



# LYMPH-Q© | UPPER EXTREMITY

## A User's Guide for Researchers and Clinicians

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## **1. What is the LYMPH-Q | Upper Extremity?**

Arm lymphedema is a debilitating diagnosis that has a huge impact on a patient's health-related quality of life (HRQOL) due to symptoms (e.g., swelling, pain, infection) and reduced arm function. The rapidly emerging field of lymphedema research lacks consensus on the most suitable outcome measures to use for this condition. Clinicians often use measures of limb volume and circumference, but such measures do not capture the burden of lymphedema on patients' HRQOL. To better understand outcomes from the patient perspective, a valid and reliable patient-reported outcome measure (PROM) is needed. Our team developed the LYMPH-Q Upper Extremity to provide a rigorously developed PROM for arm lymphedema in women with breast cancer [1].

## **2. How was the LYMPH-Q | Upper Extremity Developed and Validated?**

The LYMPH-Q represents a new generation of PROMs developed using a modern psychometric approach called Rasch Measurement Theory (RMT). In RMT, scales that compose a PROM are each designed to measure and score a unidimensional construct. In scale development, data that meet the requirement of the Rasch model provide interval-level measurement. When a scale has high content validity and is targeted to measure a concept as experienced by a sample, accurate tracking of clinical change can be achieved. In addition to their use in research studies, LYMPH-Q scales can be used with individual patients to inform clinical care.

Figure 1 shows the multiphase mixed methods approach we use to develop Q-Portfolio instruments. We followed internationally recommended guidelines for PROM development to ensure that the LYMPH-Q meets requirements of regulatory bodies.

The qualitative phase took place between January 2017 and June 2018. Qualitative interviews with 15 women who had arm lymphedema following treatment for breast cancer were conducted. The sample was aged between 40 and 74 years, mainly Caucasian (n=13) and married (n=10). Most participants had a mastectomy (n=10) and history of having a combination of chemotherapy, radiotherapy, and endocrine therapy (n=7). Analysis of the qualitative data led to the development of a framework of concepts important to patients with arm lymphedema. An item pool was developed from the qualitative data and used to develop a conceptual framework covering 3 domains: health-related quality of life (i.e., Function, Symptoms, Appearance, Life Impact, Psychological), experience of care (Information) and treatment outcome (arm sleeve). Figure 2 shows the LYMPH-Q conceptual framework. The LYMPH-Q is composed of 7 independently functioning scales. Each scale was assigned instructions, a response time frame, and four response options.

To further establish content validity, 16 cognitive debriefing interviews with patients were performed in three rounds between October and December 2018. The sample included women aged between 38 and 74 years who were mainly Caucasian (n=16) and married (n=11). Most participants had a mastectomy (n=10) and axillary lymph node dissection (n=14). Their cancer treatment included a combination of chemotherapy, radiotherapy, and endocrine therapy (n=11). Feedback was also obtained from 12 multi-disciplinary experts from Canada, Denmark, Poland, and the United Kingdom. The experts included 8 plastic surgeons, 2 breast surgeons, a medical oncologist, and a nurse practitioner. Feedback from patients and experts was used to refine the LYMPH-Q Upper Extremity module.

The LYMPH-Q was translated into Danish following best practice guidelines [2]. Field-test data were collected online between October 2019 and January 2020 using the Research Electronic Data Capture System (REDCap). Recruitment took place in the USA (364 members of the Love Research Army; <https://www.loveresearcharmy.org/>) and Denmark (2858 patients from the Danish National Health Data Authority). Sample characteristics for the 3222 participants are shown in Table 1.

RMT analysis provided evidence of reliability and validity for 6 LYMPH-Q scales. The reliability statistics with and without extremes for the Person Separation Index were  $\geq 0.80$ , Cronbach's alpha values were  $\geq 0.89$ , and interclass correlation coefficients were  $\geq 0.92$  for all scales. Lower (worse) scores on LYMPH-Q scales were associated with the reporting of more severe arm swelling, a major (versus minor or none) arm problem caused by cancer and/or its treatment, and wearing an arm sleeve in the past 12 months.

