

ORIGINAL REPORT

ICF CORE SETS FOR LOW BACK PAIN: DO THEY INCLUDE WHAT MATTERS TO PATIENTS?

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Objective: To investigate whether the International Classification of Functioning Disability and Health (ICF) Core Sets for low back pain encompass the key functional problems of patients.

Design: Cross-sectional evaluation of patient-centred problems with low back pain.

Subjects: A total of 402 patients living in the UK recruited into a randomized clinical trial.

Methods: Patients with acute or subacute low back pain were asked to identify: (i) the one thing they find most difficult to do, and (ii) something they usually enjoyed but were unable to do because of their back pain. Two raters classified responses according to the ICF. Inter-rater agreement was measured using the kappa statistic. The response categories were examined for inclusion within the Core Sets.

Results: For question (i) above, agreement between raters was 323/397 (81%), kappa (95% confidence interval (95% CI)) = 0.78 (0.73–0.82). A total of 329 (83%) fell within the ICF Brief Core Set; all except 3 were contained within the Comprehensive Core Set. For question (ii) agreement was 290/312 (93%), kappa (95% CI) = 0.91 (0.87–0.95). Only 54 (17%) of these fell within the Brief Core Set; the 2 most chosen categories (recreation and leisure: d920; caring for household objects: d650) accounted for 70% of responses, and were not included. All except 2 responses were encompassed by the Comprehensive Core Set.

Conclusion: Addition of codes d920 and d650 to the low back pain Brief Core Set would significantly increase the inclusion rate in this cohort.

Key words: ICF, Core Sets, low back pain, outcome assessment.

J Rehabil Med 2007; 39: 353–357

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Submitted July 26, 2006; accepted December 27, 2006

INTRODUCTION

The development of the International Classification of Functioning, Disability and Health (ICF) under the auspices of the World Health Organization has been described as a landmark event for medicine and society (1–3). The ICF comprises 4 components – body functions, body structures, activities and participation, and environmental factors. Each of these is sub-

divided into chapters, and then split into categories, providing in excess of 1500 descriptors when taken to the fourth level. Health scientists and rehabilitation professionals in clinical practice and research have been among the first to recognize the potential of the ICF to improve clinical practice and to stimulate research with the aim of optimizing participation from both the individual and societal standpoint (4).

In order to overcome practical concerns relating to the sheer number of categories afforded within the ICF, the *Core Sets* project was initiated in 2001. The aim of this process was to make available a link between the salient ICF categories and specific conditions or diseases. The *Comprehensive ICF Core Sets* were created to provide “standards for multi-professional comprehensive assessment” and should include “the typical spectrum of problems in functioning in patients”. The *Brief ICF Core Sets* were intended to “serve as minimal standards for the assessment and reporting of functioning and health for clinical studies” (4).

The categories identified as most appropriate for the study and management of low back pain (LBP) were published in 2004 (5). Following preliminary studies including a Delphi exercise and a systematic review, 18 international experts from different backgrounds took part in a formal consensus process. The Comprehensive Core Set incorporates 78 second-level categories; comprising 19 from the component *body functions*, 5 from *body structures*, 29 from *activities and participation*, and 25 from *environmental factors*. The Brief Core Set (a sub-set of the above) includes a total of 35 second-level categories, with 10 on *body functions*, 3 on *body structures*, 12 on *activities and participation* and 10 on *environmental factors*.

If the Core Sets are to fulfil their intended purpose, then they must be relevant to the key everyday issues that patients with LBP encounter. We explored data collected during the course of a randomized controlled trial of physiotherapy interventions for LBP. The aim of this study was to investigate whether, in the real world, functional problems raised by these patients were included within the Core Sets.

METHODS

A total of 402 patients were recruited into a randomized clinical trial to compare the clinical effectiveness in primary care of a brief pain management programme delivered by physiotherapists with that of a programme of spinal manual physiotherapy in the treatment of non-specific LBP of between one week and 12 weeks duration. Favourable ethical opinion was gained from the North Staffordshire Local Research Ethics Committee

(project no. 1123), and the main findings of this trial were published in 2005 (6). The primary outcome was change in self-reported back pain related disability at 12 months. Within the baseline questionnaire were 2 individualized questions:

(i) *Because of your back pain, what one thing do you find the most difficult to do?*

This question was designed to give the trial participants the opportunity to identify the aspect of their own lives in which they encountered most difficulty caused by their back pain. The responses were unprompted, without referral to a pre-constructed list of common activities or by suggestions from the researcher undertaking the assessment.

