

# Translation and validation of European Organization for Research and Treatment for Cancer quality of life questionnaire-OV-28 module into Indian languages (Hindi and Marathi) to study quality of life of ovarian cancer patients from a tertiary care cancer center

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## Abstract

**Aim:** The aim is to translate and validate the European Organization for Research and Treatment for Cancer (EORTC) ovarian cancer (OC) module (OV-28) into Hindi and Marathi to use for patients and scientific community. **Methods and Results:** The EORTC OV-28 was translated into Hindi and Marathi languages using prescribed guidelines by the EORTC. The process included forward translation by four translators (2 each for Hindi and Marathi). The questionnaires obtained were then given to independent backward-translators who then translated them back into English. These 2 questionnaires were then compared with the original EORTC questionnaire and the second intermediate questionnaires were formed. The second intermediate questionnaire was subsequently administered in twenty patients (10 each for Hindi and Marathi) diagnosed with OC who had never seen the questionnaire before, for pilot testing. Each of these ten patients after filling up the questionnaire themselves was then interviewed for any difficulty encountered during the filling up of the questionnaires. These were in the form of specific modules including difficulty in answering, confusion while answering, and difficulty to understand, whether the questions were upsetting and if patients would have asked the question in any different way. The suggestions were incorporated into the second intermediate questionnaires to form the final Hindi and Marathi ON-28 questionnaires. These questionnaires were then sent to the EORTC for the final approval to be used in clinical studies. **Conclusion:** We have successfully translated EORTC OV-28 module into Hindi and Marathi languages, and EORTC approved them to be used in clinical practice and studies for OC patients.

**Key words:** European Organization for Research and Treatment for Cancer, OV-28, ovarian cancer, quality of life, questionnaire

## Introduction

Ovarian cancer (OC) is the most fatal among all gynecological malignancies. According to GLOBOCAN estimates,<sup>[1]</sup> 238719 women worldwide were diagnosed with OC in 2012. Takiar *et al.* have estimated the number of diagnosed OCs to reach 36,199 by the year 2020 in India.<sup>[2]</sup> Due to the insidious nature of its development the disease is quite often diagnosed during the later stages in 75% of the concerned patients (International Federation of Gynecology and Obstetrics stages III and IV). Diagnosis and treatment of OC entail severe symptom burden and a significant loss of quality of life (QOL). A majority of patients in the advanced stages of OC will relapse and present with resistance to first line of therapy they have already received. Somatic and psychological impairments may persist in such patients well beyond multiple lines of invasive and noninvasive active therapies. Poor QOL may affect compliance to chemotherapy and in turn the outcome of treatment. With evidence-based medicine gaining ground in the recent past along with involving patients in treatment planning, patient-reported outcomes should be assessed in all OC patients. Thus, QOL issues are gaining importance for patients and caregivers extending treatment goals from mere prolongation of disease-free periods to maintenance of functioning and well-being.<sup>[3]</sup>

There is growing interest in the incorporation of patient-reported outcome measures in cancer clinical trials and in the routine care of patients. The European Organization for Research and Treatment in Cancer (EORTC) has evolved a series of quality-of-life questionnaires that are both general

and domain-specific and are widely used in clinical practice and research. EORTC has also developed an instrument for the evaluation of patient-reported measures in OC known as the EORTC quality of life questionnaire (QLQ)-OV28 module.<sup>[4]</sup> The current version of EORTC QLQ-OV28 module has been translated into 53 languages as of September 2017 around the world and has also been validated and tested in multicultural settings. This is the first study to validate the translated version of the EORTC QLQ-OV28 module in Indian languages. Even though the Bengali translation of the module is available for use, no published literature was available to examine various aspects of its validation process.<sup>[5]</sup> The current study was undertaken to translate the EORTC QLQ-OV28 module into Hindi and Marathi and validate it for future use.

## Materials and Methods

The permission to translate the core questionnaires (OV28) module [Table 1] was obtained from EORTC QOL Department. Before translating the instrument or sending it out to be translated, the Translation Coordinator (SV and MG) preprocessed the files using two computerized tools, the Item Bank and the Translation Memory. These files were then sent to the Project Manager (JB) who was in charge of overseeing the translation and pilot testing of a particular questionnaire.

