

## Linking osteoarthritis-specific health-status measures to the International Classification of Functioning, Disability, and Health (ICF)

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### Summary

**Objectives:** The objective of this study was to link the Western Ontario and McMaster Universities (WOMAC) and Lequesne-Algofunctional indices to the ICF on the basis of linking rules developed specifically to accomplish this aim. The linking process enables the understanding of the relationship between health-status measures and the ICF.

**Methods:** Since the fifth World Health Organisation/International Liege Against Rheumatism (WHO/ILAR) Task Force and the Outcome Measures in Rheumatology Clinical Trials (OMERACT) group recommend the use of WOMAC and the Lequesne-Algofunctional indices in patients with osteoarthritis of the hip and knee in clinical trials, these two health-status measures have been used in this study.

Both health-status measures were linked to the ICF separately by two trained health professionals. Consensus between health professionals was used to decide which ICF category should be linked to each item/concept of the two questionnaires. To resolve disagreements between the two health professionals, a third person trained in the linking rules was consulted.

**Results:** Except for the concept of 'morning stiffness', both health professionals agreed on the ICF category chosen to link all the items/concepts of both questionnaires. Altogether, 29 different ICF categories have been linked. Five ICF categories belong to the ICF component 'body functions', 23 categories to the component 'activities and participation', and one category to 'environmental factors'. Both questionnaires have 10 ICF categories in common.

**Conclusions:** The results of the linking process reflect both the structure of the two questionnaires studied and the relationship between them, showing that the ICF classification can become the cardinal reference for existing health-status measures.

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**Key words:** ICF, Osteoarthritis, Health-status measures, WOMAC, Lequesne, Linking rules.

### Introduction

Research and clinical management of patients with osteoarthritis (OA) rely on the sound measurement of pain, functional limitations, and stiffness. The Outcome Measures in Rheumatology Clinical Trials (OMERACT) group recommended the obligatory use of the domains *pain* and *physical function* in Phase-III clinical trials, and described *stiffness* as an important optional domain<sup>1</sup>. Health-status measures have been developed accordingly and applied in clinical research and practice.

A number of international organisations, like the fifth World Health Organisation/International Liege Against Rheumatism (WHO/ILAR) Task Force and the OMERACT group have examined the condition-specific health-status measures, which are currently available with respect to their properties, and have made suggestions regarding their use<sup>2–4</sup>. The Western Ontario and McMaster

Universities (WOMAC) OA index<sup>4–6</sup> and the Lequesne-Algofunctional index<sup>7–10</sup> may be the most recommended and most frequently used outcome measures for OA of the hip and knee in clinical trials.

The WOMAC is a three-dimensional, condition-specific instrument with 24 questions that cover pain, stiffness, and physical function. The WOMAC has been widely used in recent clinical studies of drug therapy<sup>11</sup>, surgical treatment<sup>12</sup>, and physiotherapy<sup>13</sup>.

The Lequesne-Algofunctional index comprises three sections with a total of 10 questions. The first section inquires about the severity of pain, the second section evaluates walking ability, and the third section relates to physical function.

Both the WOMAC and the self-administered Lequesne-Algofunctional indices are closely related disease-specific measures of symptom severity and physical disability in patients with OA of the lower extremities. Except for the WOMAC Stiffness Scale in patients with OA of the hip, which demonstrates weak intraobserver reliability, both instruments and subscales have satisfactory intraobserver reliability<sup>14</sup>.

None of the above-mentioned organisations has suggested describing or classifying health using classifications, such as the ICDH-1<sup>15</sup>. The ICDH-1 has not been widely used in research or practice in most countries.

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One obvious reason was that the classification had only been approved for field trials. However, in May 2001, the successor of the ICDH-1, the ICDH-2 or International Classification of Functioning, Disability, and Health, was approved by the World Health Assembly<sup>16</sup>, and the acronym was changed to ICF. Owing to the increasing importance of the ICF, ongoing developments have rendered the ICF practical for clinical research and clinical practice<sup>17</sup>. Therefore, the ICF will probably be increasingly used in future clinical and epidemiological trials, as well as in health reports.

