

# Cross Cultural Adaptation of Patient Reported Outcome Measures for Use in Non-English Speaking Countries: A Narrative Review of Literature

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## Abstract:

There are demanding needs of guidelines available for researchers to adapt an existing patient reported outcome measure (PROM) or develop a new culture specific outcome measure applicable to local population. The aims of this review are to illustrate concepts and theoretical frameworks underlying cross cultural adaptation of PROMs, critically review the contemporary cross cultural adaptation methods and guidelines and recommend guidelines for researchers to assist in making decision on whether to adapt an existing measure or to develop a new tool. A systematic search using Medline database was conducted to identify all studies describing cultural equivalence, methods and guidelines of cross cultural adaptation was conducted. The findings suggested there is wide spread differences on the understanding of theoretical framework underlying cultural equivalence and recommendations of methodological guidelines for cross cultural adaptations. Based on the findings of this review we recommended a decision aid to guide clinicians and researchers from non-English speaking countries in determining the process to adapt in implementing PROMs for use in practice and research

**Keywords:** cultural equivalence, patient reported outcome measure, health outcomes, cross-cultural adaptation

## INTRODUCTION

Patient Reported Outcome Measure (PROM) is defined as 'any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else (U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research et al., 2006) There is substantial work involved in developing and validating a new PROM which is usually in the form of self reported questionnaire addressing various domains of daily activities. Creating a new questionnaire implies expenditure of time and money: first to develop the questionnaire and choose domains and items that will best explore the construct of interest and second to validate the questionnaire, ensuring that it actually measures what it is intended to measure (Epstein et al.,

2015). This is an important reason for investigators from Non-English speaking countries to adapt an existing outcome measure which is mostly in English (Bowden and Fox-Rushby, 2003; Guillemin et al., 1993). This adaptation was commonly done by designing translations and adaptations of existing PROMs to replicate the originals as closely as possible that capture the content of the original, with all its nuances of meaning.

It has commonly been assumed that this approach will produce results that are comparable to the original measure; will be most likely to maintain the measurement properties of the original (such as validity and responsiveness); and they will therefore be able to generalize across nations and legitimately aggregate data from multi-national studies (Beaton et al., 2000; Guillemin et al., 1993; Guyatt, 1993). This has

led to an emphasis on the translation of existing instruments within the functional outcome measures field, rather than the development of original instruments in different cultures (Herdman et al., 1997). As a result, many instruments developed in one language are now available in other languages. The decision regarding the need for adaptation should take into consideration how much can be gained from the cultural adaptation and how much will be lost in terms of generalization and comparability (Reichenheim and Moraes, 2007). Yet, there are no clear guidelines available for researchers delineating the circumstances when it is appropriate to adapt an existing outcome measure or develop a new culture specific outcome measure applicable to local population.

Thus, the aims of this review are to: 1. Illustrate concepts and theoretical frameworks underlying cross cultural adaptation of functional outcome measures 2. Critically review the contemporary cross cultural adaptation methods and guidelines 3. Recommend guidelines for researchers to assist in making decision on whether to adapt an existing measure or to develop a new tool.

## **METHODS**

### **Identification of studies**

We aimed to identify potentially relevant articles concerning concept and theoretical framework and methodological approaches to cultural equivalence. Articles were selected on the basis of the title, abstract and key words. We aimed to include full text articles in English that described a strategy for cross cultural adaptation (CCA) of self-reported questionnaires or a review of the guidelines used for CCA or compared methods. We screened the reference lists in articles to identify additional relevant studies, including guidelines available on line.

A systematic search using Medline database was conducted to identify all studies describing cultural equivalence, methods and guidelines of cross cultural adaptation instruments. The keywords used were: patient reported outcome(s); PRO; observational studies; guidance; guidelines; standards; cross cultural adaptation; cultural equivalence. Mesh terms used: Surveys and Questionnaires, Translations, Health Survey.

## **RESULTS**

Our search identified the 37 articles related to concepts and theoretical framework on cultural equivalence and guidelines for methodological approaches to CCA. The key findings of the results are described below.

