

**Aim of the study:** The purpose of this study was to create and introduce a Polish version of the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire for Endometrial Cancer (QLQ-EN24).

**Material and methods:** The translation procedure described by the EORTC was adopted; this comprised two independent forward translations of the original English questionnaire into Polish, two independent backward translations from Polish to English and pilot testing conducted on 12 patients with diagnosed endometrial cancer. They were asked whether there was any difficulty in answering, confusion while answering, or difficulty in understanding the questions, and if the patients themselves would have framed the questions in a different way.

**Results:** During the process of translation, discussions and text corrections were performed by medical experts and native English speakers. Some sentences or phrasing were adopted from other EORTC questionnaires for different diseases. After pilot testing, further text corrections were adopted according to patients' comments. These involved wording, sentence structure, and text editing (font size, bolding).

**Conclusions:** The final version of the Polish EN24 questionnaire has been approved by the EORTC Translational Office. It is available on the EORTC web page now.

**Key words:** quality of life, questionnaire, endometrial cancer, translation, adaptation.

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# Creation of the Polish version and adaptation of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Endometrial Cancer Module (QLQ-EN24)

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## Introduction

Endometrial cancer is the most common pelvic gynecological malignancy in high-income countries, with a 2–3% lifetime risk of developing the disease [1, 2]. Most carcinomas are diagnosed at an early stage. Still, 15–20% of these recur as a metastatic disease. Patients with intermediate and high risk for recurrence are offered extensive surgery including pelvic and paraaortic lymphadenectomy, followed by adjuvant radiotherapy, chemotherapy, or both [1]. This treatment is associated with acute and delayed complications in elderly and multimorbid patients. Nevertheless, only 10–15% of these women might benefit from such additional therapy [3]. Thus there is a need for improvement in the way patients are classified into high-risk of recurrence in order to tailor surgical treatment, propose effective adjuvant therapies and introduce new target treatment for selected groups of patients in whom disease is most likely to recur. As a consequence, the development of new clinical trials is necessary. Quality of life (QOL) is a very important issue in current oncology. In contemporary clinical trials, the QOL assessment is performed together with collection of disease-specific end points. The European Organisation for Research and Treatment of Cancer (EORTC) is a professional, international institution, including a specialized Group for Quality of Life. Many questionnaires were developed and are available for different malignancies. The original, specific questionnaire for endometrial cancer was named EN24 [4]. The aim of our study was to create a Polish version of the EORTC questionnaire for quality of life assessment in patients with endometrial cancer (EN24).

## Material and methods

EORTC Quality of Life Questionnaire for Endometrial Cancer, English version of module EN24 (<http://groups.eortc.be/qol/eortc-modules>) was taken as a basis to create the Polish version [4]. The procedure was consistent with translation guidelines [5]. The EORTC Translation Office first presented

the English original version together with an EN24 Polish interim version, where some translations were adopted from a similar module for cervical cancer, CX24 [6]. Two independent forward translations (from English to Polish), together with corrections of the interim version, were performed by medical experts. The first Polish version was created. Later two independent backward translations (from Polish to English) were performed by native English speaking translators. To some extent, translation issues were discussed via e-mail, as well as direct meetings and teleconferences. Afterwards the Polish version together with the backward translation into English were presented to the EORTC Translation Office.

After the translation, pilot testing was performed to identify and solve any potential problems in the translation, including vocabulary issues and expressions that would be most suitable for the target population. Pilot testing of the Polish version was conducted on 12 patients with endometrial cancer, admitted to the Department of Gynecologic Oncology Gdynia Oncology Center between August and October 2011. Bioethical Committee approval has been granted for this project. All patients participating in the study signed a consent form before completing the questionnaire. The initial EN24 questionnaire translation was presented and after completion a structured interview with each patient was conducted to determine whether the wording presented any difficulties in answering or understanding, whether the questions were confusing, upsetting or offensive, or whether the patient would have asked the question in a different way. According to patients' comments, the final Polish EN24 questionnaire version was created and presented to the EORTC Translational Office.

