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Translation procedures for standardised quality of life questionnaires: The European Organisation for Research and Treatment of Cancer (EORTC) approach

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ABSTRACT

Background: The European Organisation for Research and Treatment of Cancer quality of life (EORTC QL) questionnaires are used in international trials and therefore standardised translation procedures are required. This report summarises the EORTC translation procedure, recent accomplishments and challenges.

Methods: Translations follow a forward-backward procedure, independently carried out by two native-speakers of the target language. Discrepancies are arbitrated by a third consultant, and solutions are reached by consensus. Translated questionnaires undergo a pilot-testing. Suggestions are incorporated into the final questionnaire. Requests for translations originate from the module developers, physicians or pharmaceutical industry, and most translations are performed by professional translators. The translation procedure is managed and supervised by a Translation Coordinator within the EORTC QL Unit in Brussels.

Results: To date, the EORTC QLQ-C30 has been translated and validated into more than 60 languages, with further translations in progress. Translations include all major Western, and many African and Asian languages. The following translation problems were encountered: lack of expressions for specific symptoms in various languages, the use of old-fashioned language, recent spelling reforms in several European countries and different priorities of social issues between Western and Eastern cultures. The EORTC measurement system is now registered for use in over 9000 clinical trials worldwide.

Conclusions: The EORTC provides strong infrastructure and quality control to produce robust translated questionnaires. Nevertheless, translation problems have been identified. The key to improvements may lie in the particular features and strengths of the group, consisting of researchers from 21 countries representing 25 languages and include the development of simple source versions, the use of advanced computerised tools, rigorous

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pilot-testing, certification procedures and insights from a unique cross-cultural database of nearly 40,000 questionnaire responses.

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1. Introduction

The European Organisation for Research and Treatment of Cancer quality of life group (EORTC QLQ) has developed a modular approach to QL measurement for use in cancer clinical trials.¹ The QLQ-C30 core questionnaire covers aspects that are important for cancer patients in general (basic dimensions of physical, psychological and social health) and allows for comparisons between various patient groups. In addition, modules tapping into symptoms and issues that are specific to particular cancer sites or therapies are being developed.² This assessment strategy is comprehensive, specific and economical in terms of resources needed and time spent in filling out the questionnaire.

The primary objective of EORTC QLQ questionnaires is their usage as outcome measures in international cancer clinical trials. This intent reflects the growing globalisation of clinical research and the international composition of the QLQ. Therefore, translation issues that ensure the compatibility of questionnaires across different countries and languages are of central importance. It is only by taking great care in translation of questionnaires that the variation in results due to language differences can be minimised. There are many other possible variables between countries and ethnic groups (cultural differences being an important one), which are harder to minimise.

The aim of this paper is to summarise the technique and accomplishments of the EORTC QLQ's translation procedure, to report on typical problems that have been encountered in the course of translations and to provide a perspective on how translations can be made more accurate in the future.

2. Methods

2.1. The goal

A translation should be conceptually equivalent to the original questionnaire or document, clear and easy to read and expressed in a language in common use.³

2.2. Resources for translations

The EORTC QLQ has a Translation Coordinator based in the EORTC Quality of Life Unit in Brussels, who collaborates with a number of professional translation agencies throughout Europe and other parts of the world. Translation problems are discussed within a Translation Committee, which meets every 6 months, and by electronic correspondence between meetings.

In addition, Group Members volunteer to help with translations by preparing translations themselves, checking translations made by other people or helping to find experienced translators in their native languages. The QL Group is com-

posed of members from 25 countries, representing 21 languages.

The QL Unit has set up an Item Bank, which contains information on items from the core questionnaire and the validated modules. It covers the development, wording and translations of the items, as well as results from pre-testing and field-testing when available. This information tool is helpful in speeding up the module development process as well as the translation process (e.g. checking for already existing translations or consistency). At present, a total of 6000 items have been entered.⁴ The Item Bank has been recently upgraded (Version 2) in an effort to enhance the performance and flexibility of this important computer-based tool.

