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PORTUGUESE LANGUAGE TRANSLATION OF THE LOWER URINARY TRACT DATA SET FOR PATIENTS WITH SPINAL CORD INJURY[1]

Adriana Cordeiro da Silva Grillo[2], Fabiana Faleiros[3], Josana Cristina Faleiros e Silva[4], Denise Galuf Tate[5], Júlia Maria D´Andrea Greve[6], Adriana Dutra Tholl[7]

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[2] Master's Student, *Programa de Pós-Graduação em Enfermagem* Fundamental, - Escola de Enfermagem de Ribeirão Preto (EERP), Universidade de São Paulo (USP). Ribeirão Preto, São Paulo, Brazil. E-mail:adriana.clsiva@hotmail.com

[3] Ph.D. in Nursing, Professor, Department of General and Specialized Nursing EERP/USP. Ribeirão Preto, São Paulo, Brazil. E-mail: fabifaleiros@eerp.usp.br

[4] Master's Student, *Programa de Pós-Graduação em Enfermagem* Fundamental, EERP-USP. Ribeirão Preto, São Paulo, Brazil. E-mail: jofsilva@usp.br

[5] PhD Professor, Medical School at Training Michigan State University. Michigan, United States. E-mail: dgtate@med.umich.edu

[6] PhD in Medicine. Professor at the Medical School of USP. São Paulo, São Paulo, Brazil. E-mail: jgreve@usp.br

[7] PhD in Nursing. Professor of the Nursing Department *Universidade Federal de Santa Catarina*. Florianópolis, Santa Catarina, Brazil. E-mail: adrianadtholl@gmail.com

ABSTRACT

Objective: to translate and adapt to the Portuguese language the data set of the lower urinary tract for individuals with spinal cord injury. International Spinal Cord Society and the American Spinal Injury Association.

Method: this is a methodological study of instrument translation, with the participation of a group of five experts who took part in the translation and back translation phases and five judges. The Data set has been translated and adapted according to the methodological recommendations of International Spinal Cord Society and the American Spinal Injury Association.

Results: for the translation stage, 56% of the sentences were unanimously translated by the three invited translators. Of the nine questions that comprised the instrument only four showed differences.

Conclusion: a translated and culturally adapted instrument for the evaluation of the lower urinary tract of people with spinal cord injury in the Portuguese language was obtained, guaranteeing the Brazilian participation in international multicenter studies on the spinal cord injury.

DESCRIPTORS: Spinal cord injuries. Rehabilitation. Urinary bladder, Nerogenic. Translation. Brazil. Surveys and questionnaires.

TRADUÇÃO PARA LÍNGUA PORTUGUESA DO *DATA SET* TRATO URINÁRIO INFERIOR PARA INDIVÍDUOS COM LESÃO MEDULAR

RESUMO

Objetivo: traduzir e adaptar para a língua portuguesa o *data set* do trato urinário inferior para indivíduos com lesão medular *International Spinal Cord Society* e *American Spinal Injury Association*.

Método: constitui-se de um estudo metodológico de tradução de instrumento, com a participação de um grupo de cinco especialistas que participaram das fases de tradução e retrotradução e cinco juízes. O *data set* foi traduzido e adaptado segundo as recomendações metodológicas da *International Spinal Cord Society* e *American Spinal Injury Association*.

Resultados: para a etapa de tradução, 56% das sentenças foram traduzidas com unanimidade pelos três tradutores convidados. Das nove questões que compunham o instrumento apenas quatro apresentaram divergências.

Conclusão: obteve-se um instrumento traduzido e culturalmente adaptado para avaliação do trato urinário inferior de pessoas com lesão medular em língua portuguesa, proporcionando a participação brasileira nos estudos multicêntricos internacionais sobre lesão medular.

DESCRITORES: Traumatismos da medula espinhal. Reabilitação. Bexiga urinária neurogênica. Instrumentos para coleta. Tradução. Brasil. Inquéritos e questionários.

