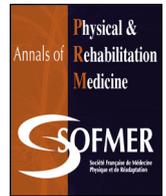




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## Review

# Cross-cultural adaptation of patient-reported outcome measures: A solution or a problem?



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Cross-cultural adaptation (CCA) is often considered a simple and easy solution to address the problem of non-availability of patient-reported outcome measures (PROMs) developed within a target culture. The demand for PROMs has been increasing because PROs are now widely recommended as primary endpoints of clinical trials testing treatment efficacy and monitoring patient improvement [1–5]. Most PROMs, which are typically in English, originated from the United States and United Kingdom for use within their health and socio-cultural contexts [6,7]. Researchers from non-English speaking regions of the world such as Europe, South America, Asia, and Africa, when faced with the unavailability of PROMs developed within their cultural context, prefer to adapt an existing instrument rather than develop a new instrument. Common underlying reasons for adapting existing instruments are:

- considerably reduced cost and faster implementation than with constructing a new instrument in a new language and the significantly reduced impediments to generalizing study results across different countries;
- the sense of security associated with an adapted instrument than a newly constructed instrument, especially when the original measure is well known and has established psychometric properties, and;
- the lack of content and methodological expertise needed for developing a new instrument in a target context [8].

However, are these reasons sufficient to justify adapting existing instruments over developing new instruments for use within different cultural contexts? To address this question, we reviewed the theoretical framework underlying CCA and identified several practical issues associated with the CCA of PROMs for use in the target culture. From this review, we provide recommendations to guide researchers wanting to adapt a PROM for use within their cultural contexts.

## 1. Theoretical framework underlying CCA methodology

CCA refers to “the process of considering any differences in an instrument between the source and the target culture so as to

maintain equivalence in both cultures” [9]. The primary aim of CCA is to establish cultural equivalence, that is, to achieve different versions of the instrument that are equivalent in each of the target countries or cultures as intended in the original measure [9,10], to ensure that the instrument is equally suitable for use in 2 or more cultures [10]. To achieve this aim, a clear theoretical framework delineating various dimensions of cultural equivalence and its determinants is necessary. Ideally, CCA methodological approaches guided by the theoretical framework of cultural equivalence would help researchers produce a culturally equivalent measure. However, use of a clearly defined theoretical framework of cultural equivalence in CCA research has been lacking [9,10].

Herdman et al. [11], based on their review of the translation and adaptation of health-related quality of life (HRQoL) questionnaires, argued that CCA researchers adopt an “absolutist” perspective of cultural equivalence as a theoretical foundation for the cultural adaptation process. The absolutist perspective assumes that health is conceived similarly across the world and culture has a minimal effect on the constructs to be measured (e.g., HRQoL, participation) and that these constructs are not culture-dependent. Researchers adopting this approach started cultural adaptation work with the initial assumption that there will be a nil or negligible change in the content organization of concepts such as participation in activities of daily living or HRQoL across source and target culture. Knowledge of 2 languages, usually English and the vernacular language, is often considered a prerequisite adequate for producing an adapted version of a PROM in the vernacular language applicable in the target context. Careful attention is paid to linguistic elements of the questionnaire. CCA methodology steps such as forward-backward translation and language experts’ review received more attention in the process of cultural adaptation. Ultimately, the absolutist approach has led to undue emphasis on establishing semantic equivalence of the instrument (i.e., transfer of meaning across languages to achieve a similar effect on respondents who speak different languages [11]) and subsequent focus on establishing psychometric properties of the instrument.

