A quality of life measure for limb lymphoedema (LYMQOL)

Vaughan Keeley, Sue Crooks, Jane Locke, Debbie Veigas, Katie Riches, Rachel Hilliam

Abstract

Background: This paper describes the validation of a 'condition-specific' quality of life (QoL) assessment tool for lymphoedema of the limbs (LYMQOL). **Aims:** To ascertain whether the tool could accurately assess QoL in this patient group. **Methods:** Face and content validity were assessed by patient questionnaires; criterion validity by comparison with European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30 questions (EORTC QLQ-C30); internal validity by Cronbach's Alpha and split half-testing of each domain; reliability by the test-retest method; construct validity by comparing LYMQOL score with initial limb volume and responsiveness by measuring changes in score following treatment. **Results:** The tool was validated in a total of 209 patients. Face, content, criterion and internal validity were supported. However, there was no correlation between initial limb volume and LYMQOL score (construct validity), a finding which is similar to that from other studies. The validation of responsiveness was limited by the small numbers of responses at three and six months after the initial assessment. **Conclusions:** LYMQOL is a validated condition-specific QoL assessment tool which can be used for lymphoedema of the limbs both in clinical assessment and as an outcome measure. **Declaration of interest:** The authors are not aware of any conflicts of interest.

Key words

QoL assessment tool
Symptom
Body image/appearance
Function
Mood

Vaughan Keeley is Consultant in Palliative Medicine; Sue Crookes is Specialist Lymphoedema Physiotherapist; Jane Locke is Matron; Debbie Veigas and Katie Riches are Research Nurses all at Lymphoedema Clinic, Derby Hospitals NHS Foundation Trust; Rachel Hilliam is Statistician, R & D Department, Derby Hospitals NHS Foundation Trust

The impact of lymphoedema on a patient's quality of life (QoL) has generally been underestimated. However, it is now clear that it can cause physical symptoms, impaired physical and social function and emotional effects (Moffatt et al, 2003).

A numb er of attempts have been made to define QoL (Higginson and Carr, 2001) which is a very personal issue. However, in healthcare it usually incorporates physical and social health and functioning and psychological and emotional wellbeing (Bowling, 1997).

This paper describes the validation of a condition-specific QoL measure for lymphoedema of the limbs (LYMQOL) which could be used routinely in clinical services.

QoL measures can be used to assess the impact of chronic oedema on the individual and also to demonstrate changes as a result of treatment (Keeley, 2008). They can be used as practical clinical tools influencing treatment decisions and measuring outcome, as well as in research studies assessing the effectiveness and cost-effectiveness of interventions (Higginson and Carr, 2001).

Health-related quality of life measures that have been used in studies of lymphoedema have been either 'general', e.g. Medical Outcome Study 36-item short form (SF-36) (Ware and Sherbourne, 1992), which assesses functional health status, or 'condition-specific', e.g. European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30 questions (EORTC QLQ-C30) (Aaronson et al, 1993) and QLQ-BR23, a 23-question tool specifically for breast cancer (Sprangers et al, 1996). However, general health-related measures may not be as accurate or informative as condition-specific tools (Morgan et al, 2005).

In recent literature, a number of lymphoedema/chronic oedema-specific QoL assessment tools have been reported. For some, the validation has been published, e.g. ULL-27 for upper limb lymphoedema (Launois and Alliott, 2000) and FLQA-L for lymphoedema of arms and legs (Augustin et al, 2005). For others, the tools have been used in studies without a formal validation being reported, e.g. Wesley Clinic Lymphoedema Scale (WCLS) or post mastectomy lymphoedema (Mirolo et al, 1995), and an un-named tool for

peripheral lymphoedema (Weiss and Spray, 2002).

This paper describes the validation of a condition-specific QoL measure for lymphoedema of the limbs (LYMQOL) which could be used routinely in clinical services. Interim stages of the validation process have been previously reported (Keeley et al, 2004).

Methods

Development of the tool

LYMQOL was developed by experienced healthcare professionals in the lymphoedema service in Derby, UK in consultation with service users. Separate tools were developed for arm and leg lymphoedema. The tools were designed as patient-completed questionnaires with a structure similar to the EORTC QLQ-C30 (*Appendices 1a and 1b*).