## **Cultural equivalence: Concepts and theoretical framework**

Cultural equivalence is defined as 'the extent to which an instrument is equally suitable for use in two or more cultures'--(Stevenson and van Brakel, 2013). The concept of equivalence between cultures and languages in cross-cultural adaptation of questionnaires in the literature, however, involves different definitions and frameworks. This confusion can be partly attributed to the lack of theoretical foundations and empirical support for the methods adopted by the CCA investigators. There was no clear consensus on how different types of equivalence should be defined, or how they should be tested (Epstein et al., 2015; Herdman et al., 1997; Reichenheim and Moraes, 2007). Herdman et al., (1997) reviewed the definitions of the different types of equivalence discussed in the Health related Quality of Life (HRQOL) literature and found references to 19 different types of equivalence. Based on their review, Herdman et al., (1997) proposed a classification of the equivalences which is considered as the most comprehensive available framework for the concept of cultural equivalence --(Bowden and Fox-Rushby, 2003; Epstein et al., 2015; Stevenson and van Brakel, 2013).

### **Herdman's cultural equivalence framework**

Based on a theoretical framework drawn from cross cultural psychology (Flaherty et al., 1988; Hui and Triandis, 1985), Herdman et al., (1998) suggested that notions of equivalence that guide the CCA research paradigm depend on the view point taken: naïve, relativist, absolutist, universalist. The first, termed "naïve," is based only on a simple and informal process of translation of the original instrument. The second, termed "relativist," maintains that it is impossible to use standardized instruments in different cultural contexts and proposes that only those developed locally should be used. In this case, the notion of equivalence is not pertinent and, by extension, there is no possibility for interlocation/discussion. The third perspective, termed "absolutist," assumes that culture has a minimal impact on the constructs to be measured and that these do not change in different contexts. Methodologically, the emphasis is all on the process of translation and back-translation of the instrument. The last perspective, termed "universalist", does not assume, a priori, that the constructs are the same in different cultural contexts. Herdman et al., (1998) contended that much of the variation in CCA methods, particularly in relation to conceptual evidence, could

be attributed to the absolutist approach adopted in much cross-cultural work in the patient reported outcome measures field. The absolutist approach makes the initial assumption that there will be a nil or negligible change in the content organization of concepts such as activities of daily living or quality of life across cultures, and that careful attention to linguistic element will make a questionnaire developed for use in one culture acceptable for use in another culture (Herdman et al., 1998).

Based on the universalist approach, Herdman et al., (1998) developed a model of cultural equivalence and proposed strategies for their evaluation and suggested an order in which testing should take place. Herdman et al., (1998) recommended this model to examine equivalence between source and target language versions of an outcome measure from a universalist perspective. This model defined six types of equivalence namely conceptual, item, semantic, operational, measurement and functional equivalence (Herdman et al., 1997, 1998). They proposed that this model would address several inherent issues identified in the absolutist approach and assist in establishing cultural equivalence in the translation and adaptation process of HRQOL instruments. With a universalist approach, Herdman et al., (1997) proposed dividing equivalence into five categories, with a sixth summary category:

1. Conceptual equivalence: domains have the same relevance, meaning and importance regarding the explored concept in both cultures.
2. Item equivalence: items are as relevant and acceptable in both cultures.
3. Semantic equivalence: the meaning of the items is the same in both cultures
4. Operational equivalence: the questionnaire can be used in the same way by its target population in both cultures; for example, a self-reported questionnaire implies literacy and an online questionnaire could be more difficult to use in some areas with low internet access.
5. Measurement equivalence: no significant difference in psychometric properties (construct validity, reliability, responsiveness etc.) of the two versions
6. Functional equivalence is a summary of the preceding five equivalences: both versions of the instrument "do what they are supposed to do equally well".

CCA studies that followed even several years after

the publication of Herdman's model of framework, has not adopted it as a theoretical foundation

### **Cross cultural adaptation methods**

Historically, the adaptation of instruments developed in another culture and/or language which were usually in English limited to a simple translation from the original or literal comparison of the original with a back-translation. As Hunt et al., (1991) pointed, this approach to adapting an instrument to a different culture has major methodological shortcomings, for example, failing to distinguish between linguistic and conceptual issues and administering the questionnaire directly after translation with no retesting of validity (Mitra and Krishnan, 2015) or reliability. Guyatt (1993) argued that it reflects the cultural hegemony of the United States, where most quality of life questionnaires have been developed and it assumes, as if concerns of non-English speaking people are only relevant to the extent that they match the concerns of the American middle-class (who are the dominant population for questionnaire development and testing). Guyatt (1993) and others (Guillemin et al., 1993; Hunt et al., 1991) have identified a number of important limitations to this approach.