In the future, health will probably be described with the existing outcome measures, as well as with the ICF, in clinical research, research on health services, and clinical practice. Both approaches have their strength. Most importantly, the disease-specific outcome measures, such as the WOMAC or Lequesne-Algofunctional index, are primarily designed as process measures. They are, therefore, useful to detect changes in the short term. In contrast to these questionnaires, the ICF is a general health-status framework. Indeed, the ICF can serve as a basis for the selection of instruments based on their content validity.

It is, therefore, very important to understand the relationship between outcome measures, such as the WOMAC and Lequesne-Algofunctional indices, and the ICF. The basis for this understanding is the linkage of individual items of the WOMAC and the Lequesne-Algofunctional indices to the ICF.

Accordingly, the objective of our study was to link the WOMAC and Lequesne-Algofunctional indices to the ICF on the basis of linking rules developed specifically to accomplish this aim<sup>18</sup>.

## Methods

### MEASURES

The WOMAC index is a three-dimensional, self-administered, disease-specific, health-status measure to investigate patient-relevant and clinically important outcomes of therapies of OA of the lower extremities. It consists of 24 items: five items are related to pain, two items to stiffness, and 17 items to physical function. Responses are given on 10-cm horizontal visual-analogue scales. Aggregate scores for each dimension are determined by summing the component item scores for each dimension<sup>19</sup>.

The Lequesne-Algofunctional index includes three sections with a total of 10 questions. It was developed using an interview format, but an adapted version for questionnaire use also exists<sup>14</sup>. The first section includes five items and measures pain or discomfort under different situations. The second section asks about the maximum walking distance. If patients use one or two walking aids, the score is increased by one and two points, respectively. The third section addresses physical disability. This section differs for patients with OA of the knee or hip. For each condition, the third section contains four items. Responses are given on Likert scales. The Lequesne-Algofunctional index is scored as the sum of all items. The score range of each section is from 0 to 8, resulting in a total score ranging from 0 to 24.

The International Classification of Functioning, Disability, and Health, known as the ICF<sup>16</sup>, is a multipurpose classification belonging to the WHO family of international classifications and is designed to record and organise a wide range of information about health and health-related states.

The ICF has two parts, each containing two separate components, described as follows:

Part 1: covers functioning and disability and includes the following components:

1. Body functions (b) and structure (s) and
2. Activities and participation (d).

Part 2: covers contextual factors and includes the following components:

1. Environmental factors (e) and
2. Personal factors.

In the ICF classification, the letters b, s, d, and e, which refer to the component of the classification, are followed by a numeric code starting with the chapter number (one digit) followed by the second level (two digits), and the third and fourth level (one digit each). For example, the *body functions* classification contains the following codes:

b2: sensory functions and pain  
 b280: sensation of pain  
 b2801: pain in body part  
 b28015: pain in lower limb

### LINKAGE OF ITEMS TO THE ICF

The WOMAC and the Lequesne-Algofunctional indices were linked to the ICF separately by two trained health professionals on the basis of 10 linking rules, which enable health-status measures to be linked to the ICF in a specific and precise manner<sup>18</sup>. The most important linking rules are presented below:

- Each item of an outcome measure should be linked to the most precise ICF category.
- If one item encompasses different constructs, the information in each construct should be linked. For example, in item 1B of the Lequesne-Algofunctional index 'morning stiffness or regressive pain after rising', the concepts 'morning stiffness' and 'pain after rising' have been linked to the ICF.
- The response options of an item are linked if they refer to additional constructs.
- If the information provided by the item is not sufficient for making a decision about the most appropriate ICF category, then this item should be linked 'nd' (not definable).
- If an item is not contained in the ICF classification, then this item is assigned 'nc' (not covered by the ICF).

Consensus between health professionals was used to decide which ICF category should be linked to each item/concept of the two questionnaires. To resolve disagreements between the two health professionals concerning the selected categories, a third person trained in the linking rules was consulted. In a discussion led by the third person, the two health professionals who linked the item stated their pros and cons for the linking of the concept under question to a specific ICF category. Based on these statements, the third person made an informed decision.