TRADUCCIÓN PARA LA LENGUA PORTUGUESA DEL *DATA SET* TRACTO URINARIO INFERIOR PARA LOS INDIVIDUOS CON LESIÓN MEDULAR

RESUMEN

Objetivo: traducir y adaptar para la lengua portuguesa el *data set* del tracto urinario inferior para los individuos con lesión medular *International Spinal Cord Society* y la *American Spinal Injury Association.*

Método: se realizó un estudio metodológico de traducción del instrumento con la participación de un grupo de cinco especialistas que participaron de las fases de traducción, retrotraducción, y también, cinco jueces. El *data set* fue traducido y adaptado según las recomendaciones metodológicas de *Spinal Cord Society* y la *American Spinal Injury Association.*

Resultados: para la etapa de traducción, 56% de las oraciones fueron traducidas con unanimidad por los tres traductores invitados. De las nueve preguntas que componían el instrumento solo cuatro de ellas presentaron pequeñas divergencias.

Conclusión: se obtuvo un instrumento traducido y culturalmente adaptado para la evaluación del tracto urinario inferior de personas con lesiones medulares en lengua portuguesa, proporcionando la participación brasileña en los estudios multicéntricos internacionales sobre la lesión medular.

DESCRIPTORES: Traumatismos de la médula espinal. Rehabilitación. Vejiga urinaria neurogénica. Instrumentos para recolección. Traducción. Brasil. Encuestas y cuestionarios.

INTRODUCTION

The spinal cord injury is a condition that brings important physical, psychological and economic impact, and not only does it affect the individual but also his/her whole family.[1] Spinal cord injuries can be classified into two categories: traumatic and non-traumatic. The non-traumatic injuries can be caused by congenital malformation (spina bifida/Myelomeningocele), tumors, infections, degenerative disease, ischemia, among others; and, the injuries are due, mainly, to traffic accidents, assaults and falls.[2-4] The number of individuals who have spinal cord injury has increased significantly in recent years, however, it is not associated with the improvement of care and access to technology.[5-6] Thus, it is estimated that, worldwide, about 20 to 40 individuals/million have spinal cord injury,[7] with significant increase in cases of traumatic spinal cord injury (TSCI), with 2.5 million people affected worldwide, and with 130,000 new cases per year due to the progressive increase of urban violence, adding to the survival of the people.[6,7-10] In Brazil, the statistics on spinal cord injury are outdated and not very specific.[11] In the 2000 census, almost 1% of the population stated having physical disability; with an incidence of 11,304 new cases per year.[7,12-13] Yet, in the 2010 census, 6.9% stated having some kind of disability.[14] Still in the Brazilian context, the highest proportion of individuals who have a spinal cord injury is among young males, at the age of 30.4 years old.[15]

One of the main health complications of individuals who have a spinal cord injury is related to the management of the neurogenic bladder (NB), in which the inability to store or remove the urine at low pressures (< 40cmH2O) is caused by the thickening of the walls of the bladder and excessive contractions or sphincter dyssynergia, which may lead to the deterioration of the upper urinary tract and subsequent kidney failure. Worldwide, the current chosen treatment for the management of the NB is the clean intermittent bladder catheterization (CIC), whose main objective is the protection of the upper urinary tract. Although the advances in the treatment and management of the complications associated with the NB have progressed, the renal deterioration currently represents the leading cause of death and morbidity among individuals who have a spinal cord injury,[16-18] being imperative to advance the studies on the improvement of the management of the NB.

Among the institutions that are globally recognized by establishing and promoting standards of excellence for all aspects of the health care of individuals who have a spinal cord injury, there is the American Spinal Injury Association (ASIA) and the International Spinal Cord Society (ISCoS).[19]

To these institutions, the increased survival associated with a reasonable quality of life for individuals who have a spinal cord injury, led to an increase in the need for data related to the life and clinical demands of these patients. These data should be collected in a common standardized international format, in order to facilitate the comparisons of the injuries, treatments and results among patients, centers and countries.[20] being this the initial process concerning the idealization of the Data sets. The data set is a data collection instrument of individuals who have a spinal cord injury, which allows the comparison of the data between different countries, enabling the development of comparative studies, exchange of experiences be-