1. Questionnaires are likely to have weaknesses even in their original English form. These may include issues of content, duplication, ambiguity, poor wording, or suboptimal response options. Thus, deficiencies in the original questionnaire are enshrined in the translation (Guyatt, 1993).
2. There are items that either do not translate well or do not make sense within the new cultural context. A translation can involve linguistic problems because two languages can have non-equivalent words or idiomatic expressions. For example, The items, 'I feel as if I'm losing control' and 'I'm feeling on edge' caused problems in many European languages since it cannot be literally translated into any and retain its English meaning (Hunt et al., 1991). The word "season" in English, which is used in the question screening for orientation in Mini Mental State Questionnaire, has caused some difficulty because the equivalent Hindi word can also interpreted as meaning 'weather' (Ganguli et al., 1995); no similar phrase existed in the South Indian language Malayalam (Thomas et al., 2005), for the phrase 'butterflies in the stomach' used in the hospital anxiety and depression scale.
3. The adaptation itself in another culture can be the problem because one item can be less relevant or

not relevant at all in a specific cultural background. For example, in the Health Assessment Questionnaire (HAQ), people are asked if they can sit in their bathtub. For the Thai version of the HAQ (Osiri et al., 2001), the action of sitting in a bath replaced with sitting down to pay homage to a sacred image, because in the Thai culture, people do not use bathtubs.

4. Items that are important for the population for whom the questionnaire was originally created can be of trivial importance in the culture of the new language. Inclusion of such items in the new questionnaire is inefficient. Similarly, crucial items for the new culture may be absent in the original questionnaire. 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 ADL in Indian context was missing and three ADL included in HAQ (i) Are you able to run or jog 2 miles? (ii) Are you able to drive a car 5 miles from your home? (iii) Are you able to participate in sports and games, as you would like? would not be applicable to most Indians. Possible approaches to this problem include leaving the items out of the new questionnaire (Kumar et al., 2002), and/ or adding new items into the translated questionnaire (Kumar et al., 2002). Unfortunately, those items that investigators omit may be among the most important, or most responsive, items in the original

(Guyatt, 1993). This problem is often further complicated by unwillingness of the original developers of the scale to permit for adding or removing items that are identified as irrelevant or not applicable in the target culture into the adapted version. For example, though the investigators found that the patients in the target population (Malayalam speaking Indians) could not relate to the phrase 'butterflies in the stomach', it was included in the Malayalam version of the hospital anxiety and depression scale, because the copyright owners insisted it to be retained as it is (Thomas et al., 2005). Researchers working in different fields have been suggesting that semantic evaluation constitutes only one of the steps needed for CCA (Badia and Alonso, 1995; Bucquet et al., 1990; Guillemin et al., 1993; Hunt et al., 1991). They have recommended that this process should be a combination of a literal translation of words and sentences from one language to another and a meticulous process of fine-tuning that takes into consideration the cultural context and lifestyle of the target population of the translation. Thus an alternative approach addressing these limitations was recommended.

#### Development of Cross Cultural Adaptation Guidelines

The term “cross-cultural adaptation” is used to encompass a process that looks at both language (translation) and cultural adaptation issues in the

**Table 1. Possible Scenarios Where Some Form of Cross-Cultural Adaptation is Required**

Wanting to use a questionnaire in a new population described as follows:	Results in a Change in . . .		Adaptation Required		
	Culture	Language	Country of Use	Translation	Cultural Adaptation
1. Use in same population. No change in culture, language, or country from source	—	—	—	—	—
2. Use in established immigrants in source country	✓	—	—	—	✓
3. Use in other country, same language	✓	—	✓	—	✓
4. Use in new immigrants, not English-speaking, but in same source country	✓	✓	—	✓	✓
5. Use in another country and another language	✓	✓	✓	✓	✓
Adapted from Guillemin et al.(1998)					



