

Patient-reported Outcome Measures: The FACE-Q Skin Cancer Module: The Dutch Translation and Linguistic Validation

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Background: Patient-reported outcome measures are becoming a standard component in the evaluation of surgical treatments. In 2010, the FACE-Q skin cancer module was developed: an English psychometric validated questionnaire that measures both patient quality of life and satisfaction with the surgical experience. The questionnaire consists of 11 subscales with a total of 96 questions. An officially translated version in Dutch is needed for accepted use in the Netherlands.

Methods: We translated the FACE-Q skin cancer module from English into Dutch in accordance with to the International Society for Pharmacoeconomics and Outcomes Research and World Health Organization guidelines. The translation occurs in three stages. First, a forward translation is performed by two independent professional translators, where discrepancies are solved by a third translator, a subject area expert. Secondly, a backward translation is performed and is compared with the original. Any discrepancies are solved by an expert panel. Version two is then pretested (cognitive debriefing) by 30 patients who have had a resection (Mohs surgery) of non-melanoma skin cancer in the face followed by reconstruction. The results of the pretesting exercise are evaluated and a final version of the translation was produced by the expert panel.

Results: In the first step, a conceptually equivalent Dutch translation of the FACE-Q was translated. In the second phase, the comparison between the forward and backward translation led to multiple retractions. In step three, 48 annotations were evaluated by the expert panel, which led to 26 minor changes in items or instructions.

Conclusion: We created a conceptually and linguistically similar translation of the FACE-Q Skin Cancer Module through a thorough translation and linguistic validation process. (*Plast Reconstr Surg Glob Open* 2019;7:e2325; doi: 10.1097/GOX.0000000000002325; Published online 29 October 2019.)

INTRODUCTION

Skin cancer is the most common type of cancer in both the Netherlands and the European Union with an

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Received for publication August 24, 2018; accepted March 29, 2019.

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DOI: 10.1097/GOX.0000000000002325

incidence of 51,000, resulting in 900 deaths per year. Non-melanoma skin cancer has increased with almost 400% between 1990 and 2017 and it is estimated that the incidence will rise with another 200%–500%.¹

Many reconstructive modalities are used, such as primary closure, healing by secondary intention, skin grafting, and local or regional skin flaps.

However, the shared decision-making process lacks scientifically substantiated data about patient satisfaction in facial surgery. It has been established that the use of patient-reported outcome measures (PROMs) lead to an improvement of the quality of treatment, better professional development, and an overall increase in quality of care.^{2–8}

Success of treatments is conventionally based on morbidity and mortality, when seeking the patients' opinion, generic measurements are used. Although generic measurements may have value in many contexts and for many conditions, they fail to measure Concepts of Interest

Disclosure: *The authors have no financial interest to declare in relation to the content of this article.*

with precision. PROMs are a tool that directly captures a patient's experience. This score can be used to improve the quality of care.⁵ For facial surgery, a well-developed, psychometrically validated and clinically relevant PROM had been missing until recently, therefore the FACE-Q has been developed.⁹ The FACE-Q was originally developed using a mixed method approach following recommended guidelines from the US Food and Drug Administration for PROM development.¹⁰ The 3-phased approach involves a qualitative study and literature review, an international field-test and a psychometric study.⁹ A special FACE-Q skin cancer module was developed.⁶ This module consists of 11 categories with a total of 96 questions (Table 1). Items are scored using the Rasch Measurement Theory to yield an overall score for the concept between 0 (worst) and 100 (best).^{11,12}

Since well-developed PRO instruments achieve content validity through careful qualitative interviews, proper translations and linguistic validation is extremely important when questionnaires are adapted to another language and culture. It has previously been shown that a combination of the guidelines set forth by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and World Health Organization (WHO) provides a sound basis for the translation and linguistic validation process.¹³⁻¹⁵ The focus of these guidelines is conceptual translation rather than literal translation. The linguistic validation ensures the meaning is correct and questionnaire is easily understood.¹³⁻¹⁷

The aim of this article is to achieve a translation and linguistic validation of the Dutch FACE-Q by achieving a conceptually equivalent FACE-Q which can be used by clinicians.

