Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema (Lymph-ICF-LL): Reliability and Validity

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Background. Patients may develop primary (congenital) or secondary (acquired) lymphedema, causing significant physical and psychosocial problems. To plan treatment for lymphedema and monitor a patient's progress, swelling, and problems in functioning associated with lymphedema development should be assessed at baseline and follow-up.

Objective. The purpose of this study was to investigate the reliability (test-retest, internal consistency, and measurement variability) and validity (content and construct) of data obtained with the Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema (Lymph-ICF-LL).

Design. This was a multicenter, cross-sectional study.

Methods. The Lymph-ICF-LL is a descriptive, evaluative tool containing 28 questions about impairments in function, activity limitations, and participation restrictions in patients with lower limb lymphedema. The questionnaire has 5 domains: physical function, mental function, general tasks/household activities, mobility activities, and life domains/social life. The reliability and validity of the Lymph-ICF-LL were examined in 30 participants with objective lower limb lymphedema.

Results. Intraclass correlation coefficients for test-retest reliability ranged from .69 to .94, and Cronbach alpha coefficients for internal consistency ranged from .82 to .97. Measurement variability was acceptable (standard error of measurement=5.9–12.6). Content validity was good because all questions were understandable for 93% of participants, the scoring system (visual analog scale) was clear, and the questionnaire was comprehensive for 90% of participants. Construct validity was good. All hypotheses for assessing convergent validity and divergent validity were accepted.

Limitations. The known-groups validity and responsiveness of the Dutch Lymph-ICF-LL and the cross-cultural validity of the English version of the Lymph-ICF-LL were not investigated.

Conclusions. The Lymph-ICF-LL is a Dutch questionnaire with evidence of reliability and validity for assessing impairments in function, activity limitations, and participation restrictions in people with primary or secondary lower limb lymphedema.

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Lymphedema is a chronic and often debilitating condition caused by lymphatic insufficiency. It leads to swelling of the limb and an increased risk of infection. It can be classified as primary or secondary lymphedema.[1,2] Prevalence estimates suggest that chronic lymphedema is present in 1.4 of 1,000 people; this prevalence is probably an underestimate. About one-fourth of all patients with lymphedema have primary lymphedema.[3]

Complications and consequences related to lymphedema of the upper limb after breast cancer treatment have been thoroughly investigated.[4] In contrast, the incidence and impact of lower limb lymphedema have been minimally investigated. A direct transfer of information about lymphedema of the upper limb to the lower limb is not possible, given the differences in the size, volume, location, or function of the lower limb.[5] Patients with lower limb lymphedema have significant physical disabilities as well as psychosocial impairments. These problems can lead to a decrease in the quality of life.[4,5]

The gold standard for measuring the volume of lymphedema is the water displacement method. Circumference-based measurement of limb volume is an alternative, rapid, and valid way to evaluate limb volume changes.[5] However, a uniform definition for lower limb lymphedema is lacking.[6] Patients with lower limb lymphedema report other problems in functioning, besides swelling, associated with their lymphedema.[4,5] A comprehensive evaluation should include other problems in functioning associated with the development of lymphedema. The taxonomy in the World Health Organization *International Classification of Functioning, Disability and Health* (ICF) provides a framework that allows the systematic categorization of clinical observations.[7] Just like the Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF) for upper limb lymphedema, a specific ICF-based tool for evaluating lower limb lymphedema is needed in daily practice.[8,9] With such a tool, individualized treatment of lymphedema would be possible, and the therapist and the patient would be able to monitor the long-term results of treatment and self-care.

Various general (nonspecific) health-related quality-of-life tools have been used to examine the impact of lower limb lymphedema.[10] The 36-Item Short-Form Health Survey questionnaire (SF-36), the Modified Barthel Index, the Short-Form McGill Pain Questionnaire, and the EuroQol instrument were administered in different studies.[10,11] The major disadvantage of these questionnaires is that they are nonspecific and consequently provide limited insights into the experiences of people with lower limb lymphedema. Another study evaluated the clinical use of the Freiburg Life Quality Assessment (FLQA-I), a disease-specific quality-of-life questionnaire for patients with upper or lower limb lymphedema.[12] However, despite the reliability and validity of the FLQA-I, a more compact tool that can be used to evaluate functional problems associated only with lower limb lymphedema is needed.

The first aim of this study was to develop a questionnaire to assess problems in functioning, that is, impairments in function, activity limitations, and participation restrictions, associated with the development of primary or secondary lower limb lymphedema (phase 1 of the study). The second aim was to examine various aspects of the reliability and validity of the questionnaire that was developed—the Lymphoedema Functioning, Disability and Health

Questionnaire for Lower Limb Lymphoedema (Lymph-ICF-LL) (phase 2 of the study).

Method

Phase 1: Development of the Lymph-ICF-LL

Problems in functioning related to the development of lower limb lymphedema were identified in 2 ways. First, a literature search was conducted. PubMed was explored by use of the following key words: lymphedema, lower limb/extremity, questionnaire, complaint/symptom, and function/activity/participation. In addition, the reference lists of the obtained articles were searched for other relevant articles. Furthermore, 20 patients with chronic or stable primary or secondary lower limb lymphedema were asked to record problems in functioning associated with their lymphedema. Patients had to be Dutch speaking. Patients were included if they had at least a 7% difference between the left and right upper leg, lower leg, or foot (see below for the measurement procedure).[13] For cases of bilateral lymphedema and cases not meeting the criterion of a 7% difference, the diagnosis of lymphedema had to be made by a lymphedema specialist (positive pitting edema test, positive Stemmer lymphedema sign, or both). Patients were excluded if they were less than 18 years old, if they had an infection at the level of the lower limb, if they had comorbidities that can induce edema (such as severe obesity, heart failure, or chronic vascular disease), and if they were not able to fill out the questionnaires.

The participants in phase 1 of the study (N=20) were recruited and assessed at the Leuven Lymphoedema Center in Leuven, Belgium. Before the start of the study, the participants signed an informed consent form.

To identify problems in functioning by consulting participants with lower limb lymphedema, we used the following open-ended questions:

- Which complaints do you have due to your lymphedema?
- Which negative feelings do you have due to your lymphedema?
- Which activities are difficult or not possible to perform because of your lymphedema?
- Do you have any other remarks?

Afterward, the reported problems in functioning were discussed and clarified with the participants.