## Results

The summary of the translation process is presented in Table 1, abbreviated to the most important linguistic controversies and solutions undertaken. In those cases where we used an available translation from another EORTC questionnaire, we did not present it in the table, though the issue was discussed for the best version. The translated and accepted first Polish version of the EORTC questionnaire EN24 was presented to 12 women with diagnosed endometrial cancer. The mean time to answer the EN24 module was 6 minutes (range 3–12 minutes) and the interview took from 1 to 10 minutes. The mean age of patients was 69 years (range 54–81 years). Polish was their native language and they lived in northern Poland. Eight of the women were retired. All patients were diagnosed based on histology examination from endometrial biopsy. In cases where metastatic disease was suspected, additional magnetic resonance imaging or computed tomography scans were performed. The cancer stages were from IA to IIIC in the studied group based on findings from staging surgery and imaging. The histological types of cancer were as follows: 9 patients with endometrioid, 2 with mixed endometrioid-serous, and one with serous adenocarcinoma. At the time of completing the questionnaire, 10 patients were about to undergo surgery, and 2 with contraindications to surgery were awaiting radical chemoradiotherapy.

## General linguistic considerations

None of the interviewed women were sexually interested or active within the relevant period of time (4 weeks) and only two of them answered items number 51–54. Nevertheless, these questions were acceptable, understood, and not confusing or offensive. Individually interviewed patients recognized these items as important and well constructed.

One patient noted a discrepancy between the heading describing the time period and following questions. She suggested changing the heading and that the question style for all items be more uniform. This is because of the heading "During the last week" which was translated into Polish: "Czy w ostatnim tygodniu". The Polish "Czy" meaning depends on further words, and can be understood as: "Have you...", or "Did you...". When "Czy" is used in the heading, than there is no need to repeat it in every question. That is why we decided to erase word "Czy" from questions 39 and 40 of the first EN24 version.

The opposite problem occurred in the heading for items 49 and 50. Because of linguistic differences and the character of the following questions, the best form of the heading would be without "Czy" (present in the first version). It was decided to use "Podczas ostatnich czterech tygodni" (During the last four weeks) in the final version. Items 49 and 50 remain unchanged.

The heading for items 51–54 did not include the word "Czy", which is why we suggested adding this "prefix" to questions 51 and 52. "Czy" is used in a question sentence form, meaning: "Have you..." or "Did you...".

One patient proposed changing the word "Wcale" (Not at all) into the heading "Nie" (No). The suggestion was proposed after a problem with question 35. The research team analyzed the problem, and decided to leave it as in the primary version with "Wcale" (Not at all), firstly because it is used in all EORTC Polish questionnaires, and secondly because we changed the problematic question 35 (see below).

## Detailed linguistic considerations

### Question 33

One patient suggested erasing the word "krzyża" meaning "back", referring to back pain. It was one opinion only, and the problem of pain in the lower back is different from and as important as pain in the pelvis, so the research team decided to leave the item unchanged.

### Question 35

The form of question: "Oddawała Pani często mocz?" (Have you passed urine frequently?) and the answer: "Wcale" (Not at all) was confusing for two patients. This answer to the question could be understood as not passing urine at all. We proposed changing the question into: "Miała Pani problem z częstym oddawaniem moczu?", which was a better translation of the original English version, and did not cause any confusion.

Other questionnaire items were found to be acceptable and the patients had no comments.

All the patients' comments were taken into consideration and the final Polish EN24 questionnaire version was

Table 1. EORTC QLQ-EN24 questionnaire translation process (abbreviated)

