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ORIGINAL PAPER

Dutch translation and cultural adaptation of the LYMPH-Q, a new patient-reported outcome measure for breast cancer-related lymphedema

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Abstract

Background The LYMPH-Q Upper Extremity module is a new patient-reported outcome measure (PROM) developed to assess patient outcomes of breast cancer-related arm lymphedema (BCRL). Content for the LYMPH-Q Upper Extremity Module was developed from the extensive input of patients and experts in the field of breast surgery and breast cancer-related lymphedema. Rasch Measurement Theory analysis was used to assess psychometric properties. The aim of this study was to perform a Dutch translation and cultural adaptation of the LYMPH-Q Upper Extremity Module.

Methods The translation process was performed in accordance with the guidelines of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).The process included two forward translations, two back translations, and cognitive debriefing interviews with patients with BCRL.

Results Comparison of the two forward translations showed that the translations for most items ($n = 60$; 88.2%) were conceptually consistent between the two translators. Translations of the remaining items were reviewed and discussed until consensus was reached. Three items in the back translation had a different meaning when compared to the original English version and required re-translation. The resultant Dutch version of the LYMPH-Q was tested in a series of cognitive debriefing interviews with seven patients and showed good content validity.

Conclusions The translation and cultural adaptation process resulted in a conceptually equivalent Dutch version of the LYMPH-Q Upper Extremity Module. This new PROM can now be used in clinical practice and research settings to evaluate outcomes in patients with BCRL.

Level of evidence: Not gradable

Keywords LYMPH-Q Upper Extremity Module · Patient-reported outcome · Translation and cultural adaptation · Quality of life · Breast cancer · Lymphedema

Introduction

Breast cancer is the most frequently diagnosed cancer among women in the Netherlands, with 15,613 new diagnoses in 2021 [1]. Due to advances in the detection and treatment of breast cancer, 5- and 10-year survival rates in the Netherlands have increased to 89 percent and 80 percent, respectively. Consequently, the long-term effects of breast cancer treatment, including breast cancer-related lymphedema (BCRL), are becoming ever more important.

BCRL is a complication of breast cancer treatment, affecting approximately 1 in 5 patients [2]. BCRL is a lifelong and progressive condition manifested by swelling of the arm, functional impairment, pain, and increased susceptibility to infections. These symptoms can substantially impact a patient's health-related quality of life (HRQoL), involving physical function and psychosocial well-being [3–6]. Although new surgical treatment options are emerging, no definitive cure for BCRL is available.

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Outcome measurement in BCRL has traditionally focused on measuring the circumference or volume of the affected limb. However, these outcomes are not sufficiently reliable, nor do they fully capture the impact of BCRL on patients [7–10]. The use of patient-reported outcome measures (PROMs) can provide valuable insights into the impact of BCRL on a patient.

In recent years, while there has been an increase in the use of PROMs in research related to BCRL, there has been little consensus on which PROM to use [5, 6, 11, 12]. Earlier literature reviews have shown a frequent use of non-validated (i.e., "ad hoc" instruments) or generic PROMs such as the SF-36 [5, 6, 11, 12]. The use of validated and condition-specific PROMs is recommended to capture the specific concerns of the target population reliably and accurately. A recent methodological analysis of existing lymphedema-specific PROMs demonstrated that none of the previously developed instruments met quality standards for PROM development as recommended by the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) [12–14]. A major shortcoming in the development of most lymphedema-specific PROMs was their lack of patient involvement, which is a crucial aspect in the development of a PROM to ensure that its content captures meaningful patient outcomes [15, 16].

The LYMPH-Q Upper Extremity Module is a new PROM developed by the team that developed the BREAST-Q [17, 18]. The LYMPH-Q Upper Extremity Module was developed following best-practice guidelines, including in-depth qualitative interviews with patients and input from experts in the field of breast cancer and BCRL. The aim of this study was to perform a Dutch translation and cultural adaptation of the LYMPH-Q Upper Extremity Module.

