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International Adaptation and Linguistic Validation of the Hypoparathyroidism Daily Diary of Symptom Experience (HPT-DD-SE) and the Hypoparathyroidism Life Impact Questionnaire (HPT-LIQ)

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BACKGROUND

- Hypoparathyroidism (HPT) is a rare endocrine condition characterised by hypocalcaemia resulting in neuromuscular, neurological, and cardiovascular issues that can range in intensity and impede patients' ability to function in their everyday lives.[1-5]
- The Hypoparathyroidism Daily Diary of Symptom Experience (HPT-DD-SE) and Hypoparathyroidism Life Impact Questionnaire (HPT-LIQ) are new, disease-specific, patient-reported outcome (PRO) measures designed to assess the effect of an investigational treatment on symptoms and health-related quality of life in patients with HPT.[6]
- The HPT-DD-SE and HPT-LIQ were developed in United States (US) English based on qualitative work conducted with patients with HPT in the US.[6]

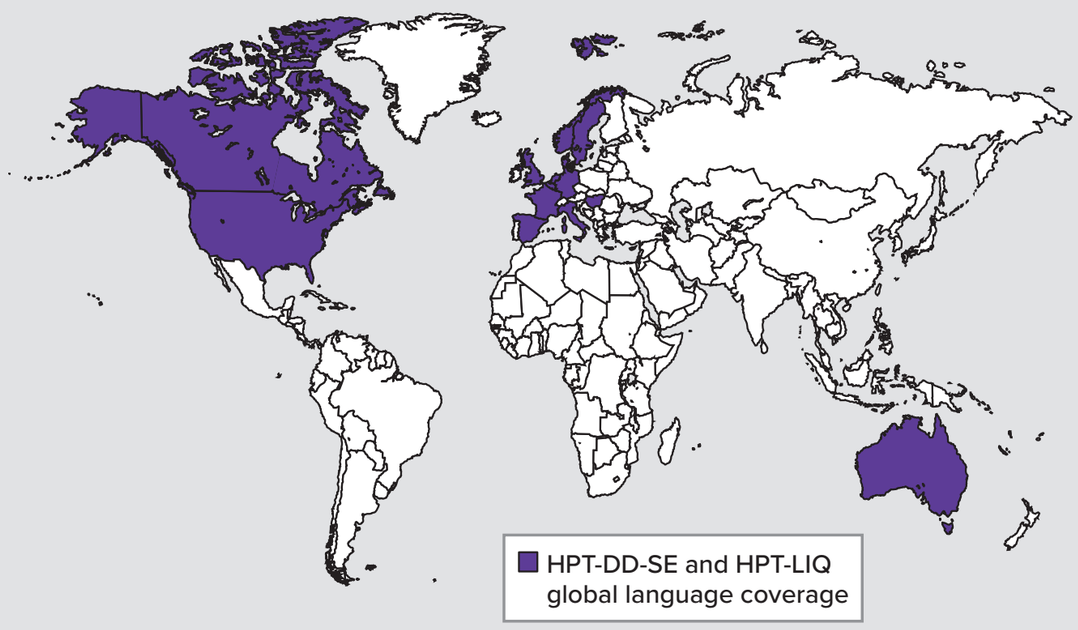
OBJECTIVE

- To linguistically adapt the US English HPT-DD-SE and HPT-LIQ for use in 16 additional languages across 14 countries.

METHODS

- The target languages for the adaptation of the HPT-DD-SE and HPT-LIQ are presented in Figure 1.