Questions / Intro / Answers English original version	1 <sup>st</sup> forward translation	2 <sup>nd</sup> forward translation	Reconciled translation	Backward translation 1	Backward translation 2	Reasoning for the linguistic decision	Comments from EORTC	Our comments
Please indicate the extent to which you have experienced these symptoms or problems.	Existing translation not changed.	Proszę zaznaczyć, jeśli występowały u Pani podane objawy, oraz określić częstotliwość ich występowania.	Proszę wskazać, w jakim zakresie odczuwała Pani te objawy lub problemy.	Please indicate the degree to which you have experienced these symptoms or problems during the past week.	Have you experienced the following symptoms or problems during the last week? Please indicate to what extent.	The best combination of the 1 <sup>st</sup> and 2 <sup>nd</sup> translation was chosen.		"Podczas ubiegłego tygodnia" means "during the past week", and it was removed from reconciled version, as it was not in original one.
Answer these questions only if you have been sexually active during the last four weeks:	Proszę odpowiedzieć na poniższe pytania, tylko jeżeli w ciągu ostatnich 4 tygodni była Pani aktywna seksualnie (podczas lub poza stosunkiem)?	Na pytania poniżej proszę odpowiedzieć tylko wtedy, jeśli była Pani aktywna seksualnie w ciągu ostatnich 4 tygodni.	Proszę odpowiedzieć na poniższe pytania, tylko jeżeli w ciągu ostatnich 4 tygodni była Pani aktywna seksualnie (podczas lub poza stosunkiem)?	Please answer the following questions only if you have been sexually active during the last four weeks.	Please answer the questions below only if you have had sexual intercourse in the last four weeks.	1 <sup>st</sup> forward translation chosen as better because already existing in questionnaire Cx24.		
Have you felt heaviness in one or both legs?	Miała Pani uczucie ciężkości jednej lub obu nóg?	Występowało u Pani uczucie ciężkości jednej lub obydwóch nóg?	Miała Pani uczucie ciężkości jednej lub obu nóg?	Have you experienced a feeling of heaviness in one or both legs?	Have you felt heaviness of one or both legs?	Translation already available was not correct. 1 <sup>st</sup> translation was better because of wording (in 2 <sup>nd</sup> : word "obydwóch" seems in a bad style).		
Have you had pain in your lower back and/or pelvis?	Miała Pani ból krzyża lub podbrzusza?	Odczuwała Pani ból w dolnym odcinku pleców i/lub w okolicy miednicy?	Miała Pani ból krzyża lub podbrzusza?	Have you experienced any pain in your back or abdomen?	Have you felt any pain in the back or the abdomen?	1 <sup>st</sup> translation in better style, shorter, not using word "miednicy", which in Polish has two meanings.	The back translation shows that the term "podbrzusze" has been translated as "abdomen". However, the word "miednica" seems to be a better translation for pelvis. Why is it a problem to use this last term instead of the other?	"Podbrzusze" means lower part of abdomen. "Miednica" in medical language means pelvis, but we considered "podbrzusze" as more professional. And "podbrzusze" is well understood by patients.
When you felt the urge to pass urine, did you have to hurry to get to the toilet?	Musiła się Pani spieszyć do toalety, gdy miała Pani potrzebę oddania moczu?	Odczuwała Pani nagłą potrzebę oddania moczu, zmuszającą Panią do szybkiego udania się do toalety?	Musiła się Pani spieszyć do toalety, gdy miała Pani potrzebę oddania moczu?	Have you had to hurry to the toilet when you felt the need to pass urine?	Have you felt the need to hurry to the toilet to urinate?	1 <sup>st</sup> translation closer to existing translation, only adaptation for women was made.		

Table 1. EORTC QLQ-EN24 questionnaire translation process (abbreviated) (continued)