The following data were collected by interviewing the participants and by verifying the information in their medical records: age, body weight and height (to calculate body mass index), type of lymphedema (primary or secondary), cause of secondary lymphedema (treatment of ovary, cervix, endometrium, vulva, or prostate carcinoma or melanoma, infection, or trauma), side of lymphedema (bilateral or unilateral), localization of lymphedema (belly, upper leg, lower leg, or foot), duration of lymphedema (in months), and current physical treatment of lymphedema (skin care, manual lymph drainage, multilayer bandaging or compression garment, or exercises).

To define lymphedema, we measured the circumferences of the left and right lower limbs with a perimeter device.[14] This device measures the circumference every 4 cm from 24 cm above the patella to 40 cm below the patella. The sum of circumferences of the upper leg included measurements made from 24 cm above the patella to the patella. The relative difference between the upper legs was calculated as follows[13]: [(highest sum of circumferences−lowest sum of circumferences)/lowest sum of circumferences] × 100. The relative difference between the lower legs (from 4 cm to 40 cm below the patella) was calculated in the same way. The volumes of the left and right ankles and feet were measured with a volumeter.[15] The relative difference between the ankles or feet was calculated as follows: [(highest volume of ankle or foot−lowest volume of ankle or foot)/lowest volume of ankle or foot] × 100.

On the basis of the information collected through the literature search and by consulting participants, the Lymph-ICF-LL was developed (Appendix). Problems in functioning were included in the questionnaire if at least 10% of the participants reported those problems in functioning. They were excluded if they were reported less frequently and were not reported in literature. Each problem in functioning received an ICF code, and the ICF codes were used to construct ICF domains. The structure of the Lymph-ICF-LL was based on the structure of the Lymph-ICF for upper limb lymphedema.[8]

Phase 2: Reliability and Validity of the Lymph-ICF-LL

Various aspects of the reliability and validity of the Lymph-ICF-LL were examined.

Phase 2 of the study involved 30 participants (different from those in phase 1) with chronic or stable primary or secondary lower limb lymphedema. They had to meet the same inclusion criteria as the participants in phase 1 of the study. Eleven participants were recruited and assessed at the lymphedema clinic at Nij Smellinghe Hospital in Drachten, the Netherlands, and 19 participants were recruited and assessed at the Leuven Lymphoedema Center in Leuven, Belgium. All participants signed an informed consent form.

Participants filled out 3 questionnaires: the Lymph-ICF-LL, a question-

naire for assessing face and content validity, and the SF-36 to assess construct validity.

The questionnaire used to assess face and content validity consisted of 3 questions:

- Was each question of the Lymph-ICF-LL understandable?
- Was the scoring system clear?
- Were all complaints related to your lymphedema mentioned in the Lymph-ICF-LL?

Participants who gave a negative answer to any of the questions were asked to provide a more detailed explanation. Afterward, during a discussion, the participants were asked to clarify their answers.

The SF-36 is a reliable and valid questionnaire for assessing general quality of life.[16] It consists of 36 questions leading to 8 domains of quality of life. A low score on the SF-36 indicates a low level of quality of life.

Participants received the various questionnaires by mail. They were asked to fill out the questionnaires 1 day before their appointment at the hospital.

For the evaluation of test-retest reliability, the participants completed the Lymph-ICF-LL a second time, within 24 to 48 hours, during their appointment at the hospital. Problems in functioning associated with lymphedema were not expected to change in such a short period of time. General and medical data were collected, and measurement of the circumferences of both legs and volumetry of both feet were performed as described for phase 1 of the study.

Data Analysis

Data were analyzed with IBM SPSS version 20.0 (IBM Corp, Armonk, New York).

Reliability. To determine the test-retest reliability of the total score on the Lymph-ICF-LL, of the scores on the 5 domains of the Lymph-ICF-LL, and of the score on each question separately, we calculated the intraclass correlation coefficient (ICC [2,1]). The internal consistency of the entire questionnaire and of each domain was determined by means of the Cronbach alpha coefficient.

To interpret the magnitude of the within-subjects variation of the 2 scores, we calculated the standard error of measurement (SEM) with the following formula: $SEM = SD_{12}\sqrt{1-ICC}$, where SD_{12} was the average standard deviation of the 2 ratings.[17] To evaluate clinically important changes, we calculated the smallest real difference (SRD) with the following formula: $SRD = 1.96 \times SEM \times \sqrt{2}$.[17] To obtain a reference range for the mean difference between the scores on the 2 test occasions, the 95% SRD was calculated as the mean difference between the scores on the 2 test occasions plus or minus the SRD.

Validity. Face validity, content validity, and construct validity were examined. It was not possible to examine criterion validity. The problems in functioning were dimensions of the ICF introduced by the World Health Organization. There is no gold standard for measuring these dimensions.

Face validity is the extent to which a test is subjectively viewed by participants as covering the concepts that it claims to measure.[18] Face validity was examined by asking the participants whether the questions in the Lymph-ICF-LL were understandable and whether the scoring system was obvious.

Content validity examines the extent to which a questionnaire represents the universe of concepts or domains.[19] The content validity of the Lymph-ICF-LL was examined by analyzing the answers given by the participants to questions about the comprehensiveness of the questionnaire. The structure and content of the Lymph-ICF-LL also were discussed with other experts in lymphology (A.H. and R.D.).

Construct validity is the extent to which a measure correlates with variables in a manner consistent with theory.[19] The relationship between scores on domains of the Lymph-ICF-LL and scores on domains of the SF-36 was examined with the Pearson correlation coefficient for interval-level data and with the Spearmen correlation coefficient for ordinal-level data. For cases with interval-level data and no normal distribution, the Pearson correlation coefficient was compared with the Spearman correlation coefficient. The findings were used to investigate convergent validity and divergent (or discriminant) validity.

To determine convergent validity and divergent validity, we formulated 10 hypotheses on the basis of the content of the questions in each domain of the Lymph-ICF-LL and the SF-36. In the case of agreement between the questions in a specific domain of the Lymph-ICF-LL and SF-36, these domains were included in a hypothesis for assessing convergent validity. In the case of disagreement, they were included in a hypothesis for assessing divergent validity. Table 1 shows an overview of the various hypotheses for determining convergent validity and divergent validity and the rationale for the various hypotheses. Construct validity was defined as very good if more than 90% of all 10 hypotheses were confirmed, as good if 75% to 90% of the hypotheses were confirmed, and as moderate if 40% to 74% of the hypotheses were confirmed.

