

THE USE OF OUTCOME MEASURES IN PHYSICAL MEDICINE AND REHABILITATION WITHIN EUROPE

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The aim of the study was to survey the use of outcome measures in rehabilitation within Europe. It was envisaged that this would provide the basis for further studies on the cross-cultural validity of outcome measures. A postal questionnaire was distributed in November 1998 to 866 units providing rehabilitation. In total, 418 questionnaires were returned, corresponding to a response rate of 48%. These 418 centres treated an estimated 113000 patients annually, undertaking 360000 assessments. The survey focused on nine diagnostic groups: hip and knee replacement, low back pain, lower limb amputees, multiple sclerosis, neuromuscular disorders, rheumatoid arthritis, spinal cord lesions, stroke and traumatic brain injury. It identified a relatively small number of dominant outcome assessments for each diagnostic group and some variation in the preference for measures across regions. A large number of measures, however, are being used in one or a small number of locations and with relatively few patients. For rehabilitation of orthopaedic patients the majority of assessments undertaken are at the impairment level. For patients with neurological disorders the emphasis is mostly upon measures of disability.

Key words: rehabilitation, outcome measure, cross-cultural, cross-diagnostic.

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INTRODUCTION

Rehabilitation has a major role to play in ameliorating the consequences of disease. A wide range of therapeutic interventions are used that are often country-specific, reflecting the different traditions of healthcare within Europe. To match this diversity of treatment modalities there is also a broad range of outcome measures used to evaluate the efficacy of treatment. The use of these outcome measures, which are an attempt to

quantify the results of rehabilitation, is seen as an increasingly important part of good clinical practice. If we wish to identify, however, the most effective and efficient treatment modalities within and across diagnostic groups at the regional, national and international level, it follows that we require outcome measures that serve this purpose.

Some attempt at standardization of outcome measurement in rehabilitation has been made in North America. The Functional Independence Measure (FIM) (1), a measure of disability, is used across a wide range of conditions and in a wide range of situations in rehabilitation. A central databank facility is provided at Buffalo, to which individual rehabilitation units submit their data for comparative purposes. The implementation of such an approach has limitations in that it requires a substantial (and continuing) investment in quality control, training and access to the central facility. There is an extensive body of literature, in general supporting reliability and validity of FIM, as also sensitivity, which, however, may vary due to the population being assessed (2). Other measures such as the Barthel Index (3,4) are also used widely within Europe, although without any attempt to establish a common database.

Further concerns have emerged about shortcomings and omissions in the traditional methods of evaluating the psychometric properties of individual outcome measures (5). Concurrent with these concerns, new methodological approaches based on scale-free measurement models have emerged (6). These advances, in the understanding of the scientific basis of measurement, have led to a re-appraisal of how measures are used. This in turn has highlighted the potential to identify outcome measures that work consistently across different diagnostic groups (where appropriate) and countries.

The requirement for outcome measures to work at the European level (cross-cultural validity) and the potential offered by new psychometric approaches, should contribute to standardization at the European level. As a first step in this process it is crucial to identify the outcome measures used. It will then be possible to evaluate the cross-cultural validity of a selection of these outcome measures. To facilitate these objectives a project called "European Standardization of Outcome Measurement in Rehabilitation" (Pro-ESOR), was established. This paper reports

Table I. Response rate by region for the survey

Region	No. surveys distributed	No. surveys returned	Response rate (%)
Scandinavia*	329	228	69
Central Mediterranean**	275	86	31
North Western Europe***	103	41	40
UK	151	55	36
Eastern Mediterranean****	8	8	100
Overall	866	418	48

The countries of the five regions (the number of surveys returned from each country is given in parentheses):

* Sweden (87), Denmark (128) and Norway (13).

** Italy (83), Austria (1), Switzerland (1) and Slovenia (1).

*** Belgium (22), France (15), Luxembourg (1) and The Netherlands (3).

UK (55).