## Forward translation

The questionnaire was initially translated from English into Hindi and Marathi and versions conceptually as close as

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**Table 1: European Organization for Research and Treatment of Cancer: Quality of life questionnaire-OV28**

During the past week	Not at all	A little	Quite a bit	Very much
31. Did you have abdominal pain?	1	2	3	4
32. Did you have a bloated feeling in your abdomen/stomach?	1	2	3	4
33. Did you have problems with your clothes feeling too tight?	1	2	3	4
34. Did you experience any change in bowel habit as a result of your disease or treatment?	1	2	3	4
35. Were you troubled by passing wind/gas/flatulence?	1	2	3	4
36. Have you felt full too quickly after beginning to eat?	1	2	3	4
37. Have you had indigestion or heartburn?	1	2	3	4
38. Have you lost any hair?	1	2	3	4
39. Answer this question only if you had any hair loss: Were you upset by the loss of your hair?	1	2	3	4
40. Did food and drink taste different from usual?	1	2	3	4
41. Have you had tingling hands or feet?	1	2	3	4
42. Have you had numbness in your fingers or toes?	1	2	3	4
43. Have you felt weak in your arms or legs?	1	2	3	4
44. Did you have aches or pains in your muscles or joints?	1	2	3	4
45. Did you have problems with hearing?	1	2	3	4
46. Did you urinate frequently?	1	2	3	4
47. Have you had skin problems (e.g., itchy, dry)?	1	2	3	4
48. Did you have hot flushes?	1	2	3	4
49. Did you have night sweats?	1	2	3	4
50. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
51. Have you been dissatisfied with your body?	1	2	3	4
52. How much has your disease been a burden to you?	1	2	3	4
53. How much has your treatment been a burden to you?	1	2	3	4
54. Were you worried about your future health?	1	2	3	4
55. To what extent were you interested in sex?	1	2	3	4
56. To what extent were you sexually active?	1	2	3	4
Answer the following two questions only if you were sexually active				
57. To what extent was sex enjoyable for you?	1	2	3	4
58. Did you have a dry vagina during sexual activity?	1	2	3	4

possible to the original English OV28 were produced. Two forward-translators, native speakers of the target languages and fluent in English, provided translations independently.

#### Back translation

This translation was back-translated by two independent backward-translators (fluent in both, the target language and English, and different from the forward-translators) to ensure that the provisional forward translation is an adequate representation of the English original. The back-translation report was sent back to EORTC for approval. The EORTC sent some comments and sought some clarifications, pursuant to which the translations were slightly modified. After reapproval from EORTC, the forward interim translation was ready for pilot-testing on twenty patients of the target population. At each step, the primary investigator recorded decisions and changes in a report.

#### Pilot testing and study population

The pilot testing of the translated questionnaires were carried out in at the Tata Memorial Centre, Mumbai. Prior ethics committee approval was obtained and all aspects related to participant safety and confidentiality mentioned in the Declaration of Helsinki was adhered to. Female patients aged above 18 years with a histopathologically confirmed diagnosis of OC along with adequate staging workup and those who have consented to undergo chemotherapy at Tata Memorial Centre

were considered for the study. Voluntary informed consent was obtained before accruing the study participants.

The interim translation was served to twenty participants (ten each for Hindi and Marathi versions) and their feedback on the questionnaire recorded in a standard format.

#### Statistical analysis

Demographic analysis related to the age, education, and correlation results of the multi-item scales and single items were performed using the tests for item convergent and discriminant validity. IBM Corporation Released 2013. IBM SPSS Statistics for Windows, Version 22.0 IBM Corp Armonk, NY, USA has been used for conducting all the statistical analysis.

#### Results

##### Forward translations (Hindi and Marathi)

For the Hindi version, the English questionnaire was given to the 2 translators. Translator I was MG and translator II was AM. Both of the translators had good command over English and Hindi. For the Marathi version, the English questionnaire was given to 2 translators. Translator I was SV and translator II was PT.