## Results

Table I shows the results of the linking process of the WOMAC and the Lequesne-Algofunctional indices. The items/concepts of the questionnaires have been linked to

Table I  
 Items of the WOMAC and the Lequesne-Algofunctional indices and the corresponding ICF domains/categories

WOMAC items	ICF code	Lequesne items
<i>Body functions</i>		
3. Pain at night while in bed 1.–5. Arthritis pain	b134 Sleep functions b28016 Pain in joints	1A–E: Pain or discomfort 1B: Morning stiffness or regressive pain after rising 1A–E: Pain or discomfort
6. Stiffness after first wakening in the morning 7. Stiffness after sitting, lying or resting later in the day	b289 Sensation of pain, other specified and unspecified b7603 Supportive functions of arm or leg b7800 Sensation of muscle stiffness or b7808 Sensations related to muscles and movement functions, other specified	3D: Pain or discomfort while getting up from sitting without the help of arms 1B: Morning stiffness or regressive pain after rising
<i>Activities and participation</i>		
10. Rising from sitting	d4100 Lying down d4101 Squatting d4103 Sitting	1B: Morning stiffness or regressive pain after rising 3C (hip): Squat or bend on the knees 1E (knee): Pain or discomfort while getting up from sitting without the help of arms
17. Rising from bed 12. Bending to floor	d4105 Bending	3A (hip): Put on socks by bending forward 3C (Hip): Squat or bend on the knees 1A: Pain or discomfort during nocturnal bed rest
4. Pain sitting or lying 7. Stiffness after sitting, lying or resting later in the day 19. Lying in bed 4. Pain sitting or lying	d4150 Maintaining a lying position d4153 Maintaining a sitting position	1E (hip): Pain or discomfort with prolonged sitting (2 h)
7. Stiffness after sitting, lying or resting later in the day 21. Sitting 5. Pain standing upright 11. Standing	d4154 Maintaining a standing position	1C: Pain or discomfort after standing for 30 min
1. Pain walking on a flat surface 13. Walking on flat surface	d4400 Picking up d4102 Transferring oneself while lying d450 Walking d4500 Walking short distances d4501 Walking long distances d4502 Walking on different surfaces d4551 Climbing	3B (hip): Pick up an object from the floor 1A: Pain or discomfort during nocturnal bed rest only on movement or in certain positions 2. Maximum distance walked (may walk with pain) 1 km (in about 15 min) from 500 to 900 m (in about 8–15 min) from 300 to 500 m from 100 to 300 m less than 100 m 2. Maximum distance walked (may walk with pain) Unlimited 3D (knee): Able to walk on uneven ground 3A (knee): climb up a one flight of stairs 3B (knee): Climb down one flight of stairs
2. Pain going up or down stairs 8. Descending stairs 9. Ascending stairs	d4559 Moving around unspecified	1D: Pain or discomfort while ambulating 3D (hip): Can get into and out of a car
14. Getting in/out of car 20. Getting in/out of bath 22. Getting on/off toilet 16. Putting on socks/stockings 18. Taking off socks/stockings 15. Going shopping 23. Heavy domestic duties 24. Light domestic duties 7. How severe is your stiffness after sitting, lying or resting later in the day?	d498 Mobility, other specified d5101 Washing whole body d530 Toileting d5402 Putting on footwear d5403 Taking off footwear d6200 Shopping d699 Domestic life, unspecified d9208 Recreation and leisure, other specified	3A (hip): Put on socks by bending forward
<i>Environmental factors</i>		
	e1201 Assistive products and technology for personal indoor and outdoor mobility	2. Maximum distance walked (may walk with pain)...with one walking stick or crutch

29 ICF categories. Disagreement between the first and second health professional occurred in one concept. The concept 'morning stiffness' was linked to the ICF category 'sensation of muscle stiffness' (b7800) by one health professional and to the ICF category 'sensations related to muscles and movement functions, other specified' (b7808) by the other. On the basis of the third opinion, the latter ICF category (b7808) was chosen.