Questions / Intro / Answers English original version	1 <sup>st</sup> forward translation	2 <sup>nd</sup> forward translation	Reconciled translation	Backward translation 1	Backward translation 2	Reasoning for the linguistic decision	Comments from EORTC	Our comments
Have you passed urine frequently?	Oddawała Pani moczę często?	Musiata Pani często odwiedzać toaletę w celu oddania moczu?	Oddawała Pani często mocz?	Have you had to pass urine more frequently?	Have you felt the need to urinate more frequently?	1 <sup>st</sup> translation used because simpler, and in 2 <sup>nd</sup> version language style not correct ("odwiedzać toaletę" – visit toilet).		Word order was changed – better style in Polish language.
Have you had pain or a burning feeling when passing urine?	Odczuwała Pani ból lub pieczenie przy oddawaniu moczu?	Odczuwała Pani dolegliwości bólowe lub pieczenie podczas oddawania moczu?	Odczuwała Pani ból lub pieczenie przy oddawaniu moczu?	Have you experienced any pain or burning sensation while passing urine?	Have you felt any pain or burning sensation while urinating?	1 <sup>st</sup> translation closer to existing translation, only adaptation for women was made.		
When you felt the urge to move your bowels, did you have to hurry to get to the toilet?	Musiata się Pani spieszyć do toalety, gdy miała Pani potrzebę oddania stolca?	Odczuwała Pani parcie na stolec zmuszające Panią do szybkiego udania się do toalety?	Musiata się Pani spieszyć do toalety, gdy miała Pani potrzebę oddania stolca?	Have you had to hurry to the toilet when you felt the need to pass a stool?	Have you felt the need to hurry to the toilet to defecate?	1 <sup>st</sup> translation closer to existing translation, only adaptation for women was made.		
Have you had any leakage of stools?	Czy miała Pani mimowolne wypróżnienia?	Występowało u Pani u siebie mimowolne oddanie stolca?	Czy miała Pani mimowolne wypróżnienia?	Have you experienced any involuntary bowel movement?	Have you had any involuntary defecation?	1 <sup>st</sup> translation closer to existing translation, only adaptation for women was made.		
Have you been troubled by passing wind?	Czuła się Pani zakłopotana oddawaniem wiatrów?	Odczuwała Pani dyskomfort związany z mimowolnym oddaniem gazów?	Czy miała Pani problemy związane z oddawaniem gazów?	Have you experienced flatulence?	Have you felt embarrassed due to involuntary flatulence?	1 <sup>st</sup> reconciled version was changed as suggested in EORTC comments.	In the original English question the focus is on the problem of passing wind and not on the embarrassment due to this fact. A suggested translation is: Czy miała Pani dolegliwości związane z oddawaniem gazów?	We agree with the comment. Your version was used as reconciled with one changed word: "problemny" – troubles, as closer to original version, and we think more suitable.
Have you had a bloated feeling in your abdomen?	Miewała Pani uczucie rozdymania brzucha?	Występowało u Pani uczucie wzdęcia?	Występowało u Pani uczucie wzdęcia?	Have you experienced bloats?	Have you felt bloated?	2 <sup>nd</sup> translation with better wording.		

Table 1. EORTC QLQ-EN24 questionnaire translation process (abbreviated) (continued)

