



# Difficulties with the application of PRO measures to cultures outside of Western Europe and North America in multi-national trials

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## Objectives:

The majority of PRO measures have been and continue to be developed using a sequential rather than a cross-cultural approach and have been developed in the US or UK. When selecting these measures in multi-national trials, the assumption is made that the translated measure is acceptable for use in a multi-national trial, providing the translation has been conducted in a rigorous manner and that linguistic validation interviews have been conducted in the target country. The objective of this study was to ascertain whether there are particular areas of concern with respect to using these PROs outside of North America and Western Europe.

## Methods:

Specialists in outcomes research from nine countries within Eastern Europe, Asia and Africa completed a questionnaire and interview about

difficulties which occur with the cultural relevance of concepts included in PROs and other health questionnaires.

## Results:

Numerous cultural and linguistic issues became apparent, including the following:

## Conclusions:

A number of issues should be considered during the sequential development of PRO measures. This can be achieved using an extended translatability check which would include representatives from countries outside of North America and Western Europe to help bridge the gap between the cultural specificity of a sequentially developed measure and a cross-culturally developed measure.

Affected Cultures/Languages	Translation issues
African Tribal languages (e.g. Xhosa, Sesotho)	The concept of witchcraft is particularly important in many places in Africa - for example, the idea that illnesses might be caused by a spell or witchcraft. It is also believed that health problems can be caused by jealousy. Therefore this may affect patients' opinions regarding their condition or their attitude towards medications and patient satisfaction. In such countries questions relating to witchcraft or the "evil eye" would therefore give a more accurate view of quality of life than some of the other questions
Japan	Japanese people often have a tendency to be more positive about their disease or emotional health which may affect their responses to measures.
Saudi Arabia, Sudan, and other Islamic countries.	The concept of 'God's will' is extremely important in the way people view their health, and may affect subjective assessment about the concepts included in many PROs
Malaysia, Ukraine, Singapore and Japan	The concept of family is much more important in some places e.g. Malaysia, Singapore, Japan and Ukraine than in the US and the UK, and therefore questions asking about whether health impacts family visits (whether this involves leaving the house or visits at home) may have a different emphasis than in the UK or US. This may also affect the way people think about caring for or helping their family when they are experiencing health problems, which would affect their results in caregiver rated-scales, particularly as in Malaysia and Japan, where family are more likely to care for other sick family-members than to call in a professional carer.
African countries, Islamic countries, some parts of Singapore and Malaysia	Some taboo issues such as alcohol and sex, particularly with older generations.
Saudi Arabia and Sudan	People of both genders in these cultures commonly pray five times a day, which may have an effect on responses to some items related to routine and activities of daily living. In Saudi Arabia it is also illegal for women to drive, which might affect responses regarding daily activities.
Russia	In general, Russia does not have technical disability equipment in public places, and therefore no terminology for the items included in some disability index questionnaires. This may also affect the items on PROs that are applicable to disabled patients (for example, they may not be able to run errands outside the house with as much as ease as a disabled person in the UK or US).
Singapore (Chinese cultures)	There's a problem in discussing death with the Chinese cultures in Singapore in that people prefer not to talk about the possibility of death. Therefore methodologies such as time-trade-off (TTO) or standard gamble interviews can be problematic, and people may not answer items based on death or life expectancy.
Saudi Arabia, Sudan, Japan, China	Problems with things related to mealtimes and routine which are commonly used in PROs – for example, in Saudi Arabia and Sudan people tend not to have regular meals but to eat throughout the day. Also some cultures do not use knives and forks to eat, which may impact their responses to questions regarding routine and ability to use eating implements in this way. This is also known to be a problem in India, although India was not included in this study.