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Cross-cultural adaptation to Brazilian Portuguese of the Indication for Common Toxicity Criteria Grading of Peripheral Neuropathy Questionnaire

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Abstract

Background: Multiple myeloma (MM) is a common hematological malignancy, and chemotherapy-induced peripheral neuropathy (CIPN) is one of its most significant adverse drug reactions. While CIPN can be managed through dose adjustments or treatment discontinuation, its assessment relies on patient-reported symptoms. The need for validated tools to accurately assess CIPN and support clinical decisions is critical to improving patient outcomes and ensuring more effective management strategies.

Aim: To perform the cross-cultural adaptation of the Indication for Common Toxicity Criteria Grading of Peripheral Neuropathy Questionnaire (ICPNQ) to Brazilian Portuguese.

Method: The cross-cultural adaptation process was conducted in five stages: (a) translation, (b) synthesis of translations, (c) submission of the translated version to a panel of experts, (d) pre-testing with the target population, and (e) back-translation into the original language.

Results: The translation team included a specialist in onco-hematology, and the adapted version of the ICPNQ was evaluated by 20 healthcare professionals (nurses, pharmacists, and physicians) with an average of 9.5 years of experience in onco-hematology. The Content Validity Index (CVI) of the overall instrument was 0.98, while the CVIs for presentation and clarity were 0.98, and 0.97 for applicability. A pilot test was performed with 22 patients with MM in a specialized outpatient clinic for onco-hematological diseases in a university hospital. The patients were predominantly male (54.55%), over 65 years (59.09%), and using at least one neurotoxic drug (81.82%**).** Back-translation confirmed the semantic and cultural equivalence of the instrument's items.

Conclusion: The Brazilian Portuguese version of the ICPNQ demonstrates semantic, idiomatic, cultural, and conceptual equivalence, suitable for application in the Brazilian context.

Keywords

Peripheral nervous system diseases, validation study, multiple myeloma, medical oncology, psychometrics

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Introduction

Multiple myeloma (MM) is one of the most prevalent hematological malignancies, characterized by the proliferation of malignant plasma cells in the bone marrow.[1] In 2020, the global incidence was 1.78 cases per 100,000 individuals, with a corresponding mortality rate of 1.14 per 100,000.[2] Advancements in diagnostic methods may account for the rising incidence of MM, while the decrease in mortality is possibly due to therapeutic innovations.[2] Nevertheless, MM remains incurable, and patients often experience relapses or develop resistance to treatment after diagnosis.[1]

MM pharmacotherapy has been consistently updated, incorporating a broad range of therapeutic classes such as immunomodulators (thalidomide, lenalidomide, pomalidomide), proteasome inhibitors (bortezomib, ixazomib, carfilzomib), and monoclonal antibodies (daratumumab), among others.[3,4] Despite being generally safer and more tolerable, these treatments can cause adverse drug reactions (ADRs), which may significantly impair the patient's quality of life.[5] One of the most critical ADRs related to MM treatment is Chemotherapy-Induced Peripheral Neuropathy (CIPN).[6,7]

CIPN affects peripheral nerves, leading to symptoms such as tingling, numbness in the extremities, dysesthesia, neuropathic pain, gastrointestinal complications, as well as motor and neurodegenerative disorders.[7–9] CIPN can severely impair patients' quality of life by limiting daily activities and hindering treatment.[9] The severity of CIPN varies depending on factors such as cumulative drug dosage, binding type, and treatment duration.[8,9] Symptoms can manifest as either acute or chronic, with 90% of patients reporting at least one acute neuropathy symptom during the initial treatment cycle. Incidence rates range between 6.9% and 89.4%.[9]

CIPN is a significant ADR for which no effective curative or preventive treatments currently exist.[10] However, early detection allows for management through dose adjustments, drug substitutions, or, in some cases, discontinuation of treatment.[8] The evaluation is typically based on the patient's clinical history and reported symptoms. Diagnostic methods such as nerve conduction studies and electromyography may be used, though these are often costly, painful, and time-consuming.[11] Several instruments have been developed to facilitate early identification of CIPN, including the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) and others designed for diseases that require neurotoxic medications.[11]

The available tools to assess CIPN are limited to identifying the presence of this adverse reaction, without, however, classifying it according to international guidelines.[11] In clinical practice, it is essential that measures be taken after the identification of CIPN to ensure proper symptom management and improvement in patients' quality of life.[12] A literature review identified a tool that, in addition to detecting CIPN, classifies it as sensory, motor, and autonomic, and also categorizes it according to the Common Terminology Criteria for Adverse Events,[13] which are crucial factors for decision-making by the care team.[12,14] This tool is the Indication for Common Toxicity Criteria—Grading of Peripheral Neuropathy Questionnaire (ICPNQ),[12] originally developed and validated in Australia to assess CIPN in cancer patients, including those with MM.