Questions / Intro / Answers English original version	1 <sup>st</sup> forward translation	2 <sup>nd</sup> forward translation	Reconciled translation	Backward translation 1	Backward translation 2	Reasoning for the linguistic decision	Comments from EORTC	Our comments
Have you had tingling or numbness in your hands or feet?	Existing translation not changed	Występowało u Pani drętwienie lub mrowienie dłoni i/lub stóp?	Odczuwała Pani mrowienie/drętwienie i/lub osłabienie czucia w rękach lub stopach?	Have you experienced any tingling or numb sensation and/or hypoesthesia in your hands or feet?	Have you had any tingling/ numbness and/ or impairment of sensation in your hands or feet?	Existing translation was changed as suggested in EORTC comments.	Perhaps, even though it is an existing translation, for general linguistic correctness it is better to say "odczuwać" instead of "mieć" in this case, since it is a better collocation for all listed feelings.	We agree with the comment. The wording "odczuwać" was used as reconciled.
Have you lost hair?	Wypadaty Pani włosy?	Zaobserwowała Pani wypadanie włosów?	Wypadaty Pani włosy?	Have you observed hair loss?	Have you been losing hair?	1 <sup>st</sup> translation shorter, without redundant words.		
Have you felt physically less attractive as a result of your disease or treatment?	W wyniku choroby lub jej leczenia czuła się Pani mniej atrakcyjna fizycznie z powodu choroby lub stosowanego leczenia?	Czuła się Pani mniej atrakcyjną fizycznie z powodu choroby lub stosowanego leczenia?	Czuła się Pani mniej atrakcyjna fizycznie z powodu choroby lub leczenia?	Have you felt less attractive physically due to your illness or treatment?	Have you felt less physically attractive because of your illness or treatment?	2 <sup>nd</sup> translation in better style, one word "stosowanego" (used) redundant..		
To what extent were you interested in sex?	W jakim stopniu była Pani zainteresowana współżyciem seksualnym?	Odczuwała Pani zainteresowanie sferą seksu?	W jakim stopniu była Pani zainteresowana współżyciem seksualnym?	To what extent have you been interested in sex?	Have you been interested in sex?	1 <sup>st</sup> translation closer to existing translation, only adaptation for women was made.		
Has your vagina felt dry during sexual activity?	Czy odczuwała Pani suchość pochwy podczas stosunku?	Odczuwała Pani suchość w pochwie podczas stosunku seksualnego?	Odczuwała Pani suchość pochwy podczas stosunku?	Have you felt dryness of your vagina during intercourse?	Has your vagina been dry during intercourse?	The best combination of 1 <sup>st</sup> and 2 <sup>nd</sup> translation was chosen.		
Has your vagina felt short and/or tight?	Czy miała Pani uczucie, że pochwa jest krótka lub wąska?	Odczuwała Pani, że pochwa jest zbyt krótka i/lub zbyt wąska?	Odczuwała Pani, że pochwa jest krótka i/lub wąska?	Have you had an impression that your vagina was too short and/or too narrow?	Have you felt that your vagina was too short and/or too narrow?	The best combination of 1 <sup>st</sup> and 2 <sup>nd</sup> translation was chosen.		

created and presented to the EORTC Translation Office. This was accepted and is officially available on the EORTC Quality of Life Group web site (<http://groups.eortc.be/qol/eortc-modules>).

## Discussion

The QOL is an important issue in most contemporary oncological trials. Different malignancies cause different symptoms, both due to clinical presentation and treatment modality. The EORTC has developed special questionnaires for different diseases. These have been translated into many languages. The same tool for assessing the quality of life can be used in clinical trials conducted worldwide, or it is possible to compare QOL issues between trials where different treatment modalities within the same disease are examined. According to the guidelines, we translated and adapted the Polish version of the EN24, which was accepted by the EORTC Translation Office and is readily available on the EORTC web site (registration and permission required).

The questionnaire consists of simple questions to be answered by matching the most appropriate available answer or level of symptom intensity. The EN24 like other EORTC questionnaires is designed to be used by patients during all possible treatment modalities or disease phases. The questions seem to be positioned randomly on the sheet, but they are grouped and assessed together in separate scales (physical, social, emotional, etc.). After using the scoring system the results are presented in numbers, separately for each scale. The EN24 was constructed to match as an additional module to the general universal C30 questionnaire, and together these cover most quality of life assessment issues. Along with physical symptoms, other aspects are also addressed.

In specific patient subgroups or profiled clinical trials it can be more appropriate to use special, focused questionnaires, e.g. for depression (HADS), or sexual functioning (FSFI) [7–10]. The questionnaire EN24 has been used worldwide [11, 12]. Researchers suggest that BMI should be considered and assessed additionally to questionnaires [13]. Another questionnaire specific for endometrial cancer is called FACT-En (Functional Assessment of Cancer Therapy – Endometrial Cancer) ([www.facit.org](http://www.facit.org)). It was used in one publication [14]. Well-known questionnaires such as the SF-36 or the shorter SF-12 are often used but there is no specific module for endometrial cancer ([www.sf-36.org](http://www.sf-36.org)).

In conclusions the EORTC-EN24 is a simple tool for a quality of life assessment with appropriate wording and an easy to complete format. Used in clinical trials worldwide and having been tested on the Polish target population, it is now available for use in Poland. The validation of the EN24 questionnaire on larger groups of patients is now being performed by the authors.

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