

# The European Organization for Research and Treatment of Cancer prostate-specific quality of life module (PR-25) in Hindi and Marathi: Translation and pilot testing process

## ABSTRACT

**Background:** The side effects of various treatments for prostate cancer have a measurable impact on the general as well as disease-related quality of life, which is of pivotal concern as an outcome measure.

**Aim:** Translation and pilot testing of the European Organization for Research and Treatment of Cancer (EORTC) prostate cancer-specific module (PR-25) into Hindi and Marathi.

**Materials and Methods:** The translation procedure described by the EORTC was adopted; this comprised two forward translations of the original English questionnaire into Hindi and Marathi each with formation of first intermediary questionnaires and two back translations of the first intermediary questionnaires into English. The first intermediary questionnaires were adapted as the second intermediary questionnaires and pilot tested in ten prostate cancer patients as no modifications were suggested by the back translators.

**Results:** Each patient, after completing the questionnaire, was interviewed by the local project coordinator who questioned them about each item in the second intermediary questionnaire. The patients were asked whether there was any difficulty in answering, confusion while answering, or difficulty in understanding the questions; whether the questions were upsetting; and if the patients themselves would have framed the question in a different way. Based on the suggestions or interpretations of this pilot testing, the necessary changes were incorporated and the final Hindi and Marathi questionnaires were formed.

**Conclusion:** Both the translations were submitted to the EORTC for review and have been subsequently approved for clinical studies.

**KEY WORDS:** Backward translation, European Organization for Research and Treatment of Cancer QLQ-PR25, forward translation, pilot testing

Prostate cancer is the most common solid-organ malignancy among North American men,<sup>[1]</sup> and has traditionally been considered a disease of the West. The incidence of prostate cancer however has been on the rise in recent years in India as indicated by the urban population-based registries.<sup>[2,3]</sup> Prostate cancer has now become one of the leading types of cancer in urban India. It is now the third commonest cancer in Delhi (previously eighth), fourth in Mumbai (previously eighth), fifth in Bangalore (previously seventh), and has maintained its ninth position in Chennai. The adoption of western culture by the native population and increasing urbanization are thought to be behind this increasing trend in urban areas. This is similar to the increasing incidence of breast cancer (surpassing cervical cancer) in urban females.<sup>[2,3]</sup>

Although the traditional measures of disease outcome like response to treatment, control of

symptoms, clinical or biochemical relapse, and survival are important in prostate cancer, health-related quality of life (HRQOL) is an equally relevant clinical end point. A wide array of treatments are available for different stages of the disease and almost all of these result in significant sexual, urinary, and bowel dysfunction, with persistence of treatment-related morbidity for prolonged periods due to the relatively long survival of most patients. These side effects of treatment are bound to have a measurable impact on the general as well as disease-related QOL. Measuring HRQOL, in addition to measurement of survival outcomes, enriches clinical research and may be decisive when the effects of different treatments on the traditional end points are similar or minimal.

QOL instruments are now a part of most prospective or cross-sectional studies. Various QOL instruments are available that assess prostate-specific symptoms

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like Functional Assessment of Cancer Therapy-Prostate (FACT-P) cancer subscale, Expanded Prostate Cancer Index Composite (EPIC), an expanded version of the University of California, Los Angeles, Prostate Cancer Index (UCLA-PCI), International Prostate Symptom Score (IPSS), European Organization for Research and Treatment of Cancer (EORTC)-Prostate Cancer Module (EORTC-QLQ-PR25), etc. All of these questionnaires are self-administered, as QOL evaluation mandates the use of patient-administered and, ideally, validated instruments, because physician ratings of patient symptoms do not correlate well with patient self-assessments of QOL.<sup>[4]</sup> Unfortunately, most of the standard questionnaires are available only in English and thus of no use for the non-English-speaking population.

In view of a dearth of QOL data in Indian patients due to the lack of an appropriate QOL instrument in the local language, we decided to undertake the translation of the English version of EORTC-QLQ PR 25 into Hindi (national language) and Marathi (local language in Maharashtra state) as it is the most widely used prostate cancer-specific QOL module in clinical studies. This paper describes the translation methodology in detail including the problems faced, how those problems were overcome, and how the results of the pilot testing specific to Indian population were interpreted. We aimed to formulate an appropriately translated and acceptable questionnaire in Hindi and Marathi languages.

## MATERIALS AND METHODS

The EORTC QLQ PR-25 module has not been translated or tested in Hindi or Marathi. We confirmed with the EORTC QL unit that the translation of the EORTC QLQ PR-25 module in Hindi and Marathi was not currently under preparation. The translation was performed as per the second edition of the EORTC Quality Of Life Group Translation Procedure. The EORTC-QLQ PR-25 is designed to be used along the EORTC-QLQ C-30, which is a core questionnaire assessing general QOL, and consists of 30 questions. The EORTC-QLQ PR-25 consists of 25 questions numbered 31 to 55 [Table 1]. In order to maintain uniformity of wording for the same item across different modules as mentioned in the translation manual of the EORTC, the item numbers 44, 49, 50, 51, and 52, which were available in Hindi and Marathi from previous translations, were not translated. Likewise, preexisting translations of the instructions and response categories were also available in Hindi and Marathi and so the original wording of these was accepted. The final Hindi and Marathi version of EORTC PR-25 module is the result of a translation process comprising of the following steps:

### *Forward translation from English to Hindi and Marathi*

1. Two forward translations of the original English questionnaire into Hindi and Marathi were done by two native speakers of the respective languages who were also fluent in English. These translators included both oncologists and non-oncologists.
2. After discussions between the translators and the local project coordinator, the first intermediary questionnaire

for Hindi and Marathi were formulated.