**** Israel (7) and Turkey (1).

on the initial part of this project: a survey of outcome measures used in rehabilitation within Europe

METHODS

Questionnaire design

After reviewing the literature to establish the most common outcome measures in use in nine diagnostic groups (see below), together with any recommended core sets (7), a list of these measures was compiled and formed into a modular questionnaire. An outcome measure was defined as an instrument that is used to measure change in patients over at least two time points.

An initial page asked for information on institutional details, and whether the respondent treated adults with the particular diagnosis and if so, how many. Separate pages were then provided for each of Hip and Knee Replacement; Low Back Pain; Lower Limb Amputees (transfemoral or transtibial); Multiple Sclerosis; Neuromuscular Disorders; Rheumatoid Arthritis; Spinal Cord Lesions; Stroke and Traumatic Brain Injury. Respondents were also asked to indicate which setting the measures were used in, whether a translated version was used and the approximate number of assessments made each year with the measure. A final page provided extra space for respondents to indicate any other outcome measures in use with a particular diagnostic group. There was also a page for comments.

A pilot study of this initial version of the questionnaire was sent to 52 centres directly associated with the project. Of these questionnaires 43 (83%) were returned.

The pilot study found that an Italian translation was necessary. In addition, certain outcome measures were found to have a very low frequency of use and were removed and replaced with outcome measures that had been specified in the 'Other' section.

Sample

The survey was distributed in November 1998 to 866 units within Europe providing rehabilitation for one or more of the nine diagnostic groups. The only exclusions for the survey were children and psychiatric units.

Questionnaires were sent to a wide range of facilities providing rehabilitation and reflecting the complexity of structure and organization of rehabilitation across countries. In this way the sample included acute settings and rehabilitation units, both public and private funded.

RESULTS

Response rate

A total of 418 surveys were returned: a response rate of 48%. For analytical purposes the countries were grouped into five regions. The region returning the greatest number of surveys was

Scandinavia (228, 54.5% of total), followed by Central Mediterranean (86, 20.6% of total), and the UK (55, 13.2% of total) (Table I). It was not possible to confirm the sample frame in every case (due to reorganization of services in some areas), therefore the response rates shown in Table I below are estimates. Eastern Mediterranean (100%) and Scandinavia (69%) showed the highest response rates.

Types of institution included in the sample

Almost two-thirds (66%) of respondents defined themselves as a Public Hospital Institution. The same proportion reported that they were rehabilitation wards or units, with most of the remainder being acute settings. A broad range of staff were employed in the various institutions with 6366 nursing staff, 3392 physiotherapists, 921 occupational therapists, and 1533 physicians. Of the 113000 patients receiving rehabilitation treatment per annum, almost equal numbers were treated as inpatients and outpatients.

From a regional perspective, Scandinavia accounted for 45% of all patients treated (Table II).

The use of outcome measures

Tables III and IV show the number of assessments per year by region and assessment instrument. Only 8–10 of the most commonly used outcome measures are included in the tables. In addition, between 4 and 11 outcome measures were presented in the list in the questionnaire for the different diagnostic groups.

Hip and knee replacement. In routine clinical practice for hip and/or knee replacement the Range of Movement (ROM) was the most commonly used outcome measure, being used in 23957 assessments/annum with hip replacement and 16993 assessments/annum with knee replacement patients. The number of FIM assessments/annum reported were 6065 and 3852, respectively. With the exception of Harris Hip Scale (4651 assessments/annum) (8) outcome measures commonly found in the research literature are not used in routine clinical practice. For example only 675 hip replacement patients were assessed using the Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) (9). Sixty other outcome measures were identified in addition to the list in the questionnaire, but only the

Table II. Number of patients reported in the survey to be treated per annum by region and diagnostic group

Region	Hip and knee replacement	Low back pain	Lower limb amputees	Neuro-muscular disorders	Multiple sclerosis	RA	Spinal cord lesions	Stroke	TBI	Total
Scandinavia	10542	11361	2138	2478	2605	8214	1728	12668	3090	54824
Central Mediterranean	6261	10070	1540	2064	1854	1502	2127	7793	1450	34661
North Western Europe	2808	3610	700	1051	889	651	1389	3291	1051	15440
UK	288	2044	1091	1240	2541	1067	1329	2303	1488	13391
Eastern Mediterranean	63	326	239	301	113	100	452	552	138	2284
Total	19962	27411	5708	7134	8002	11534	7025	26607	7217	120600

RA: rheumatoid arthritis; TBI: traumatic brain injury.

