The Translation and Linguistic Validation of the Neuropathy Total Symptom Score-6 Self-assessed Version (NTSS-6 SA)

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Objectives:

The NTSS-6 SA is a six item PRO questionnaire, which has been designed to assess the severity of peripheral neuropathy symptoms. The objective of this study was to produce translations that are conceptually equivalent to the original and to other language versions, ensuring the relevance of the translations within the target cultures.

Methods:

A standard methodology was employed: 2 forward translations, a reconciliation of the forward translations, 2 back translations, back translation review; or an in-country review; linguistic validation interviews with 5 patients in each country with diabetic peripheral neuropathy, varying in gender, age and educational levels, and 2 proofreadings.

Results:

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

Source text	Affected languages	Translation issues
1 a. <u>During the last 4 weeks</u>, how often have you experienced symptoms such as a ***deep aching, tightness, boring, pulling, or squeezing pain*** in your feet or legs? ***5. a. <u>During the last 4 weeks</u>***, how often have you experienced a ***sharp, stabbing, shooting, or electric shock-like pain***, in your feet or legs?	Numerous, particularly Indian and Asian, Chinese for Singapore, Belgian Dutch etc	Many different pain types are described in the questionnaire (e.g. stabbing, shooting, electric-shock like, boring, aching) which were particularly difficult as some languages did not have the required extensive vocabulary. A decision was made to assign the pain types into two groups, firstly dull, aching pains as in item 1, and secondly sharper, stabbing pains as in item 5. These could then be more easily conveyed and translated. For example Gujarati used the word 'abrupt' as an idiomatic and understandable representation of the pain types in item 5.
1 a 'boring' pain	English for Singapore, English for Canada, UK English, French for Belgium	The word 'boring' pain was not well known, so was replaced by 'penetrating' as the closest alternative in several languages.
3. a. <u>During the last four weeks</u>, how often have you experienced a ***"prickling"*** or ***"tingling"*** feeling in your feet or legs?	Numerous, particularly Indian and Asian	For many countries, there was no direct translation for 'prickling', or no way to distinguish this from 'tingling' in item 3. If the country had no lexical item for this sensation, 'feeling as if ants crawl on the skin' was used, which is particularly idiomatic in Indian languages.
4. a. <u>During the last 4 weeks</u>, how often have you experienced an ***asleep feeling, numbness, or loss of sensation,*** but ***<u>without</u>*** a prickling feeling in your feet or legs?	Polish, Russian, Mandarin for Singapore, Kannada	Some languages were unable to convey 'asleep feeling' in a limb; this wording was therefore converted to a synonym or removed because the target language had only one word for the sensation.
6. a. <u>During the last four weeks</u>, how often have you experienced unusual sensitivity or tenderness ***when your feet are touched or when you walk?***	Kannada; French for Belgium	No specific word existed for 'tenderness' that would be well understood, so 'pain even when you touch' was used as the closest alternative for both languages
All instructions and items asking about feet	Malay, some Indian languages, Urdu	Many of the countries involved have no specific word for 'feet', so if necessary 'from ankle to toes' was used.

Conclusions:

The NTSS-6 SA has been translated and linguistically validated using a rigorous translation process, and is suitable for use in the 24 languages in this project. A number of cultural and linguistic issues became apparent and were resolved through the back translation review and validation steps of the project. The patient interviews were found to be particularly important in the resolution of these situations, and furthermore consultation of a clinician on specific items was invaluable in finding accurate and well-known solutions.

The measure is now appropriate for use in multinational trials and conceptually comparable with other language versions which may be in existence worldwide.

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