Table 1.
Ten Hypotheses and Rationale for Hypotheses for Assessing Construct Validity[a]

Type of Validity	Hypothesis	Rationale
Convergent	Considering all correlation coefficients for various domains of the Lymph-ICF-LL and the SF-36, significant correlation coefficients would occur for:	
	Lymph-ICF-LL physical function and SF-36 bodily pain	Lymph-ICF-LL physical function: Do you have at the level of your leg(s) or foot/feet: pain, tension of the skin, tingling, infection, stiffness, or heaviness? SF-36 bodily pain: How much bodily pain have you had during the past 4 wk? During the past 4 wk, how much did pain interfere with your normal work?
	Lymph-ICF-LL mental function and SF-36 role–emotional and mental health	Lymph-ICF-LL mental function: Due to your lymphedema, do you have a lack of confidence and do you feel sad, unattractive, frustrated, insecure about the future, and disappointed in medical health care? SF-36 role–emotional: During the past 4 wk, how much time have you had problems with your work or other regular daily activities as a result of emotional problems? SF-36 mental health: How much time during the last 2 wk have you been a very nervous person, have you felt so down in the dumps that nothing would cheer you up, have you felt calm and peaceful, have you felt downhearted and low, and have you been a happy person?
	Lymph-ICF-LL general tasks/household activities and SF-36 physical functioning and role–physical	Lymph-ICF-LL general tasks/household activities: Due to your lymphedema, have you become more dependent on others and do you have problems with organizing different matters and completing household chores? SF-36 physical functioning: Does your health limit you in the following activities: vigorous activities, such as lifting heavy objects; moderate activities, such as moving a table, pushing a vacuum, lifting or carrying groceries, climbing several flights of stairs, climbing 1 flight of stairs, bending, kneeling, stooping, walking more than a mile, walking half a mile, walking 100 yd (91.44 m), and bathing or dressing yourself? SF-36 role–physical: During the past 2 wk, how much time have you had problems with your work or other daily activities as a result of your physical health? Cut down on the amount of time you spent on work and other activities, accomplished less than you would like, were limited in the kind of work or other activities, and had difficulty performing the work and other activities?
	Lymph-ICF-LL mobility activities and SF-36 physical functioning	Lymph-ICF-LL mobility activities: Due to your lymphedema, can you still sit for a prolonged time, stand for a prolonged time, kneel, walk, ride a bicycle, drive a car, and take the stairs? SF-36 physical functioning: Does your health limit you in the following activities: vigorous activities, such as lifting heavy objects; moderate activities, such as moving a table, pushing a vacuum, lifting or carrying groceries, climbing several flights of stairs, climbing 1 flight of stairs, bending, kneeling, stooping, walking more than a mile, walking half a mile, walking 100 yd, and bathing or dressing yourself?
	Lymph-ICF-LL life domains/social life and SF-36 physical functioning and social functioning	Lymph-ICF-LL life domains/social life: Due to your lymphedema, can you fulfill your job, practice sports, carry out leisure-time activities, carry out social activities with friends, wear clothes or shoes you like to wear, and go on holiday? SF-36 physical functioning: Does your health limit you in the following activities: vigorous activities, such as lifting heavy objects; moderate activities, such as moving a table, pushing a vacuum, lifting or carrying groceries, climbing several flights of stairs, climbing 1 flight of stairs, bending, kneeling, stooping, walking more than a mile, walking half a mile, walking 100 yd, and bathing or dressing yourself? SF-36 social functioning: During the past 2 wk, to what extent have your physical health or emotional problems interfered with your normal social activities with family, neighbors, or groups? During the past 2 wk, how much of the time have your physical health or emotional problems interfered with your social activities?

(Continued)

Table 1.
Continued

Type of Validity	Hypothesis	Rationale
Divergent	Considering all correlation coefficients for various domains of the Lymph-ICF-LL and the SF-36, nonsignificant correlation coefficients would occur for:	
	Lymph-ICF-LL physical function and SF-36 role–emotional and mental health	Lymph-ICF-LL physical function: Do you have at the level of your leg(s) or foot/feet: pain, tension of the skin, tingling, infection, stiffness, or heaviness? SF-36 role–emotional: During the past 4 wk, how much time have you had problems with your work or other regular daily activities as a result of emotional problems? SF-36 mental health: How much time during the last 2 wk have you been a very nervous person, have you felt so down in the dumps that nothing would cheer you up, have you felt calm and peaceful, have you felt downhearted and low, and have you been a happy person?
	Lymph-ICF-LL mental function and SF-36 physical functioning	Lymph-ICF-LL mental function: Due to your lymphedema, do you have a lack of confidence and do you feel sad, unattractive, frustrated, insecure about the future, and disappointed in medical health care? SF-36 physical functioning: Does your health limit you in the following activities: vigorous activities, such as lifting heavy objects; moderate activities, such as moving a table, pushing a vacuum, lifting or carrying groceries, climbing several flights of stairs, climbing 1 flight of stairs, bending, kneeling, stooping, walking more than a mile, walking half a mile, walking 100 yd, and bathing or dressing yourself?
	Lymph-ICF-LL general tasks/household activities and SF-36 mental health	Lymph-ICF-LL general tasks/household activities: Due to your lymphedema, have you become more dependent on others and do you have problems with organizing different matters and completing household chores? SF-36 mental health: How much time during the last 2 wk have you been a very nervous person, have you felt so down in the dumps that nothing would cheer you up, have you felt calm and peaceful, have you felt downhearted and low, and have you been a happy person?
	Lymph-ICF-LL mobility activities and SF-36 mental health	Lymph-ICF-LL mobility activities: Due to your lymphedema, can you still sit for a prolonged time, stand for a prolonged time, kneel, walk, ride a bicycle, drive a car, and take the stairs? SF-36 mental health: How much time during the last 2 wk have you been a very nervous person, have you felt so down in the dumps that nothing would cheer you up, have you felt calm and peaceful, have you felt downhearted and low, and have you been a happy person?
	Lymph-ICF-LL life domains/social life and SF-36 mental health	Lymph-ICF-LL life domains/social life: Due to your lymphedema, can you fulfill your job, practice sports, carry out leisure-time activities, carry out social activities with friends, wear clothes or shoes you like to wear, and go on holiday? SF-36 mental health: How much time during the last 2 wk have you been a very nervous person, have you felt so down in the dumps that nothing would cheer you up, have you felt calm and peaceful, have you felt downhearted and low, and have you been a happy person?

[a] Lymph-ICF-LL=Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema; SF-36=36-Item Short-Form Health Survey questionnaire.

