Towards a patient-driven approach to adverse events of targeted agents in oncology

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06 | Translation and linguistic validation of the FACT-EGFRI-18 quality of life instrument from English into Dutch.

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ABSTRACT

Purpose: The Functional Assessment of Cancer Therapy-Epidermal Growth Factor Receptor Inhibitor 18 (FACT-EGFRI-18) is a patient-reported outcomes questionnaire developed to assess the effect of EGFRI on patients. The FACT-EGFR-18 was translated into Dutch and evaluated in order to document that the translation adequately captures the concepts of the original English-language version of the questionnaire and is readily understood by subjects in the target population.

Method: Translation of the FACT-EGFRI-18 from English to Dutch was accomplished by employing the Functional Assessment of Chronic Illness Therapy (FACIT) multilingual translation methodology. Ten native-speaking residents of the target country who reported EGFRI associated dermatological adverse events (dAEs) were asked to review the translation of the harmonized FACT-EGFRI-18.

Results*:* Participants generally found the Dutch FACT-EGFRI-18 easy to understand and complete. In addition, the translation retained the original meaning of the FACT-EGFRI-18 items and instructions. Based on the results of the cognitive debriefing interviews, no changes to improve clarity and comprehension of translations were identified.

Conclusions: The Dutch FACT-EGFRI-18 demonstrates content validity and linguistic validity, and was found conceptually equivalent to its English source, thus confirming linguistic validation. The results suggest that the Dutch FACT-EGFRI-18 can be applied to measure dAE related health related quality of life in Dutch-speaking patients undergoing EGFRI therapy. Formal validation of the Dutch FACT-EGFRI-18 is ongoing.

Introduction

EGFRI

Several types of anticancer agents lead to dermatological adverse events (dAEs); dAEs are the primary side effects associated with targeted anticancer agents, especially those targeting the epidermal growth factor receptor (EGFR) signal transduction pathway (Balagula et al., 2011). The most common dAEs are defined as those affecting the skin, hair, nail bed, mucosa or eyelids. DAEs can result in skin rash (papulopustular eruption), itching (pruritus), abnormally dry skin (xerosis cutis), painful mucosal surfaces, dry conjunctivae of the eye, periungual inflammation, and oedema in up to 90% of patients during treatment with EGFR Inhibitors (EGFRI) (Iacovelli, 2007; Lacouture and Melosky, 2007; Perez-Soler and van Cutsem, 2007). They can have significant impact on quality of life because they can hinder daily activities and make it difficult to maintain patients' privacy about their illness, even when the treatment is effective in combating the cancer. The aesthetic discomfort, which is frequently associated with a burning sensation, itching or painful skin or nails, can lead to a decreased health related quality of life (HRQoL), dose reduction and even to a refusal to continue with further treatment (Hu et al., 2007). Oral complications can cause pain and affect oral function such as oral intake of food and medications, may impact nutrition, affect speech, ability to maintain oral hygiene and patients may be forced to remove their oral prostheses.

HRQoL

The concept of HRQoL can be defined as the extent to which one's usual or expected physical, emotional, and social well-being is affected by a medical condition or its treatment (Cella, 1994). One difficulty for clinicians trying to conceptualize a patient's HRQoL is due to its multidimensional nature that encompasses multiple aspects of a person's well-being (Ratanatharathorn et al., 2001). Empirical investigation of the aspects of dAEs that have the most detrimental impact on patients' HRQoL can help guide interventions to manage these toxicities and maximize patients' HRQoL (Wagner et al., 2007). Joshi et al. measured the effect of EGFRI-induced dAEs on HRQoL. They concluded that toxicities including rash, xerosis, paronychia, and pruritus adversely affect HRQoL, with rash associated with a greater decrease. Younger patients reported a lower overall HRQoL than older patients undergoing the same toxicities (Joshi et al., 2010).

dAE related HRQoL assessment

Having accurate baseline and post treatment data is essential to evaluating the HRQoL of patients and subsequently determining the effectiveness of management (Ikeda et al., 2003), which can range from counselling to pharmacologically based therapies. Prior to this study, Dutch patients with dAEs due to EGFRI treatment were not likely to have a formal assessment or reassessment of their dAEs related HRQoL because there was no Dutch EGFRI associated dAE specific HRQoL measurement

tool available. If EGFRI treatment-related HRQoL is to be improved, data on the prevalence, severity, and impact of dAE on HRQoL must be obtained and the effectiveness of various interventions on the HRQoL documented.

