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Mapping the Content of the Patient Reported Outcomes Measurement Information System (PROMIS®) Using the International Classification of Functioning, Health and Disability

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Abstract

Background—The Patient Reported Outcomes Measurement Information System (PROMIS®) is a U.S. National Institutes of Health initiative that has produced self-reported item banks for physical, mental, and social health.

Objective—To describe the content of PROMIS at the item level using the World Health Organization's International Classification of Functioning, Disability and Health (ICF).

Methods—All PROMIS adult items (publicly available as of 2012) were assigned to relevant ICF concepts. The content of the PROMIS adult item banks were then described using the mapped ICF code descriptors.

Results—The 1006 items in the PROMIS instruments could all be mapped to ICF concepts at the second level of classification, with the exception of 3 items of global or general health that mapped across the first-level classification of ICF activity and participation component (d categories). Individual PROMIS item banks mapped from 1 to 5 separate ICF codes indicating one-to-one, one-to-many and many-to-one mappings between PROMIS item banks and ICF second level classification codes. PROMIS supports measurement of the majority of major concepts in the ICF Body Functions (b) and Activity & Participation (d) components using PROMIS item banks or subsets of PROMIS items that could, with care, be used to develop

customized instruments. Given the focus of PROMIS is on measurement of person health outcomes, concepts in body structures (s) and some body functions (b), as well as many ICF environmental factor have minimal coverage in PROMIS.

Discussion—The PROMIS-ICF mapped items provide a basis for users to evaluate the ICF related content of specific PROMIS instruments, and to select PROMIS instruments in ICF based measurement applications.

Keywords

health; PROMIS; ICF; self-report; outcomes

Introduction

Clinical practice and health research has expanded across large distributed networks of often disparate geographical, cultural and clinical practice settings. The provision of health care has become increasingly digitized in the form of electronic health records, medical information databases, and electronic patient-reported outcomes (ePRO) s. This increasing complexity of communication requires a need for improved means of health information integration, data exchange, search and query of heterogeneous biomedical data, and other critical knowledge-intensive tasks [1]. As a result, there are a growing number of health terminologies, biomedical ontologies, health classification systems, and health measurement networks that extend across practice and research areas. [1]. Hence, creating linkage and operationalization among such systems by identifying similar concepts is a critical step in integrating data and applications that use different ontologies. A common terminology or link between systems not only provides a means to link such resources and networks, but can also highlight similarities and differences between the resources themselves.

The largest PRO development effort in the world, the Patient Reported Outcomes Measurement Information System (PROMIS[®]), has produced several dozen measures of physical, mental, and social health. [2, 3] Its conceptual framework is based on the WHO tripartite model of health. The conceptual framework of PROMIS and the World Health Organization's (WHO) International Classification of Functioning, Disability and Health (ICF) [4] has recently been reported [5], however the item level content of PROMIS item banks has not been described using the ICF nomenclature. Addressing this gap is important because ICF has become an international standard for describing health and functioning and a large number of health measures have been compared and mapped to the ICF. [6, 7, 8] The purpose of this manuscript is to provide a detailed item-level mapping of PROMIS adult PRO instruments to the ICF to fully describe the content of PROMIS in ICF-centric terms.

The International Classification of Functioning, Disability and Health (ICF)

The ICF was officially endorsed in 2001 as an international standard to describe and classify health, functioning and disability. It provides a scientific basis for understanding and studying health and functioning and serves as a classification system to improve communication between different users, and a systematic coding scheme for health information systems [4, 8, 9, 10, 11]. The ICF was designed to record and organize a wide

range of information about health and health-related states in a standardized, common language, thereby facilitating communication about health and healthcare in various disciplines and scientific fields worldwide.

