Translation and Pilot Validation of the EORTC QLQ-NHL-HG29 Module in Indian Languages (Hindi and Marathi) for Use in Indian Patients with Non-Hodgkin’s Lymphoma

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Abstract

Background Cancer and its related treatments have a huge impact on a patient’s quality of life (QOL). To measure such QOL in cancer patients, the European Organization for Research and Treatment of Cancer (EORTC) has introduced various scales/questionnaires for various cancers. In the present study, we aimed to translate and validate high-grade Non-Hodgkin’s lymphoma (NHL-HG) English questionnaire (EORTC QLQ-NHL-HG29) into Hindi and Marathi (two of the most popular Indian language) to make it available for patients and the scientific community.

Materials and methods The EORTC QLQ-NHL-HG29 was translated into Hindi and Marathi languages as per EORTC guidelines. The translated questionnaire was pilot-tested in a sample of 20 patients (10 for each translation) with NHL-HG.

Results After procuring required approvals from EORTC, the existing QLQ-NHL-HG29 English questionnaire was translated (forward and backward) into vernacular languages (Hindi and Marathi). Later, the translations were sent to EORTC for evaluation and all the queries raised by EORTC toward translations were discussed and included in the final questionnaires as per EORTC guidelines. On receiving approval from EORTC translation coordinator, pilot study was conducted in 20 patients. In the pilot study, 10 patients were given the Hindi questionnaire and other 10 patients were given the Marathi questionnaire. Based on the pilot testing interpretations or suggestions from the patients, all the necessary modifications were incorporated in the questionnaires and sent to EORTC for validation and approval.

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**Introduction**

Non-Hodgkin’s lymphoma (NHL) is a common hematological malignancy worldwide responsible for 544,000 new cases and 260,000 deaths in 2020 alone.¹ Incidence rates are approximately twofold higher in transitioned countries than in transitioning countries. However, the presently available treatments for NHL only improve the survival time at the cost of impaired health-related quality of life (HRQOL). To promote patient-centered care in oncology practice and research, it is important to focus on the quality of life (QOL) as an essential surrogate endpoint, in addition to traditional clinical outcomes such as overall survival and disease-free survival.²,³

To measure and assess such QOL in NHL patients, many research tools are available but the most often used tool is the NHL-HG29 module developed by the European Organization for the Research and Treatment of Cancer (EORTC).⁴ This module consists of several multi-item scales covering various aspects of the patients such as emotional impact, worries/fears on health and functioning, physical condition/fatigue, symptom burden, and neuropathy.

At present, the NHL-HG29 translation is available only in English but not in Hindi and Marathi—two of the most spoken languages (Hindi: 600 million; Marathi: 71 million) in the world from India.⁵,⁶ Therefore, a Hindi and Marathi version of NHL-HG29 can help and reach a large amount of patient population to measure their QOL. Translation of this NHL-HG29 module into two local languages and pilot testing them in a small population will ascertain its suitability, validity, and ability to assess the QOL in Indian patients with NHL.

**Materials and Methods**

The permissions required to translate the NHL-HG29 English module (¬ Fig. 1) to vernacular languages were obtained from EORTC QOL Department. The EORTC QLQ-NHL-HG29 consists of 29 questions numbered 31 to 59 (¬ Fig. 1). The translation team consists of one translation coordinator (to oversee the translation and pilot testing), four Hindi translators (two forward translators and two back translators), and four Marathi translators (two forward translators and two back translators).

Overall, the translation and adaptation process consists of multiple steps as followed:

- **Step 1:** translation preparation—procurement of required approvals, questionnaire, a translation manual, and translation review reports from EORTC.
- **Step 2:** forward translations—initial translation from English to vernacular language (Hindi and Marathi) was done by two sets of native speakers of Hindi (FT1, FT2) and Marathi (FT3, FT4) languages and fluent in English with good knowledge of clinical terminologies, slang, and phrases.
- **Step 3:** first intermediary questionnaire—translations from FT1, FT2, FT3, and FT4 are merged into two optimal reconciled versions (Hindi: RTEH1; Marathi: RTEM1).
- **Step 4:** back translations—vernacular translations (Hindi and Marathi) were back-translated to English by two sets of back translators (BT1, BT2, BT3, and BT4) with strong command in both Hindi (BT1, BT2) and Marathi languages (BT3, BT4).
- **Step 5:** second intermediary questionnaire—translations from BT1, BT2, BT3, and BT4 were merged into two optimal reconciled versions (English: RTHE1 and RTME1) by the translation coordinator and translators to develop a translated copy with adequate representation of the English original.
- **Step 6:** reporting and proofreading.