(ii) *Is there one thing that you really enjoy doing usually that you are unable to do at the moment, because of your back pain?*
(Yes/No)

Those who responded “Yes” were then asked the supplementary question – *What is this thing that you enjoy and can't do at the moment?*

This question was designed to give the trial participants the opportunity to identify a single activity that they would usually enjoy, but were unable to do at that time because of back pain. Again, the responses were unprompted, without referral to a pre-constructed list of common activities or by suggestions from the researcher.

The activities identified by patients in questions (i) and (ii) were recorded as free text. The key components were extracted, and 2 independent raters (RM and JB) classified each response according to the ICF framework. Where possible, these classifications were made to the third level. Inter-rater agreement between the 2 sets of classification was measured using the kappa statistic. Where the original independent classifications differed, discussion took place aimed at gaining consensus between the 2 raters. Where consensus could not be achieved, an experienced third rater was called upon to adjudicate. In order to map the responses directly onto the Core Sets for LBP, the response categories were taken back to level 2. These were then checked for inclusion within the Core Sets.

RESULTS

An overview of the characteristics of the patients in this cohort can be seen in Table I.

In response to question (i), 397 patients were able to identify the specific activity or task made most difficult by back pain. After independent classification, agreement between the 2 raters was 323/397 (81.4%), kappa (95% confidence interval (95% CI)) = 0.78 (0.73–0.82). Following a consensus meeting, agreement was achieved on 379/397 (95.5%) responses, with the remaining 18 items being classified through discussion with the adjudicator. Many patients reported similar problems, with 385 items (94.8%) classifiable as “activities and participation” (labelled *d*) on the ICF. Sleeping (reported 12 times) falls within the “bodily functions” dimension (labelled *b*). Of the 397 responses where a task was identified, 329 (82.9%) fell within the ICF Brief Core Set for LBP, and all but 3 (“caring for body parts” (d520) which occurred twice, and “carrying out daily routine” (d230)) were contained within the Comprehensive Core Set.

In response to question (ii), 312 patients were able to identify an activity that they would usually enjoy but were unable to do so because of their back pain. After independent classification, agreement between the 2 raters was 290/312 (92.9%), kappa (95% CI) = 0.91 (0.87–0.95). Following a consensus meeting,

Table I. Baseline characteristics of the 402 participants with low back pain.

Characteristic	Category	Summary ^a
Age, mean (SD)	–	40.6 (11.8)
Gender	Female	210 (52.2)
	Male	192 (47.8)
Employment status	Working in a paid job	184 (45.8)
	Employed but off sick	110 (27.4)
	Unemployed	20 (5.0)
	House-wife/husband	27 (6.7)
	Student	11 (2.7)
	Retired	19 (4.7)
	Other	31 (7.7)
Days off work	None	89 (30.3)
	< 7 days	141 (48.0)
	1–4 weeks	53 (18.0)
	1–3 months	11 (3.7)
Socio-economic classification (7)	Professional	78 (19.9)
	Intermediate	78 (19.9)
	Routine/manual	235 (60.2)
Start of back pain	0–7 days	84 (20.9)
	8–14 days	88 (21.9)
	15 days – 1 month	127 (31.6)
	1–2 months	62 (15.4)
	2–3 months	41 (10.2)
Widespread pain (8)	No	350 (87.1)
	Yes	52 (12.9)
VAS – pain (today), mean (SD)	–	55.6 (23.1)
VAS – pain (average past week), mean (SD)	–	69.1 (20.8)
Days of back pain	Some days	65 (16.2)
	Every day	337 (83.8)
Daily status of back pain	Part of the day	148 (36.8)
	All day	254 (63.2)
Previous episode(s) of low back pain	No	106 (26.4)
	Yes	296 (73.6)
Roland Morris (9) disability score, mean (SD) ^b	–	13.5 (4.9)
Perceived general health	Excellent	32 (8.0)
	Very good	137 (34.1)
	Good	173 (43.0)
	Fair	50 (12.4)
	Poor	10 (2.5)
Any longstanding illness	No	278 (69.3)
	Yes	123 (30.7)

^aSummary measure is frequency count (percentage) unless stated otherwise. Counts do not always sum to 402 because of some missing data.

^bScores ranged from a maximum disability of 23 to a minimum of 2. SD: standard deviation; VAS: visual analogue scale.

agreement was achieved on 306/312 (98.1%) responses, with the remaining 6 items being classified through discussion with the adjudicator. The majority of items were classifiable as activities and participation on the ICF. Of the 312 responses where an activity was identified, only 54 (17.3%) fell within the ICF Brief Core Set for LBP. All of the remainder except for 2 (“carrying out daily routine” (d230)) were encompassed by the Comprehensive Core Set.

Table II shows the frequency counts of the responses to both questions at ICF classification level 2.

