Received: 11 April 2023 | Revised: 20 June 2023 | Accepted: 22 June 2023

DOI: 10.1002/pon.6188

WILEY

ORIGINAL ARTICLE

Content comparison of the EORTC CAT Core, SF-36, FACT-G, and PROMIS role and social functioning measures based on the International Classification of Functioning, Disability and Health

Micha J. Pilz[1] | Maria Rothmund[1,2] | Emma Lidington[3] | Claire Piccinin[4] | Juan I. Arraras[5] | Mogens Groenvold[6,7] | Bernhard Holzner[8] | Marieke van Leeuwen[9] | Morten Aa. Petersen[6] | Heike Schmidt[10] | Teresa Young[11] | Johannes M. Giesinger[1] | on behalf of the EORTC Quality of Life Group

[1]University Hospital of Psychiatry II, Innsbruck Medical University, Innsbruck, Austria

[2]Institute of Psychology, University of Innsbruck, Innsbruck, Austria

[3]Cancer Behavioural Science Unit, King's College London, Guy's Hospital, London, UK

[4]Quality of Life Department, EORTC, Brussels, Belgium

[5]Medical Oncology Department, Hospital Universitario de Navarra, Pamplona, Spain

[6]Palliative Care Research Unit, Bispebjerg/Frederiksberg Hospital, Copenhagen, Denmark

[7]Department of Public Health, University of Copenhagen, Copenhagen, Denmark

[8]University Hospital of Psychiatry I, Innsbruck Medical University, Innsbruck, Austria

[9]Division of Psychosocial Research & Epidemiology, The Netherlands Cancer Institute, Amsterdam, The Netherlands

[10]University Clinic and Outpatient Clinic for Radiotherapy and Institute of Health and Nursing Science, Medical Faculty of Martin Luther University Halle-Wittenberg, Halle (Saale), Germany

[11]Lynda Jackson Macmillan Centre, Mount Vernon Cancer Centre, Northwood, UK

Abstract

Objectives: In line with the World Health Organizations' health definition, patient-reported outcome (PRO) measures frequently cover aspects of social health. Our study aimed to evaluate the role functioning (RF) and social functioning (SF) contents assessed by PRO measures commonly used in cancer patients.

Methods: We analysed the item content of the SF and RF domains of the EORTC CAT Core, the EORTC QLQ-C30, the SF-36, and the FACT-G as well as the PROMIS item bank covering the Ability to Participate in Social Roles and Activities. Following an established methodology we linked item content to the International Classification of Functioning, Disability and Health (ICF) framework.

Results: The content of 85 items was assigned to three ICF components ('Activities and Participation', 'Body Functions', and 'Environmental Factors'). The EORTC CAT Core RF items were mostly related to the first-level ICF categories 'Domestic life' and 'Community, social and civic life', while its SF item bank focused on 'Interpersonal interactions and relationships'. These three categories were also covered by the PROMIS social participation item bank. The FACT-G Social/Family scale focused on environmental factors ('Support and Relationships' and 'Attitudes') while the SF-36 Role-physical/emotional scales had a stronger focus on 'General tasks and demands' and 'Major life areas'.

Conclusions: Our results highlight conceptual overlap and differences among PRO measures for the assessment of social health in cancer. This information may help

Correspondence
Johannes M. Giesinger, University Hospital of Psychiatry II, Innsbruck Medical University, Innsbruck, Austria.
Email: johannes.giesinger@i-med.ac.at

Funding information
European Organisation for Research and Treatment of Cancer Quality of Life Group, Grant/Award Number: #0112016

to select the most appropriate measure for a specific setting or study purpose and to better understand the possibilities of linking scores across different PRO measures.

KEYWORDS
cancer, content comparison, disability and health, health-related quality of life, international classification of functioning, oncology, patient-reported outcome, psycho-oncology, role functioning, social functioning

1 | BACKGROUND

The World Health Organization (WHO) defines health not merely as the absence of disease or infirmity but as a state of physical, mental and social well-being.[1] This broad perspective is also reflected in the WHO definition of health-related quality of life (HRQOL) that refers to the "individual's perception of their position in life [...] incorporating in a complex way individuals' physical health, psychological state, level of independence, social relationships, personal beliefs and their relationships to salient features".[2] The social aspect of health including the social roles of individuals is well recognised in both definitions and has also been highlighted in early publications on the use of HRQOL measures for the evaluation of health and treatment outcomes in cancer patients.[3–5]

For social health a number of conceptual models are available that differ with regard to the concepts included and distinguished.[6,7] Two domains that are commonly assessed in cancer patients are role functioning (RF) and social functioning (SF).[8] RF can be viewed as individual capacity to cope with environmental requirements, as interaction in social systems, or as capacity to cope with activities that are specific to age and social responsibility.[6] SF entails an individual's ability to adequately interact within a social network such as family, friends or working colleagues.[9] Further definitions describe the ability to develop and maintain social relationships as the main aspect of SF.[10]

The US Food and Drug Administration (FDA) acknowledges the importance of patients' ability to work and carry out daily activities and has consequently included RF in a recommended core set of patient-reported outcomes (PROs).[11] A recent systematic review showed that RF is sensitive to differences between treatment arms in cancer clinical trials, reflecting the impact of treatment burden and disease control on this domain.[12] The European Medicines Agency (EMA) acknowledges that the assessment of SF might provide important contextual information for primary endpoints in clinical trials, furthermore stating that SF is considered to be of importance to patients.[13] Both the EMA and FDA highlight the importance of using valid and reliable measures when assessing RF and SF.[11,13]

For the measurement of RF and SF in cancer patients several multidimensional PRO measures are available, such as the widely used EORTC QLQ-C30,[14] the FACT-G,[15] and the SF-36.[10] In addition, the PROMIS initiative has developed measures of social health including an item bank for the assessment of the ability to participate in social roles and activities.[16] The fairly new EORTC CAT Core[17,18] provides item banks that measure the same concepts as the RF and SF domains of the QLQ-C30. Whilst the availability of different measures may be an advantage when selecting the most appropriate instrument for a specific application, the differences regarding the underlying concepts and frameworks make comparisons of results from different measures challenging.

