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► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/ijgc-2022-003979>).

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Received 6 September 2022  
Accepted 14 November 2022  
Published Online First  
7 December 2022



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**To cite:** Bjerre Trent P, Falk RS, Staff AC, *et al.* *Int J Gynecol Cancer* 2023;**33**:231–235.

# Translation and cross-cultural adaptation of the Gynecologic Cancer Lymphedema Questionnaire and the Lower Extremity Lymphedema Screening Questionnaire

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## ABSTRACT

**Objective** There is a paucity of international data regarding self-reported lower extremity lymphedema and quality of life after surgery for gynecological cancer. Validated questionnaires are emerging, but translated versions are lacking. Cross-cultural adaptation is important to reduce the risk of introducing bias into a study.

**Objective** To translate and culturally adapt the Gynecologic Cancer Lymphedema Questionnaire and the Lower Extremity Lymphedema Screening Questionnaire for a Norwegian population.

**Methods** Permission to use the original English versions of the Gynecologic Cancer Lymphedema Questionnaire and the Lower Extremity Lymphedema Screening Questionnaire for translation was obtained. The questionnaires were translated using a procedure based on standard guidelines, including forward translation by native speakers of the target language, synthesis, back translation, and review. Seventeen patients from the Norwegian Radium Hospital gynecological cancer outpatient clinic, all expected to have stable disease, were invited for questionnaire test–retest by completing the same questionnaires twice at 3–4-week intervals. Internal consistency was assessed by calculating Cronbach's alpha. Test–retest reliability was assessed using an intra-class correlation coefficient.

**Results** Twelve patients completed the questionnaires twice. Cronbach's alpha was 0.75 for the Gynecologic Cancer Lymphedema Questionnaire and 0.89 for the Lower Extremity Lymphedema Screening Questionnaire. The intra-class correlation coefficient was 0.86 for the Gynecologic Cancer Lymphedema Questionnaire and 0.91 for the Lower Extremity Lymphedema Screening Questionnaire.

**Conclusions** Translation and cross-cultural adaptation of these internationally validated patient-reported outcomes questionnaires for survivors of lower extremity lymphedema in gynecological cancer was feasible. The Norwegian translation of the Gynecologic Cancer Lymphedema Questionnaire and the Lower Extremity Lymphedema Screening Questionnaire showed acceptable internal consistency and the test–retest reliability was excellent.

## INTRODUCTION

According to the World Health Organization (WHO) health is defined as “A state of complete physical, mental, and social well-being and not merely

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Health quality of life is of increasing interest. In order to accurately compare results across institutions and countries, the same tools for patient-reported outcome measures must be used.

## WHAT THIS STUDY ADDS

⇒ We report a feasible process of translation and cross-cultural adaptation of patient-reported outcomes for self-reported lower extremity lymphedema into a non-English language. The pilot testing demonstrates high internal consistency and test–retest reliability.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This methodology can be adapted to other languages and other patient-reported outcomes measures, both for clinical practice and trials.

the absence of disease or infirmity”,<sup>1</sup> giving rise to the term health-related quality of life. Although the concept of quality of life has no uniform definition,<sup>2,3</sup> it has been defined as “individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns” by the WHO quality of life group.<sup>4</sup> The importance of studying health-related quality of life is well-recognized, and any clinical trial exploring novel medical or surgical therapy should include this component. To capture real-world data reflecting local conditions it is paramount that health-status measures and self-reported measures are translated and culturally adapted.

Treatment for gynecologic cancers consists of surgery with or without adjuvant radio-chemotherapy. Survival for early-stage gynecologic cancers generally is good, and treatment-associated morbidity is of particular importance and interest in this patient population.<sup>5</sup> The reported incidences of lower extremity lymphedema in gynecologic cancer survivors vary.<sup>6–11</sup> There is no gold standard for detection of lower extremity lymphedema. However, validated

## Original research

questionnaires capturing self-reported lower extremity lymphedema are emerging.<sup>12–14</sup>

Although several guidelines emphasizing the importance of standardized translation and cultural adaptation of patient-reported outcome measures have been developed,<sup>15–17</sup> no benchmark has been established. Capturing and comparing self-reported outcomes between countries and institutions is challenging due to the lack of standardized processes. These challenges highlight the need for a uniform use of appropriate and validated questionnaires and a feasible translation and culturally adapted process.