In the ICF classification, the letters b, s, d, and e, which refer to the major components of the classification, are followed by numeric codes for each hierarchical sub-level starting with the chapter number (one digit, 34 total chapters) followed by the second level (two additional digits, 362 codes), third and fourth levels (one additional digit for each level resulting in 1424+ fourth level codes) of ICF sub-categories. Categories are the units of the ICF classification. Part 1 of the ICF covers functioning and disability and includes the components: body functions (b) and structures (s) and activities and participation (d). Part 2 covers contextual factors and includes environmental factors (e) and personal factors [11]. An overview of the ICF major chapters is presented in (Table 1).

Patient Reported Outcomes Measurement Information System

PROMIS (www.nihpromis.org) is an ongoing initiative funded by the U.S. National Institutes of Health. Its purpose is to create, maintain, and improve instruments that measure adult and child self-reported health. [2, 3] PROMIS instruments are developed using a rigorous mixed-methods approach. [12] This process begins with application of qualitative research methods to define the theoretical construct and methods, such as cognitive interviews, to ensure the comprehensibility and translatability of item concepts across languages and cultures. Psychometric methods include factor and item response theory analyses to develop item banks that provide precise and efficient measurement of the underlying concepts. Instruments are administered as either fixed-length short forms or computer adaptive tests (CATs). Regardless of method, the person's score is placed on the same PROMIS metric. The calibration of the item banks using item response theory methods allows PROMIS measures to be statistically linked to other measures of the same concept, providing a means to integrate between existing legacy and PROMIS measures. [13] PROMIS item banks are translated into multiple languages, and provide measures of health across the lifespan. Additional details and updates including definitions of major constructs and the PROMIS domain framework are available at www.nihpromis.org. A comparison of PROMIS and ICF conceptual frameworks demonstrated both harmonization and synergy between the two systems [5].

Methods

We used the item-level content analysis mapping methods described by Cieza [6, 7]. All adult PROMIS item banks (Table 2) were mapped by two content experts (CT, RE) at the item level to the most precise and best fitting category of the ICF. If the PROMIS item contained more than one concept, each was mapped to a corresponding ICF code. For each item we identified a primary ICF mapping which corresponded to the conceptual definition of the corresponding item bank. Secondary ICF codes were identified for other meaningful concepts included in the item stem. In accordance with recommended ICF mapping practices, those items with meaningful concepts that do not have sufficient information to select an ICF category were labeled not definable (nd). If the meaningful concept of the

items were not in an ICF functioning category but were defined as a personal factor by the ICF, it was labeled pf (personal factors). If, however, the meaningful concepts contained in the items were not contained in the ICF and not a personal factor, it was labeled not covered by the ICF (nc). For example, the PROMIS item “How often were you too tired to watch TV” is from the PROMIS Fatigue bank. The 2 meaningful concepts are “too tired” and “watch TV”. The primary ICF concept is “too tired” which maps to ICF category b130: Energy & Drive Functions, consistent with the item belonging to the PROMIS Fatigue item bank. This item’s secondary meaningful concept is “watch TV” which maps to the ICF category d920 – recreation and leisure. The mapping of all items was independently reviewed by an additional investigator (AC) who was in agreement with the mappings.

For each PROMIS item bank, we identified the different ICF codes that were assigned to the bank’s items as both primary and secondary item concepts. We then summarized the item level ICF content in each PROMIS bank, as well as the number of PROMIS items that mapped to each ICF third level codes as the primary result of the work. We finally reviewed each PROMIS bank’s ICF item level content and concept definitions, and identified those PROMIS banks that can readily be used to measure ICF categories.