The ICCs, Cronbach alpha coefficients, and correlation coefficients were interpreted as follows: values of less than .40 were considered to be weak, values of .40 to .74 were considered to be moderate, values of .75 to .90 were considered to be strong, and values of greater than .90 were considered to be very strong.[17,20]

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Results
Phase 1: Development of the Lymph-ICF-LL
The following impairments in physical function related to the development of lower limb lymphedema were mentioned in the literature: pain, tension of the skin, multiple infections, limited range of motion, and heaviness.[21,22] The following impairments in mental function were found: being laughed at, problems with self-image,[5,21–24] mental effort of staying motivated for self-management, coping with chronic

illness,[23] increased future health worries,[22] more frequent bouts of depression,[21,22] feelings of anger, disillusionment with health care, and being ashamed of having to wear compression garments.[22] The following activity limitations and participation restrictions were found: difficult self-care/use of toilet, marital and sexual problems,[21,22] problems with activities of daily living and leisure time activities,[5,22] inability to perform a job, and problems with prolonged sitting and standing, walking, driving a car, and riding a bike.[5,23]

The 20 participants with objective lymphedema (4 men and 16 women) were, on average, 58.7 years old (SD=11.6) and had an average body mass index of 27.1 kg/m^2 (SD=6.3). Table 2 shows the lymphedema-related variables. Table 3 shows the impairments in function, activity limitations, and participation restrictions mentioned by the participants with lymphedema. Each problem in functioning received an ICF code. The following ICF domains were constructed on the basis of the ICF codes: physical function, mental function, general tasks/household activities, mobility, and life domains/social life. Some problems in functioning reported by the participants were not included in the Lymph-ICF-LL because they were not specific for lower limb lymphedema (eg, sensibility disorder of the feet or toes, general fatigue problem, and problem sleeping on one [particular] side) or because they were already addressed by another item in the Lymph-ICF-LL (eg, having difficulties with bending [item 5: reduced mobility], the time-consuming nature of self-care [item 14: having organizational problems], and decreased strength of leg muscles [item 22: less able to walk up and down stairs]).

The constructed Lymph-ICF-LL consisted of 28 questions (Appendix).

Table 2.
Characteristics of Participants With Lower Limb Lymphedema in Study Phases 1 and 2[a]

Characteristic	Phase 1 (N=20)	Phase 2 (N=30)	*P*
Sex			1.00
Men	4 (20)	6 (20)	
Women	16 (80)	24 (80)	
Age (y)[b]	58.7 (11.6)	50.9 (14.9)	.05
Body mass index (kg/m^2)[b]	27.1 (6.3)	27.1 (4.7)	.97
Bilateral or unilateral lymphedema	11 (55)	11 (37)	.20
Duration of lymphedema (mo)[c]	11 (3–132)	84 (1–588)	<.01
Meeting criterion of 7% difference between legs or between feet	15 (75)	21 (70)	.70
Relative percent difference between limbs[b]			
Upper leg	8.1 (6.2)	4.8 (7.8)	.12
Lower leg	8.6 (7.1)	6.3 (7.6)	.29
Foot	10.6 (6.4)	13.5 (8.1)	.30
Localization of lymphedema			
Belly	8 (40)	1 (3)	<.01
Upper leg	19 (95)	25 (83)	.38
Lower leg	20 (100)	26 (87)	.14
Foot	17 (85)	21 (70)	.32
Primary lymphedema	0 (0)	15 (50)	<.01
Type of cancer[d]	20	15	.19
Ovary carcinoma	8 (40)	6 (40)	
Cervix carcinoma	5 (25)	3 (20)	
Endometrium carcinoma	3 (15)	0 (0)	
Prostate carcinoma	2 (10)	0 (0)	
Melanoma	2 (10)	5 (33)	
Adenocarcinoma	0 (0)	1 (7)	
Prior medical treatment[d]			
Lymphadenectomy	20 (100)	15 (100)	1.00
Radiotherapy	5 (25)	4 (27)	1.00
Chemotherapy	13 (65)	8 (53)	.49
Current physical treatment			
Skin care	14 (70)	20 (67)	.80
Manual lymph drainage	14 (70)	18 (60)	.47
Multilayer bandaging/compression garment	20 (100)	29 (97)	1.00
Exercises	16 (80)	19 (63)	.21

[a] Unless otherwise indicated, results are reported as number (percentage). *P* values were determined with the chi-square test for discontinuous variables and the independent *t* test for continuous variables (except for the duration of lymphedema, for which the Mann-Whitney *U* test was used).
[b] Results are reported as mean (standard deviation).
[c] Results are reported as median (range).
[d] For patients with cancer-related secondary lymphedema.

Table 3.
Impairments in Function, Activity Limitations, and Participation Restrictions in Participants With Lower Limb Lymphedema[a]

Category	ICF Domain	Problem	ICF Code	% of Participants	Literature
Impairments in function	Physical (b2, b4, b7, b8)[b]	1. Pain	b28015	40	Frid et al,[21] Towers et al[22]
		2. Tension of the skin	b840	15	Frid et al,[21] Towers et al[22]
		3. Tingling	b840	10	
		4. Infection	b43501	10	Frid et al,[21] Towers et al[22]
		5. Stiffness (decreased range of motion)	b7101	35	Frid et al,[21] Towers et al[22]
		6. Heaviness	b4552	25	Frid et al,[21] Towers et al[22]
	Mental (b1)	7. Lack of self-confidence	b1266	40	
		8. Sad	b152	15	
		9. Unattractive	b1801	20	
		10. Frustrated	b152	25	
		11. Uncertain about future	b152	35	Towers et al[22]
		12. Disappointed in health care	b152	50	Towers et al[22]
Activity limitations and participation restrictions	General tasks (d2)/ household activities (d6)	13. Dependent on others	d2102	20	
		14. Organizational problems	d2303	10	
		15. Household chores	d6409	30	Lockwood-Rayermann,[5] Towers et al[22]
	Mobility (d4)	16. Prolonged sitting	d4153	45	Lockwood-Rayermann,[5] Bogan et al[23]
		17. Prolonged standing	d4514	55	Lockwood-Rayermann,[5] Bogan et al[23]
		18. Kneeling	d4105	40	
		19. Walk more than 2 km	d4501	40	Lockwood-Rayermann,[5] Bogan et al[23]
		20. Ride a bike	d4750	30	Lockwood-Rayermann,[5] Bogan et al[23]
		21. Drive a car	d4751	15	Lockwood-Rayermann,[5] Bogan et al[23]
		22. Take stairs	d4208	20	
	Life domains (d8)/ social life (d9)	23. Do a job	d850	15	Lockwood-Rayermann,[5] Bogan et al[23]
		24. Practice sports	d9201	30	Lockwood-Rayermann,[5] Towers et al[22]
		25. Perform hobbies	d9204	30	Lockwood-Rayermann,[5] Towers et al[22]
		26. Do social activities	d9205	35	
		27. Wear clothes or shoes of choice	d5404[c]	55	
		28. Go on vacation	d9209	15	

[a] ICF=*International Classification of Functioning, Disability and Health.*
[b] Physical=other than mental: pain (b2), function of the immunologic system (b4), function of the movement system (b7), and function of the skin (b8).
[c] ICF domain: self-care.