##### Difficulties encountered during the translations

The Hindi and Marathi questionnaires were evaluated by the project coordinator. There were no significant differences between the two forward Hindi questionnaires prepared by

the translators, respectively. The first intermediate Hindi questionnaire was drafted after due discussions between the project coordinator and the respective translators. Taking into consideration, the absence of any significant differences in the forward Marathi translations, the intermediate Marathi questionnaire was similarly developed after due discussions with the respective translators.

### Back translations

The Hindi and Marathi intermediate questionnaires were handed over to 2 translators each for Hindi and Marathi who were completely unaware of the original EORTC OV28 questionnaire in English. The translators were sensitized about the questionnaire and that it was a tool to evaluate the QOL in patients with OC. They were requested to draft an English translation of the intermediate Hindi and Marathi questionnaires in simple, comprehensible language. For the Hindi version, Translator I was PP and Translator II was TG. For the Marathi version, Translator I was SG and Translator II was VP.

The Hindi and Marathi back translated questionnaires were compared with the original English versions and satisfactory similarity was noted. The first intermediate questionnaires were considered as the ones to be pilot tested.

### Pilot testing

The intermediate Hindi and Marathi questionnaires were administered to the twenty patients (10 each for Hindi and Marathi versions) who were diagnosed with OC and had never come across the questionnaire before. The study population consisted of participants who were native Hindi and Marathi speakers for the Hindi and Marathi versions, respectively.

The mean age of the entire cohort was 45.7 years (27–59) while it was 44.4 years (35–55) for the participants administered the Marathi version of EORTC QLQ-OV28 and 47.1 years (27–59) for the participants administered the Hindi version. Fourteen out of the 20 participants (7 each for the Hindi and Marathi groups) had completed secondary school education while the remaining 6 (3 each for the Hindi and Marathi groups) had completed graduation.

### Hindi version

In question number 34, one patient had difficulty in understanding the word “shauch kriyao me,” but rest of the nine patients understood this word well. Hence, an optional word inside the bracket “sandash sambandhit” was added to make this question comprehensible as “Kya aapane bimari athava uske upchar ke baad shauch (sandash sambandhit) kriyao me kisi kism ka parivartan mahsoos kiya tha?”

Three out of the 7 participants who had completed only secondary school education found the word “Atyadhik” in question number 48 somewhat difficult to understand, hence “bahut jyada” which is easy to understand synonym for word “Atyadhik.” The revised question read as “Kya aapko bahut jyada garmilaganaathavachehralal hone kisamasyathi?” and asked this question to the same patients, and they responded well to it.

Two patients had interpretation difficulty in question number 50. They could not interpret the true meaning of word “vyaktitva.” Hence, we used synonymous phrase “sharireek roop se” instead of the word “vyaktitva,” and now the question read as “Kya aap apne aapko sharireek roop SE kam aakarshak South Asian Journal of Cancer ♦ Volume 7 ♦ Issue 1 ♦ January-March 2018

mahasoos kartithi?” which was easy to understand for those two patients also.

In question numbers 52 and 53 one patient found the word “Bojhil” difficult to understand. Hence, we replaced the word “Bojhil” with the words “Bojh/Bhaar” in the first instance; however, the patient still was not comfortable in interpreting. Hence, finally, we added the word “Manasikroop se” in the bracket to further explain it well. The reframed question number 52 read as “Is rog ke karan aap kitna bojh/bhaar (manasik roop se) mahasoos karti thi?” as well as question number 53 read as “Is rog keupchar SE aap kitna bojh/bhaar (manasik roop se) mahasoos karti thi?” and this time the patient understood this question well.

In question number 54 word “Aagami” is difficult to understand for one patient, so we replaced this word with synonym “aanewale (bhavishyake).” The new version of the question read as, “Kya aap apne aane wale (bhavishya ke) swasthyas ambandhit baton kolekarchintithi?” We reconfirmed for understanding with the same patient, who understood this time and respond well.

In question number 55 word “Rujhan” is difficult to understand for one patient. We replaced this word with the synonymous easy words “Ruchi/lagaav” and added word “kitani” to describe “extent.” Now the new version of this question read as “Aap sharireek sambandhon ke prati kitani ruchi/lagaav mehsoos karati thi?” We asked it to same patient and this time she understood it well.