To facilitate comparison of results from studies that use different PRO measures but assess similar concepts, linking rules and common metrics have been developed. These rely on sophisticated statistical methods[19] to make scores comparable and allow data pooling and meta-analysis of trial data. However, such quantitative analysis need to be complemented by equally important qualitative evaluations allowing for a better understanding of conceptual differences and similarities across PRO measures as reflected by the content of their questions.[20]

The International Classification of Functioning, Disability and Health (ICF)[21] provides a structured framework, which has not only been used to develop conceptual models for RF and SF[6,22] but also to compare contents of PRO measures. The standard methodology for such comparisons follows the linking rules by Cieza et al.[23–25] that allow categorisation of item content in the ICF framework to investigate overlaps and discrepancies of different PRO measures.

The aim of our ongoing project[26,27] is to evaluate the possibilities to link scores from commonly used PRO measures in cancer research, with a focus on the EORTC CAT Core.[17] This work comprises a qualitative assessment of the content of the various measures to investigate conceptual (dis)similarities, followed by quantitative analyses on the actual linking of scores from these measures. Since such information is key for understanding conceptual differences between PRO measures, the objective of this study was to compare the item content of the RF and SF domains of the following frequently used PRO measures using the ICF framework[28] and the methodology established by Cieza et al.[23–25]

- EORTC CAT Core: RF and SF item banks
- EORTC QLQ-C30: RF and SF scales
- SF-36: Social Function, Role-Physical, and Role-Emotional scales
- PROMIS Item Bank v2.0 - Ability to Participate in Social Roles and Activities
- FACT-G Social/Family and Functional Well-being scales

The selection of the PRO instruments was based on their frequent use in cancer clinical trials[8] and their content coverage of RF and SF domains.

2 | METHODS

2.1 | Comparator measures for role and social function

2.1.1 | EORTC CAT core and EORTC QLQ-C30: Social and role functioning scales

The EORTC CAT Core[17,18] provides comprehensive item banks allowing for fully compatible assessment of the symptom and functional health domains of the EORTC QLQ-C30.[14] While the EORTC QLQ-C30, the most widely used PRO measure in clinical cancer research,[8] includes two items to assess each of the domains RF and SF, the EORTC CAT Core item banks comprise 13 SF and 10 RF items. The EORTC RF domain assesses items on limitations in work, daily activities, and hobbies, while the SF domain covers family life and social activities.

Similar to the ICF classification that differentiates between limitations in activity and restrictions in participation, the EORTC CAT Core RF item bank was designed to capture the limitations in activity, whereas the EORTC CAT Core SF item bank should capture the aspects of participation.[29] The EORTC CAT Core item banks and the EORTC QLQ-C30 have a 1-week recall period and use a 4-point rating scale as response format with categories ranging from 'Not at all' to 'Very much'.

2.1.2 | FACT-G: Social/Family Well-Being and Functional Well-Being scales

The Functional Assessment of Cancer Therapy Scale – General (FACT-G)[15] is a widely used PRO measure for the assessment of HRQOL in cancer patients. It comprises 27 items that form four scales: Physical-, Functional-, Emotional-, and Social/family Well-being. The six items of the Social/Family Well-being scale assess social support, family communication, and feeling close to significant others. The Functional Well-being scale consists of seven items related to work, quality of life, enjoyment, sleep quality, and acceptance of disease. All items have a 7-day recall period and are answered on a 5-point rating scale with response options ranging from "not at all" to "very much".

2.1.3 | PROMIS item bank v2.0 - Ability to participate in social roles and activities

The PROMIS initiative has developed several PRO measures to assess social function and social relationships,[30] which are intended to assess patients with chronic diseases and are not specific to cancer patients.[31] For this analysis we selected the PROMIS item bank Ability to Participate in Social Roles and Activities 2.0, which was considered most likely to have the largest conceptual overlap with RF and SF.[32] This item bank comprises 35 items assessing limitations related to work, family, friends, and recreational activities. The questions have no specific recall period and are answered on a 5-point rating scale with response categories from "Never" to "Always".

2.1.4 | SF-36: Social function, role-emotional, and role-physical scales

The SF-36 is a generic HRQOL instrument[10,33] comprising 36 items. It includes three scales for the assessment of RF and SF: Role-physical, Role-emotional, and Social function. The 3-item Role-emotional scale assesses limitations in work or other activities due to emotional problems, and the 4-item Role-physical scale covers limitations arising from physical problems. The 2-item SF scale assesses the interference of physical or emotional problems with social activities. The response format is a 5-point rating scale ranging from "All of the time" to "None of the time" for the Role-emotional/physical scale, and from "Not at all" to "Extremely" for the SF scale. The recall period is 4 weeks.

2.1.5 | Linking of item content to the ICF framework

In 2001, the WHO introduced the International Classification of Functioning, Disability and Health.[21] It provides a standardised framework to depict health states and health-related well-being. The ICF Framework consists of two main parts. The first part covers functions and disabilities and includes the components (b) body functions, (d) activities and participation and (s) body structures. The second part refers to contextual aspects of the classification of health states and consists of the component I environmental factors. Within each component, the hierarchical structure of the ICF provides further classification levels that are presented with alphanumerical codes. The above letters describing the component are followed by a single-digit number indicating the chapter (first-level category), a two-digit number referring to the second-level categories and a further single-digit number defining the third-level category. An example of the hierarchical structure of the ICF categorisation is provided in Table 1.