The QL Unit has a budget available to enable Group Members to have their modules translated into the most commonly used languages: Danish, Dutch, French, German, Italian, Norwegian, Spanish and Swedish. If none of these languages are appropriate, as in the case of the HCC18 module (hepatocellular carcinoma) where the disease is more commonly found in Asia, then a decision to pay for translations into other languages is made.

2.3. The standard translation process

It is recommended that EORTC QLQ-questionnaires are initially developed in English. Recently, development in several (European) languages simultaneously has been possible, but additional translations are always taken from the English version. The request for a translation in any other language comes either from the QLQ or from the pharmaceutical industry, and occasionally from some other external source. Translation requests are forwarded to the Translation Coordinator of the QL Unit, who sets the translation process in motion.

The Translation Coordinator contacts a professional translation agency. The agency chooses native speakers of the target language who are fluent in English to translate the questionnaire. Translators need to be familiar with medical terminology and patient language.

Translations are produced by a forward-backward procedure, involving two forward and two backward translators (Fig. 1).³ Two individuals, both native speakers of language X, will independently translate the English version into language X. A project coordinator (usually the clinician or the methodologist requesting the translation into language X and also a native speaker of that language) compares the two translations and checks them for any discrepancies. Slight discrepancies are solved by consensus with the two translators. More serious discrepancies will necessitate consulting a third translator, who will provide another translation and will then be included in the discussion with the other translators to find a solution.