The questions cover four domains:

▸▸ Symptoms
▸▸ Body image/appearance
▸▸ Function
▸▸ Mood.

There is an overall QoL rating. The mood questions were taken from the previously validated EORTC QLQ-C30 with permission.

Scoring of LYMQOL

Each item in each domain was scored:

▸▸ Not at all   = 1
▸▸ A little   = 2
▸▸ Quite a bit = 3
▸▸ A lot   = 4.

A total score for each domain was calculated by adding all scores together and dividing by the total number of questions answered. If fewer than 50% of the items were answered, the whole domain was scored as 0. The 'overall QoL' item was scored 0–10.

In some of the analyses, the domain scores were calculated as a percentage to facilitate comparison with other measures (see below).

Validation

The study was designed to measure (Fallowfield, 1990):

▸▸ Validity, i.e. is the scale measuring what it was designed to do?
▸▸ Reliability, i.e. to what extent can the scale be reproduced under different conditions?
▸▸ Responsiveness, i.e. is the scale sensitive enough to record significant changes following treatment?

Specific aspects of these elements were measured as follows.

Face validity

The subjective assessment of the presentation of the questionnaire and its relevance was measured using a short questionnaire that was given to patients who took part in the study (*Appendix 2*).

Content validity: does the content address all the important issues?

This was assessed from the patient questionnaire and by a separate study (Veigas and Keeley, 2004). The study was a phenomenological interview of 22 patients. The main themes that emerged were loss, both actual and potential, relating to the individual's role, work, body image, self-esteem and embarrassment.

Criterion validity: how does the new measure compare with a 'gold standard' tool?

No such condition-specific tool was available at the time the study was carried out. Therefore, the results were compared with relevant sections of the EORTC QLQ-C30 in the first 50 patients, using the Spearman or Pearson correlation coefficient and intra-class correlation coefficient.

Internal validity

This includes:

▸▸ Internal consistency: by Cronbach's Alpha and split half-testing of each domain. The latter tests for homogeneity, i.e. the extent to which the questions relating to a particular domain measure only that and no other. Split half-testing was carried out in two ways, the first comparing first and second half items and the second comparing odd and even numbered items. The Spearman-Brown coefficient was used to test for similarities between the two halves

▸▸ Reliability: by the test re-test method in a subgroup of patients. The first measure was carried out at the initial assessment and the second before intensive treatment with bandaging, i.e. repeated in individual patients before any treatment had been given, and therefore it was unlikely that there would have been any significant change in QoL. Results were compared using Pearson's correlation coefficient.

Construct validity: to what extent does the tool test the theory it is measuring?

It was postulated that patients with more severe lymphoedema (i.e. larger limb volumes) would have a 'lower' QoL, i.e. higher scores in LYMQOL domains. Therefore, initial limb volume was compared with LYMQOL scores in each domain, using the paired T-test.

Responsiveness: is the tool sensitive to change?

This was assessed by measuring changes in QoL scores following treatment, using the Pearson correlation coefficient.

Inclusion criteria:

▸▸ New patients presenting to the lymphoedema clinic in Derby who consented to take part
▸▸ Patients over 18 years of age with unilateral or bilateral swelling of upper or lower limbs.

Exclusion criteria:

▸▸ Those with active malignancy
▸▸ Those undergoing chemotherapy.

Data was collected as follows:

▸▸ First visit:
  • demographics, i.e. gender, age,
  • site of lymphoedema, cause of lymphoedema
  • LYMQOL score
  • Patient questionnaire
  • EORTC QLQ-C30 (first 50 patients)
  • Limb volume measurement.

▸▸ Follow-up at one week, one month, three months and six

months after treatment either with a compression garment or multilayer lymphoedema bandaging ± manual lymphatic drainage (MLD). This involved:

- LYMQOL score
- Limb volume measurement.

The study was approved by the Southern Derbyshire Local Research Ethics Committee (Reference No: SDLREC 0202/438).

Results

A total of 209 patients took part in the study, of which 78.7% were women. The mean age of participants was 58 years (SD 16.4 years). Bilateral leg swelling was the most frequently reported site of swelling (43.8%). Approximately one quarter of the sample reported unilateral arm swelling (26.8%) or unilateral leg swelling (27.7%). 1.5% of patients reported that a combination of arms and legs were swollen.