The ICPNQ has proven to be practical and easy to apply, making it a tool that healthcare professionals can adopt in clinical practice.[12] Its use supports clinical decisions, such as dose adjustments or medication discontinuation, resulting in more effective and personalized treatment management, while preventing severe complications at a reduced cost for MM patients, with the potential to improve their quality of life.[14] In low- and middle-income countries, such as Brazil, this tool offers an affordable solution for assessing CIPN, as traditional methods like electromyography are costly and often inaccessible. Moreover, peripheral neuropathy, when diagnosed early, is often reversible, making the ICPNQ an even more valuable option for managing this condition. Thus, implementing the ICPNQ can directly benefit patients, optimizing resource use in economically and infrastructurally constrained contexts, underscoring the importance of promoting accessible tools in cancer care.

Objective

The aim of this study was to perform the cross-cultural adaptation of the Indication for Common Toxicity Criteria Grading of Peripheral Neuropathy Questionnaire to Brazilian Portuguese.

Method

The cross-cultural adaptation process was conducted in five stages: (a) translation, (b) synthesis of translations, (c) submission of the translated version to a panel of experts, (d) pre-testing with the target population, and (e) back-translation into the original language[15–17] (Figure 1).

The instrument

The ICPNQ[12] (Supplementary Material 1) is a self-assessment tool developed to provide a quick and accurate evaluation of the severity of NPIQ symptoms, based on the Common Terminology Criteria for Adverse Events (CTCAE).[13] It was created by professionals in the fields of hematology and neurology to assist in clinical decision-making, such as chemotherapy dose adjustments or treatment discontinuation. The questionnaire can be completed

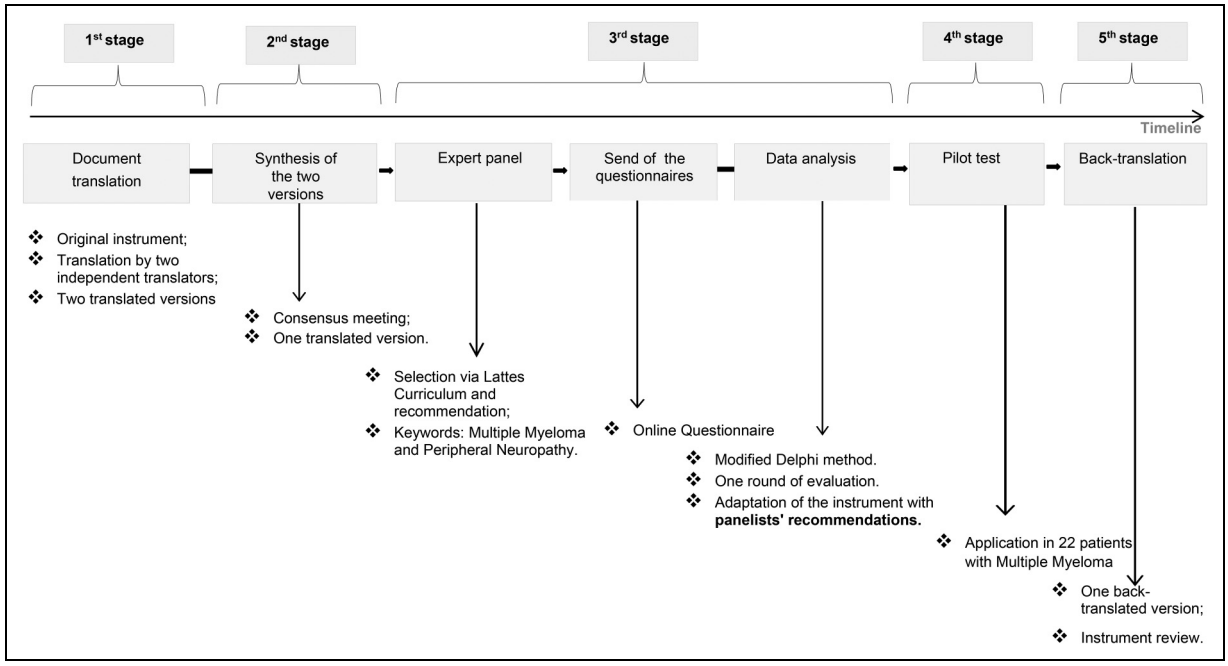

Figure 1. Stages and procedures of the cross-cultural adaptation of the Indication for Common Toxicity Criteria (CTC) Grading of Peripheral Neuropathy Questionnaire (ICPNQ).