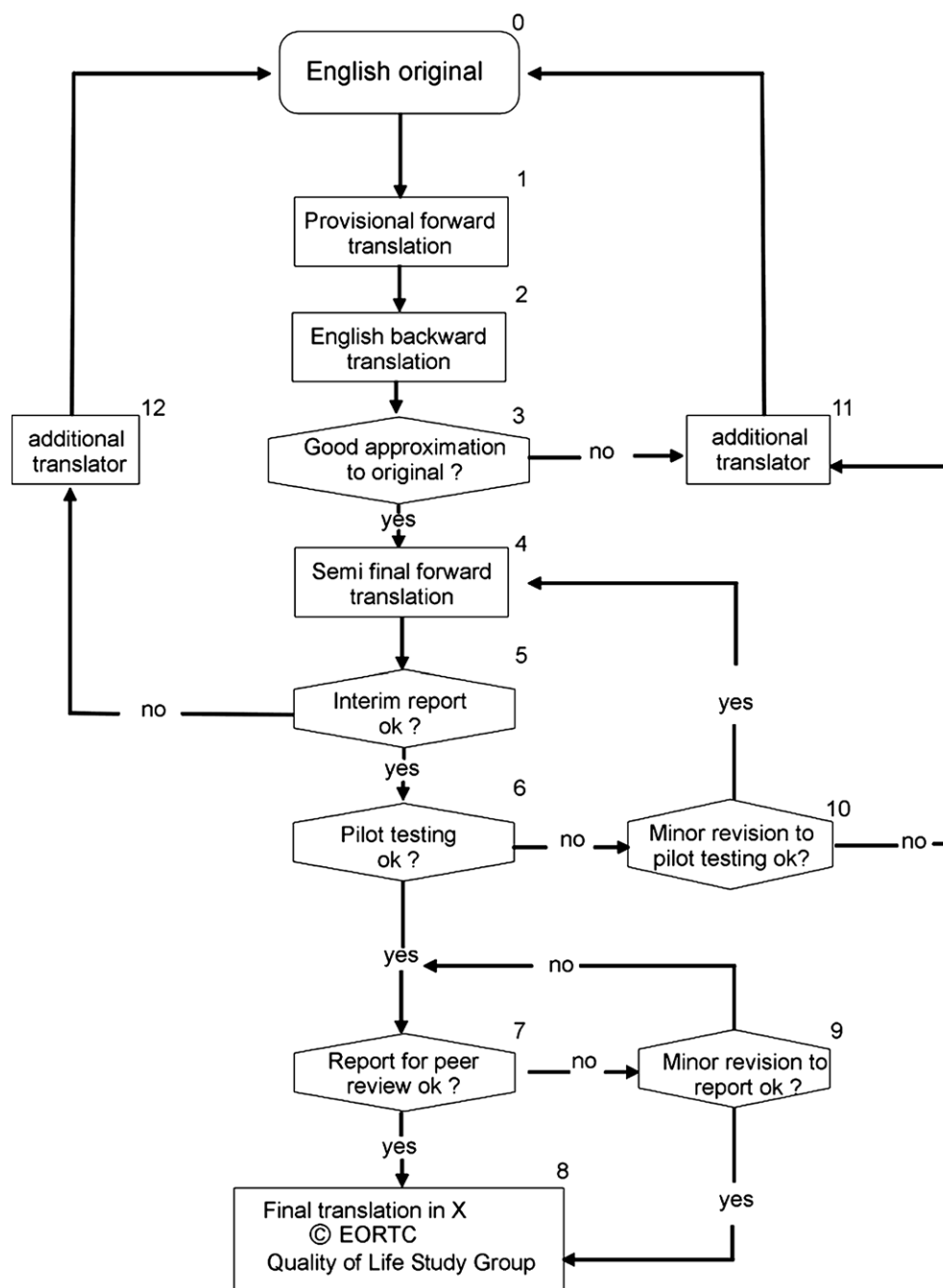


Fig. 1 – Translation procedure/algorithm.

The process results in a single provisional forward translation, which may offer alternative wordings for items which were difficult to translate. This version is then back-translated by two native speakers of English (fluent in X) from language X into English.

All the translations and the report are then forwarded to the QL Translation Coordinator. The English back translations are compared against the original English version to ensure that the meaning of the original question has been preserved. Apparent discrepancies are discussed and eventually resolved with the language X coordinator and the translators. In the (rare) case that discrepancies cannot be resolved, it may be necessary to re-start the translation process.

The translation process so far is summarised in an interim report. Then the version is ready for pilot-testing.

2.4. Pilot-testing

The translation coordinator in the target country X is responsible for carrying out the pilot-testing. A minimum of 10–15 patients belonging to the target population are interviewed to determine whether translated questionnaire items are

- difficult to answer,
- confusing,

- difficult to understand,
- upsetting/offensive.

Patients are also asked whether they would have worded the question in a different way.

2.5. Translation report

All the details of the translation process (the results from each translator, the difficulties encountered and the rationale for the solution reached), including the pooled results of the pilot-testing and suggested refinements during the pilot-testing, are summarised in a translation report, which is sent to the QL Translation Coordinator in Brussels. The report is reviewed and if it successfully passes the review process, the translation procedure is finalised.

2.6. Deviations from and extensions to the standard translation process

There are several instances in which deviations or extensions have to be made.

3. Original is not in English

In this case the language X version first has to be translated into English following the standard forward-backward algorithm depicted in Fig. 1.

4. A translation exists and a variant version is required

A famous saying speaks of ‘two countries divided by a common language’ (the United Kingdom (UK)/United States (US) version is attributed to various authors, most often G.B. Shaw and W. Churchill, the German/Austrian version is attributed to Karl Kraus). Indeed, geographical separation brings with it a language that evolves differentially. Different phrases are used, new words are adopted and the meaning of words changes. Various accents and forms of written language emerge.

If a translation in a key language (X) already exists, then a full new translation for a country speaking a variant of that language (X') is unnecessary. The translation in language X will undergo a cultural adaptation. Two native speakers of variant language X' and living in the country where the language has been adapted will go through the questionnaire and make the appropriate changes. These adaptations are checked for consistency. Discrepancies are resolved and then backward translations into English by two independent translators are performed, these are checked against the original English version. The result is a culturally adapted version of the questionnaire/module.