Table II. Frequency of patient identified "most difficult task" and "usual activity unable to enjoy" because of back pain (classified to ICF level 2) within the Activities and Participation component of the ICF.

ICF Code	Description	Q(i) Most difficult		Q(ii) Usual activity	
		Frequency	%	Frequency	%
d230	Carrying out daily routine	1	0.3	2	0.6
d240*	Handling stress / psychological demands	0	0.0	0	0.0
d410*	Changing basic body position	116	29.2	0	0.0
d415*	Maintaining a body position	41	10.3	1	0.3
d420†	Transferring oneself	0	0.0	0	0.0
d430*	Lifting and carrying objects	16	4.0	0	0.0
d445†	Hand and arm use	0	0.0	0	0.0
d450*	Walking	19	4.8	24	7.7
d455†	Moving around	12	3.0	0	0.0
d460†	Moving around in different locations	0	0.0	0	0.0
d465†	Moving around using equipment	0	0.0	0	0.0
d470†	Using transportation	10	2.5	5	1.6
d475†	Driving	12	3.0	13	4.2
d510†	Washing oneself	12	3.0	0	0.0
d520	Caring for body parts	2	0.5	0	0.0
d530*	Toileting	1	0.3	0	0.0
d540*	Dressing	95	23.9	0	0.0
d570†	Looking after one's health	0	0.0	0	0.0
d620†	Acquisition of goods and services	0	0.0	6	1.9
d630†	Preparing meals	0	0.0	0	0.0
d640*	Doing housework	19	4.8	7	2.2
d650†	Caring for household objects	5	1.3	50	16.0
d660†	Assisting others	12	3.0	9	2.9
d710†	Basic interpersonal interactions	0	0.0	0	0.0
d760*	Family relationships	0	0.0	0	0.0
d770†	Intimate relationships	1	0.3	5	1.6
d845*	Acquiring, keeping and terminating a job	0	0.0	0	0.0
d850*	Remunerative employment	0	0.0	21	6.7
d859*	Work and employment, other	11	2.8	0	0.0
d910†	Community life	0	0.0	0	0.0
d920†	Recreation and leisure	0	0.0	168	53.8
	Other‡	12	3.0	1	0.3
	Total	397	100.0	312	100.0

*Features in the Brief Core Set (and hence in the Comprehensive Core Set). †Features in the Comprehensive Core Set only (i.e. not in the Brief Core Set). ‡Sleep functions (b134) – Body Functions component.

Eleven categories from the Activities and Participation component of the ICF which are included in the Comprehensive Core Set (3 of which are also in the Brief Core Set) had a frequency count of zero on responses to both questions.

The responses given appear to be unaffected by the episodic duration of the patients' back pain. When comparing the response categories of those with a pain duration of less than 15 days with those of between 15 days and 3 months, no clear differences in the proportions were observable. For example, the most frequently cited category on question (ii) (d920) accounted for similar proportions within each subgroup when split by pain duration; amounting to 52.2% of the responses from patients with a pain duration of less than 15 days and 55.0% of those with longer duration.

On an individual level, only 8 (2.0%) of the patients gave exactly the same response to both questions. In these 8 cases, the following activities were chosen for questions (i) and (ii): caring for children, gardening, housework, running, sex, standing, walking and work.

DISCUSSION

The troublesome activities identified by patients on 2 individualized questions were classified according to the ICF, and then mapped onto the Core Sets for LBP (5). We found that the things that patients said they had most difficulty with because of their back pain were adequately covered within both Core Sets. However, many of the activities which patients usually enjoyed, but were prevented from doing because of their back pain, did not fall within the Brief Core Set. Addition of codes d920 (recreation and leisure) and d650 (caring for household objects) to the LBP Brief Core Set would have substantially increased the inclusion rate in this cohort.

Development of the Core Sets within the ICF classification system arose from the concept of using condition-specific health status measures, and was intended to provide a link between the salient ICF categories and specific conditions or diseases (2). On question (i) (the one thing most difficult to do because of back pain) most patients cited items that were classifiable within the activities and participation component. The open nature of this question allowed patients a free rein in selecting activities or "things" which they could report. Therefore, the high level of inclusion of these items within the Comprehensive Core Set is in keeping with the aims of the ICF classification system, which is to provide "a globally agreed framework and classification to define the typical spectrum of problems in functioning of patients with LBP" (5).

