



CROSS-CULTURAL ADAPTATION IN QUALITY OF LIFE INSTRUMENT: SISTEMATIC REVIEW METHOD

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ABSTRACT

Objective: To describe the process of cross-cultural adaptation and evaluation of the psychometric properties of instruments for measuring quality of life.

Methods: This is a systematic review, carried out independently by two researchers. The following keywords were used as search criteria: Transcultural adaptation, quality of life, questionnaire; Transcultural adaptation, quality of life, instrument; Instrument, validation, quality of life; questionnaire, validation, quality of life. After the unification of the two collections, the titles, abstract and full text were analyzed.

Results: 17 articles were included in the review. The most used reference was Guillemin, followed by Beaton and Herdman, and two articles did not present detailed theoretical references. Psychometric properties were not tested in all studies, with validity and reliability being the most investigated.

Conclusion: Each stage of cross-cultural adaptation needs to be duly respected and all aspects and requirements must be met. An unrealized step or an unmet criterion may weaken the whole process, jeopardizing the effectiveness of the instrument.

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INTRODUCTION

The Quality of life (QoL) is an eminently human notion and, with respect to health, requires a synthesis of collective construction of standards of comfort and tolerance that particular society establishes as parameters for you (Minayo; Hartz, 2000). The concept of QoL is relatively recent and stems, in part, to new paradigms that have influenced the practices in health in recent decades. On the conceptual level two terms are: subjectivity, which considers the individual evaluates your personal situation in each of the dimensions

related to QoL, and the multidimensionality, which refers to the recognition that the construct is formed by different dimensions (Seidl; Zammom, 2004; Iandeiro *et al.*, 2011). A large number of studies have been devoted to the development of instruments to assess QoL to over the years. Despite being one of the individual design increasingly becomes interesting to quantify, since it can be understood as a health indicator, which makes direct inference about the concept of health and disease be (Minayo, 2000; Dantas, 2010). QoL instruments are classified into two groups: specific and nonspecific, also called general instruments. On Public Health the use of specific instruments have been widely discussed, understanding that each disturbing health process different lead changes and perceptions in individuals (Iandeiro *et al.*, 2011).

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It is a great challenge to have tools to evaluate such conditions and applicable, generating information in the different situations of health / disease. The construction of a new instrument is not a very suitable option for solving this problem, as it involves a long process for the conceptualization of the measure and the selection of items (Azevedo, 2008). The least expensive option, but is challenging the use of instruments built in other cultures / countries. But for this to be possible it is necessary that this instrument will pass through a cross-cultural adaptation process, taking into account the perception of health and coping before organ dysfunction vary according to culture and the environment that the individual is inserted (Beaton *et al.*, 2000; Ferraz, 1997). The cross-cultural adaptation of a QOL instrument requires a single method for all equivalences can be obtained. Items must not only be translated satisfactorily in the linguistic aspect, but must also be culturally adapted to maintain validity. The term "cultural adaptation" is the most recommended to characterize this process as it covers a process which analyzes the language (translation) as the cultural and linguistic issues in this process that aims to verify the necessary equivalence of the questionnaire for use in another environment (Beaton *et al.*, 2000). The purpose of this article is to describe how the process is being carried out cross-cultural adaptation of quality of life instruments, making a direct inference to theoretical frameworks in order to be able to elucidate a synthesized process to guide further studies. The concept of quality of life (QoL) is being widely used and used by the media and especially in the scientific milieu in the last decades. QoL, an eminently human characteristic, is the distance between individual and real expectations, and the lower this distance, the better the quality of life.