To link the item content of the PRO measures under investigation to the respective ICF categories we relied on the methodological approach proposed by Cieza et al.[23–25] First, all meaningful concepts of an item are identified. Each of these meaningful concepts are then linked to the corresponding ICF category, that is, one or more specific ICF codes are assigned to the item. Note that an item may be linked to more than one ICF category if more than one meaningful concept is covered by the item content. Cieza et al.[23–25] acknowledged that some meaningful concepts cannot be linked to a specific ICF category. They suggest the following coding in these instances: 'not covered' (nc) for item content beyond the ICF coverage (e.g. quality of life) and for content such as 'health condition' (specific diagnosis) 'personal factors' such as age, gender, or race, which are part of the contextual factors but lack specification; and 'not definable' (nd) if an

TABLE 1 Examples of the hierarchical structure of the International Classification of Functioning, Disability and Health (ICF) categories (World Health Organization (WHO), 2001).

b	Body functions	Component
b1	Mental functions	First level (chapter)
b152	Emotional functions	Second level
b1528	Emotional functions, other specified	Third level
d	**Activities and participation**	**Component**
d7	Interpersonal interactions and relationships	First level (chapter)
d750	Informal social relationships	Second level
d7500	Informal relationships with friends	Third level
d	**Activities and participation**	**Component**
d8	Major life areas	First level (chapter)
d845	Acquiring, keeping and terminating a job	Second level
d8451	Maintaining a job	Third level
e	**Environmental factors**	**Component**
e3	Support and relationships	First level (chapter)
e320	Friends	Second level
-	-	Third level[a]

[a]No third level category is available for the component environmental factors.

item is too broad for a specific category or lacks adequate information (e.g. general health)

For this study, the item content of each HRQOL measure was linked to the respective ICF categories independently by two reviewers, following the described linking procedure. Disagreements between the codings were discussed by the reviewers, and a third reviewer helped to find consensus, if needed. Interrater agreement is provided as total agreement (%) on the second level.

Following this linking process, we descriptively analysed the number of items linked to ICF categories and the number of items not being covered by the ICF for each HRQOL measure under consideration. Furthermore, to facilitate the content comparison across PRO measures, we determined the percentage of meaningful concepts coded in each first-level category separately for each PRO measure. Codings for the item stems (e.g. "Has your physical condition or medical treatment interfered with"…) and the codings "not covered" and "not definable" were not considered for calculating the percentages for comparisons of measures. Please note, that a single item could contain meaningful concepts from more than one ICF category, thus the total number of codings was higher than the total number of items.

3 | RESULTS

Across the five PRO measures, with altogether 10 scales or item banks under investigation, 85 items were assigned to three components ('b – Body Functions', 'd – Activities and Participation', and 'e – Environmental Factors'), to 10 different first-level categories, to 24 second-level categories, and to 32 third-level categories. In total, 21 concepts were categorised as 'not definable' while 16 concepts were rated as 'not covered'. Comparison of the characteristics of the PRO measures under investigation are shown in Table 2.

All 10 items of the EORTC CAT Core RF item bank were assigned to the component 'd – Activities and Participation', while one item additionally was found to cover an aspect of 'e – Environmental Factors'. Overall, six different first-level categories were covered: 'd2 General tasks and demands' (two codings, 9%), 'd4 Mobility' (one coding, 4%), 'd6 Domestic life' (seven codings, 30%), 'd8 Major life areas' (five codings, 22%), 'd9 Community, social and civic life' (seven codings, 30%), and 'e3 Support and relationships' (one coding, 4%). The most frequently coded second-level categories were 'd920 Recreation and leisure' and 'd640 Doing housework'.

The 2-item QLQ-C30 RF scale was found to cover three first-level categories, all within the component 'd Activities and participation': 'd2 General tasks and demands' (one coding, 25%), 'd8 Major life areas' (one coding, 25%), and 'd9 Community, social and civic life' (two codings, 50%).

The 13 items of the EORTC CAT Core SF item bank were assigned to the component 'b Body functions' (with four second-level codings, 17% in 'b152 Emotional functions') and to 'd Activities and Participation'. Within the latter, the item bank was found to cover 'd7 Interpersonal interactions and relationships' (18 codings, 75%) and 'd9 Community, social and civic life' (two codings, 8%). The most frequent second-level categories within the component 'd Activities and participation' were 'd760 Family relationships' and 'd750 Informal social relationships'. For all items the item stem referring to "physical condition or medical treatment" was rated as 'not covered'

TABLE 2 Comparison of the characteristics of the patient-reported outcome (PRO) measures under investigation.

	EORTC CAT core RF item bank	EORTC QLQ-C30 RF scale	EORTC CAT core SF item bank	EORTC QLQ-C30 SF scale	SF-36 RP scale	SF-36 RE scale	SF-36 SF scale	FACT-G Social/Family well-being	FACT-G Functional well-being	PROMIS item bank Ability to participate in social roles and activities
Number of items in questionnaire	10	2	13	2	4	3	2	7	7	35
Number of items that are covered by ICF categories	10	2	13	2	4	3	2	7	7	35
Number of unique first -level ICF categories	6	3	3	2	2	3	3	5	4	5
Number of unique second-level ICF categories[a]	9	3	5	2	2	3	4	10	5	9
Number of unique third-level ICF categories	13	3	5	2	2	3	6	5	4	10
Total number of third-level ICF categories assigned to items	23	4	24	2	9	10	10	11	11	62

[a]For second-level categories that do not include third-level categories in the ICF framework, we counted the number of second-level categories.