Table 4.
Reliability of the Total Score on the Lymph-ICF-LL and of the Scores on the 5 Domains (N=30)[a]

Lymph-ICF-LL Score	Test-Retest		Consistency (α)	Variability (SEM)	Clinically Important Changes	
	ICC	95% CI			SRD	95% SRD
Total	.92	.84–.96	.96	6.0	16.5	−15.1 to 17.9
Physical function	.94	.87–.97	.97	5.9	16.3	−15.5 to 17.1
Mental function	.87	.74–.93	.93	9.1	25.2	−19.1 to 31.3
General tasks/household activities	.92	.85–.96	.96	7.7	21.3	−22.1 to 20.5
Mobility	.92	.84–.96	.96	7.7	21.3	−20.5 to 22.1
Life domains/social life	.81	.63–.90	.89	12.6	35.0	−36.3 to 33.7

[a] Lymph-ICF-LL=Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema, ICC=intraclass correlation coefficient, CI=confidence interval, α=Cronbach alpha coefficient, SEM=standard error of measurement, SRD=smallest real difference.

Each question was scored on an 11-point scale (0–10). The anchor points for the physical function, mental function, and general tasks/household activities domains were "not at all" and "a lot." Those for the mobility and life domains/social life domains were "very well" and "not at all." Participants were asked to score their average impairments in function, activity limitations, and participation restrictions due to lower limb lymphedema in the preceding 2 weeks. Furthermore, the participants were asked not to discuss the questions with anyone to maintain the self-assessment characteristic of the questionnaire. The Lymph-ICF-LL takes about 5 minutes to complete.

Each of the 28 questions accounted for a score between 0 and 10. The total score on the Lymph-ICF-LL was calculated as follows: (sum of scores on questions/total number of answered questions) × 10. In the same way, a score was determined for each of the 5 domains. The total score and the domain scores ranged from 0 to 100. As recommended in the ICF taxonomy, the scores were interpreted as follows: a score between 0 and 4 indicated no problem, a score between 5 and 24 indicated a small problem, a score between 25 and 49 indicated a moderate problem, a score between 50 and 95 indicated a severe problem, and a score between 96 and 100 indicated a very severe problem.[25]

The Lymph-ICF-LL has already been translated into English in accordance with established international guidelines described by the World Health Organization.[26–28] The Dutch version was translated into English by 2 people working independently, and the English version was translated back into Dutch by a third person.

Phase 2: Reliability and Validity of the Lymph-ICF-LL

Thirty participants (different from those in phase 1) with objective lymphedema participated in phase 2 of the study. On average, they were 50.9 years old (SD=14.9) and had a body mass index of 27.1 kg/m^2 (SD=4.7). Table 2 shows the lymphedema-related variables. The characteristics of the participants in phases 1 and 2 were comparable, except for the duration of lymphedema, the number of participants with lymphedema of the belly, and the number of participants with primary lymphedema.

Reliability. Table 4 shows the ICCs, Cronbach alpha coefficients, SEMs, and SRDs for the total score on the Lymph-ICF-LL and for the score on each domain of the Lymph-ICF-LL. The test-retest reliability was very strong (ICCs>.90) for the total score on the questionnaire and for the scores on the physical function, general tasks/household activities, and mobility domains. The test-retest reliability was strong (ICCs=.75–.90) for scores on the mental function and life domains/social life domains. The test-retest reliability was strong to very strong for scores on 24 questions (ICCs>.75) (data not shown). The reliability of the 4 remaining questions (addressing uncertainty about the future, disappointment with health care, performing hobbies, and performing social activities) was moderate (ICCs=.51–.72).

The overall internal consistency of the Lymph-ICF-LL scores ranged from strong to very strong. The Cronbach alpha coefficients were .96 for the total score on the Lymph-ICF-LL and .89 to .97 for scores on the various domains.

The total score on the Lymph-ICF-LL had a variability (SEM) of 6.0 from one test to another. The SRD was 16.5, and the 95% SRD was −15.1 to 17.9. Consequently, a decrease in the total score on the Lymph-ICF-LL of 16 or more and an increase of 18 or more should be considered clinically relevant. The score on each of the 5 domains was interpreted in the same way. The life domains/social life domains showed the greatest

Table 5.
Correlations of Various Domains of the Lymph-ICF-LL and the SF-36 for Determining Convergent Validity and Divergent Validity (N=30)[a]

	Pearson Correlation Coefficient (*P*) for:				
	Lymph-ICF-LL Domains				
	Impairments in Function		Activity Limitations and Participation Restrictions		
SF-36 Domain	Physical Function	Mental Function	General Tasks/ Household Activities[a]	Mobility	Life Domains/ Social Life
Physical functioning	−.61 (<.01)	.04 (.83)	−.76 (<.01)	−.86 (<.01)	−.74 (<.01)
Role–physical[b]	−.56 (<.01)	−.27 (.15)	−.74 (<.01)	−.65 (<.01)	−.64 (<.01)
Bodily pain	−.51 (<.01)	−.08 (.69)	−.62 (<.01)	−.66 (<.01)	−.54 (<.01)
General health[b]	−.57 (<.01)	−.12 (.53)	−.54 (<.01)	−.46 (.01)	−.48 (<.01)
Vitality	−.44 (.02)	−.53 (<.01)	−.42 (.02)	−.56 (<.01)	−.51 (<.01)
Social functioning[b]	−.61 (<.01)	−.60 (<.01)	−.64 (<.01)	−.57 (<.01)	−.64 (<.01)
Role–emotional[b]	−.16 (.40)	−.58 (<.01)	−.13 (.48)	−.29 (.12)	−.04 (.82)
Mental health	−.18 (.35)	−.46 (<.01)	−.32 (.08)	−.22 (.24)	−.18 (.34)

[a] Lymph-ICF-LL=Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema, SF-36=36-Item Short-Form Health Survey questionnaire.
[b] Not normally distributed.

variability (12.6), and the SRD was 35.0.