Results

Items (n=1007) from the publically available PROMIS Adult Item Banks in 2012 (Table 2) were mapped to ICF codes with high consensus (Kappa 0.97) between the two investigators (CT, RE), with full consensus (100% agreement) easily reached on the few discrepant mappings after discussion. More specifically, both individuals presented their rationale for their mapping, and the source material and definitions of the related PROMIS and ICF concepts were reviewed by both and subsequently discussed. In all cases, an understanding was reached. The initial discrepancies most often related to familiarity with the underlying major concept of PROMIS or the ICF. The detailed item mapping is provided in Appendix 1. These discrepancies were primarily due to differences in familiarity and interpretation with specific wording within ICF codes of the different chapters and their intent. The third investigator (AC) reviewed the mapping and was in full consensus with the final mapping of PROMIS items to ICF categories. The details of each of the 1007 PROMIS items’ primary and secondary ICF mappings are provided in Appendix 1. Table 3 summarizes PROMIS item banks by their ICF categories obtained from the item-level mappings.

The majority of PROMIS items were mapped to second and third level ICF categories, with the exception of a few general health items (n=4) which mapped to first level chapters. There were no items that received a code of “nc” or “nd”, as all items could be assigned to specified categories. The item-level mappings demonstrate that PROMIS content spans a large range of ICF categories within the chapters under Body Functions and Activities and Participation. However, PROMIS content does not include items that mapped to ICF categories in Learning and Applying Knowledge (Chapter1), General Tasks and Demands (Chapter 2) and Communication (Chapter 3). No PROMIS items mapped to Body Structure chapters concepts, which is consistent with the intent that PROs measure aspects of health perceived by the individual. PROMIS items were well represented in Body Function chapters of Mental Functions (Chapter 1), Sensory Functions and Pain (Chapter 2),

Genitourinary and Reproductive Functions (Chapter 6) and Neuromusculoskeletal and Movement-related Functions (Chapter 7). PROMIS was developed to measure individual health outcomes rather than environmental qualities; hence there was minimal coverage of most ICF environmental factor categories with the exception of Support and Relationships (Chapter 3).

The coverage of ICF categories by PROMIS banks and items (Table 3) demonstrate more clearly which PROMIS banks or subsets of items can be directly used as intended (item bank derived measures such as short forms or computer adaptive tests) to generate meaningful scores of their related ICF categories.

Discussion

This study provides valuable information about PROMIS measures by showing how their item level content relates to the ICF, an international standard for describing human health and functioning. PROMIS items were mapped and provide significant coverage of ICF components, with the exception of body structures, personal factors and environmental factors. This was expected as PROMIS is focused on health outcomes that can be self or proxy reported. Body Structures (ICF “s” categories) are often assessed using medical imaging or clinical examination, and self-report is not generally used to obtain such information. Personal and environmental factors are considered contextual factors within the ICF, rather than functioning or disability factors. Consistent with this framework, PROMIS, being a system of person reported health outcomes, includes minimal coverage of personal and environmental ICF categories. The environmental factor coverage by PROMIS items are primarily related to the social environment categories contained in ICF Chapter 3: Support and relationships.

Differences in the structure of ICF sub-categories and PROMIS item content resulted in some PROMIS items mapping to less granular ICF categories. For example, mapping of PROMIS item banks that support measurement of specific mental health constructs such as anger, anxiety and depression were at the second-level ICF categories. ICF does not classify these varied emotions as explicitly as PROMIS; there are no distinct third or fourth level ICF categories for each of these emotional concepts. Rather, the corresponding fourth level ICF categories for Emotional Functions (b152) has sub categories of Appropriateness of Emotion (b1520), Regulation of Emotion (b1521) and Range of Emotion (b1522). Hence, anger, anxiety and depression, all very different expressions of mood and emotions map to the same ICF code of b1522 (range of emotion). In mental health clinical applications, there is often a need to measure these more distinct emotions (e.g. depression, anxiety, anger), and the mapping of all three to a single ICF category may not provide the necessary granularity of these concepts in ICF terms to help select measurement instruments. Such differences in granularity provide a foundation for discussion and perhaps eventual modifications in measurement approach using the ICF in this domain.