Table III. Use of outcome measures for patients with low back pain (LBP), multiple sclerosis and rheumatoid arthritis. Approximate number of assessments/annum

Outcome measure	Scandinavia	Central Mediterranean	North Western Europe	UK	Eastern Mediterranean	Total
<i>Low back pain</i>						
Range of movement	9040	7852	3480	1964	225	22561
Pain Visual Analogue Scale	8164	4751	2327	1439	?	16681
McGill Pain Questionnaire (Long and Short Form combined)	776	450	603	1238	25	3092
Isokinetic Force Testing	1413	613	764	0	25	2815
Roland & Morris	1100	701	301	0	75	2177
Oswestry LBP Disability Questionnaire	825	525	201	425	25	2001
SF-36	1225	125	25	25	0	1400
Backill Pain/Disability Scale for LBP	0	1326	0	0	0	1326
Total	22543	16343	7701	5091	150	52053
<i>Multiple sclerosis</i>						
Kurtzke EDSS	2814	1064	325	1488	100	5791
FIM	450	1638	1390	1063	75	4616
Ashworth Spasticity Scale (Original)	763	913	1013	1100	25	3814
Barthel (Original & Modified combined)	188	663	125	2539	0	3515
Kurtzke ESS	350	650	201	25	0	1226
SF-36	38	175	25	725	75	1038
Ambulation Index	201	588	88	150	0	1027
AMPS	488	0	0	113	0	601
Total	5292	5691	3167	7203	275	21628
<i>Rheumatoid arthritis</i>						
Acute Phase Reactant	12713	425	301	1052	175	14666
Swollen Joints	10888	576	539	501	150	12654
Tender Joints	10013	601	539	526	175	11854
Physician's Global Assessment	7950	389	376	264	0	8979
HAQ	7625	125	225	626	75	8676
Pain Visual Analogue Scale	7163	401	238	239	75	8116
Patient's Global Assessment	6525	214	200	239	75	7253
FIM	100	950	175	50	25	1300
Total	62977	3681	2593	3497	750	73498

FIM = Functional Independence Measure.

Kurtzke EDSS = Kurtzke Expanded Disability Status Scale.

Kurtzke ESS = Kurtzke Environmental Status Scale.

SF-36 = Medical Outcomes Survey Short-form General Health Survey.

AMPS = Assessment of Motor and Process Skills.

HAQ = Stanford Health Assessment Questionnaire.

Table IV. Use of outcome measures for patients with spinal cord lesions, stroke and traumatic brain injury. Approximate number of assessments/annum

Outcome Measure	Scandinavia	Central Mediterranean	North Western Europe	UK	Eastern Mediterranean	TOTAL
<i>Spinal cord lesions</i>						
Manual Muscle Testing	1726	1900	2302	2252	375	8555
FIM	963	1500	2140	688	175	5466
Ashworth Scale for Spasticity (Original & Modified combined)	913	963	2177	1126	100	5279
ASIA Motor Score	1213	988	1876	926	225	5228
ASIA Light Touch Score	1213	738	1476	876	225	4528
ASIA Pin Prick Score	1213	813	1451	789	225	4491
Vital Lung Capacity	838	938	588	1240	150	3754
ASIA Impairment Scale	1163	588	1076	626	225	3678
Total	9242	8428	13086	8523	1700	40979
<i>Stroke</i>						
FIM	4363	5489	2801	963	825	14441
Barthel Index (Original and Modified combined)	6614	3163	700	2651	75	13203
MMSE	2513	2863	888	1538	38	7840
Modified Ashworth Spasticity Scale	1013	1813	1251	563	150	4790
Glasgow Coma Scale	413	1675	438	1350	25	3901
NIHSS	1738	525	0	450	150	2863
Rivermead Behavioural Memory Test	863	600	213	963	175	2814
Motricity Index	500	1263	263	175	0	2201
Western Aphasia Battery	175	1050	250	275	0	1750
Rivermead Mobility Index	0	1463	0	150	75	1688
Total	18192	19904	6804	9078	1513	55491
<i>Traumatic brain injury</i>						
GCS Glasgow Coma Score	2400	1175	689	588	150	5002
FIM	713	1200	1176	900	225	4214
MMSE	500	600	425	750	75	2350
Barthel Index (Original and Modified combined)	388	520	113	1189	25	2215
Rivermead Behavioural Memory Test	350	325	25	1150	200	2050
Glasgow Outcome Scale	163	838	476	263	25	1765
GOAT	113	1000	338	163	0	1614
COTNAB	0	25	0	1063	0	1088
Functional Assessment Measure	88	150	63	775	0	1076
Total	4715	5833	3305	6841	700	21374