5. One or more questions are already present in the Item Bank, with appropriate translations

This is the case if a translation of a module into language X is required, and translations of the core questionnaire or other

modules already exist in that language, and are stored in the Item Bank. Then, translations of the scales, introductory sentences and probably certain module items, which are commonly used in several modules, are already available. These existing translations will be used and the translation process can focus on the parts of the questionnaire that are not yet translated.

6. Non-European languages

For languages such as Bahasa Indonesia, Farsi, Kiswahili, Sinhala, Sotho and Xhosa commercial translation agencies may either be of little help or too expensive, so translations are performed by experts within the group or by individuals who are contacted and recruited by the person/organisation requesting the translation. Nevertheless, the same quality criteria apply and the standard translation process as depicted in Fig. 1 has to be followed.

6.1. Funding of translations

The QLG's budget is reserved for standard translations and those requested for non-commercial trials by QL Group Members. Pharmaceutical companies requiring translations are requested to pay for them.

7. Results

7.1. Number of translations

At present the QLQ-C30 core questionnaire has been translated and validated into more than 60 languages, with further translations in progress. The questionnaire is applicable in some 70 countries worldwide (Table 1). Translations include all major Western, East European, Asian and African languages. Of the validated modules the breast cancer module (BR23) has been translated into over 40 languages, the lung cancer (LC13) and the head and neck cancer (HN35) modules have been translated into over 30 languages. The remaining validated modules include cervical cancer (CX24), gastric cancer (STO22), multiple myeloma (MY20), oesophageal cancer (OES18), ovarian cancer (OV28) and patient satisfaction with care (IN-PATSAT32), which have been translated into 20 languages. The reader should note that further translations are constantly in the process of development. For the most recent information please check the EORTC QLG website at www.eortc.be/qol/.

In recent years, the QLQ C-30 and modules have increasingly been used in countries of South America and Asia, leading to requests for variants of the original translation (e.g. Spanish for Argentina, Chile, Colombia, Costa Rica, Guatemala and Mexico). So far more than 40 cultural adaptations have been made.

7.2. International use

The EORTC QLQ-C30 and modules are now registered for use in over 9000 clinical studies worldwide.

Table 1 – Translations of the EORTC QLQ-C30 and their target countries

Language	Main countries or regions in which the language is spoken
Afrikaans	South Africa
Arabic	Arabic countries, Israel
Bahasa Malay	Malaysia
Bahasa Indonesia	Indonesia
Bengali	India
Bosnian	Bosnia
Bulgarian	Bulgaria
Burmese	Myanmar
Catalan	Spain
Cebuano	Philippines
Chinese Mandarin	China
Chinese M. (Singapore version)	Singapore
Chinese (Cantonese)	Hong Kong
Chinese (Taiwanese)	Taiwan
Croatian	Croatia
Czech	Czech Republic
Danish	Denmark
Dutch	Netherlands, Belgium
English	United Kingdom, Ireland, USA, Canada, Australia, South Africa
Farsi	Iran
Finnish	Finland
French	France, Belgium, Canada, Switzerland
German	Germany, Austria, Switzerland
Greek	Greece
Gujarathi	India
Hebrew	Israel
Hindi	India
Hungarian	Hungary
Icelandic	Iceland
Italian	Italy, Switzerland
Japanese	Japan
Kannada	India
Kiswahili	Tanzania
Korean	Korea
Latvian	Latvia
Lithuanian	Lithuania
Macedonian	Macedonia
Malayalam	India
Marathi	India
Norwegian	Norway
Polish	Poland
Portuguese	Portugal, Brazil
Punjabi	India
Pushto	Pakistan
Romanian	Romania
Russian	Russia, former states of the Soviet Union
Serbian	Serbia
Sinhala	Sri Lanka
Slovakian	Slovakia
Slovenian	Slovenia
Sotho	Africa
Spanish	Spain, countries in Latin and North America
Swedish	Sweden, Finland
Tamil	India, Malaysia
Tagalog	Philippines
Telegu	India
Thai	Thailand
Turkish	Turkey