FACT-EGFRI-18

To date there have been two HRQoL questionnaires developed for EGFRI treated patients: the Functional Assessment of Side- Effects to Therapy-EGFRI (FAST-EGFRI) (Wagner et al., 2007) and the Functional Assessment of Cancer Therapy-EGFRI-18 (FACTEGFRI- 18) (Wagner et al., 2010). The 38-item FAST-EGFRI was the first EGFRI specific HRQoL questionnaire. The FACT-EGFRI-18 is based on the FAST-EGFRI and is a symptom specific subscale of the Functional Assessment of Chronic Illness Therapy (FACIT) measurement system used for assessing dAEs (FACIT.org, 2010). The FACT-EGFRI-18 is an 18-item Likert-scaled questionnaire, arranged in three HRQoL dimensions: physical (7 items), social/emotional (6 items), and functional well-being (5 items) (Wagner et al., 2007). To provide a better fit for scale items, the item groups are reorganized in skin, nail and hair side effect domains. The response scores ranged from 0 to 4 and the response categories include ‘Not at all’, ‘A little bit’, ‘Somewhat’, ‘Quite a bit’, and ‘Very much’. Negatively worded items (e.g. “My skin bleeds easily” or “My skin condition affects my mood”) are reverse-scored so that all participants who experience a higher severity of symptoms receive a lower score. The FACT-EGFRI-18 was developed according to the FACIT measurement system (FACIT.org, 2010; Webster et al., 2003). Table 1 shows the 18 items by subscale.

Instrument equivalence

Dutch is the native language spoken in The Netherlands and in about sixty percent of the populations of Belgium and Suriname, the three member states of the Dutch Language Union. Most speakers live in the European Union, where it is a first language for about 23 million and a second language for another 5 million people (not including speakers of closely related Afrikaans) (Ardizzoni et al., 2002; European Commission, 2006; Nederlandse Taalunie, 2012). It also holds official status in the Caribbean island nations of Aruba, Curacao, and Saint Maarten, as well as Australia, Canada, France (French Flanders), Germany, Indonesia, South Africa, and the United States.

When adapting measures for use in non-English-speaking populations, the translation process is a key factor in ensuring the appropriateness of the instrument in the target language. Qualitatively translation issues inevitably arise, such as issues related to semantic nuance, differences in dialect, or use of colloquial or idiomatic expressions. Employing a comprehensive translation methodology seeks to resolve all conceptual or linguistic concerns.

Ensuring conceptual equivalence among the adapted versions is critical, as translations that deviate from the intended meaning could affect how individuals perceive the connotation associated with specific test items: Patients may seem to understand the intent, but their perception and understanding of the intent may differ

from that of the English source. In this manner, linguistic nuances can create conceptual inequalities that can go undetected. This happens when there are significant differences in cultural values between the source and target cultures or when there are differences in how individuals of different groups qualify their symptoms (Guyatt, 1993; Kleinman, 1987; Marquis et al., 2005). This limits comparison of results from different studies, and also negates the possibility of pooling data for larger studies (Chang et al., 1999; Sireci, 1997; Yu et al., 2004) and ultimately inhibits a clinician's ability to interpret and apply assessment results because he or she may inadvertently over- or under-represent the severity of their patient's health status.

Table 1

FACT-EGFRI-18 items by subscale.

