TU597
Content Validity of the Neuropathy Total Symptom Score in Painful Diabetic Peripheral Neuropathy

Rikki Mangrum[1], Ekin Seçinti[2], Laure Delbecque[2], Heather Gerould[1], Karolina Schantz[1], Alexandra L. Bryant[1], Rebecca Robinson[2], Benjamin Behrend[2], Virginia Stauffer[2]

[1]Vector Psychometric Group, LLC, Chapel Hill, USA
[2]Eli Lilly and Company, Indianapolis, USA

Sponsored by Eli Lilly and Company

OBJECTIVE

- To evaluate the content validity of the Neuropathy Total Symptom Score-6 self-administered (NTSS-6-SA) modified for use with a 7-day recall period in a sample of people with painful diabetic peripheral neuropathy (pDPN).

CONCLUSION

Among participants with pDPN, the modified NTSS-6-SA:

- assesses relevant experiences that study participants found important for understanding pDPN and evaluating treatment.
- is well-understood, interpreted as intended, and includes content relevant to the assessment of changes in pDPN experiences that result from treatment.
- exhibits content validity for people with pDPN.

The International Association for the Study of Pain (IASP); Amsterdam, Netherlands; August 5 – 9, 2024

BACKGROUND

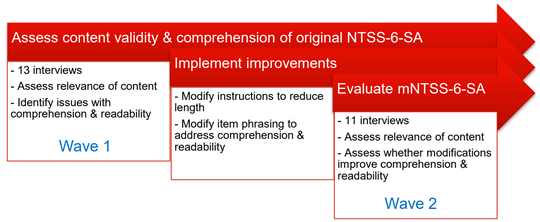
Painful Diabetic Peripheral Neuropathy (pDPN)

- People with diabetes mellitus often develop diabetic peripheral neuropathy accompanied by pain.[1]
- pDPN in the feet or legs is associated with **impairments of basic daily functioning, such as walking, concentrating, or sleeping,** that result in impacts on well-being and quality of life.[2]

Neuropathy Total Symptom Score-6 (NTSS-6)

- NTSS-6[3,4] was developed and validated to briefly assess the frequency (A items) and severity (B items) of **six neuropathic sensory symptoms and description:**
  - aching pain
  - burning pain
  - prickling sensation
  - numbness
  - lancinating pain
  - allodynia or hyperalgesia
- The measure uses 4-point response scales, resulting in possible scores of 0-21 where a higher score indicates more frequent/severe symptoms.
- Clinician-reported and self-administered[4] versions are available with a 24-hour or 4-week recall period.

STUDY DESIGN



Interviews and Analysis

- This observational study consisted of 2 waves of individual 90-minute semi-structured hybrid concept elicitation and cognitive debriefing interviews conducted virtually with 24 US-based, English-speaking adults. All participants had a physician-confirmed diagnosis and self-reported having moderate to severe pain intensity in their feet or legs.
- Participants were asked to describe their experiences with pDPN and to review the NTSS-6-SA with 7-day recall period.
- Participants' comprehension and interpretation of instructions, questions, and responses were evaluated, and perspectives on the relevance of each concept were documented.
- Based on findings from the first 13 interviews (Wave 1), the NTSS-6-SA was modified to address minor comprehension problems and incorporate patient feedback. The mNTSS-6-SA was then reviewed in 11 interviews (Wave 2).

KEY RESULT

NTSS-6-SA REVISIONS

- Modifications improved the comprehension of the measure without introducing new challenges (Table 2).

Table 2: Modifications Made To the NTSS-6-SA

Component	Wave 1 % Interpreted as intended (N=13)	Modification	Wave 2 % Interpreted as intended (N=11)
Instructions	62%	Removed detailed instructions	100%
1A (deep aching, tightness, boring, pulling, or squeezing pain)	62%	Removed the term "boring" (not understood)	100%
2A (burning sensation)	100%	Not modified	100%
3A (prickling or tingling sensation)	85%	Not modified	90%
4A (asleep feeling, numbness, loss of sensation, but without a prickling feeling)	69%	Removed the term "without a prickling feeling" and changed the phrase "asleep feeling" to "like your foot falling asleep"	82%
5A (sharp, stabbing, shooting pain, electric shock-like pain)	100%	Added the phrase "any of these" clarify that respondents should report on any experiences that matched the terms in the question	100%
6A (when your feet are touched or when you walk)	54%	The phrase "when your feet are touched" was modified to read "when something touches your feet"	82%

*Modifications were applied to both A (severity) and B (frequency) items.

Results

Study Sample

- 24 participants of varied age, sex, race or ethnicity, educational background, and income level (Table 1).
- Wave 1 (n=13) and wave 2 (n=11) samples differed slightly regarding diversity of some characteristics.
  - Wave 2 was less racially diverse and included more older participants but was more ethnically diverse. Both groups were similarly diverse in terms of sex, level of education, and employment status

Table 1: Participant Demographic Characteristics

Characteristic	N=24*
Male | Female	8 | 13
Mean age in years (range)	55.6 (39 - 67)
White | Black or African American | American Indian or Alaskan Native | Native Hawaiian or Other Pacific Islander	16 | 4 | 1 | 1
Hispanic | Non-Hispanic	5 | 19
Less than college degree | College degree/technical school and higher	12 | 9
Employed full or part time | Not employed or retired	5 | 14

*Totals may not add up to 24, as some participants preferred not to answer demographic questions

Cognitive Debriefing

Wave 1 Results: Original NTSS-6-SA

- All participants found items relevant to their experiences and had little/no difficulty recalling or rating their experiences over 7 days.
- Measured concepts aligned with pDPN experiences spontaneously reported by participants during concept elicitation.
- Participants suggested that the lengthy original instructions developed for clinicians were unnecessary.
- Identified several issues with comprehension and readability for four of the six items, including unfamiliar terms.

Wave 2 Results: Modified NTSS-6-SA (Table 2)

- Participants found the modified instructions and items clear and easy to understand and could recall and rate their experiences over a 7-day period using the available response options.
- Reducing the instructions did not affect participant understanding or their ability to respond. This change did not lead to any noticeable differences in the way responses were selected.
- Participants did not perceive the measure was missing any important content.

Relevance for Patient Care

- People with pDPN in their feet and legs commonly experience symptoms that **interfere with physical, social, and mental functioning and result in negative impacts** on well-being.
- A robust, evidence-based, patient-reported assessment of the frequency and severity of neuropathic symptoms that is **well understood and relevant to people with pDPN** is needed to support the development and evaluation of patient-centered treatments for the condition.
- This study provides evidence that the **mNTSS-6-SA is a viable option** for assessing symptom experiences through patient self-report for people with pDPN.

References

1. Jensen TS, et al., Brain 2021; 144: 1632–45.
2. Kanera IM, et al., Psychol Health 2019; 34(1): 84-105.
3. Bastyr EJ,et al., Clin Ther 2005; 27(8): 1278-1294.
4. Perrin NA, et al., Diabetologia 2004;47: A35-A35.

Disclosures: RM, HG, KS, and ALB are current employees of Vector Psychometric Group, LLC, and received funding from Eli Lilly and Company to conduct the study. ES, LD, RR, VS, and BB are current employees and shareholders of Eli Lilly and Company.