tween major International Rehabilitation centers and the improvement of the care. In this sense, the ISCoS developed them as a proposal for the advancement of studies aiming to improve the care and rehabilitation of individuals who have a spinal cord injury.[20] The creation process of the Data sets began after an international meeting of experts in the area of data collection and analysis on spinal cord injury, and which was attended by 48 participants in the workshop, during the pre-conference of the first meeting of ASIA and ISCoS, on May 2, 2002, in Vancouver, Canada. In that meeting, the elements collected in various centers of spinal cord injury were considered and the steps necessary to select and recommend every variable that should be included in the future Spinal Cord Injury Data Set were discussed.[20] The basic dataset was the first to be employed, thus being initiated the development of questions in other areas. Currently, these are the following Data Sets available for use: Basic data; Spinal cord injury; Spinal cord intervention, and surgical procedures; Non-traumatic spinal cord injury; Function of the lower urinary tract; Urinary tract infection; Urodynamic; Images of the urinary tract; Intestinal function; Male and female sexuality; Male Sexual Function; Musculoskeletal; Upper limbs; Pain; Cardiovascular function; Pulmonary function; Endocrine and metabolic function; skin function and thermoregulation; Activity and participation; Quality of life.[20]

The first draft of the Data set of the lower urinary tract was prepared by the working group consisting of members representing the International Continence Society, the European Society of Urology, representatives of ASIA and ISCoS, together with a representative of the Executive Committee of the International Data Set for Spinal Cord Injury. This first version was held at a three-day meeting in Copenhagen in November, 2005.[21] Afterwards, the Data set was reviewed by the Executive Committee members of the Data Set International Committee for Spinal Cord Injury, who made appropriate comments and changes, as well as consultations to the members of the ISCoS and ASIA, and about 40 relevant International Organizations. In addition, the proposed Data set was published for two months on the ISCoS and ASIA websites to allow comments and suggestions. The final version of the Data set was reviewed and approved by the Scientific Committee of the ISCoS and ASIA, and it includes the main issues related to the lower urinary tract of individuals who have a spinal cord injury, such as spinal cord injury date, urinary tract dysfunctions not related to spinal cord injury, perception of the urinary tract functioning, methods of bladder emptying, occurrence of urinary loss or incontinence, use of incontinence devices, use of urinary tract medications or urinary tract surgeries, and changes in the urinary tract symptoms.[21]

Since the neurogenic bladder is one of the main health complications of individuals who have a spinal cord injury, priority should be given to stimulating the development of comparative and interventional studies to improve the management of the neurogenic bladder and consequently reduce its complications.

In this direction, this study aimed to translate and adapt to the Portuguese language the Data set of the lower urinary tract for individual with spinal card injury.

METHOD

This is a methodological study, consisting of the whole translation process, divided into the stages of translation, back-translation and revision of the versions.

This research was authorized and approved by the Ethics Committee of Escola de Enfermagem de Ribeirão Preto, *Universidade* São Paulo. The translation process began only after the signing of the Free and Informed Consent Term (FICT) for participation in scientific research under the number CAAE53490416.3.0000.5393.

Data sets are instruments for the collection of data in the public domain and therefore do not have copyright for the use as well as for the application. The present group of researchers is responsible for the translation and validation of the Data set of the Lower Urinary Tract for the Portuguese Language, with authorization from the ISCoS Organizing Executive Committee responsible for their development.

The process of translation and adaptation followed the framework proposed by the Executive Committee for International Data sets for Spinal Cord Injury, according to the descriptive methodology described in Figure 1.[19]

It should be emphasized that the instrument is aimed at clinical research, in order to design studies that can be compared among research centers around the world. Therefore, this is not a psychometric study, since the current goal of Data sets is not the evaluation of individuals using scores on their instruments, for which psychometric tests are recommended for the validation of the instrument.[22]