Figure 1. Global Language Coverage of the HPT-DD-SE and HPT-LIQ

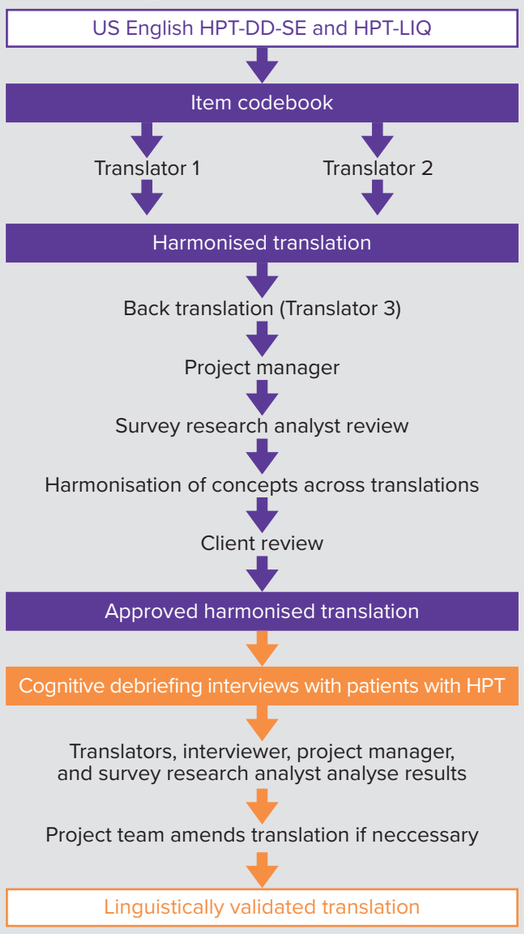


Australia (English)	France (French)	Spain (Spanish)
Belgium (Dutch)	Germany (German)	Sweden (Swedish)
Belgium (French)	Hungary (Hungarian)	United Kingdom (English)
Canada (English)	Italy (Italian)	US (Spanish)
Canada (French)	Netherlands (Dutch)	
Denmark (Danish)	Norway (Norwegian)	

Linguistic Adaptation Process

- The adaptation process (Figure 2) of the HPT-DD-SE and HPT-LIQ adhered to published ISPOR and Food and Drug Administration (FDA) guidelines requirements for PRO measures to support labelling claims.[7-8]•

Figure 2. Overview of the Linguistic Adaptation Process



Translation

- All translations were produced from the US English source language versions of the HPT-DD-SE and HPT-LIQ.
- Translations were facilitated by an item codebook. The codebook provided a detailed description of the content of the HPT-DD-SE and the HPT-LIQ, including the conceptual meaning of each item, instructions, and response scales. The item codebook helped ensure standardisation across all new languages.

Cognitive Debriefing

- In-country cognitive debriefing (CD) interviews were conducted with 5 patients with HPT in each target language to determine the face and content validity of each respective new-language version of the HPT-DD-SE and HPT-LIQ. Interview data were also used to confirm conceptual equivalence between the new language versions and the US-source language versions of the measures.
- Changes were made to the new language versions if significant comprehension issues or linguistic concerns arose, and if revisions could be made without deviating from the conceptual meaning of the original US English HPT-DD-SE and HPT-LIQ.

Patient Advocacy Group Feedback

- The final translations for selected languages of the HPT-DD-SE and HPT-LIQ also underwent a brief review by a convenience sample of representatives from country-specific HPT patient advocacy groups (PAGs). Specifically, PAG representatives in Italy, Spain, and the United Kingdom (UK) reviewed their respective country translations.
- The PAG review focused on the acceptability and appropriateness of the content and wording of the questionnaires for the respective languages.

RESULTS

Translation

- The HPT-DD-SE and HPT-LIQ were successfully translated into 16 languages for 14 countries in Europe, North America, and Australia.
- Minor changes were made to the harmonised translations prior to the CD interviews to ensure conceptual equivalence with the US English source HPT-DD-SE and HPT-LIQ.

Cognitive Debriefing Sample

- A total of 80 patients participated in the CD interviews (Table 1).
- A majority of the sample (57/80; 71%) was female. This is comparative with the female-to-male ratio of the patient samples used for the development of the HPT-DD-SE and HPT-LIQ[6] and with the gender ratio reported for HPT patient populations.[9]
- The age range for the total CD sample was 21-79 years with mean ages ranging from 36.5 years (Australia [English]) to 62.5 years (Norway [Norwegian]).
- The range in years in education for the total CD sample was 6-21 years with mean years ranging from 10.4 years (Germany [German]) to 16.6 years (Hungary [Hungarian]).