Table 1–continued

Language	Main countries or regions in which the language is spoken
Ukrainian	Ukraine
Urdu	Pakistan
Vietnamese	Vietnam
Yoruba	Nigeria
Xhosa	South Africa
Zulu	South Africa

7.3. Translation requests

Reviewing the last ten years of translation work within the QL Unit, 50% of translation requests came from within the group, 25% came from the pharmaceutical industry and 25% from other external partners such as universities.

7.4. Problems encountered in translation processes

The strict record keeping procedure of all translation processes facilitates tracking of typical translation problems.⁵ The nature and severity of translation problems vary greatly from missing punctuation marks and missing letters to incorrectly used expressions that may transform a questionnaire item into a meaningless expression. Given this variety, it is sensible to propose a taxonomy of translation problems. Table 2 summarises problem types and typical examples that were encountered in the context of translations of EORTC QLQ questionnaires.⁵

7.5. Reports of successful translations and validations outside the EORTC

In recent years researchers outside of the EORTC, among them are groups from China, Taiwan, Japan and Iran, have reported on translations and validations of EORTC questionnaires.^{6–16} All these groups requested approval for using and translating the questionnaires. The copyright remained with the EORTC and the final reports were forwarded to and checked by the Translation Coordinator within the EORTC QL Unit. All in all, the reports summarised in Table 3 portray a positive picture. The psychometric properties of the scales are in line with the observations made in the EORTC studies. Translation difficulties were reported infrequently and in most cases could be resolved by using a culturally appropriate version for certain items.

8. Discussion

The EORTC QLG's standardised translation procedure has resulted in an impressive number of translated questionnaires, and quality control procedures are becoming fully established. The high regard for EORTC questionnaire products can be most clearly seen in their wide use in international clinical trials. A recent review saw the EORTC in front of other competitors in the field of international clinical cancer trials.¹⁷

The availability of high quality translations will be of vital importance to the QLG in the future. A recent FDA guidance

Table 2 – Translation problems – taxonomy and examples

Problem type	Description of the problem	Examples
Semantic	Equivalence in the meaning of <u>words/expressions</u>	Bothered: 11 different meanings in thesaurus but no direct equivalent in other languages
Conceptual	Equivalence in the QL issue addressed by an <u>item</u> Does an item really capture the underlying QL issue (e.g. physical functioning)?	Overall quality of life (Item No. 30): The term <i>quality of life</i> has become colloquial in English, but not necessarily in other countries/cultures/languages <i>Carrying heavy suitcases or carrying heavy bags</i> are not good descriptions for physical functioning because these activities vary according to different lifestyles. Similarly, <i>eating fresh food</i> is not commonly done in some cultures (e.g. India, Thailand)
Misspelling	Compliance with language rules	Intended translations: <i>nagymértékben</i> (very much), <i>ennyit</i> (how much). Translation errors found: <i>agymértékben</i> (brain sized), <i>menny</i> (heaven)
Consistency	Same expression throughout the questionnaire	<i>Trouble, bother, problem</i> : All essentially mean the same (something is 'wrong'), but there are subtle differences that may cause problems for translators <i>Have you had...?</i> versus <i>Did you have...?</i> Both refer to past tense but the first refers to continuous episodes, the second to a single instance
Scaling	Wording of the scales: Do expressions capture intensity of symptoms, not frequency? Is the interval character of the scale intact?	German: <i>überhaupt nicht</i> [1], <i>wenig</i> [2], <i>mäßig</i> [3], <i>sehr</i> [4] the response scale is meant to have interval character, but the German expression <i>mäßig</i> [3] is much closer to <i>wenig</i> [2] than it is to <i>sehr</i> [4]
Cultural diversity/ appropriateness	Has an issue a particular connotation in a given cultural context that is different from the original meaning? Is it sensible/upsetting to address an issue in a given social context?	Social domain plays a much wider importance in the Orient and Asia Thus, back translations from these languages sound much more dramatic: <i>Have you worried about a crisis in your family life?</i> (Arabic) <i>Have you worried about the break up of your family?</i> (Chinese) Sexual issues and social contact have to be asked more politely in Asia, at the risk of losing the essence of the QL issue Social activity in Ukrainian may be mixed up with political activity (particularly with older patients) due to the Soviet presence in history In some East European languages there is no distinction between <i>arm</i> and <i>hand</i> (<i>ruka</i> in Bosnia) or <i>leg</i> and <i>foot</i> <i>Going out of the house</i> in Sweden means leaving home. Quite generally, words such as <i>house</i> , <i>stairs</i> depend heavily on the living context of individuals Questionnaire completion may take 2–3 h in African countries because old patients take this as an opportunity to give long explanations. It is considered not polite to interrupt older people