**Figure 1:** The multiphase mixed-methods approach our team follows to develop PRO measures (Reprinted from Klassen A, van Haren ELWG, Cross K, et al. International multiphase mixed methods study protocol to develop a patient-reported outcome measure for all types of chronic wounds (the WOUND-Q). *BMJ Open*. 2020;10:e032332. doi:10.1136/bmjopen-2019-032332)

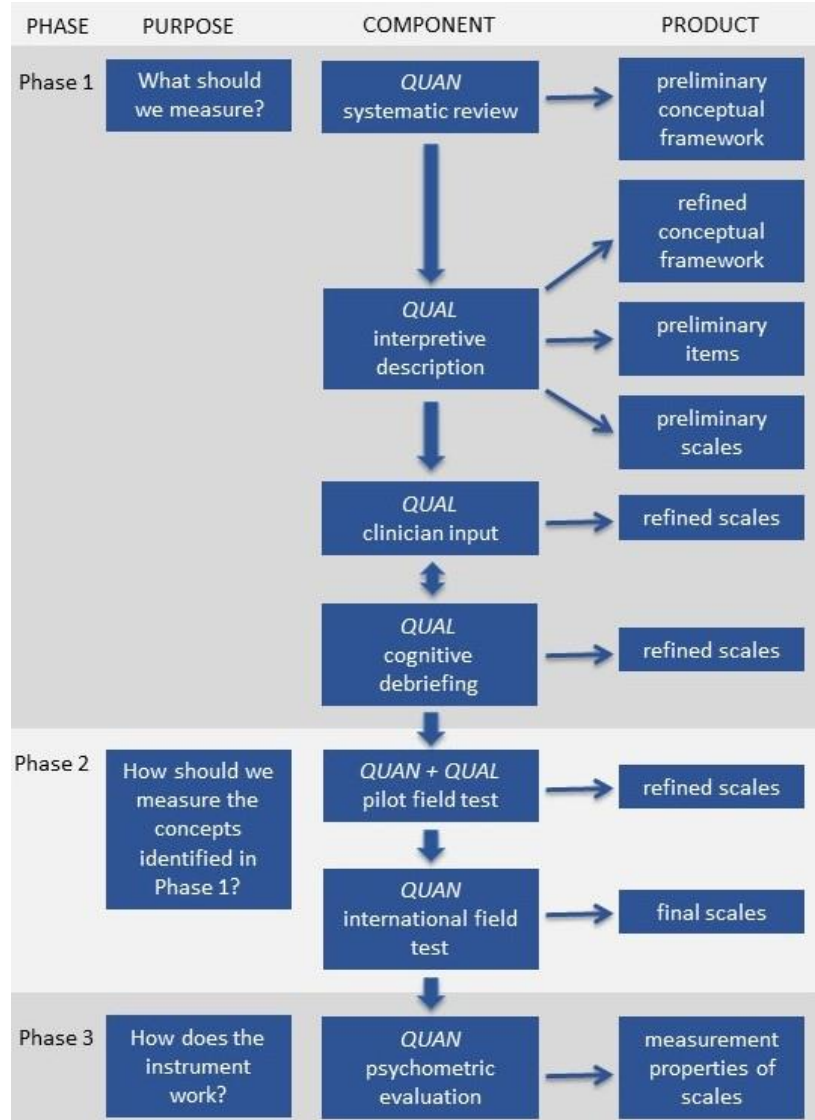
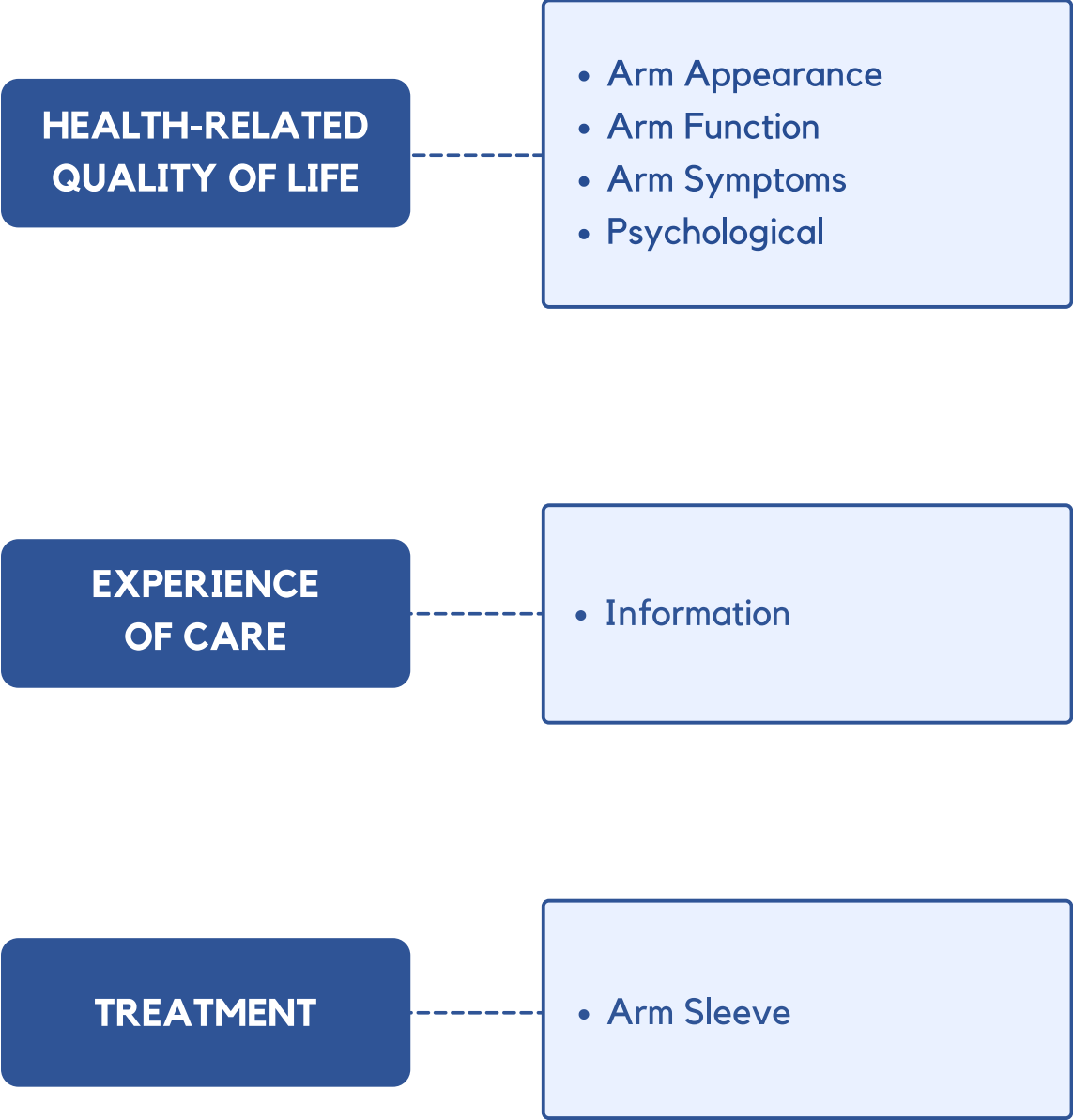