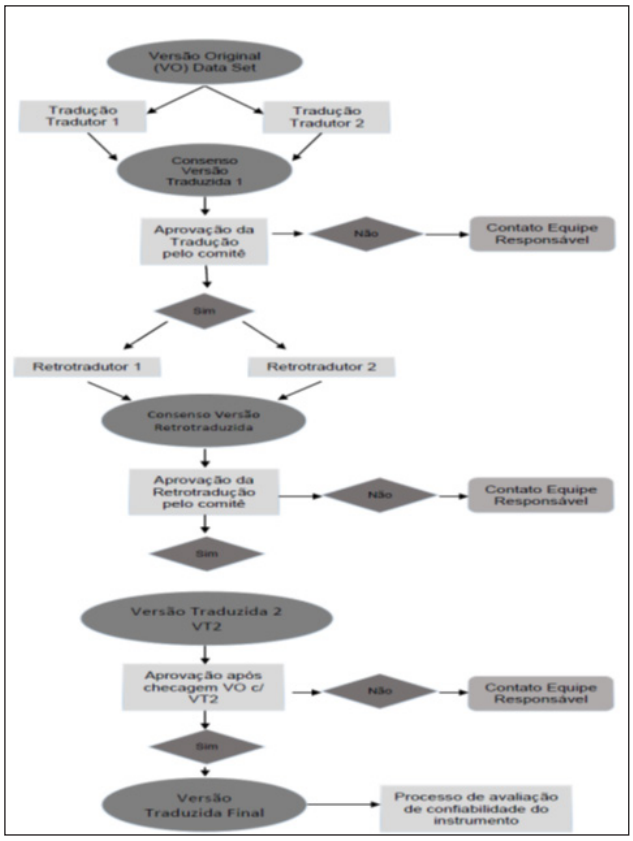

Figure 1 – Data sets Translation Flowchart

For the stages of translation, back translation and revision of the versions, an invitation was made to a group of professional experts in the area of rehabilitation, with proficiency in the original language of the instrument (medical English) and having Brazilian Portuguese as their native language. Thus, having received a positive response from all the invitations that were sent, two groups of participants were formed and divided into:Group of Experts and Committee of Judges. The Group of experts was composed of five professionals who participated in different moments; being three, in the translation stage and two in the back translation stage. The invitation to the participants was sent, via e-mail, being forwarded to each specialist the corresponding FICT to his/her participation at the stage of the study, along with the version of the instrument to be translated or back translated, as well as the guidelines on the procedures related to sending the material that was produced. None of the experts had prior knowledge of the instrument, or had received information on the experts, ensuring the impartiality of the translation and back-translation versions. The Committee of Judges was also composed by five experts, including researchers and two members of the ISCoS.

The translation of the instrument from English into Brazilian Portuguese was done by three translators with knowledge in spinal cord injury, in both languages. It should be noted that the minimum number proposed by the ISCoS Executive Committee is two translators. In this study, three translators were chosen in order to facilitate the solution of possible differences between the versions, when two of the versions agreed with the translation, that was the adopted version. From the three versions, a consensual version was formulated by the researchers, which was sent to two members of the Committee of Judges and then a version in Brazilian Portuguese was formulated. The translation was not carried out word by word, for each translator tried to maintain the equivalence of meaning, since it is a process that included the translation of language and the cultural adaptation, maintaining, for that, a simple and easily understood language. The terms that were not easily understood, or that the Judges did not agree with their translated meaning, were discussed with the specific developing group of the Data set, thus reaching a satisfactory translation of the term and obtaining the translated version 1 (TV1). After this initial stage of translation, the back translation process was started to guarantee the meaning of the original language.[19]

The back translation process was carried out by two experts in the language, also members of the Committee, with experience in medical English; these two experts were unaware of the Data set original instrument in English, being independent of the initial translators. They performed the back translation into English, from TV1. After this stage, three members of the Judges Committee performed the evaluation of the two back translation versions and the comparison of the back translation versions with the original version (OV), finding and solving differences when they occurred, and thus concluding the elaboration of the translated version 2 (TV2).[19]

Once the TV2 was finished, it has undergone an evaluation by four members of the Committee of Judges, one of them being the developer team member of the Data set, in order to ensure whether the translation was sufficient to convey the original concept.[19] Once this step was accomplished, the final translated version (FV) was obtained, being sent to the next phase: the reliability test within and between examiners.

RESULTS

Initially, the three versions translated by the specialists were compared, and language and cultural adaptations were made, with the purpose of maintaining the OV construct, and to facilitate the understanding and application of the instrument in Portuguese-speaking countries. The changes that were made to reach TV1 are described in table 1:

Table 1- Description of the divergent items in the three translation and adoption versions for translation version 1. Ribeirão Preto, SP, Brazil. 2016