process of preparing a questionnaire for use in another setting. To successfully address limitations inherent in use of outcome measures in cultures different from its origin, CCA investigators (Guillemin et al., 1993; Guyatt, 1993; Herdman et al., 1997; Hunt et al., 1991) have recommended for a systematic approach to the translation and cross-cultural adaptation process of self reported functional outcome measures. As a consequence, there is a burgeoning literature on guidelines to improve the quality of the translation process, as well as some discussion of how to gain and assess the 'equivalence' of questionnaires in different languages. CCA methodological guidelines proposed by Guillemin et al., (1993) is the commonly adopted methods in most studies and systematic reviews on CCA of outcome measures (Epstein et al., 2015). Guillemin et al., (1993) suggested five different examples of when attention should be paid to this adaptation by comparing the target (where it is going to be used) and source (where it was developed) language and culture (table 1). The first scenario is that it is to be used in the same language and culture in which it was developed. No adaptation is necessary. The last scenario is the opposite extreme, the application of a questionnaire in a different culture, language and country. For example, adapting the Mini Mental State Examination (a global cognitive screening tool) which was developed from the United States (source) to India (target) (Ganguli et al., 1995) which would necessitate translation and cultural adaptation. The other scenarios are summarized in Table 1 and reflect situations when some translation and/or adaptation are needed.

Guillemin et al., (1993) proposed a set of standardized guidelines for the cross-cultural adaptation of HRQOL measures based on the review of previous research in psychology and sociology and on published methodological frameworks for HRQOL validity. The guidelines is a five step process which include initial translation, synthesis, back translation, expert committee review, and pilot testing of the draft translation (Guillemin et al., 1993). The process is designed to achieve equivalence between the original and translated versions with respect to language (semantic and idiomatic equivalence) and culture (experiential and conceptual equivalence) (Beaton et al., 2000; Guillemin et al., 1993). The recent update on the guideline included appraisal of the adaptation process by the developers or coordinating committee

and psychometric evaluation as an additional step in CCA process (Beaton et al., 2000).

## DISCUSSION

The CCA research is still largely characterized by the lack of theoretical foundation and empirical testing of its methods. Most works are based on researcher's personal views and practical experience. This view is supported by the results of a systematic review (Bowden and Fox-Rushby, 2003) of the process of translation and adaptation of generic health-related quality of life measures in Africa, Asia, Eastern Europe, the Middle East, South America had came to similar conclusions. Bowden and Fox-Rushby, (2003) shown that majority of the research in this field either implicitly or explicitly adopts an "absolutist" conception of health. Too much emphasis is being placed on establishing the psychometric properties of an adapted instrument and evaluation of conceptual equivalence is often ignored. Bowden and Fox-Rushby, (2003) pointed out that developers and those translating and adapting instruments rarely draw on theoretical positioning in this research or question the nature of their own beliefs—both of which affect interpretations of whether instruments in source and target languages are considered conceptually equivalent. They concluded that “there is a misguided pre-occupation with scales rather than the concepts being scaled and too much reliance on unsubstantiated claims of conceptual equivalence”. However, they pointed out that the processes involved in developing and testing of the cross cultural adaptation of The World Health Organization Quality of Life (WHOQOL) scale have more rigorously evaluated equivalence, which is more likely to establish reliable conclusions concerning the equivalence of their instrument across countries.

Though there is a consensus among researchers that in order for the cross-cultural comparison of results to be valid, it is necessary to be able to show equivalence of the same questionnaire between source and target culture, there are wide differences in the methods adopted by various researchers. A recent review by Epstein et al., (2015), identified 31 different cross-cultural adaptation methods. These methods of cross-cultural adaptation differ by their main focus (technical translation, focus groups, concepts etc.), but there is a lack evidence of the superiority of one method over another (Epstein et al., 2015). The differences in CCA methods were characterized by the stage at which equivalence was addressed.

### **Stage 1: Equivalence addressed before CCA process**

Some authors proposed to develop questionnaires with items relevant for different cultures at the same time (Anderson et al., 1996; EuroQol Group, 1990; Landgraf and Nelson, 1992; "Study protocol for the World Health Organization project to develop a Quality of Life assessment instrument (WHOQOL)," 1993). The simultaneous development of instruments in different cultures could, at least in theory, give equal weight to the norms and values of the different cultures involved, though the extent to which this happens will depend to a large degree on the way in which constructs are elaborated and items chosen. This approach, however, is uncommon as this could be very expensive and labor intensive work. One of the few examples was the method used to develop in the World Health Organization Quality of Life (WHOQOL) questionnaire. In the WHOQOL, focus groups that were demographically representative of the target population were used to generate and evaluate relevant aspects and domains of the concept HRQL. After reaching consensus on cross-culturally relevant domains of quality of life, working groups from each participating country explicated the operational definition of the components to formulate culturally relevant questions. An iterative translation process was used involving forwards and backwards translation, and review by monolingual and bilingual groups to ensure semantic, conceptual and technical equivalence. It has been tested in approximately 4500 individuals from 15 different centres worldwide. ("The World Health Organization Quality of Life Assessment (WHOQOL)," 1998, "The World Health Organization Quality of Life assessment (WHOQOL)," 1995).