Methods

Permission to translate the LYMPH-Q Upper Extremity Module was obtained from the developers [17]. The present study was exempt from full ethics review, according to Dutch Medical Research Law, by the Medical Ethics Committee of the Erasmus Medical Center (Rotterdam, The Netherlands) (Non-WMO declaration, MEC-2019–0386).

Table 1 lists the LYMPH-Q Upper Extremity Module scales and the number of items. The LYMPH-Q consists of 68 items in 6 independently functioning scales measuring HRQoL, experience of care, and treatment.

The translation process was guided by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) recommendations [19]. The translation process consisted of the following steps that are also illustrated in Fig. 1.

Table 1 The LYMPH-Q Upper Extremity Module scales

		No. of items
HRQoL		
	Arm symptoms	15
	Arm function	12
	Arm appearance	10
	Psychological well-being	12
Experience of care		
	Information	9
Treatment		
	Arm sleeve	10

Forward translation and reconciliation

Two native Dutch speakers fluent in English (LvdB and MG) independently translated the LYMPH-Q items, instructions, and response options into Dutch. The translators were both medical doctors holding a research position at the Patient-Reported Outcomes, Value & Experience (PROVE) Center at Brigham and Women's Hospital and Harvard Medical School. Their independent translations were compared, and any inconsistencies were discussed and resolved. After consensus was reached, translations were merged into a single forward translation (v1) that was used in the back translation.

Back translation, review, and reconciliation

The Dutch version of the LYMPH-Q Upper Extremity Module (v1) was back translated by two residents from the Department of Plastic and Reconstructive Surgery of the Erasmus Medical Center (PvE and CK), who had not previously seen the original English version. Both back translators are native Dutch speakers who are fluent in English. Both back translations were compared to the original English version for conceptual equivalence by a member of the LYMPH-Q Upper Extremity Module development team. Discrepancies between the original English version and the back translation resulted in the re-translation of the candidate item, instruction, of response option, which was then back translated and re-checked for conceptual equivalence. Back translation resulted in v2 of the Dutch LYMPH-Q Upper Extremity Module for use in the cognitive debriefing interviews.

Cognitive debriefing interviews

One-on-one cognitive debriefing interviews were conducted with patients recruited during an outpatient clinic visit within the Department of Plastic and Reconstructive Surgery at the Erasmus Medical Center in Rotterdam, the Netherlands. Eligible patients were aged ≥ 18 years, diagnosed with BCRL of the arm by a specialist, and native Dutch speakers. The goal of the

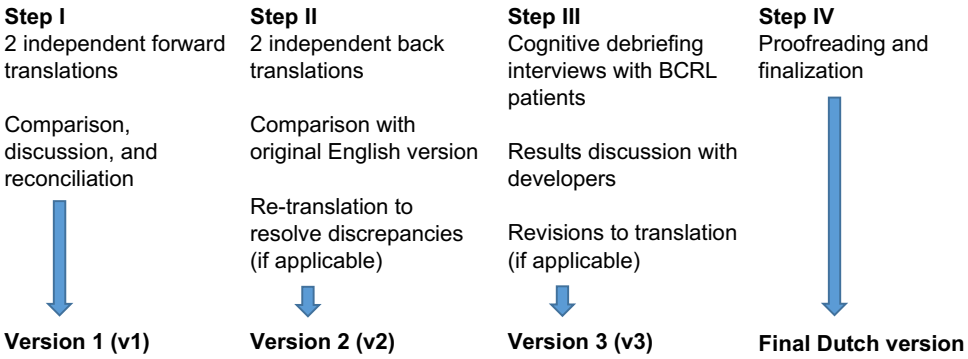

Fig. 1 Steps in the Dutch translation and cultural adaptation of the LYMPH-Q

interviews was to test whether patients understood the meaning of items, instructions and response options, the comprehensiveness of the content, and the cultural relevance of the Dutch translation of the LYMPH-Q Upper Extremity Module (v2).