Term in the original version		Translator 1	Translator 2	Translator 3	Translation version 1
1	Urinary tract impairment	*Lesão do trato urinário*	*Disfunção do trato urinário*	*Deficiência do trato urinário*	*Disfunção do trato urinário*
2	Awareness of the need to empty the bladder	*Consciência da necessidade de esvaziar a bexiga*	*Apresenta desejo miccional*	*Percepção da necessidade de esvaziar a bexiga*	*Percepção da necessidade de esvaziar a bexiga*
3	Bladder reflex triggering	*Acionamento do reflexo vesical*	*Por estímulo do reflexo vesical*	*Ativação reflexa vesical*	*Estímulo do reflexo vesical*
4	Voluntary (tapping, scratching, anal stretch, etc.)	*Voluntário (batendo, coçando, força anal, etc*)	*Voluntário (piparote, massagem abdominal, toque retal, etc*)	*Qualquer perda urinária involuntária (incontinência) nos últimos três meses*	*Voluntário (piparote, manter coceiras, toque retal, etc*)
5	Any involuntary urine leakage (incontinence) within the last three months	*Alguma perda de urina involuntária (incontinência) dentro dos três últimos meses*	*Qualquer episódio de incontinência urinária nos últimos três meses*	*Qualquer perda urinária involuntária (incontinência) nos últimos três meses*	*Qualquer episódio de incontinência urinária nos últimos três meses*

For item 1, of table 1, we chose the term *Disfunção do trato urinário*, suggested by Translator 2; for item 2, we adopted the term suggested by Translator 3, *Percepção da necessidade de esvaziar a bexiga;* for item 3, the term *triggering* has its literal translation as *desencadeando (unleashing)*. As this translation was not suggested by any of the three translators, there was a preference for using the Translation proposed by Translator 2 adapted to *Estímulo do reflexo vertical*; for item 4, the employability of the term itching was chosen; for item 5, we adopted the translation performed by Translator 2. *Qualquer episódio de incontinência urinária nos* últimos *três meses.*

In the back translation stage, the two back-translated versions, created from TV1, by the invited Experts, were confronted with the OV by the Judges Committee, in order to find divergences of meanings of the back-translated questions, when compared with the OV.

In table 2, there are the terms from which the back translators diverged, the presentation of the term in the OV, as well as the changes made from the TV1 are described.

Table 2 - Description of divergent items in back translation and correction for translation version 2. Ribeirão Preto, SP, Brazil, 2016

Term in the original version		Back translator 1	Back translator 2	Translation version 1	Translation version 2
1	Awareness of the need to empty the bladder	Perception of the need to void the bladder	Feeling of need to empty the bladder	*Percepção da necessidade de esvaziar a bexiga*	*Percepção da necessidade de esvaziar a bexiga*
2	Normal voiding	Normal urination	Normal voiding	*Micção normal*	*Micção normal*
3	Voluntary (tapping, scratching, anal stretch, etc.)	Voluntary (tapping, skin reflex or "scratching", digital stimulation of rectum, etc.).	Voluntary (Tapping, superficial or cutaneous reflex's, anal or rectal stretch, etc.)	*Voluntário (piparote, e coceiras, toque retal, etc*)	*Voluntário (piparote, reflexo cutâneo ou "coçar", toque retal, etc*)

The terms described in line 1, which in the OV were Awareness of the need to empty the bladder and in line 2, with the original Normal voiding, received divergent back-translation: Back translator 1 opted

for Perception of the need to void the bladder for line 1, and Normal urination for line 2; yet, back translator 2 presented Feeling of need to empty the bladder for line 1, and *Normal voiding* for line 2. For these items, the translation performed in TV1 was maintained for TV2. For the item described in line 3, with the original Voluntary (tapping, scratching, anal stretch, etc), Back translator 1 chose Voluntary (tapping, skin reflex or "scratching", digital stimulation of rectum, etc*)* and Back translator 2, Voluntary (Tapping, superficial or cutaneous reflexes, anal or rectal stretch etc.*)*, Back translator 1's version was the chosen one, which when transcribed to Brazilian Portuguese, it maintained the term reflexo cutâneo, followed by the term scratching, between quotation marks.