Face validity

Face validity was confirmed (*Table 1*). Patients found LYMQOL clear, easy to complete and not too long.

Content validity

There were 90 patient questionnaires returned. Although 92% of respondents felt that no questions could be left out, 20% felt that there were important areas missing. The main themes of these are shown in *Table 2*.

Criterion validity

The LYMQOL results for the domains 'function', 'symptoms', 'mood' and 'overall QoL' showed good correlation with those for comparable domains in the EOTC QLQ-C30 for both arm and leg questionnaires (*Tables 3 and 4*). There was no comparable domain in the EORTC QLQ-C30 for that of 'appearance' in LYMQOL, so no comparison could be made.

Internal validity

Internal consistency — Cronbach's alpha

Cronbach's alpha was >0.8 for all domains in both the arm and leg versions of LYMQOL, thus confirming internal consistency (*Tables 5 and 6*).

Table 1

Face validity. Response to questionnaires (n=90)

	Yes (%)	No (%) months
Was it easy to complete?	93	7
Was it too long?	1	99
Were the questions clear?	99	1

Deleting any of the items did not appear to increase the value of alpha by a large amount, i.e. did not improve internal consistency and therefore supported the reliability.

The small number in the 'symptom' domains included in the analysis reflects the relatively large number of incomplete responses in this domain.

Split half-testing of each domain

Reliability was adequate (≥0.8) or good (≥0.9) for each of the domains with the exception of 'symptoms' for LYMQOL (arm) when first and second halves were compared (*Tables 7 and 8*). This is likely to be because the questions in the first half are all part of Q11 and relate to the site and degree of pain. The second method of testing is therefore more appropriate for this domain. Reliability was found to be adequate or good for all of the domains tested.

Reliability

Reliability was supported using the test-retest method for 15 patients who had leg oedema (*Table 9*). This number is relatively small and reflects the fact that most patients were treated at the first clinic appointment and the test-retest method could only be used in those who returned for treatment at a later date. Nevertheless, there was good correlation between the mean scores for each domain at visit one and two, i.e. with no intervening treatment in this subgroup.

Construct validity

It was postulated that patients with more severe swelling, i.e. larger limb

Table 2

Examples of comments on what was missed out

- ▶▶ Sensitivity of legs
- ▶▶ Redness and soreness
- ▶▶ Burning/hot feelings
- ▶▶ Effect of other conditions, e.g. previous knee injury
- ▶▶ Impact of cellulitis
- ▶▶ Embarrassment
- ▶▶ Effect of compression garment

volume would have a 'lower' quality of life. Therefore, LYMQOL scores were compared with initial limb volume.

There was no significant correlation between any of the domains of LYMQOL and the initial limb volume.

Responsiveness

Scores at the time of presentation were compared with those at one week and one month later to see how the questionnaire responded over time. Too few responses were received at later times after presentation to allow meaningful analysis.

There were no significant differences in scores after one week and one month for LYMQOL (arm) domains.

For LYMQOL (leg), the 'appearance' scores were significantly lower, i.e. improved at one week and one month, whereas the 'function', 'symptoms'

Table 3

Correlation between LYMQOL (arm) and EORTC QLQ-C30 domains

	n	correlation coefficient	p-value	ICC	p-value
Function	15	0.689	0.005	0.686	0.001
Symptoms	15	0.688	0.005	0.643	0.003
Mood	15	0.860	<0.001	0.868	<0.001
QoL	14	0.937	<0.001	0.941	<0.001

ICC = Intraclass correlation coefficient

Table 4

Correlation between LYMQOL (leg) and EORTC QLQ-C30 domains

	n	correlation coefficient	p-value	ICC	p-value
Function	23	0.690	<0.001	0.674	<0.001
Symptoms	25	0.788	<0.001	0.614	<0.001
Mood	26	0.805	<0.001	0.782	<0.001
QoL	24	0.644	0.001	0.632	<0.001

ICC = Intraclass correlation coefficient

Table 5

Cronbach's alpha for the domains of LYMQOL (arm)

	n	alpha
Function	28	0.882
Appearance	42	0.832
Symptoms	14	0.851
Mood	50	0.867

and 'mood' domains showed no difference. The 'overall QoL' scores were significantly higher, i.e. better at one week but no different at one month from presentation (*Table 10*), although the difference at one week was small and not likely to be of clinical significance.