The purpose of this study was to report the process of translation and cross-cultural adaptation of patient-reported outcome measures for self-reported lower extremity lymphedema into a non-English language, Norwegian, and assess the internal consistency and test-retest reliability. Our aim was to ensure that the translated versions were easy to understand for women treated for gynecological cancers, as well as semantically equal to the original versions.

## METHODS

This study was conducted between October 2020 and March 2021 at the Norwegian Radium Hospital, Department of Gynecologic Cancer after approval by the Regional Committee for Medical and Health Research (reference number 149597).

A review of the literature was performed. The Gynecologic Cancer Lymphedema Questionnaire and the Lower Extremity Lymphedema Screening Questionnaire were identified as validated questionnaires for self-reported lower extremity lymphedema in women after surgery for gynecologic cancers.<sup>12, 13</sup> The Lower Extremity Lymphedema Screening Questionnaire had been specifically validated on an obese population. Approval for translation and cultural adaptation was obtained from authors of the Gynecologic Cancer Lymphedema Questionnaire and the Lower Extremity Lymphedema Screening Questionnaire. Information regarding scoring systems and syntax from the original publications was shared. Guidelines for the process of cross-cultural adaptation of self-reported measures provided by Beaton et al<sup>18</sup> were followed.

The target population was women who had undergone primary surgery for vulvar, cervical, or uterine carcinoma/sarcoma, with or without nodal assessment. Patients were all expected to have stable disease presenting for routine follow-up. Non-Norwegian speakers were not included.

Online data collection was handled by nettskjema.no, a survey solution developed and hosted by the University of Oslo. The software offers a secure platform solution in compliance with General Data Protection Regulation. For institutions where this solution is not available in-house other platforms such as Research Electronic Data Capture (REDCap) could be an option.<sup>19</sup>

### Gynecologic Cancer Lymphedema Questionnaire

The Gynecologic Cancer Lymphedema Questionnaire<sup>13</sup> is a modification of the validated Lymphedema Breast Cancer Questionnaire. The questionnaire contains seven symptom clusters (heaviness, general swelling, limb swelling, infection-related, aching, numbness, physical function), with a total of 20 questions, and four supplemental questions related to the patients' awareness of their diagnosis and treatment. Symptoms to be reported should have been present during the last 4 weeks. The answers are

dichotomized as presence/absence of symptoms. A total score can be calculated if at least 80% (16/20) of the questions are answered. The score is then calculated by summation, one point per 'yes'. The cut-off point for lymphedema was set to  $\geq 4$  or  $\geq 5$  points.<sup>13</sup>

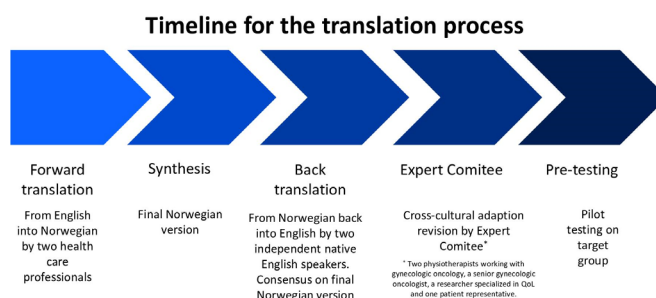
For the validation process the Gynecologic Oncology Group (GOG)-244 study group included 58 gynecologic cancers survivors, 28 with documented lower extremity lymphedema and 30 without. For the latter group, limb measurements were performed to exclude lower extremity lymphedema. Pilot testing revealed a sensitivity and specificity of 86% and 90%, respectively with a 5-point cut-off. The internal consistency reliability of the total score was reported to be 0.95. During the validation process, patients were also asked to report satisfaction and feasibility of the questionnaire as a screening tool. Ninety-five per cent of patients reported that the questionnaire was easy to understand, 97% would be willing to participate again, and 88% were confident that the questionnaire was able to detect lower extremity lymphedema.

### Lower Extremity Lymphedema Screening Questionnaire

The Lower Extremity Lymphedema Screening Questionnaire was developed based on an existing questionnaire for upper extremity lymphedema,<sup>12</sup> where 186 patients were invited to participate in a pilot test. The participating populations were women diagnosed with upper extremity lymphedema compared with women diagnosed with lower extremity lymphedema.