Figure 2: LYMPH-Q conceptual framework



**Table 1: Characteristics (Number, %) of the 3222 participants in the international field-test study**

		<b>N</b>	<b>%</b>
<b>Age group (years)</b>	≤49	322	10.0
	50-59	854	26.5
	60-69	1037	32.2
	≥70	1009	31.3
<b>BMI</b>	Under/normal weight (<25)	1226	38.1
	Overweight (25-29)	1107	34.4
	Obese (≥30)	877	27.2
	Missing	12	0.4
<b>Ethnicity</b>	Caucasian	2806	87.1
	Other	416	12.9
<b>Relationship status</b>	Married/common-law	2349	72.9
	Separated/divorced	235	7.3
	Widowed	285	8.8
	Single, never married	336	10.4
	Other	17	0.5
<b>Education status</b>	Completed some high school	313	9.7
	Completed high school	360	11.2
	Some college, trade, or university	714	22.2
	College, trade, or university	1245	38.6
	Some Masters or Doctoral	331	10.3
	Masters or Doctoral	164	5.1
	Other	95	2.9
<b>Employment status</b>	Retired	1630	50.6
	Working full-time	726	22.5
	Working part-time	499	15.5
	Other	367	11.4
<b>Time since lymphedema diagnosis (years)</b>	≤ 4	998	31.0
	5 to 9	1183	36.7
	≥10	1041	32.3
<b>Arm swelling</b>	None	418	13.0
	Mild	1346	41.8
	Moderate	1070	33.2
	Severe	356	11.0
	Missing	32	1.0
<b>Lymphedema laterality</b>	One arm	3156	98.0
	Both arms	66	2.0
<b>Arm problem as a result of breast cancer and/or treatments</b>	None	335	10.4
	Minor	2108	65.4
	Major	779	24.2

### 3. LYMPH-Q | Upper Extremity Scales

Table 2 shows LYMPH-Q scales including the number of items, response options, time frame for responding, and Flesch-Kincaid grade reading level. Below Table 2 is a brief description of each scale.