Most of the available guidelines on CCA methodological approach are based on the absolutist perspective [11], emphasizing designing translations and adaptations of existing instruments to replicate the originals as closely as possible to capture the content of the original, with all its nuances of meaning [12]. The absolutist approach to cultural adaptation is expected to produce

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results that are comparable to the original measure and maintain the measurement properties of the original (such as validity and responsiveness). A recent review identified 31 different methods of CCA used by researchers for cultural adaptation of PROMs [9]. These methodologies are predominantly expert-based; not scrutinized for their adequacy in controlling for biases such as construct bias and item bias that are prevalent in cross-cultural research [9,10,13]; and do not insist on an initial investigation of the relevance of the concepts measured by a questionnaire to the target culture [9,11]. Lack of an a priori evaluation of conceptual equivalence (i.e., investigation of which domains are important to the concept in the target culture) subverts the possibility of finding the PROM construct as conceptually not equivalent to the target culture and thereby deciding that adapting the scale might be irrelevant or unnecessary. Furthermore, methods such as the cognitive debriefing interview, which allows researchers to check for misunderstandings, incomplete concept coverage, and inconsistent interpretations, was not always used to its full potential; information on the interview focus and interviewer's expertise are often underreported in CCA studies [14–17]. Well-known CCA steps such as forward- and back-translation, involving professional translators fluent in both languages have been found inadequate [13,18,19].

Ironically, although an evaluation of conceptual equivalence is fundamental for determining the value of an instrument in the target population, it has received less attention in CCA methodology [10,11]. A notable exception to this practice was cultural adaptation of Mini Mental State Examination (MMSE) for use in largely illiterate rural older people in northern India [20]. The investigators extensively evaluated conceptual equivalence as part of the cultural adaptation, which resulted in a significant change from the original version of the MMSE [20]. For example, the concept of abstract mental arithmetic was found incomprehensible and the particular task of subtracting of 7s from 100 too difficult for the illiterate older population, so the investigators adapted the item on calculation into a simple subtraction task of counting money for the daily bus fare in the form of a story.

To address these limitations in the commonly used CCA methodology, Herdman et al. proposed that researchers adopt a universalist approach to cross-cultural research [12]. The universalist approach does not make an initial assumption that constructs will be the same across cultures. The universalist approach focuses on identifying aspects of a construct that are clearly universal across different cultures and use only those aspects for developing the instrument. Conversely, one potential outcome of adopting the universalist perspective is that an instrument is not suitable for the target culture, and thus translation and adaptation will not be worthwhile. A more useful approach to cultural adaptation would be incorporating both culture-specific and -general factors. However, few instruments have been developed and adapted for use in different cultures by using the universalist approach [21–23].

## 2. Practical issues encountered during CCA

Health constructs such as HRQoL or participation are culture-dependent, not “culture-free”. A person's conception of health and disease is subject to cultural variation. Language is central to the culture in which it is spoken, and cultural factors are often central to the language that is spoken [24]. In many regions of India, for example, language is one of the most characteristic features defining the people (e.g., Tamil, Gujarati). Thus, a “cook-book” approach to adapting an instrument for use in another culture can underestimate inherent cultural and language differences. In addition to cultural differences in constructs, differences in levels

of literacy, reading level, concordance between written and spoken versions of language and social desirability effects between cultures can introduce serious sources of error into results gathered with the target language version of the instrument [25].

Items included in the questionnaire that are important to the population for whom the scale was originally created can be of trivial importance in the culture of the new language. Patients might have difficulty relating the contents of the questionnaire to their daily life. Items that are important to patients might not have been included within the translated PROM, few included items might not be relevant [18], and few items may not carry the same meaning as intended in the original instrument when applied in the target culture [26]. For example, the items in the Nottingham Health Profile, “I feel as if I'm losing control” and “I'm feeling on edge” caused problems in many European languages because they cannot be literally translated into any items and retain its English meaning [27]. The word “season” in English, which is used in the questionnaire screening for orientation in the Mini Mental State Questionnaire, has caused some difficulty because the equivalent Hindi word can also be interpreted as meaning “weather” [20]. Likewise, in the South Indian language Malayalam [28], no similar phrase exists for “butterflies in the stomach” used in the Hospital Anxiety and Depression Scale. In the Health Assessment Questionnaire (HAQ), people are asked “if they can sit in their bathtub”. In the Thai version of the HAQ [29], the word sitting in a bath was replaced with “sitting down to pay homage to a sacred image”, because in the Thai culture, people do not use bathtubs. However, whether “sitting in a bath” and “sitting down to pray” represent the same construct is questionable. Kumar et al. (2002), in their work on developing and validating the Indian version of HAQ, reported that squatting and sitting on the floor, an important activity of daily living in the Indian context, was missing and 3 activities of daily living included in the HAQ – “Are you able to run or jog 2 miles?” “Are you able to drive a car 5 miles from your home?” and “Are you able to participate in sports and games, as you would like?” – would not be applicable to most Indians. Furthermore, scales that require patients to self-report their limitations in a written format or choose an option from 7- or 10-point response choices have limited applicability in settings with low literacy level.