Physical well-being
1. I am bothered by a change in my skin's sensitivity to the sun
2. My skin or scalp itches
3. My skin bleeds easily
4. My skin or scalp is dry or "flaky"
5. My skin or scalp feels irritated
6. My eyes are dry
7. I am bothered by sensitivity around my fingernails or toenails
Social/emotional well-being
1. My skin condition affects my mood
2. I feel unattractive because of how my skin looks
3. I am embarrassed by my skin condition
4. I avoid going out in public because of how my skin looks
5. I am bothered by increased facial hair
6. I am bothered by hair loss
Functional well-being
1. My skin condition interferes with my social life
2. Sensitivity around my fingernails makes it difficult to perform household tasks
3. My skin condition interferes with my ability to sleep
4. Changes in my skin condition make daily life difficult
5. The skin side effects from treatment have interfered with household tasks

FACT-EGFRI-18 = Functional Assessment of Cancer Therapy-Epidermal Growth Factor Receptor Inhibitor.

Translation & cultural adaptation of patient reported outcome measures

European regulatory bodies have raised concerns over the validity of measures developed in one language and then used in other languages (Chassany et al., 2002). The European Regulatory Issues and Quality of Life Assessment (ERIQA) group recommends that a rigorous approach is taken in the translation of patient-reported

outcome (PRO) measures for use in international settings to achieve conceptual and semantic equivalence across languages (Acquadro et al., 2008). Because of the increased need to translate and culturally adapt PRO measures, content integrity during translation has to be maintained (Wild et al., 2009; Wild et al., 2005; Wyrwich et al., 2013). In response to a growing demand for more global and universally applicable clinical assessment instruments, a number of outcome based assessment tools have been developed from a cross-culturally sensitive perspective. This is in an effort to aid clinicians and researchers to more accurately understand the multifaceted attributes of what constitutes HRQoL and associated well-being. The literature shows a myriad of HRQoL assessment measures being adapted and validated for use with non-English-speaking populations (Butt et al., 2005; Eremenco et al., 2005a; Eremenco et al., 2004; Peterman et al., 1997).

FACIT translation system

The Functional Assessment of Chronic Illness Therapy (FACIT) translation measurement system (Bonomi et al., 1996; Eremenco et al., 2005b) utilizes health-care and translation experts from culturally appropriate geographic regions in order to develop linguistic and culturally equivalent translations that are appropriate for individuals with an average education level for the target culture. The methodology also calls for pilot testing of the translations to ascertain if patients from different backgrounds and with similar health symptoms understand the terminology in a consistent manner. Even with these safeguards, there is the possibility of psychometric inequivalence, which may be due to small sample size used in pilot studies or the sociodemographic profile of a particular sample (Arnold et al., 2009a,b).

The present study sought to conduct a linguistic validation of the FACT-EGFRI-18 questionnaire for the Dutch speaking population in The Netherlands. The purpose is to examine whether the Dutch translation adequately captures the concepts of the original English-language version of the questionnaire and is readily understood by participants in The Netherlands.

Methods

The FACT-EGFRI-18 was originally developed and validated in English (Wagner et al., 2010 2359/id). To create a Dutch version, we followed the standard multilingual translation and validation methodology developed by Bonomi et al. (1996) and adopted by the FACIT organization (FACIT.org, 2010). Due to the non-interventional design of this study, it was exempt from review by an ethics committee, per national and institutional standards and policies.

Participants

Following the FACIT validation methodology (FACIT.org, 2010), the required ten participants were recruited by clinical investigators from three hospitals in The Netherlands. The hospitals were selected from the participating hospitals for the BeCet trial (NCT01136005), where the formal validation of the Dutch FACT-EGFRI-18 is ongoing. Participants were eligible if they spoke Dutch as their native and primary language and had the ability to read standard Dutch; had been diagnosed with cancer; treated with an EGFRI; experiencing dAEs; if they had an Eastern Cooperative Oncology Group Performance Status (ECOG PS) ≤ 2; were at least 18 years of age and provided verbal informed consent to participate in the study. Demographic data collected included age, sex, diagnosis, date of diagnosis, primary language spoken, country of origin, current place of residence, and functional performance status. Table 2 summarizes the major demographic variables that were collected.