### **Stage 2: Equivalence addressed before translation process**

Guyatt, (1993) and Herdman et al., (1998) recommended that potential conceptual equivalence should be evaluated before beginning adaptation. Herdman et al., (1998) contended it as important because it requires that those wishing to adapt an existing questionnaire take explicit account of the cultural factors which may make adaptation invalid. Conceptual equivalence is essential because concepts, such as participation and disability, may differ across cultures. For that reason evaluating the target populations' conceptualization of the construct is important, before the assessment of the suitability of the instrument in the local cultural context. Methods suggested for evaluating conceptual equivalence are: 1.

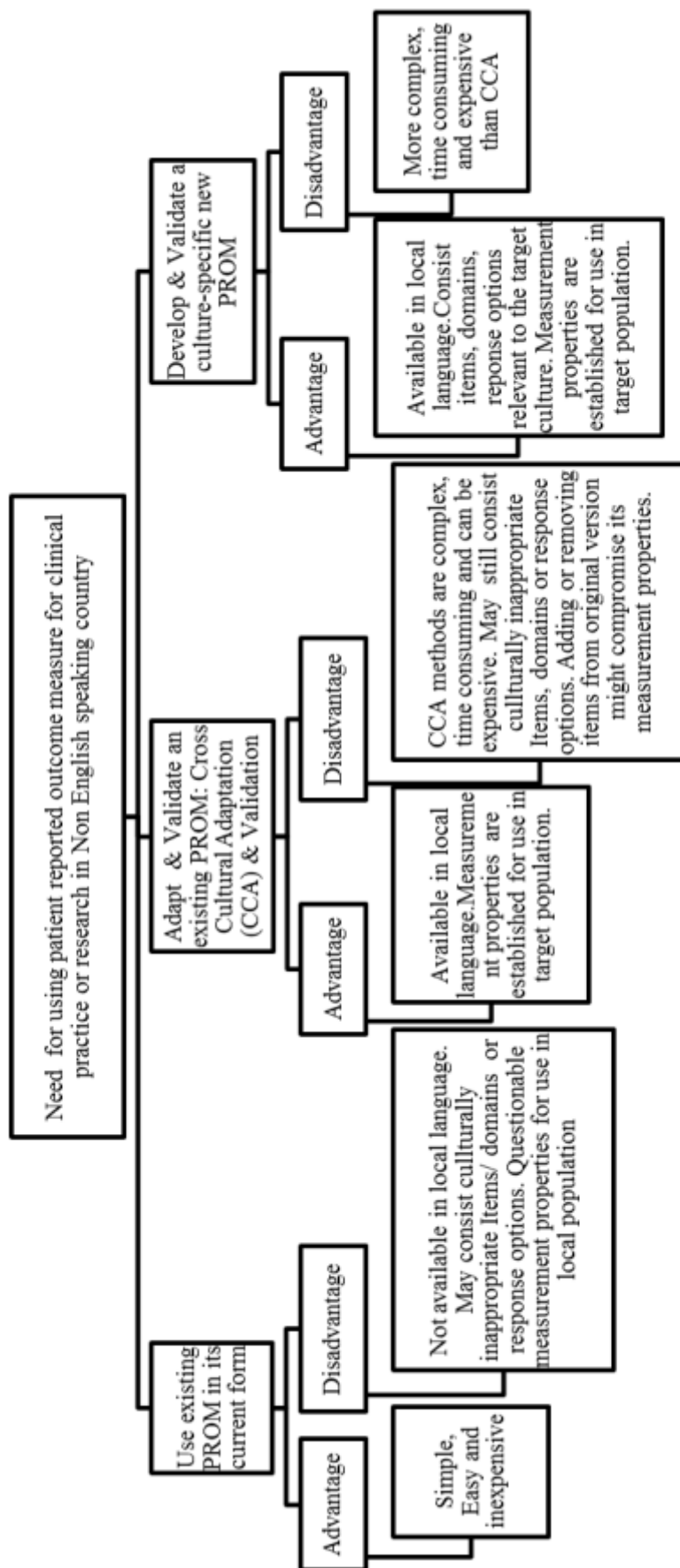
Literature review concerning the theoretical and empirical explorations of the concept and nature of construct (ADL or HRQoL) in the source culture and reviews of instrument development (Herdman et al., 1998) 2. Consultation with broad range of professionals and experts in the target culture including, for example, anthropologists, medical sociologists, linguists, QoL experts, and health professionals (Herdman et al., 1998) 3. Focus group discussions and qualitative interviews which involve a wider representation of the general population in an investigation of beliefs and behaviors regarding health daily activities and QoL (Guyatt, 1993; Herdman et al., 1998) and cognitive debriefing interviews with potential participants from target culture (Beaton et al., 2000; Guillemin et al., 1993) overlook this process --(Bowden and Fox-Rushby, 2003; Stevelink and van Brakel, 2013).

