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Preference-Based Assessments

From Translation to Version Management: A History and Review of Methods for the Cultural Adaptation of the EuroQol Five-Dimensional Questionnaire

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ABSTRACT

The EuroQol five-dimensional (EQ-5D) questionnaire is used worldwide as a patient-reported outcome (PRO) instrument for the measurement and valuation of health. Several variants of the instrument now exist, including versions with three and five levels of severity and one for respondents aged 8 to 14 years. From the outset, a demand for new language versions of the EQ-5D questionnaire meant that there was a need to implement standardized procedures, which ensured that such versions were produced following international recommendations for the cultural adaptation of patient-reported outcomes. The availability of new variants and formats of the instrument, such as telephone-administered or electronic formats, complicated the task of providing and controlling the quality of cultural adaptations. Although cultural adaptations of the instrument are widely used, the procedures currently used to produce them have not been widely disseminated. The present article therefore describes the evolution of the production of other language versions of the instrument from the

earliest days of simultaneous production and translation of the EQ-5D questionnaire to the more recent, broader-based strategy of version management. We describe current adaptation procedures and innovations within those procedures. We also describe how version management is organized within the EuroQol Group, review aspects related to quality control, and provide an overview of the number of currently available language versions for each variant of the EQ-5D questionnaire: three-level, five-level, and youth versions. We conclude by discussing some of the relevant issues related to cultural adaptation for frequently used instruments such as the EQ-5D questionnaire.

Keywords: cultural adaptation, EQ-5D, patient-reported outcomes, version management.

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Introduction

The EuroQol five-dimensional (EQ-5D) questionnaire is a standardized patient-reported outcome (PRO) instrument for the measurement and valuation of health status that has been developed by the EuroQol Group [1]. It is a relatively simple, generic, preference-based measure of health for use in clinical and economic evaluations. It is designed to be suitable for use in a wide range of health conditions and interventions and has also been used in several general population health surveys [2–4]. Its descriptive system and health “thermometer” can be used as an unweighted profile and visual analogue scale. The descriptive system can also be used as a weighted sum score on the basis of preference-based value elicitation techniques such as time trade-off.

The first widely used version of the EQ-5D questionnaire measured health in five dimensions—mobility, self-care, usual activities, pain/discomfort, and anxiety/depression—with three levels of severity in each dimension—no problems, some/moderate problems, and extreme problems/unable to perform the

activity [1]. Over the years, in response to user needs and with the aim of continually improving the instrument, new versions such as the five-level version (5L) [5] and the youth version [6,7] have been produced. The instrument has also been produced for use on an increasingly broad array of platforms, including tablet, Web, and personal digital assistant formats, and for application via different modes of administration (telephone, face-to-face interview, and proxy versions).

Almost since its inception, there was substantial demand for the instrument in other countries and languages and the EuroQol Group realized from an early stage that the cultural adaptation of the questionnaire would be an important part of instrument use. It was also felt that adopting a careful approach to cultural adaptation would help maintain measurement properties across language versions and thereby allow data from different language groups to be compared and/or pooled. Evidence in the literature supports the idea that a rigorous, multistep approach to cultural adaptation, such as that used by the EuroQol Group, is most likely to provide high-quality translations [8].

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The approach taken by the Group to the production of different language versions has evolved over the years, and one of the aims of this article was to provide a brief history of the EuroQol Group approach to the cultural adaptation of the instrument. The article also aims to provide information on the procedures for cultural adaptation currently used and to review some of the lessons learned from more than 20 years of cultural adaptation of the EQ-5D questionnaire.

Producing Other Language Versions of the EQ-5D questionnaire: A Brief History

The Earliest Versions

The earliest versions of the EQ-5D questionnaire were developed as a joint effort by researchers from Finland, The Netherlands, Norway, Sweden, and the United Kingdom. English was used as the common language when developing the instrument, but researchers from all the original five countries contributed to the content and the format of the questionnaire, because the aim was to produce an international instrument that would be relevant and appropriate for health status measurement in all these countries. The original version of the instrument measured health in six dimensions, with two or three levels of severity in each dimension, but this version was later reduced to the current five dimensions, with three levels of severity in each [1]. Language versions for the original four non-English-speaking countries were produced by the researchers from those countries on the basis of their understanding of content discussed in several face-to-face meetings at which the instrument was developed and in which they participated. Professional translators also participated in the production of some of these versions.