paper, on the use of patient reported outcomes for drug labeling claims, sets high standards for the modification, translation and/or cultural adaptation of outcome measures. The FDA recommends using standardised translation procedures and providing 'evidence that measurement properties for translated evidence are comparable'.¹⁸ Furthermore, due to implementation of strict regulations for drug clinical trials in the European Union, an increasing number of trials are being transferred to Asian and African countries. This requires the availability of QL questionnaires in many languages that from an ethnocentric Western standpoint appear 'exotic' and imply considerable translation difficulties. The need to further improve translation procedures is strongly reflected by the foundation of a Translation and Cultural Adaptation Special

Interest Group (SIG) within the International Society for Quality of Life Research (ISOQOL) in the year 2004.

In the light of these developments, the QLIG is scrutinising its translation methodology. The key to improvements may lie in the particular features and strengths of the group that are summarised in a problem X solution matrix (Fig. 2).

The first and relatively easy task concerns the development of the original English version of the module. It is important to keep English as straightforward as possible. For instance, unnecessary variations in wordings ('Have you had...', 'Did you have...', ...) and problem words (e.g. 'bother') should be avoided.¹⁹ In this context, Brislin's recommendations may serve as a guide for English source versions that are unambiguous and consistent across modules (Table 4).²⁰ A

Table 3 – Recent reports on international translations and validations of EORTC questionnaires

Authors	Questionnaire	Language	Population	Psychometric results	Problem/rewording/ cultural adaptation
Montazeri et al. ¹⁵	BR 23	Iranian	Newly diagnosed breast cancer patients: n = 168; average age: 47.2 ± 13.5	All $\alpha \geq .70$ except systemic side-effects (.63 at baseline) Known group differences: functioning scales differ ($p < .001$) according to EGOG status and disease stage	Not reported
Zhao and Kanda ¹⁰	QLQ-C30	Chinese (standard)	Gynecological cancer patients from mainland China: n = 191; average age: 42.2 ± 14.3	$\alpha > .70$ except PF and CF most item-subscale correlations $> .40$	Toilet/washroom Insomnia/sleep poorly quality of life → ‘another term’
Mystakidou et al. ¹⁴	QLQ-C30	Greek	Cancer patients under palliative care: n = 120 (46 m, 74 f); average age: 62.7 (38–87)	$\alpha \geq .70$ except symptom scales (FA, NV, PA) and PF (on-treatment) Known group difference: functioning scores vary according to Karnofsky status ($p < .05$) Responsiveness to change: pre-treatment versus on-treatment All function and most symptom scores improve ($p < .001$)	Not reported
Chie et al. ¹¹	QLQ-C30 H&N35	Taiwanese, Chinese	Head and neck cancer patients: n = 50 (39 m, 11 f); age range: $<40 \geq 50$	$\alpha \geq .70$ (except CF) Moderate to high test-retest reliability	Not reported
Chie et al. ¹³	QLQ-C30 BR 23	Taiwanese, Chinese	Breast cancer patients: n = 35; age range: $<50 > 60$ years n = 54	All $\alpha \geq .70$ (except PF and CF and AS) High test and re-test ICCs reliabilities ($\geq .75$) except CE and BS; moderate to high kappa coefficient. For single items (.45–.93) Moderate correlations with SF36 scales measuring similar dimensions (.59–.65) except RF (.37) Known group difference: patients under active treatment report more QL impairment in most scales than follow-up patients	Not reported
Chie et al. ¹²	QLQ-C30 LC13	Taiwanese, Chinese	n = 51 (32 m, 19 f); average age: 54.3 ± 12.1 (active chemotherapy). n = 48 (24 m, 24 f); average age: 55.0 ± 12.4 (follow-up)	All $\alpha \geq .70$ (except CF .58) Moderate to high test-retest reliability Symptom scores (NV, HL, AS) sensitive to adjuvant treatments (chemotherapy, radiotherapy)	Peripheral neuropathy → like <i>having been stung with needles</i>