On question (ii) (one thing that they really enjoy doing usually, but were unable to do because of back pain) many patients reported similar types of activity. However, responses to this question tended to include items which impinge on the individuals' wider role in society, rather than the purely functional activities of daily life reported in question (i). Unlike question (i), many responses (including the 2 most prevalent categories ("recreation and leisure" d920 and "caring for

household objects" d650) were not included within the Brief Core Set for LBP. These data were drawn from patients who were all participants in a clinical study, i.e. the very people for whom the Brief Core Set was devised. Whilst some of these items, e.g. sport and leisure activities, are not essential to basic functioning, they had all been chosen by the patients without prompting, as things that were not only "really enjoyed", but were also "usual", i.e. done on a regular basis, and serve to enhance quality of life. Given this, it could be argued that the low level of inclusion of these items within the Brief Core Set would severely diminish its ability to rate patients included in a clinical study, as was the intention at the outset of the Core Sets project.

ICF code d920 (recreation and leisure) is not included in the Brief Core Set, yet encompassed 54% of the responses to question (ii). Addition of just this single category to the Brief Core Set would have increased the response inclusion rate from 17% to 71% in this cohort. Participation in recreation and leisure activity is not unique to the population of the UK; and the subsequent loss of enjoyment experienced through inability to take part in such activities is likely to have a detrimental effect on quality of life. Further justification for the inclusion of this category may be found in the work of Sigl et al. (10) who compared the content covered in 3 widely used outcome measures in LBP based on the ICF. They found code d920 to be included in items on both the North American Spine Society Outcome Assessment Instrument (NASS) and the Oswestry Disability Index (ODI), although not in the Roland-Morris Disability Questionnaire. Addition of category d650 (caring for household objects) would further increase the overall inclusion rate to 87% in this cohort. However, this code was not included in the content of any of the 3 measures examined by Sigl et al. (10).

This cohort was recruited into a clinical study, with a diagnosis of non-specific LBP of less than 12 weeks' duration. These patients were in a sub-acute phase of what is known to be an episodic phenomenon, which often leads to recurrent and long-term problems (11), and 74% here had reported previous episodes of LBP. This group represents a sizeable sub-set of the LBP population, although it is possible that persistent chronic LBP sufferers may have different functional and socioeconomic priorities in life compared with this sub-acute cohort. Yet here, duration of pain did not affect the response categories cited by the patients. So whilst we have uncovered additional ICF categories which may enhance the utility of the Core Sets, we cannot exclude the possibility that further categories may arise if these 2 questions were posed to chronic LBP patients. Therefore, based on this data alone, a degree of caution must be taken when assessing whether certain categories are extraneous to the Core Sets. However, 11 categories from the Activities and Participation component of the ICF which are included in the Comprehensive Core Set had a frequency count of zero on responses to both questions. Three of these codes also feature in the Brief Core Set (d240, d760, d845) ranked 9, 10 and 12, respectively (5). Furthermore, none of these 3 codes appear in any of the measures examined for content by Sigl et al. (10).

The relevance of these items within the Brief Core Set could therefore be called into question.

Sleep functions (code b134) from the Body Functions component of the ICF was the only category to appear here from outside the Activities and Participation component. Furthermore, this category also features in all 3 measures examined by Sigl et al. (10). Clearly, poor sleep can have a detrimental effect on daily functional activities, and addressing sleep problems may be a primary focus of rehabilitation. Yet, in this cohort only 12 (3%) patients reported sleep to be the most difficult thing in their life related to back pain. Poor sleep may have featured more prominently if patients had been given the opportunity to name more than just one difficult thing in their life affected by back pain.

The validity of any conclusions drawn from this exercise relies upon the integrity of the mapping process. Initial agreement between the 2 raters' independent classifications was good for question (i) and very good on question (ii) (12). Discussion between the 2 raters achieved consensus on the majority of the remaining items, leaving few to be decided by the arbiter. Using only 2 raters may be considered a weakness. However, this limitation is somewhat offset by the fact that they came from different professional backgrounds (a physiotherapist and a rheumatologist) and both had similar levels of training and experience in using the ICF classification. The good overall levels of agreement achieved, even to the third ICF level, provided us with confidence in the mapping process.

In conclusion, an international classification system designed to rate patients included in a clinical study with LBP, that does not include "Recreation and leisure" or "Caring for household objects", may be missing 2 categories that could provide valuable insight into the impact that back pain has on people's lives. Therefore, addition of codes d920 and d650 to the LBP Brief Core Set is recommended, and would have significantly increased the inclusion rate in this cohort.

ACKNOWLEDGEMENTS

The clinical trial from which these data were derived was funded by grants from the UK National Lottery Charities Board and the North Staffordshire Primary Care Research Consortium, UK. The authors would like to acknowledge the contribution of Dr Ross Wilkie, who acted as independent adjudicator during the mapping process; and all members of the public who took part as subjects in this study.

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