Cognitive Debriefing Findings

- Following the CD interviews, minor changes were made to the new language translations, as required, to improve grammar or to ensure that wording reflected common, everyday language for greater conceptual clarity and to enhance comprehensibility of the measures (Table 2).
- The CD results demonstrate that patients in the target countries found the HPT-DD-SE and HPT-LIQ to be clear, comprehensive, and understandable.

Table 1. In-Country Cognitive Debriefing Interview Sample Characteristics

Target country (language)	Gender, (n)	Age, mean (SD); range, years
Australia (English)	0M, 5F	36.5 (8.9), 29-46
Belgium (Dutch)	1M, 4F	46.7 (17.8), 25-69
Belgium (French)	2M, 3F	40.7 (19.8), 22-67
Canada (English)	2M, 3F	48.5 (8.4), 40-60
Canada (French)	1M, 4F	58.5 (8.4), 46-75
Denmark (Danish)	2M, 3F	54.5 (8.9), 40-56
France (French)	2M, 3F	46.5 (5.5), 40-53
Germany (German)	2M, 3F	46.5 (16.7), 28-72
Hungary (Hungarian)	0M, 5F	38.5 (8.4), 28-47
Italy (Italian)	2M, 3F	46.7 (19.2), 21-72
Netherlands (Dutch)	2M, 3F	48.7 (23.6), 23-79
Norway (Norwegian)	2M, 3F	62.5 (13.0), 49-76
Spain (Spanish)	2M, 3F	50.5 (15.8), 28-67
Sweden (Swedish)	1M, 4F	56.5 (15.2), 44-78
United Kingdom (English)	0M, 5F	40.7 (11.8), 23-53
United States (Spanish)	2M, 3F	46.5 (22.7), 22-72

F = female; M = male; SD = standard deviation.

Table 2. Example Revisions to Target Language Versions Following Cognitive Debriefing

Country (language)	Section	Revision
France (French) 	HPT-DD-SE item stem (items 1-3, 7-15)	• "évaluer la sévérité" changed to "évaluer l'intensité" to increase conceptual equivalence — Patients reported that "sévérité" can convey seriousness or danger and suggested that "intensité" more appropriately described the strength of the symptom.
France (French) 	HPT-LIQ response options	• Instances of "Grandes difficultés" changed to "Difficultés importantes" to improve cultural appropriateness — Patients reported that "grand" was not commonly used in health questionnaires and that the language was too colloquial. Patients suggested including "important" instead.
Italy (Italian)	HPT-LIQ relationships and social life item stem	• "Negli ultimi 7 giorni, che impatto ha avuto l'ipoparatiroidismo su" changed to "Negli ultimi 7 giorni, che impatto ha avuto l'ipoparatiroidismo" for grammatical clarity — Patients reported that the sentence construction was incorrect because the subsequent questions were a continuation of the item stem.
Belgium (Dutch)	HPT-LIQ emotional and psychological impact instructions	•"...wat u over uzelf denkt" changed to "...over uzelf denkt" to improve cultural appropriateness — Patients reported that "wat u over uzelf denkt" was confrontational and potentially stigmatising.

Patient Advocacy Group Feedback

The PAGs in Italy, the UK, and Spain described the new-language versions of the HPT-DD-SE and HPT-LIQ as comprehensive, easy to understand, and appropriate. No changes were made to the new Italian (Italy), English (UK), or Spanish (Spain) new language versions of the HPT-DD-SE or HPT-LIQ following this review.

CONCLUSIONS

- The HPT-DD-SE and HPT-LIQ were successfully adapted into 16 new languages (14 countries) according to regulatory and industry standards.
- The new language adaptations of the measures significantly improve their suitability for use in multinational clinical trials.

ACKNOWLEDGEMENTS

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