All the files (FT1, FT2, FT3, FT4, RTEH1, RTEM1 BT1, BT2, BT3, BT4, RTHE1, and RTME1) were sent to the EORTC Translation Unit (TU) for a comprehensive review and approval. After reaching consensus, a preliminary translation was then prepared by the EORTC TU for proofreading and approval from the project manager/translation coordinator. After approval from the project manager/translation coordinator, the TU prepared preliminary translations (PTh1 and PTM1) for pilot testing.

- **Step 7:** pilot testing—after getting ethical committee clearance, the pilot testing of PTh1 and PTM1 translations was conducted at a tertiary cancer hospital located north-west of India. At this stage, the PTh1 and PTM1 questionnaires were administered to 20 patients (10 Hindi and 10 Marathi) with high-grade NHL (NHL-HG) who had never seen the questionnaire.
- **Step 8:** finalization—Finally, after reaching a consensus from both the translation coordinator and EORTC TU regarding the translation, the final versions were approved by EORTC TU, and the project was closed.

**Patient Inclusion and Exclusion Criteria for Pilot Testing**

Inclusion criteria: confirmed cases of patients with NHL-HG diagnosis, who are mentally fit to complete a questionnaire, who are able to understand the Hindi or Marathi language, and who gave informed consent were included.

Exclusion criteria: patients unable to understand the Hindi or Marathi language and mentally unfit patients to complete a questionnaire were excluded. There were no restrictions regarding the level of education, age, and gender.

**Conclusion**

Both the translations (Hindi and Marathi) submitted to the EORTC have now been approved (QLQ-NHL-HG29) by the EORTC-QOL unit and after procuring necessary permissions from the EORTC both of these translations can be used reliably in clinical practice and clinical trials to assess QOL in patients suffering from NHL-HG.
**Statistical Analysis**

Descriptive statistics were calculated using IBM Statistical Package for the Social Sciences (SPSS) Version 21 (IBM Corp Armonk, NY, USA).

**Results**

The existing English translation (Fig. 1) was translated into vernacular Hindi (Fig. 2) and Marathi (Fig. 3) languages. Before study initiation, the EORTC informed us beforehand that EORTC will prefer to keep their original available Hindi- and Marathi-translated questions from previously translated questionnaires for other diseased conditions and to keep the changes minimal, unless the changes are highly recommended and unavoidable. Keeping this suggestion from EORTC as a priority, we informed the EORTC that all the changes suggested by FT1, FT2, BT1, and BT2 were necessary to convey the exact meaning of the question in the vernacular language for better understanding by the patient.

**Forward and Backward Translation**

The study was initiated after procuring initial approval and existing translations (similar questions from other questionnaires) from EORTC.

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:

<table>
<thead>
<tr>
<th></th>
<th>Not at All</th>
<th>A Little</th>
<th>Quite a Bit</th>
<th>Very Much</th>
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<tbody>
<tr>
<td>31. Have you had muscle weakness?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>32. Have you had aches or pains in your muscles or joints?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>33. Have you had aches or pains in your bones?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>34. Have you had a dry cough?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>35. Have you had a dry mouth?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>36. Have you had problems with your sense of taste?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>37. Have you felt ill or unwell?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>38. Have you had tingling hands or feet?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>39. Have you had numbness in your fingers or toes?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

### During the past week:

<table>
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<th>Not at All</th>
<th>A Little</th>
<th>Quite a Bit</th>
<th>Very Much</th>
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<tbody>
<tr>
<td>40. Have you had shortness of breath on exertion?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>41. Have you felt you had setbacks in your physical condition?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>42. Have you had a lack of energy?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>43. Have you felt drowsy?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>44. Have you had sudden tiredness?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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</tbody>
</table>

### During the past week:

<table>
<thead>
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<th>Not at All</th>
<th>A Little</th>
<th>Quite a Bit</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>45. Have you had mood changes?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>46. Have you felt a lack of confidence in your body?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>47. Have you been dissatisfied with how your body functions?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>48. Have you had difficulty accepting limitations due to the disease?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