Reducing the number of items

Although the LYMQOL tool is not particularly lengthy (38 items for arm; 40 items for leg), analysis was carried out to see if any items were 'redundant', i.e. were unnecessary and could be removed. This was achieved by examining internal correlations of items within each domain using Spearman's correlation coefficient (rho).

If two items have a high correlation, they may be measuring the same thing and, therefore, one could be removed in the development of a revised version of LYMQOL. From a statistical point of view, a correlation of ≥0.7 was applied as the 'cut off' for a significant value in determining whether a particular item could be considered superfluous.

Items with a poor correlation to the overall domain score may equally not contribute much to the domain as a whole. These could also be removed to shorten the tool without affecting its value.

However, in the application of this methodology, consideration has also to be given to whether the items are particularly relevant clinically. If LYMQOL is to be used as part of clinical assessment and outcome measurement, keeping some potentially 'redundant' items may be appropriate if they are of clinical importance.

Finally, consideration was given to whether some items were frequently 'not answered' by respondents and could therefore be omitted. This was particularly relevant to the 'symptom' domain where the number of complete responses was low (*Tables 5* and *6*).

Using this approach, LYMQOL arm and LYMQOL leg were modified and the new versions contain 28 and 27 items respectively (*Appendices 3a, 3b*). The scoring system is also included in *Appendices 3a and 3b*.

The details of this modification process are included in *Appendix 4*.

Discussion

This paper has demonstrated the face validity, content validity, criterion validity and internal validity of LYMQOL.

The aim was to produce a condition-specific QoL tool for lymphoedema which could be used in routine clinical practice for assessment and as an outcome measure, as well as in research.

Table 6

Cronbach's alpha for the domains of LYMQOL (leg)

	n	alpha
Function	45	0.945
Appearance	78	0.874
Symptoms	12	0.917
Mood	100	0.875

Table 7

Spearman-Brown coefficients for split half-testing for LYMQOL (arm) domains

	n	1st/2nd half	Odd/even
Function	28	0.923	0.933
Appearance	42	0.853	0.830
Symptoms	14	0.642	0.859
Mood	50	0.801	0.871

Table 8

Spearman-Brown coefficients for split half-testing for LYMQOL (leg) domains

	n	1st/2nd half	Odd/even
Function	45	0.897	0.964
Appearance	78	0.835	0.936
Symptoms	12	0.887	0.964
Mood	100	0.855	0.923

As such, it is important that the tool is easy to use and not too lengthy. Although patients did not feel it was too long, and indeed suggested further items which should be added (*Table 2*), it was also clear that there was a degree of 'fatigue' in repeatedly completing the questionnaire during the course of the study, as the numbers responding decreased over time. Indeed, there were insufficient responses at three and six months to examine statistically.

On reviewing the issues raised in *Table 2*, it was felt that some could perhaps be addressed by existing items, e.g. impact on holidays covered by the item on leisure activities and embarrassment by the 'appearance' domain.

The question of the effect of comorbidity on the scores is more complex. For example, mobility may be affected by other conditions, e.g. arthritis, lung disease and

neurological problems, rather than the lymphoedema itself. This needs to be considered when using the tool to assess individual patients, since treating the lymphoedema successfully may not necessarily result in an improvement in mobility (as measured by the 'function' domain) in these situations.

Taking the above into account, it was felt important to try to reduce the size of LYMQOL to make it more acceptable to users. This process was supported by the statistical analysis, which had demonstrated that some items were potentially redundant. The revised versions of LYMQOL should also address the problem of incomplete responses to the symptom domain (*Tables 5, 6, 7* and *8*). It seems that the issue here related to the 'sites of pain', particularly in LYMQOL (arm) as described in *Table 7* and, therefore, the revised version has been amended accordingly (*Appendices 3a, 3b* and *4*).

The decline in 'response rate' at three and six months may reflect patient 'fatigue', however it is also possible that not all patients received questionnaires to complete at these times if the research nurse was not present at the follow-up appointment. Regardless of this, a less frequent use, e.g. six-monthly or annually may be appropriate when LYMQOL is employed in routine clinical practice to fit in with follow-up assessment appointments.