Altogether, 29 different ICF categories have been linked. Five ICF categories belong to the ICF component 'body functions', 23 categories to the component 'activities and participation', and one category to 'environmental factors'. Both questionnaires have 10 ICF categories in common. Two of the 10 categories correspond to the component body functions 'pain in joints' (b28016) and 'sensation of muscle stiffness' (b7800), five belong to the ICF domain 'changing and maintaining body position' (d4103, d4105, d4150, d4153, d4154), one to the ICF category 'climbing' (d4451), another to the ICF category 'putting on footwear' (d5402), and the last one to the ICF category 'mobility, other specified' (d498).

The ICF categories that are not common to both questionnaires correspond to six different activities, like 'getting on/off toilet' or 'going shopping' (see the following ICF categories in Table 1: d450, d5101, d530, d5403, d6200, d699) that are contained in the WOMAC questionnaire and not in the Lequesne-Algofunctional index. The category d450 'walking' is represented in both instruments. The Lequesne Algofunctional index accents the distance ('maximum distance walked...'), whereas the WOMAC accents the kind of surface ('walking on flat surface'). Therefore, both instruments are linked to different ICF categories within the domain 'walking' (d450). Additionally, the Lequesne-Algofunctional index contains the activities 'lying down', 'squatting', 'picking up', 'transferring oneself while lying', and 'moving around unspecified', which are not represented in the WOMAC.

## Discussion

Linking of all the items of most widely used, self-administered, condition-specific instruments for patients with OA to the ICF has been possible on the basis of widely tested linking rules.

Most of the items on both instruments could be linked on one-to-one basis to the categories of the ICF classification. Nevertheless, in a few cases, the ICF category did not cover all the information contained in the item or concepts in the questionnaires. For example, the item 'getting in and out of a car' could not be exactly linked to the ICF. Thus, this item was linked to the parent category 'mobility, other specified' (d498). The additional information contained in the item should be documented separately, making the linking exercise a more complicated process.

The important clinical symptom 'morning stiffness', which is one of the disease-defining ACR criteria for OA<sup>20</sup>, is not explicitly named in the ICF. In this exercise, it has been linked to 'sensations of muscles and movement functions, other specified' (b7808). However, there are valid arguments for the linkage of morning stiffness to b7800, muscle stiffness. The reason, why 'b7808' was preferred, was that the muscle stiffness does not necessarily represent what is being meant by morning stiffness in patients with OA, since morning stiffness in OA also encompasses stiffness related to structures other than muscles. Therefore, it was felt that the broader definition of b7808 is more appropriate. Since

there is no more precise definition of stiffness in the ICF in its current edition, it is not possible to make a final decision about the most appropriate linkage at this point. Therefore, both the linkage to b7800, muscle stiffness, as well as b7808, sensations related to muscle and movement functions, other specified, may be considered valid. Accordingly, both ICF codes are shown in Table 1.

On the basis of this exercise, it has also been shown that the ICF is very precise in describing activities of patients. For example, the WOMAC items 'putting on socks' and 'taking off socks' could be linked to the corresponding ICF codes 'putting on footwear' (d5202) and 'taking off footwear' (d5403) without losing essential information. The item 'pick up an object from the floor' could be linked very precisely to the ICF category 'picking up' (d4400). The ICF categories describing the activity 'walking' represent a further example that the ICF classification can be very precise and useful in describing impairments in patients' activities.

Although outcome-measurement instruments, like the WOMAC and the Lequesne-Algofunctional indices, can be linked to the ICF, the ICF is no substitute for these instruments. As has been shown in the example of the clinical symptom 'morning stiffness', it makes sense to use the ICF and health-status measure together in clinical studies. The ICF can be very helpful in adding additional information to the already existing instruments, and objectively describing the impairments in activities and body functions of study populations. It, thereby, improves the comparability of clinical trials. The simultaneous application of the ICF and health-status measures demonstrates the usefulness of the ICF in creating a common language for clinical practice, teaching, and research.

As has been shown in this exercise, the results of the linking process reflect both the structure of the two questionnaires studied and the relationship between them, showing that the ICF classification can become the cardinal reference for existing health-status measures.

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