*Fig. 1* Existing English translation of EORTC QLQ-NHL-HG29 module.
During the past 4 weeks:

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at All</th>
<th>A Little</th>
<th>Quite a Bit</th>
<th>Very Much</th>
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</thead>
<tbody>
<tr>
<td>49. Have you worried about picking up an infection?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>50. Have you worried about your health in the future?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>51. Have you worried about recurrence of your disease?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>52. Have you worried about becoming chronically ill?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>53. Have you worried about becoming dependent on others?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>54. Have you worried about getting another type of cancer?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>55. Have you worried about your treatment causing future health problems?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>56. Have you worried about damage to your heart and blood vessels?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>57. If applicable: Have you had problems at your work or place of study due to the disease?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>58. If applicable: Have you worried about not being able to continue working or your education?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>59. If applicable: Have you been concerned about your ability to have children?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

**Fig. 1** (Continued).

The English questionnaire was given to the two independent sets of forward translators for both Hindi (FT1 and FT2) and Marathi (FT3 and FT4) translations. Translators good at English to Hindi and English to Marathi translations have helped us in developing Hindi version, S. K. (FT1, Medical Oncologist), N. P. (FT2, Clinical Research Deputy Director), and Marathi version, V. P. (FT3, Radiation Oncologist), P. P. (FT4, Radiation Oncologist), respectively.

After the translation coordinators initial scrutiny, forward translations were given for backward translation to two independent sets of backward translators for both Hindi to English (BT1 and BT2) and Marathi to English (BT3 and BT4) translations. G. B. (BT1, Hemo Oncologist), R. B. (BT2, Pediatrician), and for Marathi version were done by N. W. (BT3, Radiation Oncologist), and N. W. (BT4, Pharmaceutical Expert).

**Difficulties Encountered during the Translations**

**Hindi Version**

The questionnaires received from both the translators were evaluated by the translation coordinator and no significant differences were found. However, minor corrections were done in the first intermediary questionnaire after discussing with the translators for better understanding.

For question numbers 31, 32, 33, 40, 41, 42, 43, and 47, the word “हामेशा में” was added at the end of the questionnaires for grammatical uniformity. In question 36, both FT1 and FT2 have translated the same but with a slight difference from an existing translation of EORTC. After discussing with EORTC, changes were included in RTEH1. Question 38, EORTC raised the query whether the words “hands and feet” are in plural in the translation. We observed that they were in singular form and necessary changes were done from “हाथों और जिंदों” to “हाथें और ज़िंदों” to change into plural form. For a better understanding of question 49, an extra word was added within the bracket along with the existing word दूरा (आरोग्य) to convey the exact meaning of the word to all the patients. In another query, EORTC raised their concern in question 52 about the word “chronic illness” and conveying of its full meaning in the translated version. The translation coordinator cross-checked the translation and confirmed to EORTC about the conveying of the correct meaning by the words used in the translated version.

**Marathi Version**

For question 32, EORTC raised a query about the Marathi translation of two specific English words “aches” and “pain.” However, due to no specific word for “ache” in Marathi, a translated version was provided with only one word for both the words as “सूक्ष्ण” and EORTC agreed for the same. In question 33 and in other questionnaires, the existing translation for the word “chronic” was modified as “स्तरापर” for uniformity of the questionnaire and EORTC also agreed with the changes suggested. The meaning for “dry cough” in question 34 was not reflected in the Marathi word “दृण कृभा” used in the existing translation. To imply the exact meaning for the word “dry cough,” the existing translation “हल्ल दृष्यम” was prefixed with the word “कोर” - dry
for better understanding by the patient. EORTC raised a query with question 47 about the possible inclusion of the words “how your body functions” in Marathi translation for a better understanding of the question by the patients. As suggested by EORTC, the Marathi translation was included with “कैम्बिशनहितसंसारेहेत” for “body functions” referring to the physical function of the body and how it may not be “working” as normal/expected. In question 53, EORTC raised a query regarding the closest back translation that conveyed the meaning of the question to the patient. Where the Marathi translation “मोहत्वपूर्व-आहस” was observed to be much closer to Marathi translation and the same was acknowledged to EORTC.