METHODS

For the purpose of making an official Dutch translation, written permission from the original authors and the Dutch Medical Research Ethics Committees United was obtained. The questionnaire was translated into Dutch according to the "Linguistic Validation of a Patient Reported Outcomes Measure" directive from and in collaboration with the MAPI Research Institute, based on the ISPOR and WHO-guidelines¹⁵ (see Fig. 1).

We performed a translation of the FACE-Q skin cancer module using the ISPOR and WHO guidelines for translation of PROMs. The original questionnaire was recently published and validated in English.⁹ It contains 5 scales measuring appearance satisfaction (Satisfaction with Facial Appearance, Appraisal of Scars), quality of life (Cancer Worry, Appearance-related Psychosocial Distress), and the patient experience (Satisfaction with Information: Appearance). Also two Checklists were translated (Sun Protection Behaviour and Adverse Effects Checklist) and three Experience scales were translated that were adopted from a previous publication (Satisfaction with the Doctor/Surgeon, with the Medical Team and with the General information provided).¹⁸ A total of 10 scales comprising 86 questions (see Table 1).

We aimed to use simple and clear formulation to create translations understandable for all patients. The focus was cross-cultural and conceptual, rather than to achieve linguistic/literal equivalence. The following steps were taken into our study for the translation:

1. Forward translation and harmonization:

Two professional independent translators with Dutch as mother tongue and fluent English language translated the questionnaire from English to Dutch. The discrepancies between these two translations were harmonized by a third translator, a clinician, which led to version 1.

2. Backward translation and review:

An independent translator with English as native language and fluent Dutch language produced a backward translation. This was then compared to the original FACE-Q, all discrepancies were discussed with the FACE-Q developers, translators and expert panel. Version 2 was created.

3. Pretesting phase:

This version was offered to 30 patients who had undergone resection (Mohs surgery) of non-melanoma skin cancer in the face followed by reconstruction. They were asked to evaluate the PROM and comment on the use of language and to report on any ambiguities of unsatisfactory expressions and concepts. All comments were evaluated by the expert panel (two plastic surgeons, one translator, and questionnaire developers). After agreement, the final Dutch translation of the questionnaire was created.

RESULTS

In the forward and backward translation, respectively 18 and 6 questions were raised and solved by the expert panel. Examples of comments in the forward translation are: "what is the definition of a scar" or "to which kind of relation is being referred? Friendly? Love?" In the backward translation differences in meaning of words were discussed, that is, the question "Do you wear a hat?" could be misinterpreted, because the Dutch meaning of the word does not include caps of other headgear, and changes with retranslations arose from these discussions.

In the pretesting phase, annotations were taken for 48 questions, plus two general comments were made. Comments included: "is this in regard to the flap or also the skin surrounding the flap." In answer to the question "Do you wear clothing to protect you from the sun?" one patient noted: "I'm not going out naked", and in return we added the word "extra" in front of clothing to clarify. Other remarks varied from "What is meant by 'form of the face'?" to what does symmetrical mean?" The direct translations of the terms "uniform" and "smooth" to Dutch are less distinct than their English equivalents. Therefore, we provided a short explanation between brackets. "Heal" was at first translated with the literal translation (helen). However, in Dutch the word "heal" (Dutch: helen) was changed to "cure" (genezen) which is a slightly better fit in Dutch given the context. In total, 10 questions and instructions needed to be changed, no major revisions were needed. All revisions were