Some minor changes were suggested by the Judges, such as the adoption of the terminology *Cateter de demora* for the translation of Indwelling catheter. There was also the addition of the word (*use)* before the original (Sacral anterior root stimulation), translated as (sacral anterior root stimulation). There were the adaptations of *Media de esvaziamento(s) vesical voluntário por dia na* última *semana* (average of voluntary emptying of the bladder per day during the previous week) to *Número médio por dia de esvaziamento(s) vesical(is) voluntario(s) ocorrido na ultima semana* (average quantity per day of voluntary emptying of the bladder during the previous week) and *Qualquer episódio de incontinência urinária nos* últimos *3 meses* (Any episode of urinary incontinence in the last 3 months) to *Ocorrência de qualquer episodio de perda (Incontinência) Urinaria* (Any occurrence of urinary loss (incontinence) in the last 3 months). Finally, the terminology *Manobra de esvaziamento vesical* (Bladder emptying maneuvers) was adopted instead of the term *Expressão vesical* (Bladder expression)

At the end of the suggested changes, TV2 was generated, which was sent to two members of the ISCoS External Relations Committee, who were invited to the final revision of the entire translation process. These experts have suggested the adaptations detailed in the Table 3.

Table 3 - Description of divergent items in the original version and translation version 2 and the correction for the final version. Ribeirão Preto, SP, Brazil, 2016

	Term in the original version	Translation version 2	Final version
1	LOWER URINARY TRACT FUNCTION BASIC *DATA SET* - FORM	*FUNÇÃO DO TRATO URINÁRIO INFERIOR - FORMULÁRIO BÁSICO*	*FUNÇÃO DO TRATO URINÁRIO INFERIOR - CONJUNTO DE DADOS BÁSICOS*

The item described in line 1 refers to the decision on the title to be adopted in the translation version, being adapted from TV2.

DISCUSSION

The present study sought to translate and culturally adapt the lower urinary tract Data set with the methodology proposed by ISCoS/ASIA. It is emphasized that the instrument translated and adapted to the Brazilian context is not an instrument of measurement, by which other methodological resources would be indicated in order to evaluate the psychometric properties.

Thus, for the translation process, ISCoS guidelines were followed, which confirm the recommendations of other international authors,[19,23] who state that the translation must take into account the context and the population to which the instrument is intended, and not just carried out with the literal translation of the terms.[24] This care seeks to ensure that the instrument is understood and that it makes sense to the population that will fill it out.

Translation and cultural adaptation studies are increasingly common in the health field, since the construction of instruments involves a strenuous process and great investment of resources. It is worth remembering that the existing instruments are usually developed in the English language, being directed to the population and the cultural context of the population that speaks that language.[24-25]

In the translation of the first question, the original term was Urinary tract impairment, we chose to use Translator 2's expression (*Urinary Tract Dysfunction*), selecting the term disfunção (dysfunction), rather than the terms *lesão* (injury) and *deficiência* (disability), suggested by Translators 1 and 3, respectively. This choice was due to the fact that this term is commonly used in the Brazilian Portuguese literature, when describing changes in the normal functioning of the urinary system. The term "dysfunction" has also been used to describe urinary and intestinal dysfunction related to neurogenic bowel and bladder.[3] The author cites Lapides' and Wein's classifications, both with good acceptance among urologists, to describe the main malfunctions

as filling/reservoir failures and emptying failures.[3]

In order to translate the word Awareness (Awareness of the need to empty the bladder), the term *percepção* (perception) (perception of the need to empty the bladder), from Translator 3, was adopted, excluding the words "consciousness" and *apresenta desejo miccional* (has a miccional desire) from Translators 1 and 2, respectively. This choice considered the greater employability of the term perception when there is intentionality to describe feeling over the very broad term consciousness or the term present, which was considered to be totally distant from the intention of the question. This term was further revisited in the revision of TV2, and after the evaluation by the Judges Committee, it was maintained for the FTV.

For the translation of the original term Bladder reflex triggering, we chose Translator 2's *estímulo do reflexo vesical* (bladder reflex stimulus), excluding Translator 1's options *acionamento do reflexo vesical* (Bladder reflex activation) and Translator 3's acionamento do reflexo vesical (Bladder reflex activation), for when the maneuvers described as options to trigger the bladder reflex are analyzed, they are all part of what is usually called in the rehabilitation programs as stimulation maneuvers for bladder emptying.