Another issue faced in the mapping process, related to PROMIS items that include more than a single meaningful concept, resulting in a mapping of one PROMIS item to multiple ICF codes. These types of mappings generally occur for two types of PROMIS item formats:

1) list of exemplars of a primary construct and 2) impact of the primary construct on functioning. In all of these cases, the item's primary mapping is the ICF category with the highest conceptual concordance with the item's PROMIS item bank construct. We also identified secondary meaningful concepts and mapped these to the related ICF classifications. An example of an item with multiple meaningful concepts as exemplars would be the PROMIS physical function item "Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?" Each of these 3 exemplars of vigorous activity (running, lifting heavy objects and participating in strenuous sports) are classified and mapped to distinct ICF codes (e.g. running to d4552; lifting (d4300); and sports d9201). In this case, the PROMIS item capture the higher level ICF category of Mobility (D5) by including a partial list of second level ICF concepts. An example of an item that has a secondary concept that is an impact is found in the PROMIS fatigue bank: "How often were you too tired to do household chores?" The primary ICF concept is "too tired" mapping to ICF classification of Energy Level (b1300), and the secondary meaningful concept is "household chores", mapping to ICF classification Doing Housework. (b640). This one-to-many mapping results in ICF categories having PROMIS items with both primary and secondary mappings identified. For ICF measurement purposes, the use of PROMIS item banks that map to the ICF category are ideal choices. If one customizes a measurement tool by selecting items that mapped to a specific ICF category, a careful review of the pool of individual items is needed to ensure they are relevant for the measurement purpose as empirically they are not representative of a single uni-dimensional PROMIS construct.

As previously noted, the ICF framework was developed as a hierarchical framework, with major classes (first level) being composed of distinct, related subcategories (second, third and fourth levels). According to ICF guidelines for classification, if there is not enough available information to specify a more distinct third level category, one classifies functioning at the higher level (second) – "rolling up" levels into the more general classification. For example, one may say that a person has no restrictions in Moving Around (d455) when there is measurement of some sub-classes but not all of the seven distinct sub-categories under d455: d4550 - Crawling, d4551 - Climbing, d4552 - Running, d4553 - Jumping, d4554 - Swimming, d4555 - Scooting and rolling, and d4556 - Shuffling. In other words, if there is inadequate measurement of a single category (or more) at the more granular levels, one would say the measure may still adequately capture the parent concept. A general heuristic is needed in these cases, perhaps that when a majority of the sub-categories (d455#) are addressed by items, then one states that the parent category (d455) can be measured. Specification of a number or percentage of coverage of the sub-categories of the parent category seems a logical approach, however for certain measurement applications or settings, these algorithms may need to be modified with one category more heavily prioritized than others. For example, most clinicians would prioritize adequate capture of the activity climbing stairs and perhaps running and jumping over climbing and swimming for most adult rehabilitation situations. In contrast, for Emotional Regulation (b152), the subcategories are not exclusive components as mentioned earlier – but represent a sequence of emotional regulation functions – initiate, sustain and terminate. In this category, measuring all three subcategories may be necessary to ensure the parent ICF

category is adequately measured. In general, when many PROMIS items map to a single ICF category, most related ICF sub-categories have coverage by PROMIS item(s). This further supports the content validity of PROMIS as measures of generic health outcomes in the.

Another finding that emerged in our mapping is that for some fourth level ICF categories (e.g. pain, range of emotion), PROMIS provides a large number of items. This suggests that these ICF fourth level concepts can be measured with great detail by existing PROMIS item banks. In this case, when items from different empirically uni-dimensional PROMIS item banks map to a single ICF category, it may suggest that defining more granularity, by specification of additional ICF sub-categories, could provide more meaningful measurement or classification of that ICF construct.