Thus, despite being a synthesis of the collective construction of the patterns of comfort and tolerance that a given society establishes, it reflects the uniqueness of being perpassed by the subjectivity of the individual (Seidel; Zannon, 2004). The parameter or weight of a group presented in relation to QoL transits through a polysemic semantic field, in the sense of seeking a balance. For on one side is the way of life of the individual and how he faces his day to day. On the other, the more macro and social thoughts, including sustainable development, healthy and pleasant living environments (Minayo *et al.*, 2000; Iandeiros *et al.*, 2011). To better understand this theme, it is necessary to adopt a conceptual model that may be complex in relation to the world, but it expresses and helps to understand the relationship between man, nature and environment (Minayo *et al.*, 2000). QoL is a universe of knowledge that expresses itself as a transdisciplinary area and encompasses a series of sciences and empiricisms, concepts that transcend the lives of people as a whole. It deals with innumerable everyday factors ranging from the subjectivity of being to the most objective issues, such as decision-making in the face of a problem (Minayo *et al.*, 2000; Seidel, 2004; Azevedo *et al.*, 2008). QoL is a topic of great importance for health, because it involves aspects inherent to the individual and to consider the person's perception about his health in different dimensions of life. Thus, a more punctual assessment of people's health status is necessary, inserting quality of life as an indicator of the effectiveness of health interventions (Dantas *et al.*, 2010). There is therefore a need to use instruments that measure and quantify these characteristics to better understand the impact of the disease and the effect of treatment on all dimensions that surround the health-disease process.

Based on the evaluation of the mechanisms that negatively affect the quality of life, it is possible to plan interventions that can improve the patient's well-being (Minayo *et al.*, 2000, Ferraz, 1997; Guillemin *et al.*, 1993).

MATERIALS AND METHODS

This is a literature integrative review conducted in July 2016, where the virtual health library was used (BVS) through Medline, Lilacs and Scielo. For search, we used registered descriptors in subject descriptors in Health Sciences (DECs) of Bireme and equally in the Mesh. In the search, the following key words in Portuguese, English and Spanish were considered: Cross-cultural adaptation, quality of life questionnaire, instrument validation. As search strategy was making the association between the descriptors as follows: Transcultural adaptation, quality of life questionnaire; Cross-cultural adaptation, quality of life instrument; Instrument, validation, quality of life; questionnaire, validation, quality of life. Totalling four search engines. The inclusion criteria were considered papers discussing the process of cultural adaptation and psychometric evaluation of the property, published between January 2000 and April 2016, in English, Portuguese and Spanish. Were excluded, theses, dissertations and monographs, review articles or different theme of the proposal and does not contemplate the established inclusion criteria. The search and selection were made independently by two researchers with postgraduate degrees and scientific maturity. The search for articles in databases occurred on the same day and time are using the same internet program.

When there was disagreement over the inclusion of a particular article, was organized a discussion of the work, based on the defined criteria, until reaching the consensus of the inclusion or exclusion of the same. When performing the search, were obtained, after discussions among researchers, a total of 402 articles. The next step was to read the titles of the articles which generated a total of 108 articles, followed for reading the abstracts remaining 27 articles. In reading the title the inclusion criterion was the presence of one of the descriptors in the text, and for the analysis of the abstracts / abstract / abstract criterion was the methodological process to correlate with the cross-cultural adaptation. Later performed the full reading of these articles, to identify whether the work addressed the subject of interest. After reading the 10 articles were excluded, due to a focus not favored the theme, totaling 17 articles in this review. Finally, we carried out the analysis of studies from relevant information that was compiled and analyzed with a view to suggest a methodology for carrying out cross-cultural adaptation of instruments dealing with evaluation of the quality of life. This is why we focused on the cited theoretical framework and its application in the study.

RESULTS AND DISCUSSION

After the search and selection of items, remained in reviewing a total of 17 articles. Approximately 29% of the articles were available only in English and two articles in Spanish, and the remaining 10 items available in Brazilian Portuguese and English. As already pre-determined in the selection, all articles deal about the process of cultural adaptation, highlighting all the recommended equivalence processes: semantic, cultural, idiomatic and conceptual. These types of studies provide a very detailed and crafted methodology for dealing with methodological studies and as such need to follow a very

detailed theoretical framework in order to have success in the adaptation process. Despite the need to have a very detailed theoretical framework for such studies two articles discuss not and have this framework, and only one of these outlines in its methodology the adaptation process; a third article presents the instrument adaptation process, but its methodology was marked in the model discussed with the authors of the instrument is not directly sheltering in a theoretical framework. The most widely used reference in Articles was to Guillemin *et al.*, (1993), theoretical model presented from a review, suggesting Guidelines for cross-cultural adaptation of instruments that measure the quality of life, published in 1993. Followed the Beaton (2000) of reference, which also suggests a guide to cross-cultural adaptation, which is published in 2000. In fact the two theoretical questions presented, the authors present studies as partners and collaborating with each other. Publishing Beaton6 reinforced and update some data proposed by Guillemin. These studies have (Beaton *et al.*, 2000; Guillemin *et al.*, 1993) theoretical model in order to propose to adapt through equivalences: Semantics, Idiomatic, conceptual and cultural or experimental. One of the very processes discussed is the translation.