Toth et al. ⁹	H&N35	Japanese	Head and neck cancer patients: n = 108 (97 m, 11 f); average age: 66.8 ± 8	Construct validity ≥.40 for all individual items and their respective scales α: reliable ≥.70 for swallowing, sense, speech, social eating, social contact and sexuality Criterion validity: high (>.70) to moderate (>.50) correlations regarding pain, social function/care/anxiety/tension/depression	Hoarse item not comprehensible having physical contact with family and friends
Hoopman et al. ⁷	QLQ-C30	Turkish, Moroccan	Ethnic minorities in the Netherlands: n = 90 Turkish; n = 79 Moroccan	High convergent validity (>.40) for all multi-item subscales α > .70 except PF and CF (Turkish) and CF and NV (Moroccan)	Reading newspaper → listening to radio Hobby, quality of life: standard Arabic words were used vomit/throw up
Jensen et al. ⁸	QLQ-C30 H&N35	Danish	Head and neck cancer patients: n = 116 (74 m, 42 f); average age: 63 (36–92)	All α ≥.70 Most item/scale correlations >.40 No definite scaling error	Heavily skewed scores: high levels of functioning, few symptoms
Huang et al. (2007)	QLQ-C30 STO 22	Taiwanese, Chinese	Gastric cancer patients: n = 100 (21 m, 15 f and 29 m, 35 f); average age: 63 (SD = 12) and 63 (SD = 14)	All α ≥.70 except CF (.18) and STOEAT (.67) High convergent validity (>.40) for all multi-item subscales except CF Known-group differences of most STO scores regarding active treatment, dysphagia grade and ECOG (clinical validity)	Not reported
AS, arm symptoms; CF, cognitive functioning; HL, hair loss; NV, nausea; vomiting, PF, physical functioning; RF, role functioning; STOEAT, eating.					

Solution

Problem type	Questionnaire development process	Item bank Translation memory	Pilot testing	Cross-cultural project	National language authority ISO Certificate
Semantic	*	*			
Conceptual	*		*	*	
Editing/ misspelling			*		*
Consistency		*			
Scaling			*	*	
Cultural diversity			*	*	*

Fig. 2 – Problem × solution matrix.