In a few instances the sub-structure of ICF classification and the related PROMIS item bank are inconsistent. For example as previously mentioned, the ICF category of Emotional Regulation (b152) has sub-codes for initiation, range, and termination. PROMIS items that map to b152 do not specifically measure each of those sub-components, but rather measure anger, depression, anxiety as complete concepts. In many health applications, measurement of the magnitude, impact and behaviors associated with emotional health are needed, and in some applications perhaps the more general initiation, maintenance and termination of emotion are more important. Such differences do not imply one approach is inherently better or preferred, simply that there are differences in how the parent concept relates to and is specified by its sub-concepts. PROMIS provides enhanced measurement of distinct emotional health concepts e.g. (anger, anxiety, depression) within ICF category b152 rather than the ICF b153 sub-concepts related to more general emotional regulation and range. This suggests that future work expansions or revisions to the ICF, for example of b152 code to reflect specific emotional health outcomes, may be informed by PROMIS's empirical data assessing dimensionality of similar concepts, and may enhance application of the ICF to measurement systems.

There are some limitations in our approach which are worth noting. This approach to item-level mapping is based primarily on identification of meaningful concepts based on single words or phrases within the items. This form of lexical mapping is relatively reductionist, but powerful in terms of catching all concepts within an item. Even so, the intent of the entire item can be de-emphasized unless one identifies a primary concept, in this case based on the concept of the item's PROMIS bank, and the additional meaningful concepts considered secondary. This mapping process is also time intensive, and requires that the reviewers are quite familiar with the ICF category definitions as well as the instruments being mapped, in this case PROMIS.

Conclusion

PROMIS instruments provide coverage of the majority of ICF activity and participation categories, as well as of mental functions. PROMIS is focused on patient reported health outcomes; hence there is minimal content coverage for ICF constructs contained in body structures or environmental contexts. The ICF is a health related and functioning

classification system, and is not explicitly a measurement system or set of instruments. It is intended for the classification of all anatomical and functional impairments, limitations in activities, and restrictions to participation independent of the underlying condition or disease and is used internationally and translated into many languages. PROMIS provides high quality PRO measures across a breadth of ICF categories, are publically available, and have undergone multiple language translations, and cross-cultural harmonization. Hence PROMIS instruments provide a source of measurement appropriate to use for ICF based measurement in specific context in which patient reports are central.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Overview of ICF categories including the number of two-level (e.g. b###) categories

	ICF Chapter	ICF Primary Concepts (Chapters)	Two-Level Classifications (n)
Body Functions (b)	B1	Mental Functions	24
	B2	Sensory Functions & Pain	18
	B3	Voice and Speech Functions	6
	B4	Functions of the Cardiovascular, Haematological, Immunological and Respiratory Functions	16
	B5	Functions of the Digestive, Metabolic and Endocrine Systems	15
	B6	Genitourinary & Reproductive Functions	11
	B7	Neuromusculoskeletal and Movement-Related Functions	17
	B8	Functions of the Skin and Related Structures	10
Body Structures (s)	S1	Structures of the Nervous System	7
	S2	The Eye, Ear and Related Structures	8
	S3	Structures involved in Voice and Speech	6
	S4	Structures of the Cardiovascular, Haematological, Immunological and Respiratory Functions	5
	S5	Structures related to the Digestive, Metabolic and Endocrine Systems	10
	S6	Structures Related to Genitourinary & Reproductive Systems	5
	S7	Structures Related to Movement	9
	S8	Skin and Related Structures	6
Activity & Participation (d)	D1	Learning & Applying Knowledge	27
	D2	General Tasks and Demands	7
	D3	Communication	18
	D4	Mobility	21
	D5	Self-Care	10
	D6	Domestic Life	11
	D7	Interpersonal Interactions and Relationships	11
	D8	Major Life Areas	20
	D9	Community, Social & Civic Life	7
Environmental Factors (e)	E1	Products & Technology	14
	E2	Natural Environment and Human-Made Changes to Environment	13
	E3	Support and Relationships	13
	E4	Attitudes	14
	E5	Services, Systems and Policies	20

Table 2

Overview of PROMIS Adult Item Banks (as of 2012)