Construct validity was not fully confirmed in that there seemed to be no significant correlation between initial limb volume and quality of life. Interestingly, other studies have reported a lack of relationship between improved QoL and a reduction in limb volume after treatment (e.g. Sitzia and Sobrido, 1997; Weiss and Spray, 2002). Thus, the initial construct that limb volume and quality of life are inversely related may be erroneous. Nevertheless, this could suggest that QoL measures may add a different dimension to patient assessment beyond the routine measurement of limb volume currently carried out by most lymphoedema services. Hence, this strengthens the case for using a

Table 9

Correlation of domain scores in LYMQOL (leg) at visits one and two without intervening treatment (n=15)

Domain	Correlation	p-value
Functional	0.543	0.036
Appearance	0.909	<0.001
Symptoms	0.861	<0.001
Mood	0.826	<0.001
Overall QoL	0.542	0.037

Table 10

Comparison of domain scores at presentation, one week and one month for LYMQOL (leg)

Domain	n	Mean (%)	SD	T-test	p-value
a) Appearance					
Presentation	76	45.2	26.1	3.109	0.003
One week	76	38.8	26.9		
Presentation	54	41.2	28.5	2.482	0.016
One month	54	34.0	27.9		
b) Overall QoL					
Presentation	74	63.1	20.3	-2.176	0.003
One week	74	66.9	18.3		
Presentation	49	63.1	17.6	-0.230	0.819
One month	49	63.7	20.9		

condition-specific QoL assessment tool as a clinical outcome measure.

Unfortunately, the data available in this study have not conclusively demonstrated the responsiveness of LYMQOL over time, although the 'appearance' scores of LYMQOL (leg) were significantly improved at one week and one month. This is largely due to the fact that few patients completed questionnaires at three and six months. More data is to be collected on this using the revised LYMQOL, but asking patients to complete questionnaires less frequently (six-monthly), with the aim of improving the response rate.

LYMQOL seems to be a potentially useful tool in assessing and monitoring patients with chronic limb oedema. One limitation in its use, however, is that it does not specifically address 'midline' oedema, e.g. trunk, genital and head and neck oedema.

A number of other condition-specific QoL tools for lymphoedema have been developed and reported. Only two other groups have published the validation of the tools — ULL-27 for upper limb lymphoedema (Launois and Alliott, 2000) and FLQA-L for lymphoedema of the arms and legs (Augustin et al, 2005).

Key points

▸▸ The validation of LYMQOL, a quality of life assessment tool for limb lymphoedema is described.

▸▸ LYMQOL covers four domains: symptoms, body image/appearance, function and mood, as well as an overall QoL score.

▸▸ As a result of the validation process, a revised version of LYMQOL has been produced and is available for use in the assessment of patients with lymphoedema and their response to treatment, data and monitoring of changes over time.

The former is a 27-item tool specifically designed for upper limb lymphoedema. The latter is a 92-item questionnaire derived from a previously validated tool (FLQA vein questionnaire). LYMQOL represents an alternative to these, being a relatively short tool covering both arm and leg oedema.

LYMQOL has not been designed for use in children, therefore it is not recommended for this age group. In addition, as described above, it does not specifically address 'mid-line' lymphoedema. This is going to be the subject of future work

Conclusions

LYMQOL is a validated QoL assessment tool for use with people with limb lymphoedema. Further work is underway to confirm its responsiveness over time. Readers who are interested in using LYMQOL are invited to contact vaughan.keeley@derbyhospitals.nhs.uk for further information and to share experiences of its use. JL

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Appendix 2

Lymphoedema quality of life questionnaire responses

(1) Was it easy to complete?

If no, please say why:

....

....

(2) Was it too long?

(3) Were all the questions clear?

If no please record the relevant question numbers, and state why:

....

....

(4) Were there any important areas where your swollen limb(s) affects the quality of your life that were not covered?

If yes please comment:

....

....

(5) Were there any questions which you feel we could have left out?

If yes please give examples:

....

....

(6) Any other comments?

....

....

Appendix 1a

Lymphoedema Quality of Life Study (LYMQOL)   ARM

If any of the items are not applicable to you, please write N/A in the relevant answer box(es).

(1) How much does your swollen arm affect the following daily activities?

	Not at all	A little	Quite a bit	A lot
a) occupation				
b) housework				
c) combing hair				
d) dressing				
e) doing up/undoing buttons				
f) writing				
g) eating				
h) washing				
i) cleaning teeth				
j) putting on make-up/shaving				

(2) How much does it affect your leisure activities/social life?

