within this study it was demonstrated that the ICF can be used to differentiate the different aspects of rehabilitation that are included in the most common measurement instruments used in TBI trials. The monitorization of outcomes can help clinicians to understand better the effectiveness of an intervention and to compare the results from different studies that used different measures. The use of a common language such as the ICF can be of help to different professionals to integrate information coming from different tools. Further work towards a development of a specific TBI ICF Core Set is needed. The ICF Core Sets for TBI are to be developed through a decision making process that integrates evidence from different studies conducted to capture the health professional perspective, the patients perspective, the clinical perspective and the researcher's perspective. The data gathered from this study aims to provide information from

the researcher's perspective during the consensus conference for the development of the ICF Core Sets for TBI.

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