### *Backward translation from Hindi and Marathi to English*

3. Two backward translations of the first intermediary questionnaire into English were done by two independent translators.
4. The second intermediary questionnaire was the outcome of comparison of the backward translations with the original English questionnaire followed by appropriate modifications.

### *Pilot testing in patients with prostate cancer*

5. This second intermediary questionnaire was then administered to ten patients who had never seen the questionnaire before. Each patient, after completing the questionnaire, was interviewed by the local project coordinator who questioned them about each item in the second intermediary questionnaire; they were asked whether they was any difficulty in answering, confusion while answering, or difficulty in understanding the questions; whether the questions were upsetting; and whether the patients themselves would have framed the question in a different way.
6. Based on the suggestions or interpretations of this pilot testing, the final Hindi and Marathi questionnaires were formed.

## RESULTS

**Forward translation: (Steps 1 and 2)** The two independent forward translations were done by a radiation oncologist (SK) and a management executive (RK) in Hindi and by a non-oncologist (AK) and a medical dosimetrist (CT) in Marathi.

**First intermediary questionnaire:** The two forward-translated questionnaires in Hindi and Marathi were evaluated by the project coordinators (authors: TW and VM). If the translations by both the forward translators were identical to each other and were thought to convey the correct meaning from English then no changes were made. Wherever there were differences between the two versions, the points were discussed with the translators to arrive at a consensus regarding the changes necessary. Because the language structure of Hindi and Marathi is significantly different from English, the literal translation of the original English version was sometimes not possible. So we chose or modified the sentences such that a conceptually comparable meaning could be drawn that was as close as possible to the original meaning. We also, on certain occasions, opted to use the vernacular in order to facilitate comprehension. Thus, a first intermediary questionnaire was formed, one each for Hindi and Marathi. In the following text, we discuss the major difficulties encountered in the formation of the first intermediary questionnaire.

**Question 36:** The translation of this question was satisfactory in both the languages but the word 'leakage' could not be translated as there is no appropriate, easily understandable, and commonly used word for 'leakage' in either Hindi or

Marathi. We omitted it as we did not think there would be much change in the meaning of the question due to its omission.

**Question 38 and 41:** This was a difficult question for translation into Hindi as well as Marathi as there is no appropriate word for 'incontinence aid.' We therefore accepted the translation, which meant 'uncontrolled urination.' The Hindi translation, being unsatisfactory, required the formulation of a third intermediate question with substitution of a few words. The Marathi translation by AK was accepted after substitution of the phrase 'laGaval naKLi t na haaj- dNaa'ya' with the words 'Ainaayal-t laGavalsaaZl'.

**Question 43:** No literal translation of 'bloated feeling' could be decided upon. It is described in Hindi and Marathi by various

meanings, eg, 'formation of gas in stomach' or 'increase in size of the abdomen' or 'swelling of the abdomen.' For Hindi, there was no agreement in the translation between the two translators. We combined both the questions and framed an intermediate one after discussion with both the translators. For Marathi, the question as translated by AK was short and meaningful. To make it even more appropriate, 'fūlaalyaasaar Kō' was replaced with 'fūgalyaasaar Kō'.

**Question 55:** It was extremely difficult to translate this question. Neither of the Hindi translators could appropriately translate the words 'sexually intimate'. After a long and exhaustive discussion with the two translators and an official Hindi translator employed at the Tata Memorial Hospital, we agreed that 'शारीरिक संबंध की घनिष्टता' was the most appropriate