All these patients were assessed in telephonic conversation with the optional words, and all were able to understand them easily.

Due to cultural taboos prevalent in India people feel uncomfortable in talking about sexual behavior in general. Similar observation is noted while patients were asked to respond to question number 55–58. Patients initially felt hesitation in responding; however, on explaining, they could realize the importance of such questions and answered appropriately.

Internal consistency was satisfactory (Cronbach  $\alpha > 0.70$ ) in most of the scales like, body image (0.896), sexuality (0.972), attitude to disease and treatment (0.821), abdominal/gastrointestinal symptoms (0.752) [Table 2].

### Marathi version

In question number 34, two patients had difficulty in understanding the word “shauchachya,” but remaining eight patients understood this word very well. Hence, an optional word “sandashachya” was added within brackets as in “Tumhi tumachya aajaramule kinva upcharamule tumachya shauchachya (sandashachya) savayimadhye kahi farak anubhavala ka?” The question with the above change was easier to understand for all including those two patients too.

In question number 42, word “badhirata” was difficult to understand for one patient, but rest of the nine patients understood it well. Hence, we replaced it with “sanvedanet” and when the modified question was asked again to the same patient the patient opined that word “sanvedana” was more difficult to understand than “badhirata.” Due to this scenario, we kept the word “badhirata” as it is and added the phrase “sunnapanajanavalahota” within brackets to make the question more comprehensible. The question which was then read

**Table 2: Multi-trait scaling analyses with Pearson correlations between scale items on ovarian cancer module of the European Organization for Research and Treatment of Cancer quality of life questionnaire for Hindi and Marathi speakers**

Scale	Mean±SD	Cronbach $\alpha$	Item-own scale correlation*	Item-other scale correlation
<b>Hindi</b>				
Functional scales				
Body image (items 50-51)	71.6±33.3	0.886	0.977-0.946	0.095-0.602
Sexuality (items 55-58)	10.0±31.62	0.972	0.166	0.215-0.409
Attitude to disease and treatment (item 52-54)	68.88±29.53	0.821	0.785-0.808	0.059-0.502
Symptom scales/items				
Abdominal/gastrointestinal symptoms (item 31-37)	75.23±21.74	0.791	0.036	0.373-0.534
Peripheral neuropathy (item 41-43)	75.55±23.30	0.424	0.562-0.840	0.158-0.373
Hormonal/menopausal symptoms (items 48-49)	91.6±14.16	0.369	0.574-0.986	0.215-0.255
Other chemotherapy side-effects; (items 38-40 items 44-47)	75.07±14.15	0.321	0.035	0-0.102
<b>Marathi</b>				
Functional scales				
Body image (items 50-51)	71.68±28.38	0.889	0.934-0.938	0.065-0.750
Sexuality (items 55-58)	20.00±42.10	NA	0.250	0.045-0.787
Attitude to disease and treatment (item 52-54)	50.0±35.62	0.830	0.826-0.894	0.004-0.180
Symptom scales/items				
Abdominal/gastrointestinal symptoms (item 31-37)	65.23±25.79	0.822	0.424-0.910	0.044-0.488
Peripheral neuropathy (item 41-43)	77.77±21.55	0.776	0.723-0.915	0.027-0.278
Hormonal/menopausal symptoms (items 48-49)	81.66±14.59	NA	0.231-0.891	0.003-0.583
Other chemotherapy side-effects; hair loss (items 38-40 and 44-47)	72.38±12.94	0.701	0.016-0.854	0.183-0.527

\*Corrected for overlap. SD=Standard deviation, NA=Not available

question “Tumhala hata-payanchya botanmadhye badhirata janavali hoti (sunnapanana janavala hota) ka?” Was again asked to the patient and it was fairly comprehensible to the patient this time.

In question number 48, the phrase “Garamzala” was little difficult to understand for three patients, hence we used the word “ushnapana” which is synonymous to “Garamzala” and easier to interpret. The revised question read as “Tumhala shareerat ushnapanana janavala hota ka?” was asked to the same patients and this time they understood it well and responded accordingly.