Please give example(s) of this.

....

....

Question	
(3) How much do you have to depend on other people?	
(4) How much do you feel the swelling affects your appearance?	
(5) How much difficulty do you have finding clothes to fit?	
(6) How much difficulty do you have finding clothes you would like to wear?	
(7) Have you had difficulty wearing jewellery, e.g. wedding ring?	
(8) Does the swelling affect how you feel about yourself?	
(9) Does it affect your relationship with your partner?	
(10) Does it affect your relationships with other people?	
(11) Does your lymphoedema cause you pain?	
If so, do you have pain in the arm	
shoulder	
back	
neck	
elsewhere — if so, where?	
(12) Do you have any numbness in your swollen arm?	
(13) Do you have any feelings of 'pins and needles' or tingling in your swollen arm?	
(14) Does your swollen arm feel weak?	
(15) Does your swollen arm feel heavy?	
(16) Does your hand feel 'cold'?	
(17) Do you feel tired?	
In the past week	
(18) Have you had trouble sleeping?	
(19) Have you had difficulty concentrating on things, e.g. reading?	
(20) Have you felt tense?	
(21) Have you felt worried?	
(22) Have you felt irritable?	
(23) Have you felt depressed?	

(24) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

If you have any comments or queries about it, please discuss these with..

Dr V L Keeley, Consultant

Questions 18 to 24 have been reproduced with permission from the EORTC
These questions are only a part of the QLQ-C30 Questionnaire.

Appendix 1b

Lymphoedema Quality of Life Study (LYMQOL) LEG				
If any of the items are not applicable to you, please write N/A in the relevant answer box(es).				
(1) Has your swollen leg(s) affected:				
	Not at all	A little	Quite a bit	A lot
a) your walking				
b) your ability to go up and down stairs				
c) your ability to bend, e.g. to tie shoelaces or cut toenails				
d) your ability to kneel				
e) your ability to stand				
f) your ability to get into/out of a car				
g) Your ability to get on/of public transport, e.g. trains/buses				
h) your ability to get up from a chair				
i) your ability to drive a car				
j) your occupation				
k) your ability to do housework				
(2) Does the swelling affect your leisure activities/social life?				

Please give example(s) of this.

....

....

	Not at all	A little	Quite a bit	A lot
(3) How much do you have to depend on other people?				
(4) How much do you feel the swelling affects your appearance?				
(5) How much difficulty do you have finding clothes to fit?				
(6) How much difficulty do you have finding clothes you would like to wear?				
(7) Do you have difficulty finding shoes to fit?				
(8) Do you have difficulty finding socks/tights/stockings to fit?				
(9) Does the swelling affect how you feel about yourself?				
(10) Does it affect your relationship with your partner?				
(11) Does it affect your relationships with other people?				
(12) Does your lymphoedema cause you pain?				
If so, do you have pain in the foot/feet				
leg/legs				
hip(s)				
back				
elsewhere — if so, where?				
(13) Do you have any numbness in your swollen leg(s)?				
(14) Do you have any feelings of 'pins and needles' or tingling in your swollen leg(s)				
(15) Does (do) your swollen leg(s) feel weak?				
(16) Does (do) your swollen leg(s) feel heavy?				
(17) Does (do) your swollen foot (feet) feel 'old'?				
(18) Have you had any leakage of fluid from your leg(s)				
In the past week				
(19) Have you had trouble sleeping?				
(20) Have you had difficulty concentrating on things, e.g. reading?				
(21) Have you felt tense?				
(22) Have you felt worried?				
(23) Have you felt irritable?				
(24) Have you felt depressed?				
(25) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:				

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

If you have any comments or queries about it, please discuss these with...   Dr V L Keeley, Consultant

Questions 19 to 25 have been reproduced with permission from the EORTC. These questions are only a part of the QLQ-C30 Questionnaire.

Appendix 3a

LYMQOL ARM-Scoring System
Lymphoedema Quality of Life Tool

The score for the individual responses are given below. If the item is not scored and left blank or not applicable this is scored with a 0. Domain totals are calculated by adding the individual scores and dividing the total by the number of questions answered. (If >50% of questions per domain are not answered this cannot be calculated and =0).
The four domains and their corresponding questions are: Function 1 (a–h), 2, 3;
Appearance 4, 5, 6, 7, 8; Symptoms 9, 10, 11, 12, 13, 14; and Mood 15, 16, 17, 18, 19, 20.
Overall quality of life (Q21) is scored as the value marked by the patient, between 0–10.