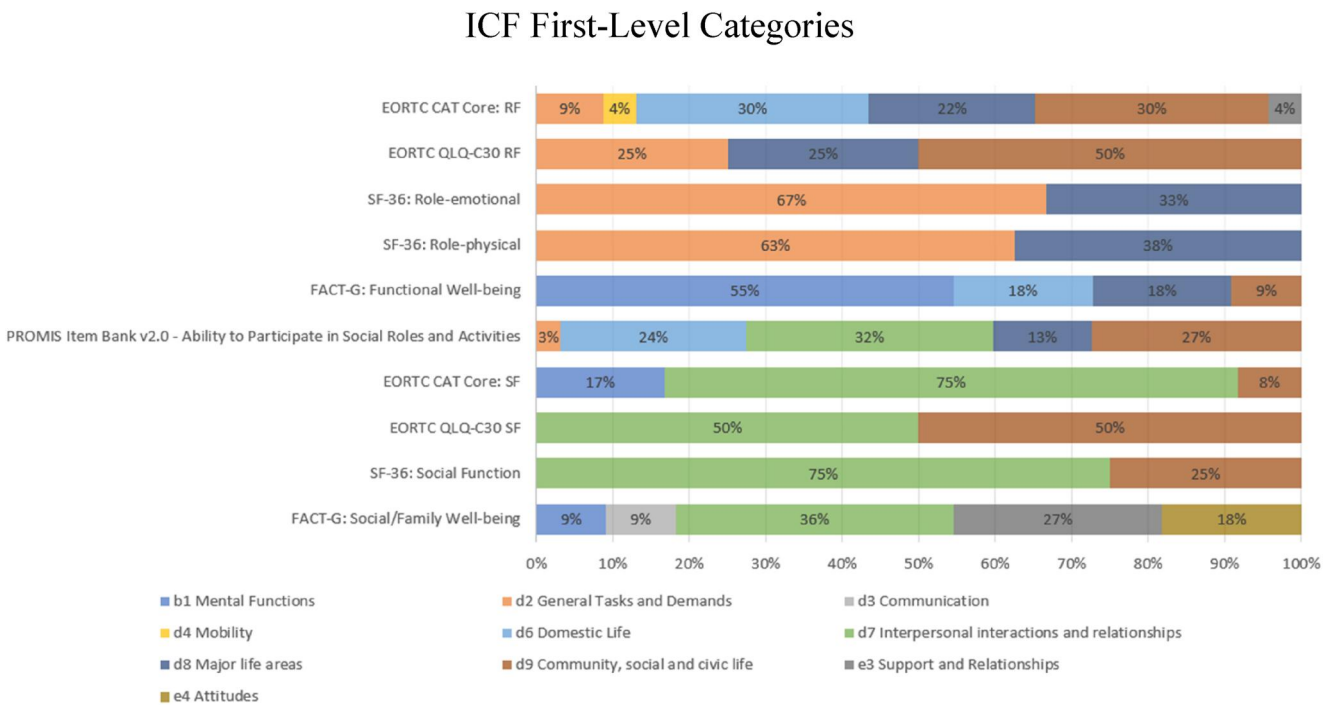

FIGURE 1 Percentages of first-level categories represented for the patient-reported outcome (PRO) measures under investigation (Please note that codings for the item stems and the categories "not covered" and "not definable" were not included in this figure and for calculating the percentages).

(medical treatment) and 'not definable' (physical condition). The 2-item QLQ-C30 SF scale was found to cover two first-level categories in the component 'd Activities and participation': 'd7 Interpersonal interactions and relationships' and 'd9 Community, social and civic life' (one coding, 50% each). Again, the item stem referring to "physical condition or medical treatment" was rated as 'not definable' and 'not covered'.

The 7-item FACT-G Social/Family Well-being scale were found to cover categories in the components 'b Body Functions', 'd Activities and Participation' and 'e Environmental factors'. The following first-level categories were assigned to the items: one coding (9%) in 'b1 Mental functions', one coding (9%) in 'd3 Communication', four codings (36%) in 'd7 Interpersonal interactions and relationships', three codings (27%) in 'e3 Support and relationships' and 2 codings (18%) in 'e4 Attitudes'. The 7-item Functional Well-being scale had codings in 'b – Body Functions' (six codings, 55% in 'b1 Mental functions') and 'd – Activities and Participation' (two codings, 18% in 'd6 Domestic life', tow codings, 18%in 'd8 Major life areas', and one coding, 9% in 'd9 Community, social and civic life').

The 35 items of the PROMIS item bank 2.0 Ability to participate in social roles and activities were all assigned to 'd Activities and participation' and were found to cover five different first-level categories: 'd2 General tasks and demands' (two coding, 3%), 'd6 Domestic life' (15 codings, 24%), 'd7 Interpersonal interactions and relationships' (20 codings, 32%), 'd8 Major life areas' (8 codings, 13%), and 'd9 Community, social and civic life' (17 codings, 27%). The most frequent second-level categories were 'd920 Recreation and leisure', 'd640 Doing housework', 'd750 Informal relationships', and 'd760 Family relationships'.

For the SF-36, the 3-item Role-emotional scale had four codings (67%) in 'd2 General tasks and demands', and three codings (33%) in 'd8 Major life areas'. The 4-item Role-physical scale was assigned to 'd2 General tasks and demands' (five codings, 63%) and 'd8 Major life areas' (threecodings, 38%). Furthermore, the item stem referring to "physical health" was coded as 'not definable'. The 2-item SF scale covered 'd7 Interpersonal interactions and relationships' (six codings, 75%) and 'd9 Community, social and civic life' (with two codings, 25%).

Please note that these percentages are based on the total number of ICF codings excluding the codings "not covered" and "not definable". Further details regarding content comparisons of the PRO measures are shown in Figure 1. Further details regarding first-, second-, and third-level ICF codings for all PRO measures under investigation are shown in Table 3. The interrater agreement was 76% (57 out of 75 items) whereby for the remaining 18 items a third reviewer was consulted to resolve the conflict.

4 | DISCUSSION

We compared the item content of 10 scales and item banks assessing RF and SF from five PRO measures commonly used in cancer patients, the EORTC CAT Core, the EORTC QLQ-C30, the FACT-G, the SF-36 and the PROMIS measure assessing the Ability to Participate in Social Roles and Activities. Relying on the ICF framework, we

TABLE 3 First-, second and third-level categories of the International Classification of Functioning, Disability and Health (ICF) represented for the patient-reported outcome (PRO) measures under investigation.