Possible approaches to this problem include leaving the items out of the new questionnaire [30] or adding new items into the translated questionnaire [4]. Unfortunately, items that investigators omit may be among the most important, or most responsive, items in the original [31]. This problem is further complicated by unwillingness of the original developers of the scale to permit adding or removing items that are identified as irrelevant or not applicable in the target culture into the adapted version [28] because such changes could potentially compromise already established psychometric properties of the scale. An author of this article (SS) who performed a cultural adaptation of the Oswestry Disability Index in the Gujarati language was denied permission to remove an item on sexual function, which was identified as culturally inappropriate by both patients and experts [32].

Consequently, adapting PROMs for use in a different cultural context would likely require significant changes in the instrument contents, mode of administration (from self-reported to interviewer-administered) and format of response options. Incorporating these changes into the original version increases the probability of producing an adapted version of the scale, which might be significantly different from the original and thus compromise the validity of the original scale. To avoid such an undesired outcome, CCA researchers and the developers of the original version are often disinclined to modify, add or remove items. Instead, they emphasize the process of translation and back-

translation of the instrument and produce a linguistically rather than a culturally valid version of the original scale.

### 3. Recommendations

Test developers and CCA researchers have an obligation to ensure that the adaptation process takes full account of linguistic and cultural differences among the populations for whom adapted versions of the instrument are intended. In addition to language and cultural differences, geographical variations in weather and terrain and physical and social infrastructure such as housing structure and transportation modes available in a country can determine the suitability of an instrument to the target population. Conversely, constructs such as motor performance in older individuals is relatively universal. The extent of influence of cultural differences on such motor performance is likely minimal. Thus, cross-cultural adaptation of performance-based clinician-rated scales such as the Berg balance scale may not raise similar problems associated with adapting PROMs that measure constructs such as HRQoL and participation in daily activities.

Methodological approaches to CCA need to involve 2 key steps:

- investigating the extent to which the instrument measures the underlying concept and the parameters of latent trait in the target culture as well as it did in source culture and;
- ensuring the transfer of meaning across languages to achieve a similar effect on respondents who speak different languages.

In contrast to common perceptions (Table 1), the cultural adaptation process required for generating a culturally equivalent scale can be as challenging as developing a new scale; even strict adherence to recommended CCA guidelines might not guarantee that the new language version would be culturally equivalent to the original version and valid for use in the target countries or cultures. The standard approach recommended by Guillemin [33] and Beaton and colleagues [34] is necessary but not sufficient to achieve the cross-cultural equivalence of a PROM for use in a target culture significantly different from the source culture.

Researchers wanting to adapt an existing PROM into the language of the target population are encouraged to adhere to methodological approaches that incorporate a meticulous process involving fine-tuning item contents that accounts for the cultural context and lifestyle of the target population. The usefulness of a scale, in terms of relevance and significance of concept of measurement, domains and contents, mode of administration, and response options to the target population within the context, need to be assessed before translation and psychometric property-testing. The Herdman et al. [12] paper on a universalist approach to cultural equivalence provides a valuable guide for CCA researchers by defining 6 key types of equivalence and proposes various strategies for examining each type of equivalence. Questions listed in Table 2 could provide useful guidance for researchers planning to adapt an existing scale into another language.