in about five minutes, making it practical for clinical use. In addition to distinguishing between different grades of NPIQ, the ICPNQ is valid for standardizing the assessment of neuropathy severity, which facilitates symptom management and contributes to an improved quality of life for patients undergoing chemotherapy.

Study development

Stage 1: translation of the instrument

The representative responsible for the ICPNQ was contacted via email, and permission for the translation, adaptation, and validation process was granted on October 1st, 2018. The translation of the original instrument from English to Brazilian Portuguese was carried out by two qualified translators, both native Brazilian Portuguese speakers and fluent in English. One was a pharmacist specializing in hematology and hemotherapy, while the other was not from the healthcare field. Each translator produced an independent version of the instrument, resulting in ICPNQ V.1 and ICPNQ V.2.

Stage 2: synthesis

The two translated versions (V.1 and V.2) were consolidated into a single version (ICPNQ V.3) based on the comparison between the original instrument and the translations. Consensus was reached during a meeting involving two researchers experienced in cross-cultural adaptation, the translators from the previous stage, and members of the research team. Each item was individually reviewed, considering the translators' versions and the team's expertise. Linguistic adjustments were made to ensure clarity and coherence of the terms, resulting in a final version that incorporated all suggested modifications.

Stage 3: expert panel

The synthesized version of the ICPNQ (ICPNQ V.3) was reviewed by a panel of experts using the e-Delphi method.[18,19] The panel consisted of nurses, physicians, and pharmacists with experience in onco-hematological diseases. These experts were selected through the snowball sampling technique,[20] using keyword searches on the Lattes Platform and professional recommendations. The evaluation of ICPNQ V.3 considered semantic, idiomatic, cultural, and conceptual equivalences,[15] with each item rated on a Likert scale from 1 (total disagreement) to 5 (total agreement). Agreement among the experts was analyzed using the Content Validity Index (CVI), and items with a $CVI \geq 0.8$[21,22] were incorporated into the instrument, resulting in the preliminary version ICPNQ V.4.

Data were collected through an online questionnaire sent to the experts, who received a link containing the questionnaire and the original instrument in English. This allowed for anonymous analysis and suggestions for modifications. The e-Delphi form was divided into two parts: the first addressed the sociodemographic, academic, and

professional profile of the experts, and the second assessed the items of the instrument.

Stage 4: application of the instrument in mm patients for pilot testing

The preliminary version of the instrument (ICPNQ V.4) underwent a pilot test with patients undergoing treatment for MM, conducted in a specialized hematology outpatient clinic at a tertiary hospital. The aim was to assess the understanding of the terms, the relevance of the items, and identify any potential comprehension difficulties. After completing the forms, individual interviews were conducted to clarify any doubts the patients might have had, and the interview round was concluded upon reaching the saturation point, when no new doubts or questions were raised. The information was analyzed by the research team, who made adjustments and modifications to the terms and questions that had generated the most inquiries, and the interview results were summarized and tabulated in Excel® 2019 for analysis. Based on the feedback from the interviews and the necessary technical adjustments to tailor the instrument to the target population, the final version (ICPNQ V.5) was completed (Supplementary Material 2). Additionally, descriptive analyses of the patients' sociodemographic and clinical variables were performed.

Stage 5: back-translation

After the application to the target population, the modified version was back-translated by a specialized company. The translators had no prior knowledge of the original instrument, ensuring methodological rigor in the cross-cultural adaptation process. The back-translated version (Supplementary Material 3) was then compared by the research team with both the original instrument and the final translated version in Portuguese. This comparison aimed to identify any potential discrepancies between the versions. Finally, the completed instrument was sent to the ICPNQ representative, who was responsible for the original research.

The outline of all stages of the cross-cultural adaptation is available in Figure 1.