FIM = Functional Independence Measure.

ASIA = American Spinal Injury Association.

MMSE = Mini-Mental State Examination.

NIHSS = National Institute of Health Stroke Scale.

GOAT = Galveston Orientation and Amnesia Test.

COTNAB = Chessington Occupational Therapy Neurological Assessment Battery.

Barthel Index (3, 4) and the Harris Hip Scale were used in more than five centres.

Low back pain (LBP). Similar to hip and knee replacement, the most commonly used assessment was the ROM (Table III). The visual analogue pain scale (VAS Pain Scale) (10) was the second most widely used measure. The most widely used questionnaire was the Roland and Morris Disability Questionnaire (11), followed closely by the McGill Pain Questionnaire-Short Form (12), while its long form was used for 952 assessments/annum. Over 110 outcome measures not listed in the questionnaire were reported for LBP. Only three of these measures, however, were used in more than six centers, namely FIM (1), Multidimensional Pain Inventory (13), and the Beck Depression Inventory (14).

Lower limb amputees. The two most widely used assessments with lower limb amputees were not questionnaire-style instruments, rather they were the ROM (4602 assessments/annum) and Muscle Testing (3364 assessments/annum). The second most commonly used measure was the FIM (1) (1638 assessments/annum), whereas 926 assessments were carried out with Barthel Index (3, 4). Approximately 40 other outcome measures were used which were not listed in the questionnaire. None of these measures were used in more than five centres.

Multiple sclerosis (MS). The most widely used measures with MS patients were Kurtzke Expanded Disability Status Scale (EDSS) (15), the FIM (1) and the Ashworth Spasticity Scale (16) (Table III). These three measures accounted for over three-fifths of the 22441 assessments undertaken on this group in the year.

Just over 100 outcome measures not listed in the questionnaire were reported as being used to assess patients with MS. The majority of these measures were only used in a small number of centres. Kurtzke Incapacity Status Scale (17), Berg's Balance scale (18) and Rivermead Mobility Index (19) were the only measures that were used in more than five centres.

Neuromuscular disorders. The two most popular assessments in the rehabilitation of neuromuscular disorders were the Manual Muscle Testing (9367 assessments/annum) and the ROM (5628 assessments/annum). The most frequently used questionnaire was the FIM (1) (3352 assessments/annum). Over 70 other outcome measures not in the list in the questionnaire were identified. Only a few instruments were used in five or more centres: SF-36 (20), Sickness Impact Profile (21), Barthel Index (3, 4) and Life Satisfaction Index (22).

Rheumatoid arthritis (RA). The three most popular assessments with RA patients reflect the American College of Rheumatology's (ACR) core set for use in clinical trials (7) (Table III), these were Acute Phase Reactant, Swollen Joints and Tender Joints. The most popular questionnaire was the Stanford Health Assessment Questionnaire (HAQ) (23). Approximately 60 other instruments not listed in the questionnaire were used. Only the SF-36 (20) and the Barthel Index (3, 4) were used in more than six centres.

Spinal cord lesions. Manual Muscle Testing was the most widely used assessment, followed by the FIM (1) and the ASIA Motor Score (24) (Table IV). There were 1,651 assessments/annum using the Barthel Index (3, 4). Once again the influence of a recommended core set of outcome measures is shown by the frequency of those associated assessments. Over 70 outcome measures not listed in the questionnaire were identified, but the majority of these were only used in few centres.