There was trouble in finding a unanimous decision among the members of the Committee of Judges for the proper translation of the term scratching, inserted in the OV in Bladder reflex triggering - Voluntary (tapping, scratching, anally stretch, etc.) being translated by Translator 1 as *voluntário – batendo, coçando força anal entre outros* (Volunteer beating, scratching, anal strength, among others), by Translator 2, as *voluntário – piparote, massagem abdominal, toque retal, entre outros* (Volunteer flick, abdominal massage, digital rectal examination, among others) and, by Translator 3, as *voluntário – estímulo cutânea, tipo tapinhas e coceiras, distensão anal, entre outras* (Volunteer cutaneous stimuli, like patting and itching, anal distension, among others). In the literal translation *scratching* means *raspagem* (scraping), however, this translation would not be considered adequate for the context of rehabilitation and maneuvers for bladder emptying. Faced with this difficulty, one of the ISCoS Data set researchers was contacted to discuss the problem. Then, the use of the term *coceiras* (itch) was chosen. In the revision of the back translated versions with the OV, once again it was noticeable the lack of unanimity for a proper translation of the term *scratching*. Assessing this, the Judges Committee adapted the TV1 sentence *voluntário piparote, e coceiras, toque retal, etc* (Volunteer flick, and rectal itching, etc) *to voluntário piparote, reflexo cutâneo ou coçar, toque retal, entre outros* (Volunteer flick, cutaneous reflex or "scratching ", digital rectal examination, among others) on TV2, keeping the use of *reflexo cutâneo*(cutaneous reflex), followed by the term scratch, in quotation marks, giving the explanation of how the cutaneous reflex would happen. This translation was maintained and approved in the FTV.

The last divergent term of the translation, in the original Any involuntary urine leakage (incontinence) within the last three months, was translated as suggested by Translator 2 as *qualquer episódio de incontinência urinaria nos* últimos *três meses* (Any episode of urinary incontinence in the last three months", excluding translation 1, *alguma perda de urina involuntária nos* últimos *três meses* (Some involuntary urine loss incontinence within the last three months), and translation 3, *qualquer perda urinaria involuntária (incontinência) nos* últimos *três meses* (Any involuntary urinary loss (incontinence) in the last 3 months) because it was considered by the Judges as the closest translation of the literal translation , without losing the meaning of the OV. For the FTV, this was adapted as a suggestion of the Judges Committee as *ocorrência de qualquer episodio de perda (incontinência) urinaria nos* últimos *três meses* (Occurrence of any episode of urinary loss (incontinence) in the last three months).

For the translation stage, 56% of the sentences were unanimously translated by the three invited Translators. Of the nine issues that comprised the instrument, only four presented minor differences, as described and discussed above.

After translation, TV1 was sent to the back-translation phase. As in other methodological studies of instrument translation, back translation is an important step because it has the purpose of ensuring the fidelity of the content of the original document and its investigative and comparative purpose.[19]

In the back translation, the Judges Committee compared the two back translated versions with the OV and suggested the changes that are detailed below, some of which were secondary to the previous changes, still in the translation stage, and have already been discussed previously.

For the translation of bladder expression the terminology *manobras de esvaziamento vesical* (Bladder emptying maneuvers) was preferred and therefore substituted the term *expressão vesical* (bladder expression). This choice was justified, since the

Judges, together with the researchers, understood that this terminology in Brazilian Portuguese does not reflect the meaning of its use in the OV. The question in which this terminology is inserted in the OV is previous to the options of methods of bladder emptying, through bladder compression maneuvers, subdivided in maneuvers of effort compression (abdominal contraction, Valsalva Maneuver) or by external compression (Credé maneuver). Thus, the most appropriate term to reflect its meaning, based on the experience of the Judges in the area of rehabilitation, was that of *Manobras de esvaziamento vesical* (Bladder emptying maneuvers), since, in rehabilitation programs, the maneuvers described above for compression of the bladder, are patient-oriented and encompassed within this terminology.

For the translation of *Indwelling catheter,* it was adopted the terminology *cateter de demora* (delay catheter), instead of *cateter permanente* (permanent catheter) since it was understood that the use of the term "permanent", in Brazilian Portuguese would convey the incorrect idea of a catheter that would be irreplaceable, and within the OV this question refers to the use of a catheter that remains in the bladder for a longer period than a catheter used for intermittent emptying. This type of catheter is known in Brazil as *cateter de demora*, or long-term catheter, however, as the concern with the use of simple terminology and easy recognition for the population with spinal cord injury was present, as well as for healthcare professionals, it was decided to retain the term *cateter de demora* in the final translation version.