Pilot Testing
A total of 10 patients diagnosed with NHL-HG were included in the pilot study. All the participated patients were native speakers of either Marathi or Hindi and who had never seen the questionnaire before. No major queries were raised by the patients regarding the given questionnaire. Any small doubts or suggestions given by patients were considered,
Finalization

The final Hindi and Marathi questionnaire (EORTC QLQ-NHL-HG29) after pilot testing was submitted to the EORTC QOL unit for final approval. In both the questionnaires, culturally relevant changes in the original questionnaire were accepted and approved by the EORTC.

The final version of the EORTC QLQ-NHL-HG29 is now available through the headquarter of the EORTC QOL Department (https://qol.eortc.org/).

Discussion

Cancer ranks as a leading cause of death worldwide with an estimated 10 million deaths in 2020 alone.¹ Leading concern in patients diagnosed with cancer is their QOL, which is largely disturbed due to disease burden and its associated long-term treatment effects. Over time, with the development of novel treatment options, the number of cancer survivors is also growing steadily and increasingly to a point where all the clinical trials are now focused not only on designing on survival but also on studying late effects and HRQOL of the patients.⁷,⁸

To understand, assess, and know such patient-oriented perspectives, experiences, and QOL after getting affected by cancer, EORTC has developed a wide range of questionnaires for various cancers to capture the full range of physical-, mental-, and social health-related QOL issues seen in cancer patients. Outcomes from these studies can play a vital role in cancer clinical trials “where the intervention may not be designed to cure the disease but may only modestly prolong life.”⁷

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Evaluating the QOL of such patients is usually done in two ways: (1) by designing an instrument ex novo or (2) by translating one of the existing and validated instruments available. Among those two available options, designing a new set of instruments with a questionnaire and its validation is a time-taking process involving large manpower. Therefore, the other simple and quick option left out is to translate the existing questionnaire (possibly available in English) into the vernacular language (here, Hindi and Marathi) and complete pilot-testing for improving its credibility.

This will be the first study from India to translate and validate the EORTC QLQ-NHL-HG29 module available in English to Hindi and Marathi for use in the Indian NHL-HG population.

As India is one of the most populous nations and claims to be the world's second largest English-speaking country, the translation process went smoothly without a problem. Compared with designing an instrument ex novo, translating existing English questionnaire into vernacular language was opted by us. In this study, such translated questionnaire was later on validated in the patients from the Indian cultural scenario itself.

Fig. 3 Final Marathi questionnaire of EORTC QLQ-NHL-HG29 module. Note: All the copyrights for this translation are reserved with EORTC and it may not be used without prior consent.
Throughout the translation process, we strictly adhered to EORTC guidelines and each step was overlooked and audited by the EORTC TU. EORTC’s only reminder and suggestion to our team were to use the “existing translations as much as possible, provided that they are understandable and grammatically consistent.” This recommendation by EORTC was helpful in ensuring the consistency and comparability between the different available EORTC questionnaires for various cancers and our translations. Throughout the translation process and in the pilot testing, we have not encountered any major difficulties and we have shared all our translation experiences here in the hope that it will help other research teams all over India/worldwide intending to translate similar or other disease-specific EORTC questionnaires.

In the end, the entire translation process and final versions of translated questionnaires (English to Hindi and Marathi) were submitted to EORTC for validation and accuracy. After EORTC translation coordinator validation and approval, the final versions were transferred to EORTC for copyright purposes. After receiving required copyrights, the final translated questionnaires are now eligible to use freely in various clinical trials/multicentric studies of NHL-HG as well as in routine QOL assessments in Hindi- and Marathi-speaking patients.

**Conclusion**

In this study, we presented the results of a validation study of the EORTC QLQ-NHL-HG29 questionnaire in Indian patients with NHL-HG. QOL is an important outcome, which helps in measuring and assessing patients’ experiences during various stages of treatment. Our translations are validated by EORTC and the final translations are reliable in using various clinical trials/or epidemiological cancer research studies to measure QOL of Hindi- and Marathi-speaking patients with NHL-HG. These translated questionnaires are freely available on request and they can be used further in all the NHL-HG QOL study patients after procuring necessary permission from the EORTC QLQ unit.

**Financial Disclosure**

None.

**Conflict of Interest**

None declared.

**Acknowledgments**

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