step is to observe the understanding of the instrument in the population, it is recommended that a group of 30 to 40 persons is used, but this number may vary according to the group to be studied. Based on the model proposed by the authors Guillemin and colleagues Articles (1993) that mentions using such theoretical frameworks were analyzed in order to observe the application of the proposed method. The Table 1 shows the important information about the cross-cultural adaptation process. In all studies, followers of this method is used the term cross-cultural adaptation, respecting the pre-set steps, but along the article description remains some information that does not support the chosen model. The process of cultural adaptation, can be guided by different perspectives, one discussed by Herdman (1998) is the universal, assuming a posture that there is a conceptual difference of the instrument in different cultures and that these need to be cut and worked in order to be able to achieve the goals measurement. Guillemin and Beaton (2000) recommend that the adaptation process is obtained several translations in order to analyze the semantic and language differences. The entire process is aimed at the various equivalences which was previously discussed.

Table 1. Equivalence Steps verified on items that used the methodology of Guillemin & Beaton

Instrument	Year of Adaptation	Number Translators	Translators aware of the purpose of the study	Unification of translations	Number of translators for back translation	Translators aware of the purpose of the study in back translation	Number of members in the expert committee	Number pretest participants
QOLI-89	2008	2	Yes	Yes	2	No	*	21
AQUAREI	2006	3	*	Yes	2	*	6	23
MINICHAL	2008	2	Yes	Yes	1	No	3	20
DQOL-Brasil	2008	2	Yes	Yes	1	No	*	**
KIDSCREEN-52	2011	2	Yes	Yes	2	*	9	77
EHP-30	2008	2	Yes	Yes	1	No	**	9
HAT-Qol	2009	2	*	Yes	2	*	*	10
KDQOL-SF	2003	*	Yes	**	2	*	*	**
VEINES/QOL-Sym	2011	2	*	Yes	2	*	*	30
EORT	2009	2	Yes	Yes	1	No	No	20
KIDSCREEN-52	2009	1	*	Yes	1	No	*	*
HAT-QOL	2011	2	1	Yes	2	No	*	10
MIDAS	2016	2	2	Yes	2	No	5	20

* Performed step, but In detailed in Article

** It was not possible to infer held this step

It is proposed that this occurs in five stages. First time translation, the less must be performed by two translators, native in the language in which to adapt the instrument, but who is fluent in the same language original. The recommended is that one of these translators has been informed of the study and another is lay in this way is guaranteed a literal translation without possible bias. This obtain form two translations (T1 and T2), this needs to go through a synthesis process so there is a unification, reaching the T12 version. This synthesis process should be performed between the researchers and translators, discrepancies need to be discussed to reach a consensus on. The step three it is the "back-translation", in this process the Portuguese version is re translated into English. This process should be performed by two translators who are native speakers of the original language of the instrument, but having fluency in the language you want to adapt the instrument. After we have two English translations. The next step is to review all of these processes by an expert committee or experts. In this group should have bilingual professionals and representatives from various areas.

Finally the fifth stage that it is the pre-test, this time the instrument was modified and approved by the committee should be applied to a group of people. The purpose of this

The first step of the process after already having chosen instrument and have done a review of its concepts and objectives is the translation. In this process it is advisable that is made of at least two translators. With regard to this stage most of the studies had two translators, except in the validation of KIDSCREEN-52 (Guedes *et al.*, 2011), for the Spanish language, which was presented only a translator and KDQOL-SF (Duarte *et al.*, 2003), *thet although* there was mention that the realization of this step does not specify the number of wrapped translators. All studies followed the pattern in which the translator should be a native of the language of the instrument would be adapted and fluent in the source language. Most studies all translators knew the purpose of the study and were in the health field, with only the HAT-QOL (Holmes, *et al.*, 1998) translated by a translator considered layman, this according to the text presented in the article. According to autores (beaton *et al.*, 2000; Guillemin *et al.*, 1993) is recommended that the translator first be aware of the concepts and objectives that are being examined in the questionnaire to be translated. Its translation equivalence aims at a more clinical perspective, and may produce a clinical translation. The translator 2 should not be aware or informed of the concepts that are being quantified and preferably should not be in the health area, known as naive translator. Through this