Table 4 – Brislin's guidelines to improve the quality of the source versions for translations

1	Use short, simple sentences
2	Employ the active rather than the passive voice
3	Repeat nouns instead of using pronouns
4	Avoid metaphors and colloquialisms
5	Avoid the subjunctive
6	Add sentences to provide context for key ideas
7	Avoid adverbs and prepositions telling 'where' or 'when'
8	Avoid possessive forms where possible
9	Use specific rather than general terms
10	Avoid words indicating vagueness regarding some event or thing
11	Use wording familiar to the translators
12	Avoid sentences with two different verbs if the verbs suggest two different actions

Adapted from Brislin RW. The wording and translation of research instruments. In: Lonner WJ, Berry JW, editors. Field methods in cross-cultural research. Beverly Hills: Sage; 1986. p. 137–164.

very important step is the group's policy to have a representative of the Translation Committee involved in module development. This helps to avoid foreseeable translation difficulties and transforms the questionnaire development process from a strictly sequential procedure (single source from which all other translations are derived) to a simultaneous mode (various language versions are considered at the initial development). The simultaneous approach has proven to be a powerful method to avoid many semantic and conceptual problems.²¹ The international composition of the group suggests the use of a simultaneous approach.

The Item Bank is a potentially powerful tool to check for semantic and consistency problems. Its value may become

even more apparent through the implementation of a more user-friendly software architecture and its inclusion in the module development process.² The Item Bank may also serve as a platform to document the translation history of each item.²² Another promising computer-based tool is Translation Memory, a software program that recycles translations. Ideally, this tool will speed up the translation process and make it more cost-effective and transparent. Currently, pilot-tests are underway to check whether it can become a standard component of the translation process.²³

Pilot-testing is already an integral part of the EORTC translation process to detect editing and spelling mistakes, scaling issues and cultural diversity. Pilot-testing is also useful in detecting conceptual problems. This feature may even be strengthened by including elements of cognitive debriefing into the pilot-testing phase.²⁴ Cognitive debriefing allows respondents to articulate their subjective opinions on what concepts are assessed by questionnaire items.

Variation in QL responses obtained from different countries can stem from two main origins: cultural differences or language/translation issues. These two causes of diversity or bias are difficult to distinguish, but it is of importance since the translation diversity may be possible to correct, whereas the cultural diversity will not. A huge data set (involving data from nearly 40,000 respondents completing the QLQ-C30) are currently being analysed in the context of the Cross-Cultural Analysis Project.^{25,26} This work promises to shed light on the distinction between cultural diversity and 'true' translation problems. This distinction cannot be clarified by advanced psychometric analyses (such as differential item function, DIF) alone; input from more 'qualitative' sources is necessary. If differential item functioning is observed, checking the

translation process with regard to a particular language (how difficult it was, how many problems/ambiguities arose?) may help to explain to what degree the existing translation may be responsible for observed DIF effects. Indeed, a pair of recent analyses has suggested that differences may be more likely due to translation difficulties than they are to cultural problems.^{25,26}

Native speakers are necessary throughout the various stages of the translation process. They are also vitally important in the final stage of editing to detect spelling errors. A further option would be to include national language authorities where these exist; the aim here would not be looking for a perfect textbook language, but rather to ensure that spelling, the use of tenses and the use of punctuation marks are in concordance with the 'official' and the most recent rule of that language. An alternative would be a form of international translation quality certification (ISO 9001:2000 or CEN/BTTF 138) documenting the EORTC's commitment to comply with internationally accepted standards. The benefit of such rigorous external review processes would be to gain an official linguistic quality stamp.

9. Conclusions

The availability of QL questionnaires in many languages is of increasing importance for international clinical research. The development of such assessment tools will strengthen the issue of QL in medical research. However, it is important to communicate to the clinical researchers that the availability of questionnaires in many different languages cannot be taken for granted. There is little recognition outside the QL arena that the development and translation of QL instruments is a highly sophisticated, labour intense and costly process. Furthermore, it has to be convincingly argued (and also empirically shown) that the QL perspective broadens the narrow biomedical paradigm. QL assessment is by definition patient-oriented and thus provides a more complete picture of the patient.²⁷ This is important when it comes to assessing effects of new treatments. In addition, QL assessment in international clinical trials may well shed some light on intriguing cross-cultural differences in health perception and symptom reporting that may go unnoticed when clinicians rely solely on what used to be called 'hard' clinical criteria.

Conflict of interest statement.

None declared.

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