Four patients had mild difficulty in interpreting question number 50 because of the word “sharireek drushtya.” Hence, we used a synonym “sharireek” instead of “sharireekdrushtya.” The modified question read as “Aajaramule kinva upacharamule tumache sharireek aakarshan kami zale ahe ase vatale hote ka?” was asked again to the same patients and this time they understood the question well.

Three patients had interpretation difficulty in question number 51. Hence, we replaced the word “shareera baddal” with the word “sharireek sthiti baddal” and reframed the question as “Tumhi tumachya sharireek sthitibaddal asamaadhani hota ka?” This time the question was well understood by them.

In question number 52 and 53, two patients found the word “Ojhe” difficult to understand. Hence, we replaced the word “Ojhe” by the word “taanvatata” to simplify these questions. The word “Taan” has same meaning as burden in Marathi

and reframed question 52 as “Tumhala tumachya aajaracha kitpat taan vatata?” and question 53 as “Tumhala tumachya upcharacha kitpat taan vatata?” Further, retesting on the same patients, they could interpret it well this time.

All these patients were assessed during follow-up visits or with telephonic conversation for the optional words, and all were able to understand them easily.

Due to cultural taboos prevalent in India, people feel uncomfortable in talking about sexual behavior in general. Similar observation is noted while patients were asked to respond to question number 55–58. Patients initially felt hesitation in responding; however, on explaining they could realize the importance of such questions and answered appropriately.

Internal consistency was satisfactory (Cronbach  $\alpha > 0.70$ ) in most of the scales like, body image (0.889), attitude to disease and treatment (0.830), abdominal/gastrointestinal symptoms (0.822), peripheral neuropathy (0.776), hair loss (0.701) and other chemotherapy side-effects [Table 2].

## Discussion

With the increasing acceptance of QOL as an end point in oncology clinical trials across the globe, it has become imperative to develop tools to effectively assess QOL of patients undergoing treatment for various cancers. The EORTC QOL (QL) group has developed the psychometrically robust core EORTC QLQ-C30 tool which has been accepted across various geographies and cultures.<sup>[3]</sup> Various disease-/

treatment-specific modules have been developed subsequently to address additional issues. OC and its management is known to have a significant effect on the overall QOL. QOL issues such as that of living with the disease burden and long-term treatment effects also affect the quality of care in such patients. Current treatment approaches for OC are increasingly focusing on improving the QOL alongside survival outcomes and acceptable toxicity profiles of the respective treatment modalities. To address most of these issues, the EORTC QLQ-OV28 tool was developed to supplement the EORTC QLQ-C30 to adequately assess and record OC specific disease and/or management-related issues.<sup>[6]</sup> India is a diverse country which has 23 constitutionally recognized official languages. Hindi, Bengali, Telugu, and Marathi are the most spoken languages. In such a scenario, it was essential to translate the original EORTC QLQ-OV28 into major Indian languages. The adaptation of QOL tools for multi-cultural settings requires linguistic validity and subsequently its psychometric validation. Guidelines suggested by the EORTC were adopted by us in translating and validating the QLQ-OV28 toll into Hindi and Marathi languages. The final translated questionnaires were submitted to the EORTC for testing their accuracy. Few queries raised by the EORTC were discussed with the translators along with the project manager, and the suggested changes were incorporated in the final questionnaires which have been approved by the EORTC for suitable use in patients with OC. Statistical analysis of both the questionnaires showed acceptable item-convergent and discriminant validity. The questions related to sexuality were the probable limiting factors owing to the culturally sensitive Indian population.

### Conclusion

The goal of current management strategies for OC is to not only improve survival but also to improve the overall QOL of patients. The importance of assessing patients' experiences during various stages of treatment is becoming increasingly important among clinicians and the policymakers. QOL has varied interpretations around the globe. Taking into consideration, the need to address the requirements of the

local Indian population, we translated the EORTC QLQ-OV28 tool into Hindi and Marathi. Our versions of the EORTC QLQ-OV28 tool are a reliable and valid measure of the QOL of patients with OC. Our results indicate that this questionnaire could be used in clinical and epidemiological cancer research to study the QOL of Hindi and Marathi speaking patients with OC which represent a sizeable proportion among all patients diagnosed with OC.

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### Conflicts of interest

There are no conflicts of interest.

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