translation is more likely to detect different meaning of the original than the first translator. This translator will be less influenced by their training and will offer a translation that reflects the language used by this population, often highlighting ambiguous or conflicting meanings. Step 2 was carried out in order to synthesis of translations, the two or more translations obtained were treated seeking equivalence between them, this process has always been held by a group of expert, that much of the time included the researchers themselves. In the adaptation of KDQOL-SF, it is unclear whether this step was performed. The next step is to re translation, all the studies carried out this process, it ensures the analysis of the translated instrument retains the sense of the original instrument, through this process many terms can be changed in order to adjust the direction of instrument (Ferraz, 1997; Herdman *et al.*, 1998).

As Table 1 five instruments only had a translator. The ideal that re translation is performed two native people from countries that have a native speaker of the original language of the instrument, but who is fluent in the language to be adapted. The two translators should not be aware of or be informed of the concepts explored, and should be, preferably, without training in health (Beaton *et al.*, 2000, Herdman *et al.*, 1998). The main reasons are to avoid information bias and extracting unexpected meanings of the questionnaire items translated increasing the likelihood of finding imperfections or idiomatic differences. Although all studies were conducted with the inclusion of step 3, only seven instruments make clear in your writing the profile of translators. As shown already it is important that they are "blind" in referring to the process and purpose of the instrument, increasing the reliability of this process (Beaton *et al.*, 2000, Herdman *et al.*, 1998). The expert committee has a unique role in this process, it is at this point that the equivalences are effectively carried out and is made further discussion regarding the true meaning of the instrument and its applicability. Only three articles showed the numbers of participants of this committee. There is no exact number but it is desirable to have a number of participants sufficient to increase such discussion (Beaton *et al.*, 2000, Herdman *et al.*, 1998). The role of the expert committee is to consolidate all the versions of the questionnaire and develop what would be considered the pre-final version of the questionnaire for field testing. The committee therefore review all translations and reach consensus on any discrepancy. Comprised of bilingual professionals in various areas such as methodology, languages and health professionals. In seven studies discussed in the text the formation of the committee but does not make clear what was the real composition in the study. The validation of the EHP-30 (Mengarda, 2008) the EORT (Sánchez *et al.*, 2009) was not determined if the committee was held. It needs to be made such a discussion in the study, that this step has an important value. The appropriate composition of the committee is essential for cross-cultural adaptation. After version be approved by the committee we have is the pre-final version. To complete this process first moves toward completion of the pre-test.

At this stage the goal is not to characterize the population to expose the results of the instrument or perform psychometric. Right now what we want is to see the applicability of the instrument in the target group and their understanding, because this way really the instrument will have its feasible adaptation. Beaton (2000) recommends using a group of 30 to 40 people, but in reality there is no established standard and not the

sample calculation is necessary. Since the goal is to actually apply the instrument to capture the perception of the questions by the participants. Nine instruments were validated using the pre-test group and this informed in the article, ranging from nine to 77 participants. The validation of the KIDSCREEN-52 (Berra, 2009) in 2009 reported that held this step but it is not clear the total participants. Validation of DQOL-Brazil (Correr, 2008) and KDQOL-SF was not informed as the pre-test was carried out, if this was done with the sample for psychometric analysis. The studies that have been exploited by Herdman (1998) and colleagues showed no uniformity in the drawings. The P-CPQ (Goursand *et al.*, 2009) called the process of translation and cultural adaptation, in which first time the instrument was translated by two translators, with only a native in the language you want to adapt the instrument, not being clear knowledge of the study.

This version was reviewed and discussed by practitioners a group of 5 and then applied to a test group of 20 patients. After this step the instrument was re translated into the native language and appreciated by a group of evaluators, professionals in the field of applicability of the study, following them to review the measure. The HRQ (Costa *et al.*, 2011) also went through a process called cross-cultural adaptation following the Herdman (1998) framework. First time was made the discussion of evaluation methods in equivalence, the next step was to search semantic equivalence in which the instrument was translated by three researchers, which is consolidated into a single version by the research group, which is re translated version for the language of origin for only a native translator in the source language, any discrepancies and discussions were held to propose the final version thus following for measurement equivalence.