PROMIS Item Banks (2012)	Number of Items
PHYSICAL HEALTH – Functioning & Symptoms	
Physical Function	124
Physical Function - Mobility-Aids Subset	114
Sexual Function & Satisfaction	7
Sleep Disturbance	27
Sleep-Related Impairment	16
Fatigue	95
Pain Intensity	3
Pain Behavior	39
Pain Interference	41
PROMIS MENTAL HEALTH – Affect, Behaviors & Cognition	
Emotional Distress – Anxiety	29
Emotional Distress – Depression	28
Emotional Distress – Anger	29
Psychosocial Illness Impact - Positive	39
Psychosocial Illness Impact - Negative	32
Applied Cognition – General Concerns	34
Applied Cognition -- Abilities	33
Alcohol Use – Problem Drinking	37
Alcohol Use - Consequences - Positive	20
Alcohol Use – Consequences - Negative	31
Alcohol Use – Expectancies - Positive	9
Alcohol Use – Expectancies - Negative	11
PROMIS Social Health- Relationships & Function	
Ability to Participate in Roles and Activities	35
Satisfaction with Roles and Activities	44
Companionship	6
Emotional Support	16
Instrumental Support	11
Informational Support	10

Table 3

The number of PROMIS items that map to each of the ICF body function, activity and participation and environmental factor categories. Only ICF categories that had one or more PROMIS items are included in this table.

PROMIS ITEMS	ICF Categories	Labels
375	b1	mental functions
4	b110	consciousness functions
67	b126	temperament and personality functions
113	b130	energy and drive functions
30	b134	sleep functions
25	b140	attention functions
33	b144	memory functions
70	b152	emotional functions
14	b160	thought functions
6	b164	higher-level cognitive functions
7	b167	mental functions of language
3	b172	calculation functions
86	b2	Sensory Functions & Pain
1	b230	hearing functions
85	b280	sensation of pain
22	b455	exercise tolerance functions
67	b6	Genitourinary & Reproductive Functions
67	b640	sexual functions
12	b7	Neuromusculoskeletal/Movement Related Functions
3	b710	mobility of joint functions
9	b730	muscle power functions
2	d1	Learning & Applying Knowledge
2	d160–179	Applying knowledge
30	d2	General Tasks & Demands
8	d210	undertaking a single task
5	d220	undertaking multiple tasks
10	d230	carrying out daily routine
5	d240	handling stress and other psychological demands
12	d3	Communication
2	d350	conversation
131	d4	Mobility
18	d410	changing body position
13	d415	maintaining a body position
1	d420	transferring oneself
8	d430	lifting and carrying objects

PROMIS ITEMS	ICF Categories	Labels
25	d440	fine hand use
16	d445	hand and arm use
14	d450	walking
18	d455	moving around
8	d460	moving around in different locations
1	d475	driving
37	d5	Self-Care
7	d510	washing oneself
5	d520	caring for body parts
1	d530	toileting
10	d540	dressing
2	d550	eating
1	d560	drinking
6	d570	looking after one's health
75	d6	Domestic Life
7	d620	Acquisition of goods and services
4	d630	preparing meals
31	d630-d649	Household tasks
27	d640	doing housework
7	d650	caring for household objects
22	d660	assisting others
102	d7	Interpersonal Interactions and Relationships
24	d710	basic interpersonal interactions
4	d720	complex interactions
73	d730-d779	Particular interpersonal relationships
26	d750	informal social relationships
21	d760	family relationships
26	d770	intimate relationships
31	d8	Major Life Areas
25	d840-d859	Work and employment
3	d850	remunerative employment
67	d9	Community, Social & Civic Life
8	d910	community life
56	d920	recreation and leisure
11	e1	Products and Technology
11	e115	products and technology for personal use in daily living
51	e3	Support and Relationships
4	e340	personal care providers and personal assistants
6	e4	Attitudes