ICF categories	EORTC CAT core	EORTC QLQ-C30	EORTC CAT core	EORTC QLQ-C30	SF-36	SF-36	SF-36	FACT-G	FACT-G	PROMIS item bank
Component										
First level	RF item bank	RF scale	SF item bank	SF scale	Role-physical scale	Role-emotional scale	SF scale	Social/Family well-being	Functional well-being	Ability to participate in social roles and activities
Second level										
Third level										
b - Body functions	**0**	**0**	**4**	**0**	**0**	**3**	**2**	**1**	**6**	**0**
b1 Mental functions			4			3	2	1	6	
b134 Sleep functions									1	
b1343 Quality of sleep									1	
b152 Emotional functions			4			3	2	1	5	
b1528 Emotional functions, other specified			4			3		1	5	
b1529 Emotional functions, unspecified							2			
d - Activities and participation	**22**	**4**	**20**	**2**	**9**	**7**	**8**	**5**	**5**	**62**
d2 General tasks and demands	2	1			5	4				2
d230 Carrying out daily routine	2	1			5	4				1
d2301 Managing daily routine	1									
d2303 Managing one's own activity level					1	1				
d2309 Carrying out daily routine, unspecified	1	1			4	3				1
d240 Handling stress and other psychological demands										1
d2400 Handling responsibilities										1
d3 Communication								1		
d350 Conversation								1		
d3508 Conversation, other specified								1		
d4 Mobility	1									
d455 Moving around	1									
d4554 Swimming	1									

TABLE 3 (Continued)

ICF categories	EORTC CAT core	EORTC QLQ-C30	EORTC CAT core	EORTC QLQ-C30	SF-36	SF-36	SF-36	FACT-G	FACT-G	PROMIS item bank
d6 Domestic life	7								2	15
d640 Doing housework	5								2	9
d6402 Cleaning living area	2									
d6403 Using household appliances	1									
d6408 Doing housework, other specified	2									
d6409 Doing housework, unspecified									2	9
d649 Household tasks, other specified and unspecified	1									
d650 Caring for household objects	1									
d6501 Maintaining dwelling and furnishings	1									
d660 Assisting others										6
d6608 Assisting others, other specified										1
d6609 Assisting others, unspecified										5
d7 Interpersonal interactions and relationships			18	1			6	4		20
d720 Complex interpersonal interactions			1							
d7200 Forming relationships			1							
d750 Informal social relationships			8				4	1		9
d7500 Informal relationships with friends			8				2	1		9
d7501 Informal relationships with neighbours							2			
d760 Family relationships			9	1			2			9
d7608 Family relationships, other specified							1			
d7609 family relationships, unspecified			9	1			1			9
d770 Intimate relationships								2		
d7702 Sexual relationships								1		
d7709 Intimate relationships, unspecified								1		
d779 Particular interpersonal relationships, other specified and unspecified								1		2

(Continues)

TABLE 3 (Continued)

ICF categories	EORTC CAT core	EORTC QLQ-C30	EORTC CAT core	EORTC QLQ-C30	SF-36	SF-36	SF-36	FACT-G	FACT-G	PROMIS item bank
d8 Major life areas	5	1			4	3			2	8
d859 Work and employment, other specified and unspecified	2	1			4	3			2	8
d860 Basic economic transactions	3									
d9 Community, social and civic Life	7	2	2	1			2		1	17
d920 Recreation and leisure	7	2	2	1			2		1	17
d9200 Play	1									
d9201 Sports	1									
d9202 Arts and culture	1									
d9204 Hobbies	1	1								
d9205 Socializing										2
d9208 Recreation and leisure, other specified	2									4
d9209 Recreation and leisure, unspecified	1	1	2	1			2		1	11
e - Environmental factors	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**5**	**0**	**0**
e3 Support and relationships	1							3		
e310 Immediate family								1		
e315 Extended family								1		
e320 Friends								1		
e399 Support and relationships, unspecified	1									
e4 Attitudes								2		
e410 Individual attitudes of immediate family members								1		
e415 Individual attitudes of extended family members								1		
Not Defined			13	2	4		2			
Not covered			13	2					1	

found that a large majority of items were linked to ICF categories within the component 'd - Activities and participation', mostly covering 'd6 Domestic life', 'd7 Interpersonal interactions and relationships', 'd8 Major life areas' and 'd9 Community, social and civic life'.

Comparing the item content coded in the ICF categories, we found that the EORTC CAT Core RF item bank consisted mostly of the content in the first-level category 'd6 – Domestic Life' and 'd9 – Community, social and civic life'. The FACT-G Functional Well-being scale covered mostly 'b1 Mental functions', 'd6 Domestic Life' and 'd8 Major life areas'. For the SF-36 Role-Emotional scale 'd2 General Tasks and Demands' was the most common first-level category, followed by 'd8 Major Life Areas'. The SF-36 Role-Physical scale consisted as well of content from 'd2 General Tasks and Demands' and 'd8 Major Life Areas'. The PROMIS Ability to Participate in Social Roles and Activities covered predominantly 'd7 Interpersonal interactions and relationships', 'd9 – Community, social and civic life', and 'd6 Domestic Life'.

For the SF measures, we had similar heterogeneous observations. Whereas the FACT-G Social/Family Well-being scale consisted mainly of content in 'd7 Interpersonal interactions and relationships', 'e3 Support and Relationships', and 'e4 Attitudes'. The EORTC CAT Core SF item bank focused mainly on 'd7 Interpersonal interactions and relationships' and 'b1 Mental Functions', and the SF-36 SF scale covered, aspects within 'd7 Interpersonal interactions and relationships' and 'd9 Community, social and civic life'. For the EORTC measures, our analysis provides further evidence for the conceptual distinctness of RF and SF. The EORTC CAT Core SF item bank was found to cover primarily 'd7 Interpersonal interactions and relationships', while the RF item bank covered mostly 'd6 Domestic life', 'd9 – Community, social and civic life', and 'd8 Major life areas'. In more detail, the most frequent second-level categories for SF were 'd670 Family relationships' and 'd750 Informal social relationships', while for RF this was 'd920 Recreation and leisure' and 'd640 Doing housework'. There was (some) content overlap between the QLQ-C30 RF and SF scales, but between the corresponding EORTC CAT Core item banks, this overlap was less pronounced. Moreover, quantitative analyses of scale structure have confirmed the distinctness of the two concepts in the QLQ-C30.[34,35]

The PROMIS Ability to Participate in Social Roles and Activities item bank was found to cover 'd7 Interpersonal interactions and relationships', 'd6 Domestic Life' and 'd9 Community, social and civic life' to a similar extent, with the most frequent second-level categories being 'd920 Recreation and leisure', 'd640 Doing housework', 'd750 Informal social relationships', 'd760 Family relationships', and 'd859 Work and employment, other specified and unspecified'. The combination of these categories in a single item bank shows the broader perspective on social health taken by PROMIS[16] which distinguishes social function and social relationships, but not RF and SF as the EORTC measures do. In the PROMIS model, the content of the Ability to Participate in Social Roles and Activities item bank is considered to cover SF specifically.