Results

The main versions of the ICPNQ during the cross-cultural adaptation process are presented in Table 1.

Translation and synthesis

Of the 52 items in the original instrument, 33 cultural and linguistic adaptation changes were made in consensus with the team. For example, the term "*Patient number*" was replaced with "*Medical record number,*" as it is not a commonly used expression in the Brazilian context. Regarding linguistic changes, the term "*Baseline test*" was replaced with "*Baseline assessment*" to improve comprehension, as well as "*Have you experienced changes in the following functions during the last week?*" which was replaced with "Have you noticed changes in the following functions since the last evaluation?" (Box 1).

Expert panel

The adapted version of ICPNQ was evaluated by 20 specialists. Regarding the characterization of the expert panel, it was observed that the majority were female (n = 17; 85%) and pharmacists (n = 13; 65%). At least half of the participants (n = 10; 50%) held a specialist title, with an average of 14.4 years of academic training and 9.5 years of experience in the care of onco-hematological patients. Healthcare professionals from three regions of the country participated of the study, with the majority coming from the Southeast (n = 9; 45%) and Midwest (n = 8; 40%) regions (Table 2).

Regarding the content validity of the instrument, the overall Content Validity Index (CVI) was 0.98. The CVI values for specific aspects, such as presentation and clarity of the instrument, were also 0.98, while applicability scored 0.97 (Supplementary Material 4).Some questions received suggestions for changes, which included word and structure modifications, removal of terms, and/or addition of words to better adapt the instrument to the target population (Table 1). Although all items demonstrated content validity (CVI > 0.8), all suggestions raised by the expert panel were evaluated for potential incorporation into the final version. Suggestions that enhanced the understanding of the questions, without altering the intended meaning of the original instrument, were considered.

Among the items modified according to the experts' recommendations, question two received the most suggestions, related to the terms used, lack of information, and alignment with current chemotherapy protocols. Examples include: "Avoid using abbreviations" and "Use only the generic name of the drug." Some experts also suggested adding an additional line to the question's table, as mentioned: "We are already using 4-drug regimens (e.g., DARA-VMP), so I would add another line to the table" (Table 1). All suggestions that provided greater clarity and conformity to the instrument were incorporated.

Pre-test in the target population

Twenty-two patients undergoing treatment for MM were interviewed, the majority of whom were male (n = 12; 54.55%) and over 65 years old (n = 13; 59.09%). Most had an elementary education level (n = 13; 59.09%) and were using at least one neurotoxic drug (n = 18; 81.82%), with bortezomib (n = 16; 72.73%) and thalidomide (n = 7;

Table 1. Original version, synthesis version of translations, retrotranslated versions, and final version of the Indication for Common Toxicity Criteria (CTC) Grading of Peripheral Neuropathy Questionnaire (ICPNQ).