Validity. For 28 participants (93%), the Lymph-ICF-LL was understandable. The other 2 participants remarked that it was hard to fill out the questionnaire because of other problems at the level of their lower limb. Twenty-seven participants (90%) found the scoring system (11-point scale) to be clear. One participant preferred a scoring system with words (like that used in the SF-36), and 2 other participants mentioned that the scoring system was confusing because of the changing anchors above the 11-point scale.

For 27 participants (90%), all complaints were addressed in the Lymph-ICF-LL. One participant stated that it was difficult to fill out the questionnaire because the problems in functioning differed from 1 day to another. Two other participants mentioned the burden of having to wear compression garments, especially during the summer, as an extra complaint. The experts had only 2 comments regarding the content and structure of the Lymph-ICF-LL. A question in the mobility domain asked, "Due to your lymphedema, can you still sit for a prolonged period of time, stand for a prolonged time, . . . ?" The experts advised removing the word "still" from the question. The other comment was related to question 23: "Due to your lymphedema, can you fulfill your job?" The Dutch word for "job" is different for a Dutch-speaking inhabitant of Belgium and a Dutch-speaking inhabitant of the Netherlands. The experts suggested using 2 words for this concept ("job" and "paid work") in the question.

Table 5 shows the Pearson correlation coefficients for the various domains of the Lymph-ICF-LL and the SF-36 and their *P* values. For all data that were not distributed normally, the Pearson and Spearman correlation coefficients were comparable. Concerning convergent validity, the domains of the Lymph-ICF-LL correlated significantly with the expected corresponding domains of the SF-36. The correlation coefficients ranged from −.46 to −.86 (moderate to strong correlation), and all *P* values were less than .01. Consequently, all 5 hypotheses for assessing convergent validity were accepted. Concerning divergent validity, the domains of the Lymph-ICF-LL correlated nonsignificantly with the expected corresponding domains of the SF-36. The correlation coefficients ranged from .04 to −.32 (no to weak correlation), and the *P* values ranged from .08 to .83. Consequently, all 5 hypotheses for assessing divergent validity were accepted.

Discussion

The Lymph-ICF-LL is the first Dutch questionnaire based on the terminology of the ICF and with evidence of reliability and validity for assessing impairments in function, activity limitations, and participation restrictions in people with primary or secondary lower limb lymphedema.

Like that of the Lymph-ICF for upper limb lymphedema,[8] the reliability of the Lymph-ICF-LL was good for participants with lower limb lymphedema. The ICC for the total score

on the questionnaire was very strong, and the ICCs for the scores on the various domains varied from strong to very strong. The FLQA-I, a questionnaire used by Augustin et al[12] to measure problems related to the development of lower and upper limb lymphedema, had weaker reliability. They reported moderate to strong test-retest reliability. Moreover, instead of using the ICC to determine test-retest reliability, they used a correlation coefficient (which is less accurate). In the present study, the test-retest reliability for 24 of the 28 questions was strong to very strong. The reliability of the remaining 4 questions was moderate. The lowest ICCs were found for questions about performing hobbies and social activities. To improve the reliability of these questions, we suggest mentioning the type of hobby or social activity that a patient has scored on the questionnaire. Thus, the therapist can ask the patient to score the same hobby or social activity the next time the patient fills out the Lymph-ICF-LL. However, the ramifications of this suggestion must be examined.

The Cronbach alpha coefficient for the total score on the Lymph-ICF-LL was .96, and the coefficients for the various domains ranged from .89 to .97. The coefficients for the total score and the domain scores on the Lymph-ICF for upper limb lymphedema were lower.[8] The internal consistency of the FLQA-I was comparable and ranged from .83 to .91.[12] Like the Lymph-ICF for upper limb lymphedema, the Lymph-ICF-LL was evaluated for measurement variability and clinically important changes as recommended by Lexell and Downham.[17] For both questionnaires, the SEMs and the SRDs for the total scores and the domain scores were comparable. Augustin et al[12] did not report the SEM or the SRD for the scores on the FLQA-I.

The face validity of the Lymph-ICF-LL for participants with lower limb lymphedema was very good, as was the content validity. Ninety percent of the participants found the Lymph-ICF-LL to be comprehensive. Two participants mentioned that the burden of having to wear compression garments, especially during the summer, was not included in the questionnaire. According to the ICF system, the use of a compression garment is an external factor. Internal and external factors were not addressed in the Lymph-ICF-LL. Perhaps a separate questionnaire should be developed to collect information about internal and external factors that may be associated with lymphedema. The burden of having to wear compression garments was considered to be addressed by the questions "Do you feel frustrated because of the problems at the lower limbs?" and "Do you feel sad?" One participant mentioned that it was hard to fill out the questionnaire because the problems in functioning related to the development of lymphedema differed from 1 day to another. In this case, the therapist emphasized that the participants were asked to score their average problems over the preceding 2 weeks. Augustin et al[12] did not investigate face validity or content validity.

Construct validity was tested by examining convergent validity and divergent validity. Correlation coefficients for the various domains of the Lymph-ICF-LL and the SF-36 were determined. Franks et al[10] concluded that of all examined nonspecific questionnaires (SF-36, Modified Barthel Index, Short-Form McGill Pain Questionnaire, and EuroQol instrument), the SF-36 appeared to be the most appropriate for use in patients with lower limb lymphedema. The Lymph-ICF-LL had very good construct validity. All hypotheses were accepted. Relative to the Lymph-ICF-LL (r values ranging from .46 to .86), similar correlation coefficients for the FLQA-I and questionnaires that had already been evaluated for reliability and validity (Alltag and Nottingham Health Profile) were reported by Augustin et al[12] (r values ranging from .66 to .77).

A strength of the present study was that the Lymph-ICF-LL was developed in accordance with the guidelines of the Food and Drug Administration.[29] Thus, the construct and application of the questionnaire were defined, a literature/expert review was performed, patient input was obtained, the recall period was selected, and a preliminary questionnaire was developed and evaluated for test-retest reliability, internal consistency, content validity, and construct validity (convergent and divergent). Additionally, in contrast to other studies about problems in functioning associated with lower limb lymphedema,[11,12,21–24] the present study provided an objective definition of lymphedema.