Table 2. Statistical methods used to obtain psychometrics

INSTRUMENTO	TESTES ESTATÍSTICOS
HAT-QOL	Alpha cronbach, ICC*, Spearman correlation
VEINES-QOL	Alpha cronbach, ICC, Spearman correlation
QOL-AD	Alpha cronbach, Kappa, Spearman correlation
HRQL	Alpha cronbach, ICC
PFI	Alpha cronbach, ICC
P-CPQ	Alpha cronbach, ICC
KDQOL-SF	Alpha cronbach, ICC
HAT-Qol	Alpha cronbach, ICC
DQOL	Alpha cronbach, Spearman, Mann-Whitney, Kruskal-Wallis test
KIDSCREEN-52	Análise factorial, Alpha cronbach
EHP-30	Kolmogorov-Smirnov test, Alpha cronbach, Spearman correlation
MINICHAL	factor analysis, t-student, Alpha cronbach
AQUAREL	Alpha cronbach, Spearman correlation
MIDAS	Alpha cronbach, Spearman correlation, ICC, Bland-altman

* Intraclass correlation coefficient

Validation of the QOL-Ad (Novelli, 2005) instruments, VSP-A (Aires and Werneck, 2012), PFI (Boza *et al.*, 2013), although not cite the methodological support, followed steps featuring a concern to make the whole process of to reach the adapted version by following steps translations, re translations, committees, testing to the necessary equivalence, it is noteworthy that these articles bring in their authors references which recognize such a methodology, but it is not clear in the text the way you use. Herdman (1998) despite not get much in detail every step of the cross-cultural adaptation process reinforces the need to have a universal model for validation of

quality of life instruments. It is reinforced in their study the need to reach the item, semantic, operational and measurement. Guillemin (1993) indicate that there is controversy regarding the verification of the properties of the instrument measures, since the translation process is carried out and equivalence properly maintaining the psychometric instrument, but in contrast also states that the instrument is adapted considered a new instrument and need to have their assessed psychometrics. It is understood that the measurement equivalence include review of this information and is a stage to be included in process (Wild *et al.*, 2005). In the process of cultural adaptation, the EORT instruments, KIDSCREEN, QOLIE-89 (Azevedo *et al.*, 2008) and the VSP-A has been no kind of psychometric test or to assess psychometrics, so the measurement equivalence was not prioritized. As discussed above there is a current that propose that once reached the other measuring the equivalence is given by consequent. There is no consensus among studies between psychometrics to be used, what is needed is that the reliability, reproducibility and validity can be assessed for that researchers use the support of statistics. In Table 2 presents the statistical tests used to validate each instrument that inferred the use of measurement equivalence. The use of statistical tests are justified provided that they comply the items that include the assessment of equivalence. Some issues are already well established and are routinely used in these studies, for example the internal consistency being assessed by Cronbach's alpha, the reproducibility using the intraclass correlation coefficient (ICC) through inter and intra observer assessment, which is consistent with statistical K, validity assessment with factor analysis and other features that are verified by Pearson and Spearman. But as important as the choice of appropriate statistical test is applicability of the instrument properly, the appropriate population and when correct (Iandei *et al.*, 2011; Ferraz, 1997; Beaton *et al.*, 2000).

Conclusion

The cross-cultural adaptation shown a tool known and used for the instruments of quality of life. But their use needs to be thought out and conducted so as to meet the methodological aspects involved in this. Although there are well-defined in the methodological reference literature, many studies do not follow the steps proposed and can thus be committing some errors in cross-cultural adaptation. Each step needs to be duly respected and all aspects and questions need to be met. A step not performed, a non-fulfilled criterion or a process in disagreement could undermine the whole process, compromising the effectiveness of the instrument. Psychometrics is an important tool for evaluation of the new instrument now adapted to a new culture, but to proceed with the measurement equivalence process it is essential that all other equivalences have been achieved. The process of cultural adaptation needs to be properly planned; the first step is to seek in national literature there is a specific and sensitive tool for the phenomenon that want to evaluate if not, you should outline the goals you want to achieve, and discernment in choosing the instrument to be validated, the method to be used and psychometrics to be adopted for effectiveness of the process.

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