OBJECTIVE

To assess and establish the linguistic validity of 13 versions of the Lupus Quality of Life (LupusQoL) Questionnaire into 13 languages.

BACKGROUND

Patients with Systemic Lupus Erythematosus (SLE) have shown improved survival over recent years, along with an increased focus on the evaluation of health-related quality of life (HRQoL). The LupusQoL Questionnaire was developed to reflect the experiences of SLE patients throughout the course of their illness and to provide a tool to assess this measure; however, the LupusQoL is the only disease-specific HRQoL instrument currently validated in 11 languages.

LINGUISTIC VALIDATION

Validation of questionnaires is important to confirm that a Patient-Reported Outcome (PRO) questionnaire is acceptable to the intended cultural-subgroup for which the questionnaire is intended. Without this, the questionnaire may not be interpretable or meaningful in the intended language or country, and in country, language, the questionnaire may not be valid. Once the translation has been completed, a back-translation is performed to check for conceptual equivalence and clarity. Linguistic validation is a process that is conducted to confirm that a PRO questionnaire is acceptable to the intended cultural-subgroup for which the questionnaire is intended.

METHODS

To evaluate the linguistic validity of 13 versions of the LupusQoL, a linguistic validation study was completed. Three versions of the LupusQoL were used: English (US/Canada), Spanish (Argentina/Chile, Mexico, US/Canada), and Swedish (Sweden). Language and English) interviewers cognitively debriefed subjects to assess their ability to paraphrase and understand the instructions, questions and responses within each translation.

All items had a comprehension rate of greater than 91.8%, while most had 100%.

All countries had at least a 98.1% rate.

45% of the subjects were male; 55% were female.

CONCLUSIONS

The final version of the LupusQoL consists of eight domains:

- Pain (3 items)
- Intimate relationships (2 items)
- Emotional health (6 items)
- Physical function (1 item)
- Satisfaction (1 item)
- Employment (1 item)
- Financial resources (1 item)
- Life satisfaction (1 item)

These domains reflect the major areas of illness-related concerns experienced by SLE patients. A total of 600 outpatients participated in this study, with varying demographic and educational backgrounds, to check for conceptual equivalence and clarity.

The results of the debriefings were compared on the basis of comprehension and number of suggested changes. Language, Country ICR Comprehension Issue Change made (if any)

- Chinese Taiwan 99.3% Not Applicable (2)
- English US/Canada 98.5% SLE (2) Change made from “LES” to “Lupus Eritematoso Despertado”
- French Belgium/France, Canada 97.6% Not applicable (1)
- Greek Greece 97.1% Not applicable (1)
- Hungarian Hungary 98% Not applicable (1)
- Italian Italy 98% Not applicable (1)
- Portuguese Brazil 98.5% SLE (2) Change made from “non pertinente” to “non appropriate”
- Spanish Argentina/Chile 98.1% Most of the time (1) Change made from “durante el tiempo que SGE me afecta, soy incapaz de…” to “durante el tiempo en que SGE me afecta, soy incapaz de…”
- Spanish US/Canada 98.6% Sometimes (3) Change made from “debido al Lupus, soy incapaz…” to “debido a SLE, soy incapaz…”
- Swedish Sweden 97.3% Not applicable (1)

CONCLUSION

The translation of the questionnaire into each of the 13 languages validated the construct and content validity of the LupusQoL and its ability to capture the experiences of SLE patients. A total of 600 outpatients participated in this study, with varying demographic and educational backgrounds, to check for conceptual equivalence and clarity. Over time; often used by physicians to measure the effects of chronic illness in their patients to better understand how an illness interferes with a person’s day-to-day life. [9]

Linguistic Validation of the Lupus Quality of Life (LupusQoL) Questionnaire into 13 Languages

Mary C. Gawlicki, MBA; Melissa Linda, BA; Shawna McKown, MA

Corporate Translations, Inc.

Driven by Definition

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Table 3: Item Comprehension Rates

<table>
<thead>
<tr>
<th>Language/Country</th>
<th>ICR</th>
<th>Comprehension Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chinese Taiwan</td>
<td>99.3</td>
<td>Not Applicable (2)</td>
</tr>
<tr>
<td>English US/Canada</td>
<td>98.5</td>
<td>SLE (2)</td>
</tr>
<tr>
<td>French Belgium/France, Canada</td>
<td>97.6</td>
<td>Not applicable (1)</td>
</tr>
<tr>
<td>Greek</td>
<td>97.1</td>
<td>Not applicable (1)</td>
</tr>
<tr>
<td>Hungarian</td>
<td>98%</td>
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</tr>
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</tr>
</tbody>
</table>

Terms and phrases with comprehension rates lower than 100% across languages for the LupusQoL were as follows:

- “Because of my Lupus I am unable to perform everyday tasks such as my job, childcare, housework as well as I would like to” was understood by 95.9% of subjects (67/73)*
- “Because of my Lupus I avoid planning to attend events in the future” was understood by 98.6% of subjects (72/73)
- “Due to my SLE I am unable to perform everyday tasks such as my job, childcare, housework as well as I would like to” was understood by 97.1% of subjects (70/73)
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* The number of subjects (n) varies across languages for the LupusQoL due to availability of subjects.

Confusion rates were lower than 100% across languages for the LupusQoL were as follows:

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Limitations of the study include the limited scope of its developmental phase; that the concept behind the self-administered nature of the PRO is not widespread; that the subjects were not representative of the entire population affected by the disease; that the validation was conducted only in a limited number of languages; and that the study design did not allow for comparing cultural differences in the responses.

CONCLUSION

The final version of the LupusQoL consists of eight domains:

- Pain (3 items)
- Intimate relationships (2 items)
- Emotional health (6 items)
- Physical function (1 item)
- Satisfaction (1 item)
- Employment (1 item)
- Financial resources (1 item)
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These domains reflect the major areas of illness-related concerns experienced by SLE patients. A total of 600 outpatients participated in this study, with varying demographic and educational backgrounds, to check for conceptual equivalence and clarity.

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