The present study also had some limitations. In phase 1, only participants with secondary lymphedema were included, whereas in phase 2, half of the participants had primary lymphedema. This difference in the inclusion of participants was related to the addition of Nij Smellinghe Hospital in Drachten, the Netherlands, as a recruitment location; many people with primary lymphedema were seen at that location. Furthermore, the present study did not investigate the responsiveness of the Lymph-ICF-LL or known-groups validity. Further investigation of those properties and of cross-cultural validity is needed. The Dutch version of the Lymph-ICF-LL has already been translated into English in accordance with established international guidelines described by the World Health Organization.[26–28] However, the degree

to which the items on a translated or culturally adapted Lymph-ICF-LL adequately reflect the items on the original (Dutch) version of the Lymph-ICF-LL must be investigated.[30]

The Lymph-ICF-LL may be used in clinical practice to assess problems in functioning related to the development of lower limb lymphedema and to monitor the evolution of these problems in functioning. In addition, the Lymph-ICF-LL may be applied to clinical research. Besides the volume of lymphedema, the effects of various physical and surgical treatments on the lymphedema-associated problems in functioning must be evaluated. Patients must fill out the questionnaire by themselves and must score their average problems in functioning over the preceding 2 weeks. Therapists and assessors must instruct patients who repeatedly fill out the Lymph-ICF-LL to score the same hobbies and social activities each time. For the interpretation of follow-up assessments with the Lymph-ICF-LL, a change (decrease or increase) of 20 or more in the total score and in each domain score separately (with the exception of the life domains/social life domain score) should be considered a clinically relevant change. For the life domains/social life domain score, a change of 40 or more should be considered a clinically relevant change.

In conclusion, the Lymph-ICF-LL is a reliable and valid Dutch questionnaire for assessing problems in functioning in people with primary or secondary lower limb lymphedema.

Dr Devoogdt and Dr Van Kampen provided concept/idea/research design. Dr Devoogdt, Ms Christiaansen, and Ms Vervloesem provided writing. Dr Devoogdt, Ms De Groef, Mr Hendrickx, Dr Damstra, and Ms Christiaansen provided data collection. Dr Devoogdt, Mr Hendrickx, and Ms Christiaansen provided data analysis. Dr Vergote and Dr Van Kampen provided project management and fund procurement. Dr Devoogdt, Mr Hendrickx, Dr Damstra, and Dr Vergote provided study participants. Dr Devoogdt, Dr Damstra, Dr Vergote, and Dr Van Kampen provided facilities/equipment. Dr Damstra, Dr Geraerts, Dr Vergote, and Dr Van Kampen provided institutional liaisons. Mr Hendrickx, Dr Damstra, and Ms Christiaansen provided clerical support. All authors provided consultation (including review of manuscript before submission). The authors thank all participants for their participation in the study. They also thank the people, in particular, Sarah Huelskamp, who helped with the translation of the questionnaire.

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Appendix.

Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema (Lymph-ICF-LL)[a]

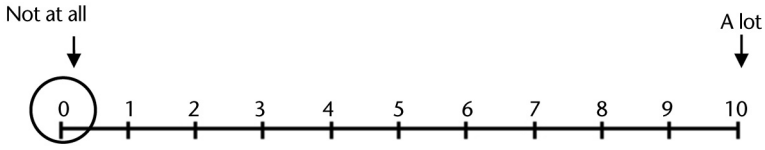
Last and first name: Date:

A swelling of the leg (legs) and/or foot (feet) may, besides the physical and mental consequences, entail some limitations in conducting activities. This can lead to problems participating in social activities. The Lymph-ICF-LL measures these dysfunctions.

The Lymph-ICF-LL contains 28 questions and was constructed based upon information from people with the same condition as yours. Next to each question there is an 11-point scale. For each question, you should **circle the number** that matches your situation the best. If you encounter no problems at all with the complaint, you should circle "0." If you are having very severe problems with the complaint described, you should circle "10." If the activity does not apply to you, please check the circle "not applicable."

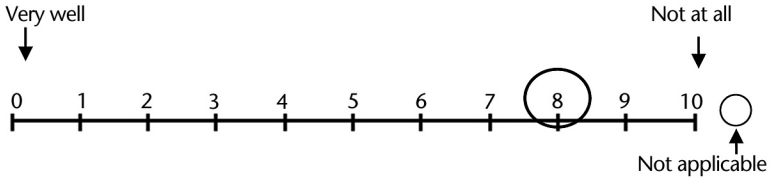
Example

1. Do you have pain at the level of your leg (legs) and/or foot (feet)?



You should circle "0" if you feel no pain at all.

2. Due to your lymphedema, do you have difficulties completing household chores?



You encircle a number more to the right if you practically cannot complete household chores anymore because of your leg edema. If you never have to complete household chores, but your household help is doing this, you should mark "not applicable."

Mark the answer that matches your situation best **during the last 2 weeks**.

Try not to overthink each question, and try to **answer each one**.

This is a **personal questionnaire**, and has to be filled out by you. Try not to discuss the questions with others when filling out the questionnaire.

Also, try not to ask questions about the content of the statements. If you are not sure, answer the question according to what you think is meant by it.

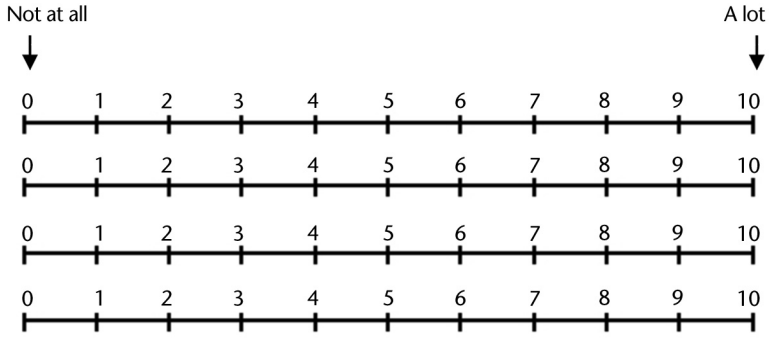
(Continued)

Appendix.
Continued

Physical function

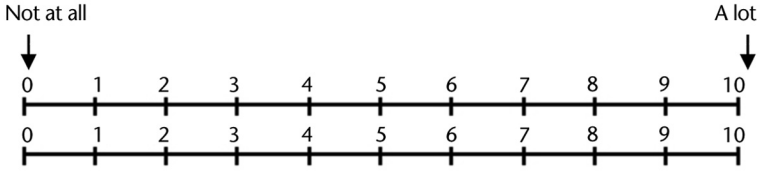
Do you have at the level of your leg (legs) and/or foot (feet):

1. Pain?
2. Tense skin?
3. Tingling?
4. Infections (at this time or occasionally)?



Does your leg (legs) and/or foot (feet) feel:

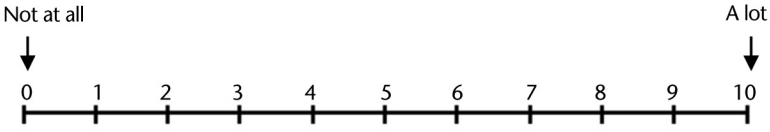
5. Stiff (reduced mobility)?
6. Heavy?