Informed consent was obtained from all individual participants included in the study. The interviews were conducted by one researcher (LMB) and took place in a consulting room within the Plastic and Reconstructive Surgery outpatient clinic. The interviews were guided by a cognitive interview guide. Participants were asked to use the "think aloud" approach, i.e., to verbalize what they think each item, instruction, and response is asking. Any items, instructions, or response options that were difficult for participants to understand were explained by the researcher. Participants were then asked to provide an alternative word or phrase to enhance comprehension. Probing questions were also asked on the content and cultural relevance, and if there was any missing content. All interviews were audio recorded and transcribed verbatim. Difficulties or suggested changes by participants were documented on a Microsoft Excel worksheet and shared with the LYMPH-Q Upper Extremity Module development team member. Necessary changes from the cognitive debriefing interviews were incorporated into the Dutch version of the LYMPH-Q Upper Extremity Module (v3).

Proofreading, finalization, and final report

v3 of the Dutch LYMPH-Q Upper Extremity Module was proofread by two clinicians to correct any spelling or grammatical errors. This led to the development of the final Dutch version of the LYMPH-Q Upper Extremity Module.

Results

Forward translation and review

Comparison of the two independent forward translations revealed that most items ($n=60$; 88.2%) were consistently translated across the two translators. Several items had minor variations in the chosen word, tense, or word order. For example, the words "you/your" were translated differently by both translators, using either a more formal ("u/uw") or informal ("je/jij") pronoun. After discussion between the two translators, the more formal pronoun was selected and applied throughout.

Several words ($n=18$) within the LYMPH-Q Upper Extremity Module can be portrayed by multiple Dutch words. For example, the word "aching" can be translated as "pijnlijk" (English: painful) or "zeurend" (English: nagging). The word "weak" can be translated as "slap" (English: weak, limp) or "zwak" (English: weak, lacking physical strength). The word "clumsiness" can be translated as "onhandigheid" (English: clumsiness, awkwardness) or "klungeligheid" (English: clumsiness, gawkiness). Discussion between the two translators resulted in agreement on the most suitable translation.

Eight items were difficult to translate into Dutch. For example, the item "reaching across yourself" was translated differently by both translators: "het om u heen reiken" (English: reaching around you) and "kruisen/reiken over jezelf" (English: to cross/to reach over yourself). However, neither of these versions directly translated to be conceptually equivalent to the original English version. Discussion between the two forward translators resulted in the item being translated as "het maken van een overdwarse armbeweging om uzelf" (English: making a transverse arm movement around yourself). Another example is the item "depressed," which was initially translated as "depressief," but the meaning of this word in Dutch is "to suffer from depressive disorder." Therefore, a more conceptually equivalent word was chosen ("somber" (English: sad, gloomy, somber)).

Back translations and review

After comparing the back translation to the original English version, three items were found to differ in their meaning. First, the item "(how bothered are you by) people seeing your arm?" was back translated into "how other people think your arm looks." Second, the item "(how bothered are you by) any difference between the size of your arms?" was back translated as "the difference between the size of your arms," and third, the item "(how dissatisfied or satisfied were you

with) your ability to enjoy life with the arm sleeve on?" was back translated into "the opportunity to enjoy while wearing your arm sleeve." These three items were re-translated until conceptual equivalence was achieved.

Cognitive debriefing and review

Seven patients participated in the cognitive debriefing interviews. All participants were female, had a mean age of 61 years (range 43–71 years), and unilateral BCRL ($n=6$). Clinical and demographic characteristics are shown in Table 2.