Table 2

Demographic and clinical characteristics of the validation sample (N = 10).

Characteristics	Mean (range)	N
Age	70 (63-81)	
Gender		
Male		6
Female		4
Diagnosis of cancer		
Colon cancer		6
Lung cancer		3
Breast cancer		1
EGFRI treatment		
Panitumumab		6
Erlotinib		2
Gefitinib		1
Lapatinib		1
ECOG PS; rating (0-4)		
0		3
1		4
2		3

ECOG PS = Eastern Cooperative Oncology Group Performance Status.

Procedure

Translation of the English FACT-EGFRI-18 into Dutch was conducted according to the FACIT translation methodology (Cella and Webster, 1997; Eremenco et al., 2005a; FACIT.org, 2010; Webster et al., 2003). Two forward translations, one reconciliation of the two forward translations, a back translation into English, and a review by Dutch-speaking health-care experts were required, along with field testing on a small patient population. A schematic overview of a typical linguistic validation process is illustrated in Table 3.

During the translation from English to Dutch, priority was given to achieving appropriate translation of the meaning/intent of each question in a grammatically correct manner, as opposed to simple translation of every individual word. Additional reviews by the FACIT organization and a committee of bilingual Dutch EGFRI therapy experts confirmed that the Dutch version was a harmonized translation of the English questionnaire. The translations were then tested via cognitive debriefing interviews in participants with EGFRI associated dAEs residing in The Netherlands. Cognitive

debriefing is a standardized interview conducted by a trained interviewer following a subject's review and completion of a PRO instrument.

Participants were interviewed in their homes as it was assumed they would feel more comfortable and talk more candidly there. A field tester monitored the administrations and then participants were asked to complete the FACT-EGFRI-18. Afterwards the field tester conducted a cognitive debriefing interview with each participant to assess if they experienced any difficulty understanding items, to see if items were irrelevant or offensive to them, to assess the items' personal and cultural relevance as well as the patients' overall comprehension of them, and to determine if any translations were poorly phrased or overly colloquial. Interviewing was conducted using a script that was read to the participants: "As you know, we are testing a questionnaire for use in clinical trials and want to know if it can be easily understood. Would you please tell me which items were difficult to understand and why they were difficult? Also, could you suggest a better way to phrase these items?" The interviewer judged whether items were correctly paraphrased and recorded any comprehension problems or proposed changes to the wording. In keeping with regulatory guidelines and good clinical practice, cognitive debriefing information was captured on a data collection form.

In the subsequent qualitative analysis, linguistic validation teams, consisting of the original translators, back translator, project manager, interviewer, and survey research expert, evaluated the debriefing results. The teams categorized problems that emerged during the debriefing as: conceptual e a function of the original English; linguistic e a function of the words used to translate the English concept; or stylistic e a function of the subject's preference for a different wording. When warranted, the original translators of the questionnaire created a new harmonized translation of problem words or sentences and the back translator created a new back translation for review by a survey research expert. Once all issues were resolved, final forward and back translations were created.

Results

Participants

After creating comprehensive translations which were approved by the translators, project manager, and survey research expert involved in its production, debriefing interviews were conducted with 10 participants with EGFRI associated dAEs from the Netherlands. Participants were a-select recruited. The study coordinator contacted the hospitals to find out if they had patients who met the inclusion criteria. All patients who were approached were included. No one refused. The participants ranged in age from 63 to 81 years, mean age was 70 years. Among the 10 participants, 6 patients were male and colon cancer was the most common cancer diagnosis (Table 2).