A 13-question questionnaire was developed. The questions were graded with five ordered response categories ranging from 0 ('not at all') to 4 ('very much'). Missing items were replaced by non-missing items if a minimum of 50% (7/13) of questions were answered. A total score was calculated as a sum of all items, ranging from 0 to 52. During development of the original questionnaire several cut-off points were investigated, showing comparable specificity and sensitivity.<sup>20</sup> However, the cut-off point is commonly set as  $\geq 5$  points.<sup>21</sup> The tool's sensitivity and specificity for detecting lower extremity lymphedema was 96% and 87%, respectively, in all patients and 95% and 77%, respectively, in obese patients. The authors added 10 background questions regarding co-morbidities related to risk of developing lower extremity lymphedema.<sup>21</sup> These questions were also included in our process of translating and culturally adapting the questionnaire.

*Translation and cross-cultural adaptation* comprised five stages in line with recommendations from Beaton et al<sup>18</sup> (Figure 1):



**Figure 1** Timeline of the translation process and cross-cultural adaptation of the Gynecologic Cancer Lymphedema Questionnaire and the Lower Extremity Lymphedema Screening Questionnaire.

1. *Forward translation* from the original English versions into Norwegian was performed by two Norwegian native speakers with excellent knowledge of English. Both translators were healthcare professionals.
2. *Synthesis*: Disagreements were discussed and resolved. A final Norwegian translation was prepared for back translation.
3. *Back translation*: The Norwegian translations were back translated by two independent bilingual translators. Both native English speakers, living and working in Norway. They were unfamiliar with the questionnaires and blinded to the original English versions. The two separate back translations were merged into one final English version for each questionnaire. The original English versions, translated Norwegian versions, and the back translated English versions were then compared and reviewed by the four translators who agreed on final Norwegian versions.
4. *Expert committee*: The final Norwegian versions were distributed for expert review by two physiotherapists working with gynecologic oncology, a senior gynecologic oncologist, a researcher specialized in quality of life and one patient representative. Based on expert feedback, no cultural adaptations were necessary for the lymphedema-specific questions. Minor changes related to nomenclature were made. Importantly, the patient representative stated that the Norwegian versions were easy to comprehend. The translated and culturally adapted versions were shared with the authors of the original English questionnaires for their records.
5. *Pre-testing*: The final translated questionnaires were uploaded to a digital platform and administered to a random sample of women undergoing surveillance for cervical, vulvar, or endometrial carcinoma/sarcoma. We planned to include 15 patients, as 10–15 patients are considered satisfactory for the translation procedure.<sup>15</sup> All subjects were native Norwegian speakers. Subjects were approached by one researcher (PBT) after their clinical outpatient visit to the Department of Gynecologic Oncology, Oslo University Hospital, Norway. An explanation of the questionnaire and purpose of the pilot study was given. The participants subsequently completed the online questionnaires (using the software nettskjema.no). They were automatically reminded to answer the questionnaires for retesting after 3 weeks. Women who did not respond after the digital reminder were reminded by phone. After completion of the test and retest, participants were asked to give feedback regarding if questions were relevant for their own situation (yes/no/unsure), and if they believed the questionnaire would capture complaints for patients in a similar situation (high relevance/little relevance/neither-nor/no relevance/completely irrelevant/don't know). Participants were asked if they felt that additional questions should have been included, and were also given an opportunity to give written feedback in free text.

### Statistical Analysis

Responses to each item were scored by the same principles as the original questionnaires. Internal consistency was assessed using Cronbach's alpha. Test–retest reliability was assessed by intra-class correlation coefficient at first and second time points. The intra-class correlation coefficient was calculated using a two-way mixed effects model. All analyses were made using Stata software, version 16.1.

## RESULTS

### Translation and Cross-Cultural Adaptation

For both questionnaires, minor grammatical changes (differences between singular and plural) were the main issues discussed during the translation process. In regards to specific terminology the following points were discussed: In the original version of the Gynecologic Cancer Lymphedema Questionnaire the term '*groin swelling? (genital, labia/vulvar)*' is used (question 19). The term was discussed with the questionnaires' first author, resulting in use of 'swelling of the groin/labia/vulva' in Norwegian. '*Pockets of fluid*' (question 20) was also discussed in detail. After discussion with the main author, the wording was kept as in the original version.