The cognitive debriefing interviews resulted in minor changes to the sentence structure and wording of three items. First, the item "(how bothered are you by) having to dress in a way to hide your arm?" was initially translated to "het met kleding op een bepaalde manier uw arm te verbergen" (English: using clothes in a certain way to hide your arm) but multiple participants struggled with the sentence structure and found the item not easy to read. The translation was then changed to "dat u zich op een bepaalde manier moet kleden om uw arm te verbergen" (English: to have to dress a certain way to hide your arm). Second, the item "(how dissatisfied or satisfied were you with) your ability to be physically active with the arm sleeve on?" was initially translated to "hoe lichamelijk actief u kon tijdens het dragen van de armkous" (English: how physically active you could while wearing the arm sleeve), which was grammatically incorrect and it was necessary to add a verb ("zijn," English: to be). Third, the item "(how dissatisfied or satisfied were you with) how you looked when you were dressed and wore the arm sleeve?" was initially translated to "hoe u er uitzag in uw kleding en uw armkous droeg" (English: how you looked in your clothes and wearing your arm sleeve). To improve comprehensibility and readability, the translation was changed to "hoe u eruit zag in uw kleding terwijl u uw armkous droeg" (English: how you looked in your clothes while wearing your arm sleeve).

Overall, patients found the scales to be easy to understand, comprehensive, and culturally relevant. They felt that the items touched upon important concepts that are often overlooked during consultation with their care providers. Examples of the changes made throughout the translation process are provided in Table 3.

Table 2 Clinical and demographic characteristics of cognitive debriefing interviews participants

		N	%
Age in years	40–49	1	14
	50–59	1	14
	60–69	4	58
	70–79	1	14
Gender	Female	7	100
	Male		
BCRL location	Unilateral	6	86
	Bilateral	1	14
Lymph node surgery	ALND	6	86
	SLNB	1	14
Breast cancer surgery	Lumpectomy	2	29
	Mastectomy	5	71
Other breast cancer treatment	Radiation therapy	7	100
	Chemotherapy	7	100
	Hormonal therapy	3	43

Proofreading, finalization, and final report

Proofreading resulted in minor changes to punctuation, typography, and grammar. These changes improved the readability of the items, instructions, and response options, resulting in the equivalent Dutch translation of the LYMPH-Q Upper Extremity Module.

Discussion

Translation and cultural adaptation resulted in a conceptually equivalent Dutch translation of the LYMPH-Q Upper Extremity module. The items, instructions, and response options for the six scales were translated to preserve the meaning of the items. Cognitive debriefing interviews with the target population demonstrated strong content validity and that items, instructions, and response options were easily understood.

The ISPOR translation guidelines provide a comprehensive approach to ensure that high-quality translations are produced. Although the translation process is resource intensive, both in respect to time and personnel, these steps are necessary as poor translations of PROMs will threaten their validity and the subsequent quality of data collected [19]. We conducted seven cognitive interviews, a sample size congruent with both the ISPOR translation guidelines and the COSMIN quality standards for establishing content validity [13, 14, 19].

The Dutch version of the LYMPH-Q Upper Extremity Module provides clinicians and researchers with a well-developed and validated PROM for meaningful outcome measurement in Dutch-speaking patients with BCRL. The use of Rasch Measurement Theory (RMT) analysis in the development of the LYMPH-Q ensures that the scales are well-suited for use in individual patient care settings [17]. The assessment of outcomes from the patient perspective can help improve care delivery and treatment decision-making. Furthermore, standardized PRO assessment can aid future international research efforts aimed at improving treatment methods and HRQoL in patients with BCRL.

Our study had some limitations. First, the patient sample for the cognitive debriefing interviews included only females.