Item	Original	Synthesis Version (ICPNQ V.3)	Back Translation	Final Version
1	Patient number	Número de prontuário	Medical record number	Número do prontuário
2	Treatment regiment	Protocolo de quimioterapia	Chemotherapy protocol	Protocolo de quimioterapia
3	Baseline testing	Avaliação basal	Baseline assessment	Avaliação basal
4	Yes or no please circle as applicable	Sim ou não (favor circular o que se aplica)	Yes or no please circle as applicable	Sim ou não (favor circular o que se aplica)
5	Assessment grade	Grau de avaliação anterior	Previous evaluation degree	Grau de avaliação anterior
6	Name of physician/nurse	Nome do profissional	Name of health professional	Nome do profissional
7	Indication for Common Toxicity Criteria Grading of Peripheral Neuropathy	Avaliação do Grau de Neuropatia Periférica conforme Critérios Comuns de Toxicidade	Assessment of Chemotherapy-Induced Peripheral Neuropathy Degree according to Common Toxicity Criteria	Avaliação do Grau de Neuropatia Periférica conforme Critérios Comuns de Toxicidade
8	No changes observed since the previous test	Você observou alguma alteração desde a última avaliação?	Have you noticed any changes in neuropathy symptoms since the last assessment?	Você observou alguma alteração nos sintomas de neuropatia desde a última avaliação?
9	Are you experiencing changes in sensation during the past week?	Você tem percebido alterações na sensibilidade durante a última semana?	Have you noticed any of these sensitivity changes below?	Você tem percebido alguma destas alterações de sensibilidade a seguir?
10	Changes in temperature sensation	Alterações na sensação de temperatura	Changes in temperature sensation	Alterações na sensação de temperatura
11	Are you experiencing any pain (burning, stabbing, stinging, or cramping)	Você está sentindo alguma dor? (queimação, pontadas, ardência ou câimbra)?	Are you feeling any pain? (Burning, stabbing, stinging, or cramping)?	Você está sentindo alguma dor? (queimação, pontadas, ardência ou câimbra)?
12	Are you experiencing changes in the following function during the past week?	Você tem percebido alterações nas seguintes funções desde a última avaliação?	Have you noticed changes in the following functions since the last evaluation?	Você tem percebido alterações nas seguintes funções desde a última avaliação?
13	Difficulty holding urine or fully emptying bladder	Incontinência urinária ou dificuldade de esvaziar totalmente a bexiga	Urinary incontinence or difficulty in fully emptying the bladder	Incontinência urinária ou dificuldade em esvaziar totalmente a bexiga
14	Constipation	Constipação intestinal	Constipation	Prisão de ventre
15	Reduced sweating	Sudorese reduzida	Decreased sweat	Suor aumentado/ Suor reduzido
16	Are you experiencing a loss of muscle strength?	Você tem percebido perda de força muscular?	Have you noticed loss of muscle strength?	Você tem percebido perda de força muscular?
17	Are you experiencing any problems carrying out the activities below during the past week?	Você tem percebido dificuldades para realizar as seguintes atividades desde a última avaliação?	Have you noticed difficulties in the following activities since the last evaluations?	Você tem percebido dificuldades para realizar as seguintes atividades desde a última avaliação?
18	Dressing/undressing without assistance	Vestir-se/despir-se sozinho	Dressing/ undressing alone	Colocar/tirar a roupa sozinho
19	Washing unaided, washing and combing hair unaided	Tomar banho, lavar e pentear os cabelos sozinho	Showering, and washing and combing hair yourself	Tomar banho, lavar e pentear os cabelos sozinho
20	Holding cutlery and eating unaided	Segurar os talheres e comer sozinho	Hold the cutlery and eat alone	Segurar os talheres e comer sozinho
21	Walking independently	Andar sozinho	Walking without assistance	Andar sozinho
22	Opening/closing doors unaided	Abrir/fechar portas sozinho	Opening/closing doors on its own	Abrir/fechar portas sozinho

(continued)

Table 1. Continued.

Item	Original	Synthesis Version (ICPNQ V.3)	Back Translation	Final Version
23	Driving a car unaided	Dirigir	Driving	Dirigir
24	Buttoning/unbuttoning	Abotoar e desabotoar roupas	Buttoning and unbuttoning clothes	Abotoar e desabotoar roupas
25	Preparing meals	Preparar refeições	Preparing meals	Preparar refeições
26	Are you using any walking aids? (e.g., crutches, rollator, etc)	Você tem usado algum auxílio para andar? (por exemplo, bengala, muletas, andador, etc.)	Have you been using any walking aids? (For example, walking stick, crutches, walker, etc.)	Você tem usado algum auxílio para andar? (por exemplo, bengala, muletas, andador, etc.)
27	Is pain affecting your daily activities?	A dor tem afetado suas atividades da vida diária?	Has the pain affected your daily activities?	A dor tem afetado suas atividades da vida diária?
28	If the patient experiences change in sensation	Se o paciente percebe alterações de sensibilidade	If the patient notices change in sensitivity	Se o paciente percebe alterações de sensibilidade
29	If the patient experiences in muscle strength	Se o paciente percebe alterações de força muscular	If the patient notices muscle strength changes	Se o paciente percebe alterações de força muscular
30	If the patient experiences limitations in instrumental activities of daily living (IADL) due to neuropathic symptoms or pain	Se o paciente percebe limitações nas atividades instrumentais da vida diária (AIVD*) devido a sintomas neuropáticos ou dor	If the patient perceives limitations in instrumental activities of daily living (IADL*) due to neuropathic symptoms or pain	Se o paciente percebe limitações nas atividades instrumentais da vida diária (AIVD*) devido a sintomas neuropáticos ou dor
31	If the patient experiences limitations in activities of daily living (ADL) due to neuropathic symptoms or pain instrumental activities of daily living	Se o paciente percebe limitações nas atividades de autocuidado devido a sintomas neuropáticos ou dor	If the patient perceives limitations in self-care activities due to neuropathic symptoms or pain	Se o paciente percebe limitações nas atividades de autocuidado devido a sintomas neuropáticos ou dor
32	If the patient experiences autonomic functions changes	Se o paciente percebe alterações na função autonômica	If the patient notices change in autonomic function	Se o paciente percebe alterações na função autonômica
33	In the event of disabling neuropathy	No caso de neuropatia incapacitante	In the case of disabling neuropathy	No caso de neuropatia incapacitante