For the Gynecologic Cancer Lymphedema Questionnaire supplemental question 23, the terms '*manual lymphatic drainage*' and '*specialized lymphedema massage*' are used. It is not specified if this should have been performed by the patient herself or by a healthcare professional. In Norway these procedures are performed exclusively by a physiotherapist. After discussing with the first author it was clarified that '*manual lymphatic drainage*' refers to a patient-performed procedure, and '*specialized lymphedema massage*' a procedure by a healthcare professional. The wording in the Norwegian version was adapted accordingly. The Gynecologic Cancer Lymphedema Questionnaire supplemental question 24 refers to '*lymphedema specialist*'. In Norway this does not exist, and thus, this alternative was excluded from the Norwegian version.

No wording changes were necessary for the Lower Extremity Lymphedema Screening Questionnaire. The final Norwegian versions are available online (Online supplemental file 1 and Online supplemental file 2).

### Pilot Testing

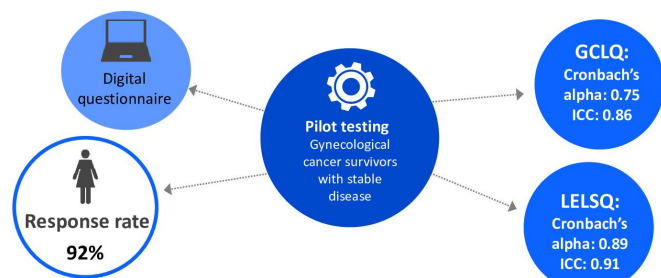
Seventeen women were invited, 13 responded at the first time point. Twelve women answered twice, yielding a 92% response rate for test and retest. Four of 12 women had endometrial carcinoma (stage 1A–3B), two uterine sarcoma (stage 1B–2A), two cervical carcinoma (stage 1A1–1B1), and three vulvar carcinoma (stage 2–3A). Median age was 64 years (range 30–83). The median time since primary treatment was 27 months (range 9–228). Cronbach's alpha was 0.75 for the Gynecologic Cancer Lymphedema Questionnaire and 0.89 for the Lower Extremity Lymphedema Screening Questionnaire. The intra-class correlation coefficient for the Gynecologic Cancer Lymphedema Questionnaire was 0.86 (95% CI 0.59 to 0.96) and for the Lower Extremity Lymphedema Screening Questionnaire 0.91 (95% CI 0.75 to 0.96) (Figure 2).

Two (17%) and three (25%) women screened positive for lower extremity lymphedema according to the Gynecologic Cancer Lymphedema Questionnaire and the Lower Extremity Lymphedema Screening Questionnaire at the time of initial test, respectively (cut-off value 5 points for both). At the retest three women screened positive according to the Gynecologic Cancer Lymphedema Questionnaire and two according to the Lower Extremity Lymphedema Screening Questionnaire.

Regarding participant feedback, 33% (n=4) of women thought the questions were relevant for their own situation, 50% (n=6) reported the questions to be irrelevant, and the remaining 17% (n=2) reported 'neither/nor'. None of the women who screened positive for lower extremity lymphedema reported the questions to be irrelevant. The majority of women (83%, n=10) believed the



## Overview of the pilot testing



**Figure 2** Overview of the pilot testing presenting the Cronbach's alpha and intra-class correlation coefficient (ICC) between the test and retest for the Gynecologic Cancer Lymphedema Questionnaire (GCLQ) and the Lower Extremity Lymphedema Screening Questionnaire (LELSQ).

questionnaire would capture complaints for patients in a similar situation, the other two women were unsure. No one provided written feedback regarding the structural composition, or feedback related to difficulties in understanding the questionnaire.

## DISCUSSION

### Summary of Main Results

In this study we have described and demonstrated a feasible and comprehensive stepwise translation and cross-cultural adaptation process of two validated questionnaires measuring patient-reported lower extremity lymphedema. We demonstrated acceptable internal consistency, and the test–retest reliability was excellent, in line with the Cronbach's alpha found in the original article for the Gynecologic Cancer Lymphedema Questionnaire.<sup>13</sup>

### Results in the Context of Published Literature

Endometrial carcinoma is the most common gynecological malignancy affecting women in Europe and North America.<sup>22</sup> With endometrial cancer on the rise and improved overall survival,<sup>5</sup> the focus on quality of life is gaining increasing attention in this patient population.<sup>23</sup> Questionnaires capturing patient-reported outcomes including self-reported lower extremity lymphedema may be more clinically relevant than objective measures as well as more reliable in diagnosing lower extremity lymphedema, as confirmed by the GOG-244 study group.<sup>6,7</sup> However, the prevalence of, and use of different questionnaires to capture, lower extremity lymphedema varies.<sup>7,8,21</sup> This also holds true for cervical and vulvar carcinoma.<sup>24–27</sup> This heterogeneity in measurement tools limits the ability to conclude if true differences in lower extremity lymphedema between studies exist, or if the reported differences are due to questionnaire biases. This highlights the need for standardized tools as well as the importance of translated and culturally adapted patient-reported outcome measures to ensure comparable results.