Table 3 Examples of the problems and revisions throughout the LYMPH-Q Dutch translation process

LYMPH-Q Scale	Item no	Item	Forward translation	Back translation	Comparison back translation with original	Cognitive debriefing interviews
Symptoms	6	Aching feeling in your arm?	"Aching" can be translated into multiple Dutch words, with different meanings	A nagging feeling?	No changes	No changes
Arm function	5	Reaching across yourself (e.g., to put on a car seatbelt)?	"Reaching across yourself" was hard to translate to Dutch	Reaching over yourself with your arm?	No changes	No changes
Appearance	1	…people seeing your arm?	No problem	…how other people think your arm looks?	Changed to: …when other people see your arm?	No changes
Appearance	3	…having to dress in a way to hide your arm?	No problem	…using clothing in a certain way to hide your arm?	No changes	Change in sentence structure
Appearance	6	…the overall size of your arm?	"Size" can be translated into two words with slightly different meanings	…the size of your arm?	No changes	No changes
Appearance	9	…any difference between the size of your arms?	"Size" can be translated into two words with slightly different meanings	…the difference in size between both arms?	The developers stated that "the" and "any" did not have the same conceptual meaning. Changed to: …difference in size between both arms?	No changes
Psychosocial	4	Depressed?	Was translated literally, which changed the meaning to "suffering from depression."	Depressed?	No changes	No changes
Psychosocial	6	Afraid?	Can be translated into two different emotions, with slightly different meanings	Scared?	No changes	No changes
Information	5	How to monitor your lymphedema at home?	The verb "to monitor" can be translated literally, or to a different verb which matches the meaning more closely	How you can check up on your lymphedema at home?	No changes	No changes
Information	9	The impact lymphedema can have on your life?	Can be translated into influence or impact	The impact lymphedema can have on your life?	No changes	No changes
Arm sleeve	6	Your ability to be physically active with the arm sleeve on?	Slightly different translation, similar meaning	How physically active you could be while wearing the arm sleeve?	No changes	Change in sentence structure
Arm sleeve	9	How you looked when you were dressed and wore the arm sleeve?	Slightly different translation, similar meaning	How you looked in your clothing and you wore your arm sleeve?	No changes	Change in sentence structure

However, due to the low incidence of breast cancer in males – 133 males vs. 15,613 females in the Netherlands in 2021 – our sample is representative of the natural distribution of the target population [1]. Second, all patients in our sample underwent extensive breast cancer treatment, including breast cancer surgery (mastectomy, $n=5$), lymph node surgery (ALND, $n=6$), radiation therapy ($n=7$), and chemotherapy ($n=7$). This could be explained by the increased risk of developing lymphedema for patients with advanced stage breast cancer and for patients who receive (a combination of) certain treatments, such as ALND and radiotherapy [2]. Third, the back translators were fluent in English but non-native English speakers. To ensure quality in this step of the translation, two independent back translations were performed instead of one, and the process of reviewing the back translation against the original English version was performed by a member of the LYMPH-Q development team (ET).

Conclusions

Translation and cultural adaptation was performed in accordance with internationally accepted guidelines, resulting in a conceptually equivalent Dutch version of the LYMPH-Q Upper Extremity Module. The Dutch version of the LYMPH-Q Upper Extremity Module is now available for use in clinical care and research to measure outcomes in patients with BCRL, providing valuable information from the patient's perspective. The Dutch version of the LYMPH-Q will be available via https://qportfolio.org.

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Author contribution All authors contributed according to the journal guidelines.

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Code availability Not relevant.

Declarations

Ethics approval According to the Dutch Medical Research with Human Subjects Law (WMO), the present study did not have to undergo full ethics review because participants are not subject to procedures and are not required to follow rules of behavior. A non-WMO declaration was provided by the Medical Ethics Committee of the Erasmus Medical Center (MEC-2019–0386).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent for publication All participants gave their consent.

Conflict of interests Anne F. Klassen and Andera L. Pusic are co-developers of the LYMPH-Q. As such, they receive royalties when this PROM is used in for-profit clinical trials. Louise Marie Beelen, Anne-Margreet van Dishoeck, Elena Tsangaris, and Dalibor Vasilic have no relevant financial or non-financial interests to disclose.

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