31.82%) being the most commonly used. Regarding the grade of NPIQ, most patients had grade 2 with pain (n = 6; 27.27%) (Table 3)

Regarding the patients' evaluation of the instrument, more than half (n = 12) did not understand the technical term "sudorese" (sweating), which was replaced by "increased/reduced sweating" to improve comprehension by the target population. Similarly, the term "micção" (urination), which caused confusion in 10 patients, was replaced with "urinating more frequently than before." Questions where only one patient expressed doubt or lack of understanding, and that were not related to technical terms, were considered isolated cases and, therefore, were not modified (Table 1).

Back-translation

After comparing all versions (back-translated, original, and Brazilian Portuguese), it was concluded that the items of the instrument were adapted to an equivalent expression without altering their original cultural meaning.

Discussion

Our study translated and culturally adapted the ICPNQ to Brazilian Portuguese, establishing it as a relevant assessment tool compared to other instruments due to its speed, standardization, validity, and ease of interpretation. The tool's validity and reliability in distinguishing between different NPIQ grades are critical for determining chemotherapy dose adjustments during cancer treatment. This makes it a promising tool for the effective evaluation and management of NPIQ. Furthermore, its implementation in clinical practice can play a key role in improving patient care and quality of life for those undergoing MM treatment.[12]

The process of adapting an instrument involves several stages,[15] all of which must be followed to ensure the final

Box 1. Suggestions adopted from the panelists and patient concerns for each question, along with the changes made to the translated instrument.

Question	Panelists' suggestions	Respective panelist (number of suggestions) Pacient (P)
1	• I suggest: Assessment of the degree of chemotherapy-induced peripheral neuropathy according to common toxicity criteria	P13 (1)
2	• "I would not adopt the use of abbreviations as suggested* and would add a column for mg/m².'' • ''I suggest not using the institution's standardized abbreviation, as it may vary significantly between institutions.*'' • ''I suggest using only the generic name of the drug.*'' • ''We are already using 4-drug regimens (e.g., DARA-VMP), so I would add another row to the table.*'' • ''Does this record correspond to the current protocol under which the patient is being treated*?"	P2–P3 -P4–P6 - P7–P8–P9–P12–P15–P18 (10)
3	• "I'm not sure if it's been proposed, but include the cycle day to which the evaluation refers.*''	P13–P20 (2)
4	• "I suggest detailing the meaning of the baseline assessment.*''	P5–P18–P19 (3)
6	• "It is unclear whether this change refers to the perception of the professional or the patient.*''	P7–P15–P18 (3)
8.7	• "I suggest replacing it with a more common term for the patient, or adding a glossary below the item*, e.g., 'Intermittent: A situation where interruptions occur; it stops and starts again at intervals; sporadic, discontinuous.''	P9–P17–P18 (3)
9.1	• "I would assess the frequency of urination. Urination 'more frequent than before.''	P7–P9–P18 (3)
9.4	• "Just: reduced lubrication or reduction in lubrication?!".	P9–P11 (2)
14	• "The translated text describing the different grades, as included in the English instrument, was missing.*"	P5–P18 (2)
15	• In the end, I couldn't classify the neuropathy of a hypothetical patient because I don't know what grade X is.*	P12–P 18 (2)