Mental function

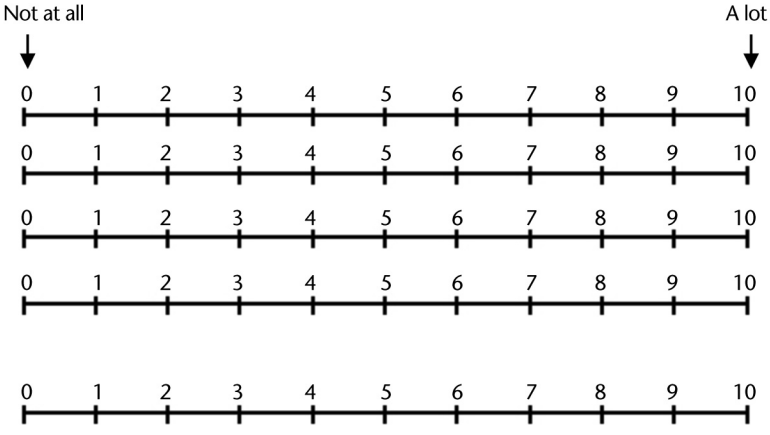
Due to your lymphedema, do you have:

7. A lack of confidence?



Due to your lymphedema, do you feel:

8. Sad?
9. Unattractive?
10. Frustrated (tense)?
11. Insecure about the future (eg, your work situation)?
12. Disappointed in medical health care (eg, lack of information?



(Continued)

Appendix.
Continued

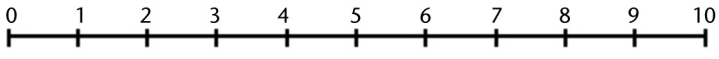
General tasks/household

Due to your lymphedema, have you:

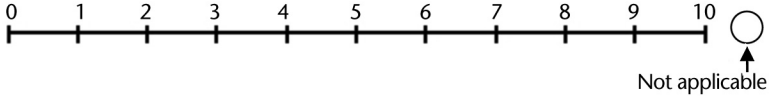
13. Become more dependent on others?

Due to your lymphedema, do you have difficulties with:

14. Organizing different matters (eg, chores, appointments)?



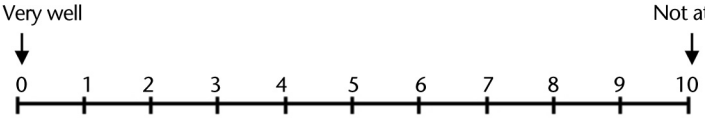
15. Completing household chores?



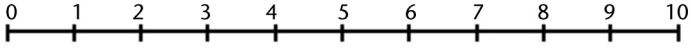
Mobility

Due to your lymphedema, can you:

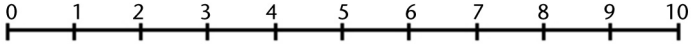
16. Sit for a prolonged period of time?



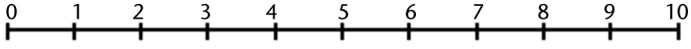
17. Stand for a prolonged time?



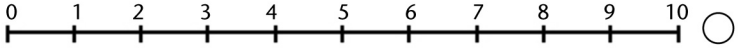
18. Kneel?



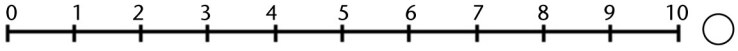
19. Walk (>2 km)?



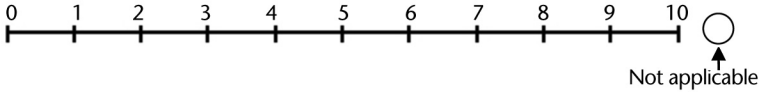
20. Ride a bicycle?



21. Drive a car?



22. Take the stairs (or get on and off a bus)?

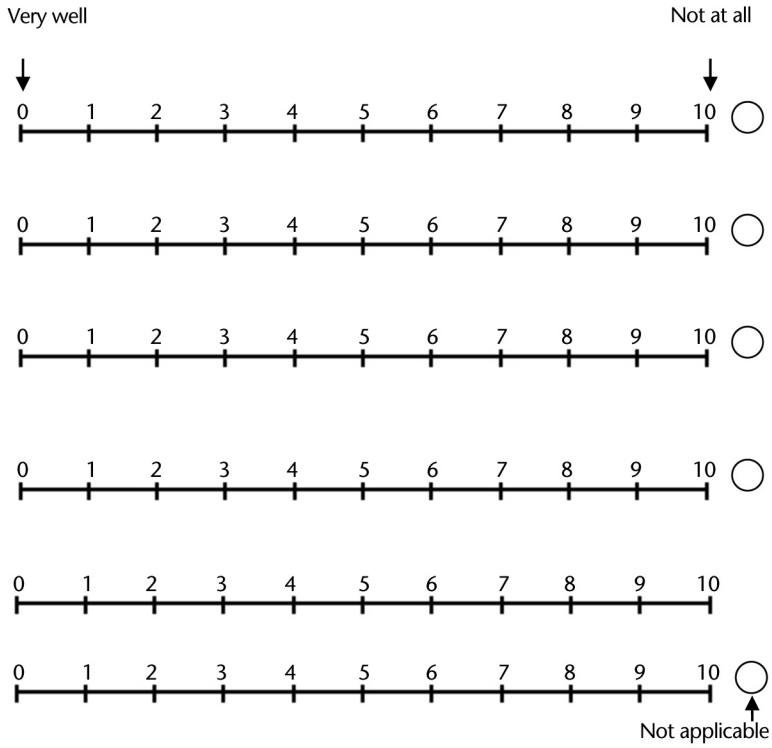


(Continued)

Appendix.
Continued

Life domains/social life

Due to your lymphedema, can you:



[a] The Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema (Lymph-ICF-LL) may not be used or reproduced without written permission of the authors.