(1) How much does your swollen arm affect the following daily activities?

	Not at all	A little	Quite a bit	A lot
a) occupation	1	2	3	4
b) housework	1	2	3	4
c) combing hair	1	2	3	4
d) dressing	1	2	3	4
e) writing	1	2	3	4
f) eating	1	2	3	4
g) washing	1	2	3	4
h) cleaning teeth	1	2	3	4
(2) How much does it affect your leisure activities/social life?	1	2	3	4

Please give example(s) of this.

....

....

(3) How much do you have to depend on other people?	1	2	3	4
(4) How much do you feel the swelling affects your appearance?	1	2	3	4
(5) How much difficulty do you have finding clothes to fit?	1	2	3	4
(6) How much difficulty do you have finding clothes you would like to wear?	1	2	3	4
(7) Does the swelling affect how you feel about yourself?	1	2	3	4
(8) Does it affect your relationships with other people?	1	2	3	4
(9) Does your lymphoedema cause you pain?	1	2	3	4
(10) Do you have any numbness in your swollen arm?	1	2	3	4
(11) Do you have any feelings of 'pins and needles' or tingling in your swollen arm?	1	2	3	4
(12) Does your swollen arm feel weak?	1	2	3	4
(13) Does your swollen arm feel heavy?	1	2	3	4
(14) Do you feel tired?	1	2	3	4
In the past week	1	2	3	4
(15) Have you had trouble sleeping?	1	2	3	4
(16) Have you had difficulty concentrating on things, e.g. reading?	1	2	3	4
(17) Have you felt tense?	1	2	3	4
(18) Have you felt worried?	1	2	3	4
(19) Have you felt irritable?	1	2	3	4
(20) Have you felt depressed?	1	2	3	4
(21) (24) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:	1	2	3	4

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

If you have any comments or queries about it, please discuss these with...

Dr V L Keeley, Consultant

Questions 15 to 20 have been reproduced with permission from the EORTC.
These questions are only a part of the QLQ-C30 Questionnaire.

Appendix 3b

LYMQOL LEG-Scoring System
Lymphoedema Quality of Life Tool

The score for the individual responses are given below. If the item is not scored and left blank or not applicable this is scored with a 0. Domain totals are calculated by adding the individual scores and dividing the total by the number of questions answered. (If >50% of questions per domain are not answered this cannot be calculated and =0).
The four domains and their corresponding questions are: Function 1 (a–f), 2, 3
Appearance 4, 5, 6, 7, 8, 9, 10; Symptoms 11, 12, 13, 14, 15 and Mood 16, 17, 18, 19, 20, 21.
Overall quality of life (Q22) is scored as the value marked by the patient, between 0–10.

(1) How much does your swollen leg affect the following daily activities?

If any items are not applicable, please write N/A in the relevant box(es)	Not at all	A little	Quite a bit	A lot
a) your walking	1	2	3	4
b) your ability to bend, e.g. to tie shoelaces or cut toenails	1	2	3	4
c) your ability to stand	1	2	3	4
d) your ability to get up from a chair	1	2	3	4
e) your occupation	1	2	3	4
f) your ability to do housework	1	2	3	4

	Not at all	A little	Quite a bit	A lot
(2) Does the swelling affect your leisure activities?	1	2	3	4

Please give example(s) of this.

....

....