The Move to a More Standardized Approach

After the establishment of the original five language versions of the instrument, the next versions (Spanish and Catalan) were the first to be produced according to what was then becoming accepted as a standard procedure for the production of other language versions of PRO instruments. This methodology was based on guidelines suggesting that the use of independent forward translators followed by back translation into the source language, and cognitive debriefing of the version in small numbers of the target population, would help to avoid some of the potential pitfalls associated with a less standardized approach to translation [9,10]. The process used to develop the Spanish and Catalan versions of the instrument served as a template for translation guidelines developed by the group in 1994 and 1995 [11]. The essential features of the approach used at that time are retained in the procedures used today and consist of the following: 1) forward translation, 2) reconciliation of the two forward translations, 3) back translation, and 4) pilot testing of a provisional version of the instrument in the target language in cognitive interviews with respondents from the target language group (see below for more details). EuroQol Group reviewers also comment on the process after stages 2 to 4. This approach has been recommended in more recent guidelines for the cultural adaptation of PROs [12,13]. The steps to be followed are summarized in translation guidelines that are provided to organizations responsible for producing new language versions of the instrument.

From Translation to Version Management

Although the use of standardized guidelines was a major step in ensuring quality control in the production of new language

versions, it became apparent that there was a need for an expanded structure within the Group to deal with the increasing number of requests for cultural adaptations, which, in part, stemmed from the availability of new variants and formats of the EQ-5D questionnaire. These new variants of the EQ-5D questionnaire include the 5L version, which was finalized in 2009 and was designed to improve the instrument's sensitivity and reduce ceiling effects [5], and a version of the three-level (3L) instrument that was produced for use in pediatric populations aged 8 to 14 years: the youth version [6,7]. That meant that three major versions of the instrument were now available, together with proxy, telephone, and face-to-face interview versions for the standard 3L instrument. Although the increase in actual translations could be adequately dealt with, because they were generally done by professional translation bureaus, the contextual checks and formal reviews by scientists from the EuroQol Group as well as the archiving and control of all versions and adaptations increased the administrative burden for dealing with new language requests. It was therefore decided to create a EuroQol Version Management Committee (EQ-VMC) that would be responsible for overseeing the production and archiving of all versions as well as ensuring the quality of the procedures and outcomes of cultural adaptation.

EQ-VMC: Activities and Structure

The EQ-VMC's remit includes: 1) organizing and overseeing adaptations of the EQ-5D questionnaire into other language versions; 2) vetting potential translation suppliers; 3) archiving and tracking of language versions of the questionnaire in all formats; 4) quality control and auditing of the translations of the language versions; 5) quality control of screenshots for electronic versions; 6) input into design and content of new versions and formats; 7) production and updating of template versions of key questionnaires and formats; 8) development and updating of adaptation methodologies and guidelines; 9) development and updating of Definition of Concepts documents (explained later); 10) overseeing production of translation certificates; 11) involvement in copyright issues; 12) deciding on modifications to existing versions, and tracking modifications; and 13) dealing with user queries related to version management. Currently, the EQ-VMC has four members and works in close cooperation with EuroQol Group's office, which provides administrative support. The EQ-VMC reports directly to the executive director of the EuroQol Group's Office.

Producing Other Language Versions of the EQ-5D Questionnaire: Current Procedures

As mentioned earlier, the basic procedures involved in producing other language versions of the EQ-5D questionnaire were established at an early stage of the instrument's development and use and were based on guidelines for the cultural adaptation of this type of instrument emerging at the time [9]. The procedures are shown in Figure 1.

Definition of Concepts Documents

The EuroQol Group's Definition of Concepts documents are an important tool in the cultural adaptation procedure. They provide a standard interpretation of key terms in the instrument and their aim is to ensure consistency of interpretation across all language versions. All professional translation bureaus working with the EuroQol Group on adaptations are provided with these, as are any local research teams who undertake a translation in their country. Translation guidelines and Definition of Concepts documents are currently available for the adult 3L and 5L

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