**Table 2: Description of LYMPH-Q | Upper Extremity scales**

Name of scale	Items	Response options	Recall period	Flesch-Kincaid
HEALTH-RELATED QUALITY OF LIFE				
Appearance	10	extremely → not at all bothered	now	2.4
Function	12	extremely → not at all difficult	past week	4.2
Psychological	12	always → never	past week	12.0
Symptoms	15	severe → none	past week	4.4
EXPERIENCE OF CARE				
Information	9	dissatisfied → satisfied	n/a	7.4
TREATMENT				
Arm Sleeve	10	dissatisfied → satisfied	most recent	2.2

#### HEALTH-RELATED QUALITY OF LIFE

**Appearance:** This 10-item scale measures the appearance of the arm with lymphedema. The items measure how bothered (extremely, moderately, a little, not at all) the patient is by how the arm looks now. Items ask about how the arm looks in photos, in sleeveless and long-sleeved shirts, overall size of the arm, how clothes fit the arm, etc.

**Function:** This 12-item scale measures arm function. The items measure how difficult (extremely, moderately, a little, not at all) tasks were in the past week. Items ask about putting on clothes, holding a phone, using hand and fingers, reaching, etc.

**Psychological:** This 12-item scale measures how the patient feels. Items ask respondents to indicate how often (always, often, sometimes, never) in the past week they felt hopeless, depressed, fed-up, unattractive, frustrated, etc.

**Symptoms:** This 15-item scale measures how the arm feels. Items measure the severity (severe, moderate, mild, none) of symptoms in the past week, asking about pain, numbness, pressure, feeling tired, etc.

#### EXPERIENCE OF CARE

**Information:** This 9-item scale measures the patient’s experience of care in terms of information they received from their health care providers about arm lymphedema. Items ask respondents how dissatisfied or satisfied they were with information they received



about topics such as how lymphedema is treated, how to avoid infections, how to monitor their lymphedema, how lymphedema feels, etc.

## **TREATMENT**

**Arm Sleeve:** This 10-item scale measures the use of an arm sleeve as a treatment for lymphedema. Items measure how dissatisfied or satisfied the patient was with how the arm sleeve fit, how helpful it was in reducing swelling, how easy it was to put on, how comfortable it was to wear, etc.

### **4. Administration of the LYMPH-Q | Upper Extremity**

The LYMPH-Q was designed to be completed by patients on their own (self-report). Each scale is independently functioning, which means that only scales relevant to the clinical situation or research question need be completed. Patients can thus be asked to complete a subset of scales relevant to their situation. Brief instructions are provided at the start of each scale. The LYMPH-Q was field-tested using two modes of data collection, i.e., online data collection using REDCap and paper-and-pencil. You may use the paper and pencil format or create an online version for ease of administration in non-profit academic research (e.g., REDCap) and in clinical care (e.g., hospital EMR such as Epic). If you plan to have an ePRO company capture and manage LYMPH-Q data collection, the ePRO company may need a license. If you have had LYMPH-Q scales converted into an electronic format and require an e-conversion review and certificate, please email [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com).

### **5. Scoring the LYMPH-Q | Upper Extremity**

There is no overall or total LYMPH-Q score. Instead, the LYMPH-Q is composed of independently functioning scales. To score a scale, the raw scores for the set of items in a scale are added together to produce a total raw score. If missing data is less than 50% of the scale's items, the within person mean for the completed items can be imputed for the missing items prior to computing a total raw score. As necessary, the imputed raw score for each item should be rounded to an integer. Then the items can be summed to produce a total scale raw score. Once a total raw score for the scale is computed, the Conversion Table can be used to convert the raw score into a score that ranges from 0 (worst) to 100 (best). The conversion, which linearizes the scores, is based on the findings from the Rasch analysis. Higher scores for LYMPH-Q scales reflect a better outcome. The Conversion Tables for changing raw scores into 0 to 100 scores are available after a license agreement is signed.

## 6. Conditions of Use

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Use of the LYMPH-Q questionnaire requires completion of a licensing agreement. The use of the LYMPH-Q and its modules in non-profit academic research and in clinical care is free of charge. The use of the LYMPH-Q by ‘for-profit’ organizations (e.g., pharmaceutical companies, contract research organizations, ePRO companies) is subject to a licensing fee.