Translation

The translation process went smoothly except one phrase. In the item 'I am bothered by a change in my skin's sensitivity to the sun', 'I am bothered by' was first back translated into 'annoying' ('dat ik last heb'), which was not acceptable to the FACIT organization based on Dutch translations of the item in other linguistically validated FACIT questionnaires. The FACIT organization provided the phrase 'Ik vind het vervelend'. However, that phrase was too long and vague in this context; participants would not understand what this item was about. Because it was strongly recommended that we used this phrase, we were limited in providing a fluent sentence. We agreed to be consistent with this item but be inconsistent with the word 'sensitivity' in order to be able to create a fluent Dutch sentence.

The word 'sensitivity' was first back translated into 'has become more sensitive', which was not acceptable to the FACIT organization. The forward translation from

Table 3
FACIT translation methodology (FACIT.org, 2010).

Step	Process	Personnel	Requirements/ Purposes
1	Using the English source, produce two forward translations of each item	2 native speakers of target language (1 in the US and 1 in native country)	Use simple language and capture meaning
2	Reconcile the initial translation of the items based on the two forward translations	1 native speaker, familiar with multiple dialects	Resolve discrepancies
3	The reconciled translation is back-translated by a native English speaker fluent in the target language	1 native English speaker	Use simple language
4	Three independent professional bilingual translation experts review the reconciled translation	3–4 bilingual experts and coordinating team	Review steps 1–3 and finalize translations
5	The translation team finalizes and subsequently harmonizes the translations across all countries and/or languages within the scope of the project	Language coordinator and bilingual expert	Proof-read
6	Final translations are proofread	2 bilingual experts from the translation team	Proof-read
7	The translated questionnaire is field tested with cancer patients from the target population to determine if further revisions are necessary	Native speaking patients (10) with relevant diagnosis	Assess comprehension and acceptability
8	The final instrument is considered conceptually equivalent to its English source and is ready to be used in clinical or research settings	-	-

'sensitivity' was 'gevoeliger is geworden'. The FACIT organization provided the word 'gevoeligheid' because this was the word used in other Dutch FACIT questionnaires. I

few would have used this word, the literal back translation then would be: 'I am bothered that the sensitivity of my skin for the sun is changed' which was not acceptable for the translators. So we agreed to be inconsistent with the translation of this word compared to previous translations of other FACIT questionnaires and use the Dutch word 'gevoeliger' ('more sensitive') instead of 'gevoeligheid' ('sensitivity').

Cognitive debriefing

During the linguistic validation process, special attention was paid to ensure that the translated items communicated the desired intent. Since the forward translators had some discussions during the translation process about the phrase 'I am bothered by a change in my skin's sensitivity to the sun', additional questions about this item were added by the FACIT Translation Services to the 'Patient Interview Form'. Questions were: "What does the phrase 'I am bothered' mean in this item?", "What are some examples of 'change in your skin's sensitivity to the sun'?" and "The idea of this item is to ask if you are distressed, both physically and emotionally. Is there a better way to express this idea? If so, please provide your suggestion." The term 'bothered' was described by our participants as 'not being allowed to do what you want to'; 'limited in opportunities', 'troublesome because others have to take you into account', 'you have to adapt', and 'you must remember to take a cap and sunscreen with you'. Participants' responses confirmed that the meaning of this item is correctly understood and the item 'Ik vind het vervelend' captured the original concept. Further, to confirm that participants were appropriately interpreting items, they were asked to give examples of undesirable events. For example, for the phrase 'change in your skin's sensitivity to the sun', participants reported that they have to sit in the shade, others needed to be more considerate with the patients, and they needed to wear a hat, even in the car. Qualitative analysis of all translations derived from employing the FACIT translation methodology revealed no important issues to change.

Overall, patients commented that the Dutch FACT-EFRI-18 was easy to complete and the items were relevant. Results from the post-questionnaire debriefing interviews suggested that the translations were accurately understood by the participants in a manner that was conceptually equivalent to the English source.