For the FACT-G our results corroborate previous findings[36,37] that highlighted the conceptual differences between the FACT-G and EORTC approach to measuring social health. The Functional Well-being scale was found to include quite heterogenous content ranging from 'b Body Functions' (sleep and emotional function) to 'd Activities and participation'. The FACT-G Social/Family Well-being scale was the only scale included in this analysis that also covered environmental factors (besides one coding for the EORTC CAT RF scale), that is, 'e3 Support and Relationships' and 'e4 Attitudes' (of people other than the patient). This finding supports the previous recommendation by Luckett et al.[38] to use the QLQ-C30 if the research focus is on social activities and to rely on the FACT-G if relationships and support are of interest.

In contrast to the broader PROMIS approach to measuring social health, the SF-36 not only distinguishes social and RF, but also further separates a role-emotional and role-physical domain. Compared to the EORTC and the PROMIS measures, the SF-36 role domains were found to focus more on 'd2 General tasks and demands' and 'd8 Major Life areas', whereas the SF-36 social function scale, with its focus on 'd7 Interpersonal interactions and relationships' and 'd9 Community, social, and civic life', was more congruent with the PROMIS item bank and the EORTC SF domain.

While the ICF framework has been used frequently in the literature for the analysis of item content of PRO measures, our study presents the first such analysis for the EORTC CAT Core item banks for RF and SF and provides a content comparison against other common PRO measures used in cancer patients. For the PROMIS item banks, Tucker et al.[39] provided a comprehensive analysis mapping the PROMIS measures on ICF categories, and their results largely align with ours. The comparability with other content analyses of PRO measures in cancer patients is limited, because results were usually not reported per subscale, but only for the overall questionnaires.[40,41]

Our study clearly confirms that the differences in content assessed by PRO measures reflect the heterogeneity of the underlying concepts of social health. This heterogeneity has also been discussed by Hahn et al.[16] who related it to the fact that social health has been less a focus of outcome measurement than the physical and emotional domains. These authors also emphasised that not all social factors are necessarily outcomes. Depending on the type of intervention being evaluated, a concept such as social support may provide contextual information or may be considered as effect modifier rather than serving as an informative outcome parameter. However, SF assessed with the EORTC QLQ-C30 has been shown to differ frequently between treatment arms in cancer trials,[12] suggesting that aspects of social health can be important outcome parameters in clinical trials.

Given the diversity of social health models and measures we argue that a detailed analysis of scale (and item bank) content is especially important to better understand what is being measured and how different PRO measures may be different or similar. It is important to bear in mind though that our comparison relies on the social health model of the ICF framework, and its hierarchical

structure determines how content is mapped. Applying other models may lead to conclusions regarding (dis)similarities of PROs that are not fully consistent with our analysis.

4.1 | Study limitations

A limitation of our study is that the selection of PRO measures included in our study was based on their common use in cancer research but did not follow a more systematic approach for identifying a larger number of such measures. In particular, PROMIS offers a number of additional measures for other social health aspects that were not included in this analysis (e.g. PROMIS item banks for Emotional Support, Satisfaction with Social Roles and Activities, or Social Isolation[30]). Furthermore, we would like to highlight that our content analysis does not provide information about the content validity of the measures in the cancer patient population, which would require a different methodological approach.[42]

4.2 | Clinical implications

The PRO measures, included in this analysis, are frequently used in clinical practice to monitor RF and SF of cancer patients. The various names given to questionnaires and their subscales can make it difficult to understand the precise concepts being evaluated by each PRO measure. Our analysis and results inform the selection of PRO measures in clinical practice and offer a detailed understanding of the measured content and underlying concepts. This makes it easier to decide which PRO measure would be best suited for a certain clinical situation. Additionally, this information aids to interpret the obtained scores from the domains and to contextualise it regarding the underlying measured concept.

5 | CONCLUSION

In conclusion, the results from our analysis highlight conceptual differences between PRO measures for RF and SF and provide insight into the content covered by each measure. Such information on the concepts covered by the PRO measures may help to select the most appropriate measure for a specific application, and may also support item selection when creating static short-forms from item banks[43] or implementing content balancing in computer-adaptive assessments.[44] Furthermore, our results will inform the development of possible linking procedures for score conversion of PRO measures for social and role function.

AUTHORS' CONTRIBUTIONS

MJP - Data acquisition, Analysis and Interpretation of Data, Drafting of manuscript, Statistical Analysis. MR - Data acquisition, Analysis and Interpretation of Data, Drafting of manuscript, Critical revision of the manuscript. EL - Data acquisition, Analysis and Interpretation of Data, Critical revision of the manuscript. CP - Data acquisition, Analysis and Interpretation of Data, Critical revision of the manuscript. JIA - Provision of study materials or patients, Administrative-technical or logistic support, Critical revision of the manuscript. MG - Provision of study materials or patients, Administrative-technical or logistic support, Critical revision of the manuscript. BH - Obtaining funding, Administrative-technical or logistic support, Critical revision of the manuscript. MvL - Analysis and Interpretation of Data, Provision of study materials or patients, Critical revision of the manuscript. MAP - Provision of study materials or patients, Administrative-technical or logistic support, Critical revision of the manuscript. HS - Provision of study materials or patients, Administrative-technical or logistic support, Critical revision of the manuscript. TY - Provision of study materials or patients, Administrative-technical or logistic support, Critical revision of the manuscript. JMG - Concept and design; Analysis and Interpretation of Data, Drafting of Manuscript, Supervision.