Non-profit users can access the LYMPH-Q using the following link:

<https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=WTNMDPJRC7>

For questions regarding fees to be paid by ‘for-profit’ organizations, please contact:

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### PLEASE NOTE

**When you sign a LYMPH-Q license, you agree to the following terms:**

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- **You will not sell, sublicense, rent, loan, or transfer the LYMPH-Q to anyone**
- **You will not reproduce any LYMPH-Q scales in publications or other materials**
- **You will not translate the LYMPH-Q without permission from our team**

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## 7. Frequently Asked Questions

### ***Do I have to use all of the LYMPH-Q | Upper Extremity scales?***

Each scale functions independently, therefore patients can be asked to complete one or more of the LYMPH-Q scales. It is not necessary for a patient to complete all of the scales as there is no overall or total LYMPH-Q score. A researcher or clinician may therefore select a subset of scales depending on the particular purpose of the study or use.

### ***Can I delete or add or change any items or response options of the LYMPH-Q | Upper Extremity?***

You cannot delete or add or change the wording of any items or response options of the LYMPH-Q. Any modification to the content of the LYMPH-Q is prohibited under copyright laws. Making changes to the LYMPH-Q would invalidate its psychometric properties.

### ***Can I reproduce LYMPH-Q | Upper Extremity scales in a publication or other public document (e.g., PhD thesis)?***

According to the license agreement, you cannot reproduce the content of LYMPH-Q scales verbatim in a publication. However, it is possible to show shortened versions of items. The short forms of items that can be used in a publication are shown in Table 3 below from the psychometric publication describing the LYMPH-Q field-test study [1].

### ***Can I translate LYMPH-Q | Upper Extremity scales into a new language?***

Yes, with permission, you can translate the LYMPH-Q into different languages. Before starting a translation, check our translations list on [www.qportfolio.org](http://www.qportfolio.org) to see if there is a translation in the language you need. If there is not a translation available in the language you need, you will need to obtain permission from our team, sign a translation licensing agreement, and receive information on the method you need to follow. Email us at [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com) for more information. Please note that the developers of the LYMPH-Q own the copyright of all translations of the LYMPH-Q.

### ***Are there specific time points when patients complete the scales?***

A researcher or clinician can decide the time points they would like to administer the scales.

### ***Does it cost money to use the LYMPH-Q | Upper Extremity?***

Use of LYMPH-Q scales is free to non-profit users, including use by hospitals in patient care. For-profit users should contact Memorial Sloan Kettering Cancer Center for information about fees ([gardnerb@mskcc.org](mailto:gardnerb@mskcc.org)).

**Table 3: Shortened items for LYMPH-Q | Upper Extremity scales to use in a publication**

<b>SYMPTOMS</b>	<b>FUNCTION</b>	<b>APPEARANCE</b>	<b>PSYCHOLOGICAL</b>	<b>INFORMATION</b>	<b>ARM SLEEVE</b>
pain touch	clothes	people seeing	desperate	what it is	fits
pain rest	wash hair	long-sleeved shirt	hopeless	care for it	swelling
temperature	buttons	dress to hide	angry	avoid infections	looks
stiff	hold phone	photos	depressed	how it's treated	skin
sleeping	reach across	noticeable	stressed	how to monitor	put on
aching	grip handle	size	afraid	possibility	active
numb	hold book	certain clothes	anxious	healthcare team	long wear
pressure	use hands	clothes fit	fed-up	how it feels	comfortable
pain move	reach overhead	symmetry	unattractive	impact on life	dressed
clumsy	hold groceries	sleeveless shirt	worried		clothes fit
tingling	do chores		irritated		
tired	move arm		frustrated		
weak					
heavy					
swelling					

## **8. Acknowledgements**

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## 9. Publications Related to LYMPH-Q Development and Validation

1. Klassen AF, Tsangaris E, Kaur MN, Poulsen L, Beelen LM, Jacobsen AL, Jørgensen MG, Sørensen JA, Vasilic D, Dayan J, Mehrara B, Pusic AL. Development and Psychometric Validation of a Patient-Reported Outcome Measure for Arm Lymphedema: The LYMPH-Q Upper Extremity Module. *Ann Surg Oncol*. 2021 Jul 5. doi: 10.1245/s10434-021-09887-y. Epub ahead of print. PMID: 34224044.
2. Madsen CB, Poulsen L, Jørgensen MG, Klassen A, Tsangaris E, Lorenzen MM, Sørensen JA. Danish translation and linguistic validation of the LYMPH-Q Upper Extremity Module. (submitted)