Discussion

As more and more patients will be treated with targeted therapies including EGFRI, it becomes increasingly important to understand the multidimensional experiences of these agents associated dAE related HRQoL. The FACT-EGFRI-18 is the first instrument measuring dAE related HRQoL in Dutch cancer patients undergoing EGFRI therapy. Further, use of validated and standardized tools will allow comparison of outcomes in different studies and in meta-analyses, to advance patient care and improve outcomes.

In our study, use of the established FACIT translation methodology in conjunction with the qualitatively based debriefing interview indicated that the constructs being

measured in the Dutch version of the FACT-EGFRI-18 were conceptually equivalent with the original English version prior to field testing with patients. All patients responded that the FACT-EGFRI-18 was easy to understand and items were relevant to measuring HRQoL. This methodology facilitated the translation of the instrument, and use in further translations of this and other survey tools is therefore recommended.

Study limitations

Study limitations included participants with different kinds of cancer, EGFRI treatment, and dAEs. At the same time, different cancers and treatment allows testing of the questionnaire across a range of patients. Another limitation was the relatively small participant sample, however, the number of 10 participants was prescribed by the FACIT organization. All participants were residents from the Netherlands as spoken Dutch tends to vary based on geography and differences in dialect could be present in different regions. Since demographic, economic, geographic, political, and sociological differences make each culture unique, linguistic and conceptual equivalence may not necessarily assume generalizability of results across cultures (Anderson and Gerbing, 1988). The Dutch questionnaire is only linguistically validated for the population from The Netherlands. To cover a Dutch version for all the native Dutch speakers around the world, validation should be done in those countries and in other languages.

Clinical and research implications

The results of the linguistic validation suggest that the Dutch version of the FACT-EGFRI-18 can be applied to measure EGFRI associated dAE related HRQoL in Dutch speaking cancer patients in The Netherlands. Before the Dutch version can be used in other Dutch speaking countries like Belgium, the Caribbean island nations of Aruba, Curacao, and Saint Maarten, as well as Australia, Canada, France (French Flanders), Germany, Indonesia, South Africa, and United States the linguistic validation should be performed in at least in Belgium and Surinam before we called it a universal version. A single (universal) Dutch version of the questionnaire is warranted.

This scale development will help clinicians in the Netherlands to collect more information about the impact of dAEs on the HRQoL due to EGFRI. The result of this scale development process can be applied to all patients treated with EGFRI. The instrument can help researchers and clinicians to assess mcAE related HRQoL, to be able to select interventions, and evaluate their effectiveness. Thus, the use of this tool will be able to improve patients' dAEs treatment and HRQoL.

Formal validation and reliability testing of the Dutch FACTEGFRI-18 is being conducted in the BeCet multicenter trial (NCT01136005) of 160 patients with all dAEs severity grades (National Cancer Institute Cancer Therapy Evaluation Program, 2010). In addition, the translation and linguistic validation of the FACT-EGFRI-18 into German is ongoing. The FACT-EGFRI-18 is available at www.facit.org.

Conclusions

Translations of the FACT-EGFRI-18 questionnaire from English into Dutch adequately captured the concepts in the original English version of the questionnaire, thereby demonstrating the conceptual, semantic, and cultural equivalence of the translation. Participants experiencing EGFRI associated dAEs demonstrated an ability to understand the concepts in the questionnaire. Based on the results of the cognitive debriefing interviews, no changes to improve clarity and comprehension of translations were needed. Additionally, by utilizing the FACIT translation methodology and incorporating translation experts, the translation of the Dutch FACT-EGFRI-18 is considered a promising clinical tool for evaluating the HRQoL of Dutch speaking patients with EGFRI associated dAEs from The Netherlands. These methods and this current study have implications for HRQoL questionnaire development using different questionnaires and in different languages.

Conflict of interest

The authors declare no conflicts of interest. All authors had full control of all primary data and agree to allow the journal to review the data, if requested.

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Appendix A. Supplementary data

Supplementary data related to this article can be found online at http://dx.doi.org/10.1016/j.ejon.2013.03.004.

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