CONFLICT OF INTEREST STATEMENT

The authors declare no competing interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Not applicable.

ORCID

Micha J. Pilz https://orcid.org/0000-0003-4092-8797
Maria Rothmund https://orcid.org/0000-0002-5299-9165
Emma Lidington https://orcid.org/0000-0001-6176-8054
Claire Piccinin https://orcid.org/0000-0002-3918-1174
Juan I. Arraras https://orcid.org/0000-0002-4415-2570
Mogens Groenvold https://orcid.org/0000-0002-3153-780X
Bernhard Holzner https://orcid.org/0000-0002-3389-3621
Marieke van Leeuwen https://orcid.org/0000-0003-1976-5831
Morten Aa. Petersen https://orcid.org/0000-0002-3117-632X
Heike Schmidt https://orcid.org/0000-0002-0922-4022
Teresa Young https://orcid.org/0000-0003-0367-2980
Johannes M. Giesinger https://orcid.org/0000-0003-2744-5950

REFERENCES

1. World Health Organisation. *Constitution of the World Health Organisation*. New York; 1946.
2. WHO. The World health organization quality of life assessment (WHOQOL): position paper from the World health organization. *Soc Sci Med*. 1995;41(10):1403-1409.
3. Aaronson NK. Methodologic issues in assessing the quality of life of cancer patients. *Cancer*. 1991;67(3):844-850. https://doi.org/10.1002/1097-0142(19910201)67:3+<844::aid-cncr2820671416>3.0.co;2-b

4. Moinpour CM, Feigl P, Metch B, Hayden KA, Meyskens FL, Jr, Crowley J. Quality of life end points in cancer clinical trials: review and recommendations. *J Natl Cancer Inst*. 1989;81(7):485-495. https://doi.org/10.1093/jnci/81.7.485
5. Roila FCE, Cortesi E. Quality of life as a primary end point in oncology. *Ann Oncol*. 2012;12(3):3-6. https://doi.org/10.1093/annonc/12.suppl_3.s3
6. Anatchkova MDBJB, Bjorner JB. Health and role functioning: the use of focus groups in the development of an item bank. *Qual Life Res*. 2010;19(1):111-123. https://doi.org/10.1007/s11136-009-9570-3
7. Goodman SH, Sewell DR, Cooley EL, Leavitt N. Assessing levels of adaptive functioning: the role functioning scale. *Community Ment Health J*. 1993;29(2):119-132. https://doi.org/10.1007/bf00756338
8. Giesinger JM, Efficace F, Aaronson N, et al. Past and current practice of patient-reported outcome measurement in randomized cancer clinical trials: a systematic review. *Value Health*. 2021;24(4):585-591. https://doi.org/10.1016/j.jval.2020.11.004
9. Bosc M. Assessment of social functioning in depression. *Compr Psychiatr*. 2000;41(1):63-69. https://doi.org/10.1016/s0010-440x(00)90133-0
10. Ware JE, Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care*. 1992;30(6):473-483. https://doi.org/10.1097/00005650-199206000-00002
11. U.S. Department of Health and Human Servicess, Food and Drug Administration. *Core Patient-Reported Outcomes in Cancer Clinical Trials: Guidance for Industry*. Silver Spring; 2021.
12. Giesinger JM, Blazeby J, Aaronson NK, et al. Differences in patient-reported outcomes that are most frequently detected in randomized controlled trials in patients with solid tumors: a pooled analysis of 229 trials. *Value Health*. 2020;23(5):666-673. https://doi.org/10.1016/j.jval.2020.02.007
13. European Medicines Agency. *Reflection Paper on the Use of Patient Reported Outcome (PRO) Measures in Oncology Studies*. London; 2014.
14. Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst*. 1993;85(5):365-376. https://doi.org/10.1093/jnci/85.5.365
15. Cella DF, Tulsky DS, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *J Clin Oncol*. 1993;11(3):570-579. https://doi.org/10.1200/jco.1993.11.3.570
16. Hahn EA, Devellis RF, Bode RK, et al. Measuring social health in the patient-reported outcomes measurement information system (PROMIS): item bank development and testing. *Qual Life Res*. 2010;19(7):1035-1044. https://doi.org/10.1007/s11136-010-9654-0
17. Petersen MA, Aaronson NK, Arraras JI, et al. The EORTC CAT Core - The computer adaptive version of the EORTC QLQ-C30 questionnaire. *Eur J Cancer*. 2018;100:8-16. https://doi.org/10.1016/j.ejca.2018.04.016
18. Petersen MA, Aaronson NK, Conroy T, et al. International validation of the EORTC CAT Core: a new adaptive instrument for measuring core quality of life domains in cancer. *Qual Life Res*. 2020;29(5):1405-1417. https://doi.org/10.1007/s11136-020-02421-9
19. Choi SW, Lim S, Schalet BD, Kaat AJ, Cella D. PROsetta: an R package for linking patient-reported outcome measures. *Appl Psychol Meas*. 2021;45(5):386-388. https://doi.org/10.1177/01466216211013106
20. Kolen MJ, Brennan RL. *Statistics for Social and Behavioral Sciences: Test Equating, Scaling, and Linking; Methods and Practices*. 3rd ed. Springer; 2014.
21. World Health Organisation. *International Classification of Functioning*. disability and health ICF; 2001.
22. Badley EM. Enhancing the conceptual clarity of the activity and participation components of the international classification of functioning, disability, and health. *Soc Sci Med*. 2008;66(11):2335-2345. https://doi.org/10.1016/j.socscimed.2008.01.026
23. Cieza A, Brockow T, Ewert T, et al. Linking health-status measurements to the international classification of functioning, disability and health. *J Rehabil Med*. 2002;34(5):205-210. https://doi.org/10.1080/165019702760279189
24. Cieza A, Geyh S, Chatterji S, Kostanjsek N, Ustün B, Stucki G. ICF linking rules: an update based on lessons learned. *J Rehabil Med*. 2005;37(4):212-218. https://doi.org/10.1080/16501970510040263
25. Cieza A, Fayed N, Bickenbach J, Prodinger B. Refinements of the ICF Linking Rules to strengthen their potential for establishing comparability of health information. *Disabil Rehabil*. 2016;41(5):574-583. https://doi.org/10.3109/09638288.2016.1145258
26. Rothmund M, Pilz MJ, Egeter N, et al. Patient-reported outcome measures for emotional functioning in cancer patients: content comparison of the EORTC CAT Core, FACT-G, HADS, SF-36, PRO-CTCAE, and PROMIS instruments. *Psycho Oncol*. 2023;32:628-639. https://doi.org/10.1002/pon.6109
27. Schurr T, Loth F, Lidington E, et al. Patient-reported outcome measures for physical function in cancer patients: content comparison of the EORTC CAT Core, EORTC QLQ-C30, SF-36, FACT-G, and PROMIS measures using the International Classification of Functioning, Disability and Health. *BMC Med Res Methodol*. 2023;23(1):21. https://doi.org/10.1186/s12874-022-01826-z
28. Ustün TB, Chatterji S, Bickenbach J, Kostanjsek N, Schneider M. The International Classification of Functioning, Disability and Health: a new tool for understanding disability and health. *Disabil Rehabil*. 2003;25(11-12):11-12. https://doi.org/10.1080/0963828031000137063
29. Gamper EM, Petersen MA, Aaronson N, et al. Development of an item bank for the EORTC role functioning computer adaptive test (EORTC RF-CAT). *Health Qual Life Outcome*. 2016;14(1):72. https://doi.org/10.1186/s12955-016-0475-x
30. Northwestern University. HealthMeasures: transforming how health is measured. https://www.healthmeasures.net/
31. DeWalt DA, Rothrock N, Yount S, Stone AA. Evaluation of item candidates: the PROMIS qualitative item review. *Med Care*. 2007;45(5):12-21. https://doi.org/10.1097/01.mlr.0000254567.79743.e2
32. Hahn EA, DeWalt DA, Bode RK, et al. New English and Spanish social health measures will facilitate evaluating health determinants. *Health Psychol*. 2014;33(5):490-499. https://doi.org/10.1037/hea0000055
33. Ware JE. SF-36 health survey update. *Spine*. 2000;25(24):3130-3139. https://doi.org/10.1097/00007632-200012150-00008
34. Giesinger JM, Kieffer JM, Fayers PM, et al. Replication and validation of higher order models demonstrated that a summary score for the EORTC QLQ-C30 is robust. *J Clin Epidemiol*. 2016;69:79-88. https://doi.org/10.1016/j.jclinepi.2015.08.007
35. Gundy CM, Fayers PM, Groenvold M, et al. Comparing higher order models for the EORTC QLQ-C30. *Qual Life Res*. 2012;21(9):1607-1617. https://doi.org/10.1007/s11136-011-0082-6
36. Holzner B, Bode RK, Hahn EA, et al. Equating EORTC QLQ-C30 and FACT-G scores and its use in oncological research. *Eur J Cancer*. 2006;42(18):3169-3177. https://doi.org/10.1016/j.ejca.2006.08.016
37. Blazeby JM, Kavadas V, Vickery CW, Greenwood R, Berrisford RG, Alderson D. A prospective comparison of quality of life measures for patients with esophageal cancer. *Qual Life Res*. 2005;14(2):387-393. https://doi.org/10.1007/s11136-004-0622-4