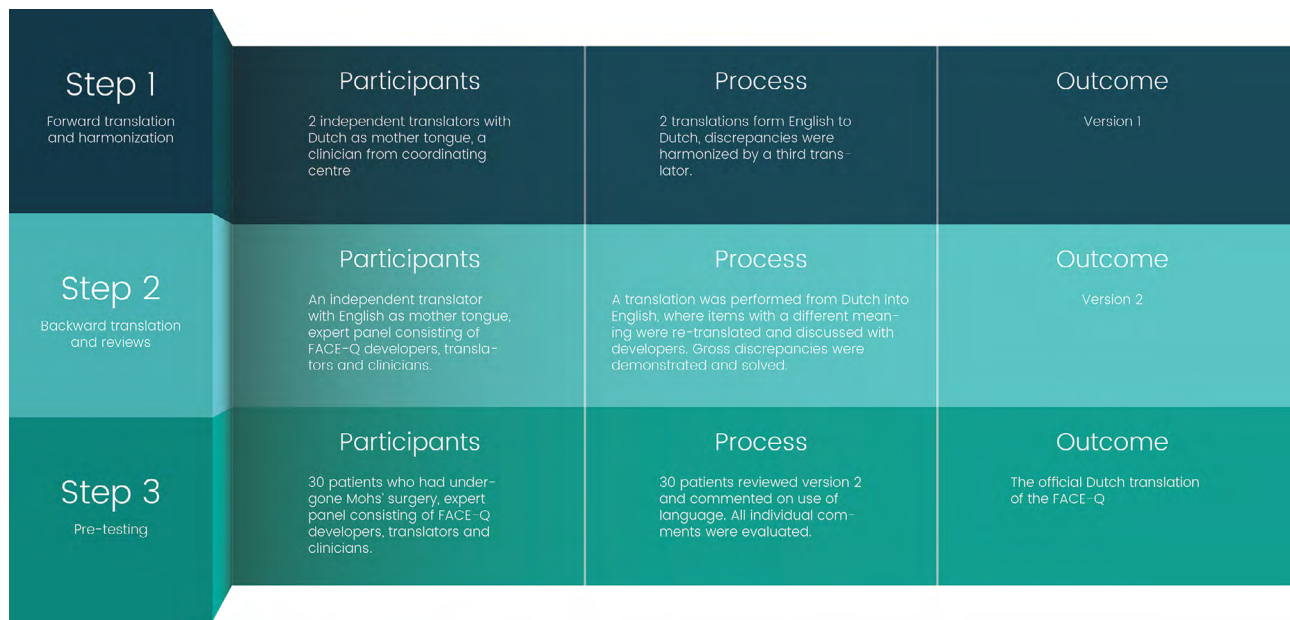


Fig. 1. This figure depicts the different steps in the translation process. The steps are derived from the official WHO and ISPOR guidelines for translating a questionnaire.

evaluated by the expert panel again, and the final Dutch translation of the FACE-Q was created. The Dutch version of the FACE-Q Skin Cancer Module that we developed is now available upon request. The copyright of the respondents' Dutch version also belongs to the Memorial Sloan Kettering Cancer Center and The University of British Columbia.

DISCUSSION

Using official guidelines from the WHO and ISPOR, we achieved a linguistically validated translation of the English FACE-Q skin oncology module to a conceptually equivalent Dutch version. With the forward and backward translation, we found that the professional translators and clinicians used various wordings for some items, as their framework differed, which required discussion to reach consensus, that is, sometimes translators wanted to implement examples of certain words. Both parties provided information, which was found to complement each other.¹⁹

For patient characteristics, we looked at sex (41% male) and age [Mean age (SD): 69.41 (12.06)], but as there is a homogenous distribution of patients in our test population, the chance it influences outcomes is very little.^{20–23}

Until now, no validated tool assessed multiple aspects of (cancer-related) facial surgery, while dissatisfaction with appearance is unquestionably invalidating for patients.^{9,24} PROMs like “the scar assessment questionnaire” or “Skindex” don't cover all aspects of postcancer reconstruction, most importantly, a review by Klassen et al²⁴ showed that no PROM had included procedural-related questions, while we believe that this is valuable information.^{9,25–28}

The expert panel, which was a mix of clinicians and professional translators proved to be of importance, as clinicians often use different terms than non-specialists.¹⁹ Also, the pretesting phase proved to be useful in our case

as the feedback from patients was ample and led to critical linguistic changes.

Although the translation is mostly accurate to the original questionnaire, a literal translation is never possible, meaning there is always a slight interpretation bias.

Idiomatically, the FACE-Q has been translated now, but the framework of Dutch patients will also be implemented in a transcultural validation.

CONCLUSIONS

By creating an official Dutch translation of the FACE-Q by thorough translation and linguistic validation, a promising tool has been created which is available for use in clinical practice, research and benchmarking of outcomes internationally and can now be downloaded from <http://qportfolio.org/faceq/>.

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