Patient concerns for each question with the corresponding changes made

Question	Patient concerns	Pacient (P)	Suggestions
1.	• Patient was unable to answer the question due to not understanding it / took time to respond / asked about which changes	P2; P3; P7; P10; P13; P18	✓ "Have you noticed any changes in neuropathy symptoms since the last assessment?*''
2.	• Patient understands the term 'sensitivity' as sensitivity to touch. • ''Patient shows a lack of understanding by asking 'What do you mean?'"	P1;P2;P3; P13	✓ "Have you noticed any of the following changes in sensitivity?*"
3.1	• Patient did not understand the term 'urination'	P1;P2;P3; P7;P8;P17; P18; P19; P20; P22	✓ "Urinating more frequently than before*"
3.5	• Patient hesitated to respond. Did not understand the question.	P2; P18	✓ "Vaginal dryness during sexual arousal*"
3.6	• ''Patient did not understand the term 'constipation''' • ''Patient asked, 'What is constipation?'"	P2;P3;P13	✓ "*Being backed up*"
3.10	• ''Patient id not understand the term 'sweating''' • ''Patient asked 'Sweat?' 'Does the sweating decrease?'"	P3;P7;P8; P11;P12; P14; P16;P17;P 19;P20;P21; P22	✓ "More sweat/ Less sweat"

Legend: * Adopted suggestions.

product accurately measures what it is designed to assess. We adhered to all steps outlined by Beaton et al. (2000) for cross-cultural adaptation. This method is widely recognized and accepted in the scientific community due to its strong theoretical foundation and systematic approach, ensuring the validity and comparability of data in multinational studies. Additionally, we employed the Delphi method, which is widely recognized for giving equal weight to each participant, allowing experts from diverse regions to effectively reach a consensus. It is considered

Table 2. Sociodemographic. academic profile. and experience characterization of the panelists.

Variables	Participants N (%)
Age	[a]39.4 (9.89)
Time of academic training	[a]14.4 (10.17)
Time of experience with onco hematological diseases	[a]9.5 (8.21)
Sex	
Female	17 (85%)
Male	3 (15%)
Undergraduate degree	
Pharmacist	13 (65%)
Physicist	4 (20%)
Nurse	3 (15%)
Academic degree	
Specialization	10 (50%)
Master's degre	7 (35%)
Doctorate (PhD)	3 (15%)
Regions of Brazil.	
Southeast	9 (45%)
Central-West	8 (40%)
Northeast	3 (15%)

Legend: [a]Mean (Standard deviation) in years.

valid due to its multiple rounds and the consensus achieved among professionals with expertise in the subject.[23]

Regarding the expert panel, the literature does not provide a consensus on the ideal number of participants. Some authors suggest including at least 3 to 5 judges at this stage,[24,25] a number lower than that used in our study. The literature emphasizes the importance of the judges' technical expertise.[24,25] Our results align with these recommendations, as all panelists were onco-hematology experts, with half holding a master's or doctoral degree and over nine years of professional experience. Additionally, the panel included diverse healthcare professionals, as recommended by key methodological guidelines for cross-cultural adaptation studies. These guidelines suggest the formation of multidisciplinary expert committees.[26]

Regarding the overall CVI of the instrument, our findings are consistent with the literature. Davis (1992)[27] established a minimum acceptable threshold of 0.8 for the CVI, while Waltz et al. (2005)[28] suggested that 0.90 be considered acceptable. The CVI is recognized as a reliable and effective tool for validating the content of instruments, which is an essential step for validation and improvement in research and professional practice.[29] For content validity, a qualitative approach is recommended, which involves analysis by an expert committee, followed by a quantitative assessment using the CVI.[30] A CVI value of 0.78 or higher

Table 3. Sociodemographic and health characterization of patients undergoing multiple myeloma treatment in the pilot phase.

Variables	Participants (Total = 22) N (%)
Time since diagnosis in years	[a]3.7 (2.4)
Sex	
Male	12 (54.55%)
Female	10 (45.45%)
Age	
< 65 years	9 (40.91%)
≥ 65 years	13 (59.09%)
Level of education	
Illiterate	4 (18.18%)
literate	2 (9.09%)
Primary education	13 (59.09%)
Secondary education	3 (13.64%)
Staging (according to ISS[b])	
Stage I	9 (40.91%)
Stage II	4 (18.18%)
Stage III	6 (27.27%)
Not available	3 (13.64%)
Previous treatments	
Chemotherapy	20 (90.91%)
Transplant + Chemotherapy	2 (9.09%)
Number of comorbidities at diagnosis	
≤1	8 (36.36%)
≥2	14 (63.63%)
Age at diagnosis	
<65 years	9 (40.91%)
≥65 years	13 (59.09%)
Number of neurotoxic drugs	
1 drug	18 (81.82%)
2 or more drugs	3 (13.64%)
No medication	1 (4.55%)
Drug used	
Bortezomib	16 (72.73%)
Prednisone	11 (50.00%)
Dexamethasone	9 (40.91%)
Thalidomide	7 (31.82%)
Melphalan	4 (18.18%)
Cyclophosphamide	4 (18.18%)
Daratumumab	2 (9.09%)
Doxorubicin	1 (4.55%)
NPIQ[c] Grade—CTCAE[d]	
Grade 0	5 (22.73%)
Grade 1	4 (18.18%)
Grade 2	3 (13.64%)
Grade 3	3 (13.64%)
Grade 1 with pain	1 (4.55%)
Grade 2 without pain	6 (27.27%)