### **Stage 3: Equivalence addressed during the CCA process, once a translation has been started**

Most guidelines address this case (Epstein et al., 2015). In some of these guidelines, the first step of considering the possibility of conceptual equivalence is implicit but is not described (Epstein et al., 2015). The guideline proposed by Guillemin et al., (1993), the commonly adopted method in most CCA studies (Epstein et al., 2015), which do not perform any initial investigation of cultural equivalence is a good example. In this guideline, Guillemin et al., (1993) recommended evaluation of equivalence as final step in CCA process. This evaluation is usually done by consultation with expert committee comprising methodologists, health professionals, language professionals, and the translators (forward and back translators) involved in the process during earlier stage of adaptation and interviews with potential participants (patients) from the target setting. The major drawback of this approach is it will be very difficult to know how conceptually appropriate a given questionnaire will be for use in the target culture without some degree of qualitative work to establish a working idea of what the concept means in the target culture (Herdman et al., 1998). Sufficient information on conceptual equivalence at an early stage of the validation process will prevent problems in operationalization and measurement at a later stage (Stevelink and van Brakel, 2013). This will help to justify the use of the instrument in a different culture than it was initially developed for.

Patient reported outcome measures cannot be considered culture-free. (Ganguli et al., 1995) Based on

Figure 1 Decision aid for clinicians and researchers from non English speaking countries for including patient reported outcome measure in practice and research



### Decision 1

Do not use the existing PROM in its current form without translating in local language and evaluating for cultural equivalence in the local culture

### Decision 2

Adapt & validate an existing PROM in target population, when

- Evaluation of conceptual equivalence of the original version demonstrated majority of items or domains and the response option is culturally relevant to the local culture
- Adapted version demonstrated acceptable measurement properties

### Decision 3

Develop & Validate a New culture specific PROM, when

- Evaluation of conceptual equivalence of the original version demonstrated majority of items or domains and the response option is culturally *not relevant* to the local culture.
- When adequate resources including expertise, time and funds are available for undergoing the extensive process involved



this review we suggest that for CCA methods to produce valid results, evaluation of conceptual equivalence of the construct within the target cultures with active involvement of patients through interviews or focus groups is essential. One possible outcome of the conceptual evaluation process could be that the construct or the domains of the PROM is different in from source culture. In that case, the questionnaire should not be considered for adaptation. Either adaptation of another instrument should be considered or a new culture-specific questionnaire should be developed. Although the inclusion of this stage may make the adaptation process lengthier, it ensures that adapted versions are likely to be relevant to the target population. Based on the findings of this review, we have developed a decision aid (figure 1) to guide clinicians and researchers from non-English speaking countries in determining the process to adapt in implementing PROMs for use in practice and research.

## CONCLUSION

The differences in the outcomes valued by patients from Non-English speaking countries compared to English speaking countries are not only limited to the linguistic features of the language spoken by its people but also imbibed in differences in cultural norms, customs, values of the people, which varies across countries. Investigators from non-English speaking countries are encouraged to first evaluate and establish the conceptual equivalence of the construct measured by the instrument before initialing translation of its contents.

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