Stroke. The most widely used measure in stroke rehabilitation was the FIM (1), followed by the Barthel Index (3, 4) and the Mini Mental-State Exam (MMSE) (25) (Table IV). These three assessments account for 56% of all assessments undertaken on this group during the course of the year. Over 150 other outcome measures not listed in the questionnaire were used. The three most common of those instruments were the Scandinavian Stroke Scale (2925 assessments/annum) (26), the Katz ADL Index (2275 assessments/annum) (27) and the European Stroke Scale (1513 assessments/annum) (28). The majority of the other instruments were used in only a small number of centres.

Traumatic brain injury (TBI). The measures used most frequently in TBI rehabilitation were the Glasgow Coma Score (29), the FIM (1), and the MMSE (25) (Table IV). These three assessments account for 48% of all assessments undertaken within the year. Over 150 outcome measures not listed in the questionnaire were used. The majority of these instruments were only used in a small number of centres, and none were used for more than 1000 assessments.

DISCUSSION

This survey of over 400 centres confirms our assumptions of the

heterogeneity of outcome measurement in each diagnostic group. A large number of measures are being used in one or a small number of locations and with relatively few patients. For rehabilitation of orthopaedic patients the majority of assessments undertaken are at the impairment level, dominated by ROM. For patients with neurological disorders the emphasis is mostly upon measures of disability. What emerges is a picture of a relatively small set of dominant outcome assessments for each diagnostic group and some variation in the preference for measures across regions. This variation however is likely to reflect the differing choice between competing instruments, such as the FIM (1) versus the Barthel Index (3, 4), than variation in the domains to be measured. A surprising finding was the low level of use of the so-called 'generic measures' in routine clinical practice. Although the Medical Outcome Study Short-Form General Health Survey (SF-36) (20) and the Nottingham Health Profile (NHP) (30) may be popular in bio-medical research, they do not seem to have a foothold in the routine assessment of rehabilitation within Europe.

There are a number of limitations to the study.

As there is no specific European-wide 'sample frame' from which to draw respondents for the survey, this survey does not purport to be a 'representative' sample of all those facilities providing rehabilitation within Europe. Rather, it relies on the number of facilities involved, the number of patients treated, the variety of therapeutic settings included, and the number of annual assessments undertaken to support its findings as a substantive review of current practice. The survey highlights the difficulties involved in obtaining information on aspects of rehabilitation practice in a European context. Even local studies experience the same problems and have been reported with much lower response rates than the current study (31).

Given the population disparities between Scandinavia and Central Mediterranean or the UK, the results reflect the fact that units providing rehabilitation were more readily identified in Scandinavia. In countries such as the UK, although there are an increasing number of dedicated stroke wards, rehabilitation is a very diffuse activity and specialized rehabilitation centres are relatively few.

It should be noted, that the number of patients given in Table II depends upon the variable sampling frames available within each country. The numbers give background information of the size of the patient population reported by the responding centres, but it must be recognized that these are likely to be only basic estimates.

Outcome measures are an important tool in quality assurance procedures. They can help measure to what extent there was compliance with established programmes or deviation of it, and inform us if selected targets were achieved individually or on the average. They may be used as indicators for programme evaluation, i.e. what treatment programmes had better achievements, at different time windows, in different impairments, etc. Finally, they can be used in the accountability process of justifying expenses and resources towards Health Medical Organizations (HMO) central authorities, services purchasers

such as insurance companies, Ministries of Health and international agencies.

Given the globalization process that is taking place in the realm of medical rehabilitation, standardization and unification of procedures is becoming central. Outcome measures are vital part of this process. In Europe our ability to compare the efficacy of different rehabilitation traditions, as well as conducting cross-national clinical trails, will depend upon reliable and valid outcome measures that transcend cultural differences. The results of this survey provide the foundation for examining critical issues of cross-cultural validity in various diagnostic groups by reporting the most commonly used outcome measures within Europe.

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