Legend: [a]Mean (Standard deviation);
[b]International Staging System (ISS);
[c]Chemotherapy-induced peripheral neuropathy (CIPN);
dCommon Terminology Criteria for Adverse Events (CTCAE).

for each item, along with an overall CVI of 0.90 or higher, is considered an excellent measure of content validity.[29] Our study achieved a valid CVI and followed this qualitative approach by carefully analyzing the expert panel's suggestions, ensuring that the instrument is suitable for the target population.

Regarding the sociodemographic and clinical profile of participants in the pilot phase, results are consistent with the literature. The age of patients in our study is similar to global data[2] and to patients in the study that validated the instrument, with an average age of 67.5 years.[12] Furthermore, the profile of patients in our study is comparable to that of the validation study, with a higher frequency of male patients (71%) diagnosed an average of 3.3 years ago, most in stage I of the disease and using neurotoxic drugs such as bortezomib and thalidomide.[12] The occurrence of severe NPIQ (grades 3–4) in our patients was similar to that reported in other studies, with values ranging from 1% to 33.2%.[9,26] The similarities in sociodemographic and clinical profiles between studies strengthen the reliability and validity of the instrument's cross-cultural adaptation, making it suitable for different contexts and populations.

Our study presents several strengths, notably the rigorous methodological process employed in adapting the ICPNQ, which followed a systematic and multidisciplinary approach to ensure its validity within the Brazilian context. The expert panel, composed of a multiprofessional team, broadened the scope of evaluations and ensured the consideration of different perspectives during the adaptation process. This diversity enhanced the quality of suggestions, allowing the instrument to be adjusted to the country's clinical and cultural realities, reinforcing its applicability in clinical practice. Additionally, the study was conducted in a specialized hematology outpatient clinic, where patients routinely use neurotoxic drugs and often present with NPIQ. This setting highlights the practical relevance of the results and underscores the effectiveness of the ICPNQ in assessing these complications in a real-world oncology treatment environment.

As for limitations, it is important to note that the pilot phase was conducted exclusively in an outpatient clinic serving patients from the Brazilian Unified Health System, which may represent a different profile from those treated in the supplementary healthcare system. However, this limitation does not compromise the results. Although public healthcare patients may differ socioeconomically, the adaptation was carried out with patients of lower educational levels, making the adapted version applicable to a broader population. Although socioeconomic differences exist, the clinical characteristics of patients do not vary significantly between the two systems. For future research, it is suggested that the ICPNQ be applied to patients in the supplementary healthcare system to evaluate potential differences in term comprehension.

Conclusion

The Brazilian Portuguese version of the ICPNQ demonstrates semantic, idiomatic, cultural, and conceptual equivalence to the original instrument's items. Thus, the ICPNQ is a valuable tool for evaluating CIPN in patients with MM.

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Author contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Leonardo Teodoro de Farias, Pryscila Rodrigues Moreira, Aline dos Santos Iwasse, Luana Clara de Souza, Raíra Macário Silvério, and Ana Carolina Figueiredo Modesto. The first draft of the manuscript figures written by Leonardo Teodoro de Farias and all authors commented on previous versions of the manuscript. All authors read and approved the final version of the manuscript and agree to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Consent to participate

All participants who agreed to take part in the study signed the Informed Consent Form (ICF).

Consent for publication

All authors declare their consent for the publication of this article.

Data availability

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical considerations

The study received approval from the Research Ethics Committee (CEP) of the Hospital das Clínicas, Federal University of Goiás (approval number: CAAE No. 90585018.2.0000.507). Informed Consent Forms were provided to all participants, ensuring their awareness of the study's aims and procedures at every stage of

the research. The study was conducted in accordance with the ethical guidelines of the Brazilian National Health Council Resolution No. 466/12 and the Declaration of Helsinki.

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Supplemental material

Supplemental material for this article is available online.

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