In the translation of Sacral anterior root stimulation, adopted for TV2 as estimulação da raiz sacral anterior (Stimulation of the Anterior Sacral Root), the use of the word *uso* (use) prior to estimulo da raiz sacral anterior (stimulation of the anterior sacral root) was added to make the intentionality of the option of this alternative as a form of treatment more evident in which the use of anterior sacral root stimulation could be performed in more than one way, such as implanted electrodes or other stimulation methods.

Lastly, the original sentence was modified, Average number of voluntary bladder emptyings per day during the last week, translated initially as media de esvaziamento vesical voluntário por dia na última semana (Mean value of voluntary emptying of the bladder per day during the last week), to número médio por dia de esvaziamento(s) vesical(is) voluntario(s) ocorrido na última semana (Average number per day of bladder emptying (s) during the last week) in order to maintain greater proximity to the terminology used in the OV, without losing the meaning in Brazilian Portuguese.

The suggested amendments were adhered to, and so the TV2 was formulated, which was sent to two members of the ISCoS External Relations Committee. After evaluation, these Specialists only suggested the adequacy of the instrument title, with the original version Lower urinary tract function basic data set - form to função do trato urinário inferior – conjunto básico de dados.

This stage was fundamental for the finalization of the translation process. From it, the final translated version (FTV) was originated and used to test the reliability of the translated instrument.

The accuracy to perform the translation step was retained in this study, in view of the ever-present concern that multicenter studies, among countries, are fundamental for the improvement of the care to individuals who have a spinal cord injury. In the area of urinary and fecal incontinence, several instruments have been formulated and tested, however, few have been translated and validated in other languages, or, when inserted in other studies in the area, the translation stage of the instrument used is treated as a less important part of the study, thus being used without the necessary attention and criticality.[26]

Usually, in methodological studies of translation of instruments, it is important to verify the agreement of the authors of the original instruments to be translated, in order to yield greater trustworthiness to the final translation.[24-25] Being able to have the support of the ISCoS experts in the final stage of the translation, promotes greater security to refer the instrument to the next stage of the reliability tests. The main limitations found in this stage of the study were the occurrence of terms without literal translation in the Portuguese language, for which it was necessary to find a unanimous decision among the Judges to choose the translation that would best be adapted to the culture and to the applicability of the instrument in Brazil, with great regional and cultural differences. In this way, future studies could adopt a Judiciary Committee with better regional distribution, and that contemplates at least four different regions, in order to guarantee a wider cultural adaptation of the instrument.

CONCLUSION

With increasing survival rates in individuals with spinal cord injury, there is also a growing

demand for advances in studies that may offer improvement in the quality of life of these individuals. The collection of standardized data regarding the health conditions of this population should be prioritized so that any rehabilitation or health care center that meets this demand has available instruments to collect this data. In this way, it is possible to have comparisons regarding the treatments and outcomes of the spinal cord injury between rehabilitation centers and countries, also potentiating the elaboration of an electronic database, with a larger number of individuals, which can be used worldwide.

The use of instruments already available reduces costs with the creation of new instruments, besides providing the interchange between researchers in international scope. Thus, it is essential to emphasize that the process of translation and cultural adaptation of these instruments must be carried out according to strict methodology to ensure equivalence between the original version and the translated questionnaire.

During the translation and adaptation of the instrument, some adjustments were necessary to be made by the researchers, as well as suggestions by the rehabilitation professionals who were consulted, with the purpose of adapting both the language and the culture of Brazilians. It should be noted that, although some adjustments were made in the translated version, the cultural adaptation process maintained the equivalence between the Brazilian and the original versions of the instrument, since there was a comparison between the original version and the back-translation.

This instrument, after being submitted to the next step, which is instrument reliability, can be very useful for rehabilitation centers, clinics and hospitals, as well as for health professionals and rehabilitation researchers who can discover methods and develop strategies for improving the health and quality of life of the population with spinal cord injury. In addition, it can provide a national database with relevant information to be shared worldwide.

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Correspondence: Fabiana Faleiros
Avenida dos Bandeirantes, 3900 - Campus Universitário
14.040-902- Monte Alegre, Ribeirão Preto, SP, Brasil
E-mail: fabifaleiros@eerp.usp.br

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