The Gynecologic Cancer Lymphedema Questionnaire has previously been translated into Korean and German.<sup>9,28</sup> The publication by Lim et al reported a Cronbach's alpha of 0.83 and an ICC of 0.96, both comparable to our results.<sup>28</sup> The translation process into Korean is not described in detail; however, the authors did provide explanations of certain changes related to expressions. The Korean group performed a new validation in a larger cohort of patients, demonstrating a

sensitivity similar to that of the original validation. The same questionnaire has also been used for evaluating patients with vulvar carcinoma in a German study.<sup>9</sup> The translation process was not described in that publication, and it is unknown if cultural adaptation was performed. We have not found any publications describing translation and cross-cultural adaptation of the Lower Extremity Lymphedema Screening Questionnaire.

### Strengths and Weaknesses

In our study we used non-professional translators, as obtaining professional translators can be a challenging and costly process. We followed the recommendation by Schuster et al of using translators who are native speakers of the target language with excellent language skills of the source language and informed about the purpose.<sup>29</sup> We believe this approach is adequate linguistically and culturally, and allows for a wider adaptation of the translation process among clinicians and researchers globally. Expert review was performed by individuals with a variety of professional backgrounds as well as a patient representative. We believe this is a strength of our study, as viewpoints may vary depending on clinical experience, and the patient perspective is key for maintaining conceptual and operational equivalence of the original questionnaires.

The pilot testing was performed on a digital platform. Lack of digital literacy might have contributed to four of 17 (24%) women not responding. For future studies both online and paper versions of the questionnaires can be offered to optimize response rates. Creating the online questionnaires was feasible.

Twelve participants completed the questionnaires twice, yielding a loss to follow-up of 8%. This number may be considered a limitation of our study. The pilot testing was, however, designed as a feasibility study, and the recommended number of participants for this type of study is 10–15. Interestingly, we found a lower extremity lymphedema prevalence of 17–25%, in line with the prevalence we would expect to find in a larger cohort. The majority of participants believed the questionnaires could be of use for others in a similar situation. Of interest, only women who screened positive for lower extremity lymphedema reported that the questions could be relevant for their own situation.

### Implications for Practice and Future Research

This study demonstrates a feasible way to translate validated questionnaires into a non-English language without the use of professional translators. The method can easily be repeated by colleagues globally for any language and any questionnaires. This is especially important for translations in low-resource or high-cost settings. This is the first study describing the translation of questionnaires used for screening of self-reported lower extremity lymphedema into Norwegian. The translated questionnaires will be used in a national multicenter study.

## CONCLUSION

In the present study the Gynecologic Cancer Lymphedema Questionnaire and the Lower Extremity Lymphedema Screening Questionnaire have been translated and culturally adapted to Norwegian using a comprehensive, yet feasible, procedure. Pilot testing of the translated versions showed acceptable internal consistency and excellent test–retest reliability. The Norwegian versions can now

be used in clinical practice and studies for a Norwegian population, enabling comparison with results from other countries or regions using a similarly translated and validated form of the questionnaire.

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**Acknowledgements** We are grateful for assistance with the translation process by Dr Athena Goulimis. We would also like to thank the expert committee: Professor Ingvild Vistad, Lena Fauske, Gro Jacobsen Haugen, Mina Finnerud, and Eva Kantor.

**Contributors** PBT: conception, data acquisition, data management, statistical analysis, critical analysis, drafting/final editing. RSF: statistical analysis, critical analysis, drafting/final editing. ACS: supervision, critical analysis, drafting/final editing. DJ: critical analysis, drafting/final editing. AGE: conception, critical analysis, drafting/final editing, supervision, guarantor.

**Funding** This study was funded by Oslo University Hospital.

**Competing interests** None declared.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by Regional Committees for Medical and Health Research. Reference number:149597. Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request. Data for the participants in the pilot test are available upon reasonable request.

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