	Not at all	A little	Quite a bit	A lot
(3) How much do you have to depend on other people?	1	2	3	4
(4) How much do you feel the swelling affects your appearance?	1	2	3	4
(5) How much difficulty do you have finding clothes to fit?	1	2	3	4
(6) How much difficulty do you have finding clothes you would like to wear?	1	2	3	4
(7) Do you have difficulty finding shoes to fit?				
(8) Do you have difficulty finding socks/tights/stockings to fit?				
(9) Does the swelling affect how you feel about yourself?	1	2	3	4
(10) Does it affect your relationships with other people?	1	2	3	4
(11) Does your lymphoedema cause you pain?	1	2	3	4
(12) Do you have any numbness in your swollen arm?	1	2	3	4
(13) Do you have any feelings of 'pins and needles' or tingling in your swollen arm?	1	2	3	4
(14) Does (do) your swollen leg(s) feel weak?	1	2	3	4
(15) Does (do) your swollen arm(s) feel heavy?	1	2	3	4
In the past week	1	2	3	4
(16) Have you had trouble sleeping?	1	2	3	4
(17) Have you had difficulty concentrating on things, e.g. reading?	1	2	3	4
(18) Have you felt tense?	1	2	3	4
(19) Have you felt worried?	1	2	3	4
(20) Have you felt irritable?	1	2	3	4
(21) Have you felt depressed?	1	2	3	4
(22) (24) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:	1	2	3	4

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

If you have any comments or queries about it, please discuss these with...

Dr V L Keeley, Consultant

Appendix 4

LYMQOL Modifications after further analysis

LYMQOL arm:

Arm function: questions 1(a–j)–3

- Question 1e: doing up/undoing buttons demonstrated high correlations to dressing, eating and putting on make up and shaving, all were >0.7. This question was therefore removed as it was felt that this action was covered by these questions.
- Question 1j: Putting on make up/shaving was also highly correlated with writing, eating and washing, all >0.68. This question was also removed.
- Questions 1a and i: Occupation and cleaning teeth were poorly correlated to the other questions and the domain as a whole. Despite this it was decided that these questions should be kept. Despite a maximum of 37 participants answering Q1a it was felt to have clinical significance if recognised as a problem by the patient. Q1i was not omitted as it was felt that this activity required a level of dexterity and actions not covered by the other questions.

Arm appearance: questions 4–10

- On the whole the individual questions in this section were poorly correlated with each other; however, they were correlated to the domain as a whole. There were two questions that were not correlated to the domain 7 and 9: difficulty wearing jewellery and whether the swelling affects the relationship with their partner. Both of these questions were removed.

Arm symptoms: questions 11–17

- Question 11 asks whether the lymphoedema causes pain and the five subsequent questions detailed specific areas. It was felt that the presence of pain was the significant question and knowing the specific area did not add to this, as further questions regarding the presence of pain would be covered in a clinical assessment. These five questions have been removed from the modified version of LYMQOL.
- Question 16 asked whether the hand felt cold and this was poorly correlated with the other questions and also the domain as a whole. This question was therefore removed.

Arm mood: questions 18–23

- These questions were taken from the EORTC questionnaire and therefore have been previously validated. However, they have been taken from different domains in the EORTC. They are all correlated to the domain and therefore all remain in the modified version.

LYMQOL leg:

Leg function: questions 1(a–k)–3

- The majority of the questions correlated well with each other and the domain as a whole. There was one aspect, however, that did not demonstrate any significant correlations with any other aspect or to the domain. This was the ability to drive a car (1i). This has subsequently been removed in the modified version.
- Question 1j: The effect of the swelling on the patient's occupation did not demonstrate a high correlation with the other functional aspects but was correlated with the domain. Similarly to the arm LYMQOL, this was perceived as having clinical significance and was retained.
- As a result of the high correlations each question was reviewed and questions 1b (the ability to go up and down stairs), d (the ability to stand), f (the ability to get into/out of a car), g (the ability to get on/get off public transport) have been removed, as it was felt that these aspects were covered by the remaining questions.

Leg appearance: questions 4–11

- Similarly to the arm questionnaire, question 10, 'relationship with your partner' was poorly correlated and it was felt that this could be answered by the following question, relationship with others. Therefore this has been removed.

Leg symptoms: questions 12–18

- Once more the relationships demonstrated in the analysis of the arm questionnaire were mirrored in the leg questionnaire. The sub-questions relating to the areas of pain (12 a–e) and also the feeling of coldness (17) have been removed.
- Question 18, leakage of fluid was not correlated with any of other questions and did not add to the domain as a whole, therefore it been removed. This symptom can be addressed in the clinical assessment.

Leg mood: questions 19–24

- These questions were taken from the EORTC questionnaire and therefore have been previously validated. However, they have been taken from different domains in the EORTC. They are all correlated to the domain and some with each other (21, 22, 23 and 24 are all significantly correlated with each other) and therefore all remain in the modified version.