**Table 1: English version of EORTC QLQ - PR25**



### EORTC QLQ - PR25

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week	Not at all	A little	Quite a bit	Very much
31. Have you had to urinate frequently during the day?	1	2	3	4
32. Have you had to urinate frequently at night?	1	2	3	4
33. When you felt the urge to pass urine, did you have to hurry to get to the toilet?	1	2	3	4
34. Was it difficult for you to get enough sleep, because you needed to get up frequently at night to urinate?	1	2	3	4
35. Have you had difficulty going out of the house because you needed to be close to a toilet?	1	2	3	4
36. Have you had any unintentional release (leakage) of urine?	1	2	3	4
37. Did you have pain when you urinated?	1	2	3	4
38. Answer this question only if you wear an incontinence aid. Has wearing an incontinence aid been a problem for you?	1	2	3	4
39. Have your daily activities been limited by your urinary problems?	1	2	3	4
40. Have your daily activities been limited by your bowel problems?	1	2	3	4
41. Have you had any unintentional release (leakage) of stools ?	1	2	3	4
42. Have you had blood in your stools?	1	2	3	4
43. Did you have a bloated feeling in your abdomen?	1	2	3	4
44. Did you have hot flushes?	1	2	3	4
45. Have you had sore or enlarged nipples or breasts?	1	2	3	4
46. Have you had swelling in your legs or ankles?	1	2	3	4
Please go to the next page				
During the last 4 weeks	Not at all	A little	Quite a bit	Very much
47. Has weight loss been a problem for you?	1	2	3	4
48. Has weight gain been a problem for you?	1	2	3	4
49. Have you felt less masculine as a result of your illness or treatment?	1	2	3	4
50. To what extent were you interested in sex?	1	2	3	4
51. To what extent were you sexually active (with or without intercourse)?	1	2	3	4
Please answer the next four questions only if you have been sexually active over the last 4 weeks				
52. To what extent was sex enjoyable for you?	1	2	3	4
53. Did you have difficulty getting or maintaining an erection?	1	2	3	4
54. Did you have ejaculation problems (e.g. dry ejaculation)?	1	2	3	4
55. Have you felt uncomfortable about being sexually intimate?	1	2	3	4





Table 3: Final Marathi questionnaire

**EORTC QLQ - PR25**

हाही वेडा मग पाहिले मध्ये अजय आरोग्यसुख कचरा. तेव्हा आरोग्यसुख अजय कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच. हाही वेडा मग पाहिले मध्ये अजय आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.

प्रश्न	अजय	वेडा	मग	सुख
प्रश्न	अजय	वेडा	मग	सुख
1. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
2. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
3. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
4. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
5. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
6. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
7. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
8. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
9. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
10. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
11. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
12. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
13. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
14. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
15. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
16. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
17. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
18. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
19. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
20. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
21. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
22. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
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24. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
25. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4

प्रश्न किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.

26. आरोग्यसुख किंवा आरोग्यसुख कचराच नसावेच किंवा आरोग्यसुख असल्याच किंवा अजय अजय आरोग्यसुख कचराच नसावेच.	1	2	3	4
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so there was no question of any problem arising from it. They said that the question was neither difficult to understand nor confusing or upsetting. On further questioning, they said that these questions presume that one has weight loss or weight gain and the questions are only asked to know whether one is facing any problem from this weight loss or weight gain. For both the languages, we tried to reframe these questions in order avoid such misinterpretation. The new questions were 'D;k otu ?Kvuk vki dsfy, lEl;k jgh gS and "D;k otu c=uk vkidsfy, lEl;k jgh gS' for Hindi and 'vajana GaTNaohI tmcAl samsyaa hatI ka?' and 'vajana vaaZNaohI tmcAl samsyaa hatI ka?' for Marathi. This change was accepted for the final Hindi and Marathi questionnaires.

**Question 52, 53, 54, and 55:** Six patients from each language group did not attempt these questions. They either left these questions blank or wrote that these questions were not applicable to them because of their old age. However, when specifically asked whether the questions were appropriately translated, all six patients stated that there was no difficulty at all in understanding these questions. Only four patients (SuS, KP, DS, and SS from Hindi and EP, LV, SK, and SA from Marathi) answered the questions and none of them encountered any problem.

**Final questionnaire**

The final Hindi and Marathi questionnaire which were submitted to the EORTC as the end result of this translation process were formed taking into consideration all the above points. Both the translations have been approved and accepted by the EORTC [Tables 2 and 3].

**DISCUSSION**

The EORTC QLQ PR-25 module is still under development and thus is being shared only with those groups willing to provide data relevant to the evaluation of its psychometric properties. The module comprises 25 questions that seek to assessing disease symptoms, side effects of treatment, and some specific psychosocial issues of importance to patients with prostate cancer. These 25 questions have been divided into four proposed or hypothesized (not yet finalized) scales or domains pertaining to: urinary symptoms (1-9), bowel symptoms (10-13), treatment-related symptoms (14-19), and sexual functioning (20-25). The full psychometric properties of the module will be published soon by the EORTC after factor analysis. Until this is available, scoring of the module should be done on the basis of information provided by the principal investigator of the module.

We tried to fulfill the aim of producing clear (easy to read and understand) and conceptually equivalent translations in the commonly used local languages. The translation procedure described by the EORTC was rigorously followed and the relevant information required was sought from the

translation coordinator of the QL Unit. The entire translated questionnaire was well understood by the patients in both the languages and required revision for only two questions following pilot testing.

An interesting aspect that we came across (probably not surprising in our population) was that the majority of the patients chose not to answer the questions related to sexual functioning. This could be related to the cultural barriers, especially in elderly patients. Although these questions are important constituents of the overall HRQOL, their relevance in the context of the average Indian population needs to be kept in mind.

The entire translation process was written up as a project report separately for Hindi and Marathi and duly submitted to the EORTC. These reports were reviewed by the translation coordinator of the EORTC. Both the translations were finally accepted with the requisite of transferring the copyright for the translated versions to the EORTC. These modules can now be used in various clinical trials on prostate cancer for QOL assessment.

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