From our review of the theoretical framework and contemporary practice of cultural adaptation of PROMs, we recommend the following steps as a decision guide for researchers contemplating adapting an existing measure developed elsewhere for use in their own context:

- before beginning the CCA process, investigators should discuss with the original developers of the measure whether they would agree to modify the contents (e.g., adding new items or deleting irrelevant items) from the original version of the measure. If original developers do not agree to modifying the contents even

**Table 1**

Myths and facts about cross-cultural adaptation of patient-reported outcome measures (PROMs).

Myth: the preferable strategy is always to adapt an existing PROM rather than develop a new PROM for the target language population
Fact: development and validation of a new instrument within the context of the target culture should be the preferred strategy if the prospects of the cross-cultural adaptation (CCA) process producing a culturally valid and appropriate measure are significantly limited
Myth: anyone who knows the 2 languages can produce an acceptable translation of a PROM in the target language
Fact: in addition to familiarity with 2 languages, the professionals involved in translation need to be familiar with both cultures and the measurement construct
Myth: a well-translated PROM guarantees that the instrument will be valid in a target language or culture
Fact: the meaning and relevance of items included in the PROM may not be consistent across cultures, which could limit the applicability of a scale in a target culture
Myth: constructs are universal, and therefore all PROMs can be translated into other languages and cultures
Fact: the constructs such as activities of daily living and quality of life are culture-dependent. So cultural equivalence should be evaluated before deciding to adapt the measure for use in the target culture

**Table 2**

Key questions to be addressed before beginning cross-cultural adaptation.

1. Is the construct including domains and items included in the scale similar in both the source and target culture?
2. Is the importance of behaviours associated with the construct similar in both the source and target culture?
3. Does the measurement procedure (e.g., mode of administration – interviewer vs. self-administered, response options) appropriate for application in the target culture?
4. Does the original developer of the scale agree to modify the scale according to the context of target culture?

when the context of the target culture requires it, investigators should not further proceed with adapting the scale;

- a priori translatability assessment (TA) should be considered a first step in CCA before translation [35]. The primary aim of TA is to ensure that the contents of PROMs are conceptually equivalent to the source text and culturally and linguistically appropriate in the target country. TA can be performed by conducting cognitive interviews and focus group discussions with stakeholders, including patients, clinicians and experts. A prior evaluation of conceptual equivalence can help investigators determine the value of contents of the PROMs in the target culture and the extent of changes that might be required from the original version. When such evaluation demonstrates significant limitations in applicability of the PROM, then development of a new PROM measuring the construct of interest in the target context should be the preferred choice;
- alternate approaches to back-translation such as using a group of individuals fluent in both languages, familiar with both cultures and expertise in the construct of measurement [36], a dual panel approach that involves a translational panel consisting of a team of professional translators working under an experienced bilingual coordinator and a monolingual lay panel working as a focus group in the target language [13] are recommended.

In summary, generating a culturally equivalent version of an original PROM instrument in the target culture requires:

- a comprehensive understanding of the conceptual and theoretical framework underlying the measurement construct (e.g., HRQoL, functional status);

- in-depth knowledge of intricacies of cross-cultural differences between the source and target culture and;
- knowledge of good practices of scale development. However, these principles are often overlooked during the process of translation and cultural adaptation of PROMs.

#### 4. Conclusion

CCA of PROMs often creates more problems than it solves. To avoid such a scenario, CCA researchers are encouraged to ask “Will the domains and items of the scale be relevant for the target population?” before deciding to translate and adapt the PROM in the language of the target population. If prospects of CCA producing a culturally equivalent measure are significantly limited, then the development and validation of a new instrument within the context of the target culture should be considered necessary and unavoidable.

#### Disclosure of interest

The authors declare that they have no competing interest.

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