38. Luckett T, King MT, Butow PN, et al. Choosing between the EORTC QLQ-C30 and FACT-G for measuring health-related quality of life in cancer clinical research: issues, evidence and recommendations. *Ann Oncol*. 2011;22(10):2179-2190. https://doi.org/10.1093/annonc/mdq721
39. Tucker CA, Escorpizo R, Cieza A, et al. Mapping the content of the patient-reported outcomes measurement information system (PROMIS®) using the international classification of functioning, health and disability. *Qual Life Res*. 2014;23(9):2431-2138. https://doi.org/10.1007/s11136-014-0691-y
40. Ģiga L, Pētersone A, Čakstiņa S, Bērziņa G. Comparison of content and psychometric properties for assessment tools used for brain tumor patients: a scoping review. *Health Qual Life Outcome*. 2019;19(1):234. https://doi.org/10.1186/s12955-021-01863-0
41. Tschiesner U, Rogers SN, Harréus U, Berghaus A, Cieza A. Content comparison of quality of life questionnaires used in head and neck cancer based on the international classification of functioning, disability and health: a systematic review. *Eur Arch Oto-Rhino-Laryngol*. 2008;265(6):627-637. https://doi.org/10.1007/s00405-008-0641-9
42. Terwee CB, Prinsen CAC, Chiarotto A, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. *Qual Life Res*. 2018;27(5):1159-1170. https://doi.org/10.1007/s11136-018-1829-0
43. Segawa E, Schalet B, Cella D. A comparison of computer adaptive tests (CATs) and short forms in terms of accuracy and number of items administrated using PROMIS profile. *Qual Life Res*. 2020;29(1):213-221. https://doi.org/10.1007/s11136-019-02312-8
44. Zheng Y, Chang CH, Chang HH. Content-balancing strategy in bifactor computerized adaptive patient-reported outcome measurement. *Qual Life Res*. 2013;22(3):491-499. https://doi.org/10.1007/s11136-012-0179-6

How to cite this article: Pilz MJ, Rothmund M, Lidington E, et al. Content comparison of the EORTC CAT Core, SF-36, FACT-G, and PROMIS role and social functioning measures based on the International Classification of Functioning, Disability and Health. *Psychooncology*. 2023;32(9):1372-1384. https://doi.org/10.1002/pon.6188