Tradução transcultural de instrumentos de qualidade do processo de doação de órgãos


Escola Paulista de Enfermagem
São Paulo, Brasil

Available in: http://www.redalyc.org/articulo.oa?id=307030418012
Cross-cultural translation of quality instruments in the organ donation process

Tradução transcultural de instrumentos de qualidade do processo de doação de órgãos

Neide da Silva Knihs¹
Janine Schirmer²
Bartira de Aguiar Roza²

Abstract

Objective: To carry out the cross-cultural translation of quality instruments in the organ donation process from the National Transplantation Organization of Spain.

Methods: Methodological research with quantitative approach conducted in three Neurology reference hospitals in the South of the country. The instruments validation was carried out by mean of the steps of translation, backtranslation, synthesis and expert committee. The reliability was conducted by means of inter-observer equivalence and test and retest stability.

Results: There was a 100% match among all the judges in 89% of the items in the cross-cultural translation (11% of the items were not equivalent). In the reliability analysis, the Kappa coefficients corresponded to 0.86 and 0.95.

Conclusion: The versions of the instruments were considered valid and reliable for use by institutions that carry out the organ donation process in Brazil.

Keywords
Nursing assessment, Nursing audit; Transplantation; Validation studies; Direct tissue donation; Translating

Descritores
Avaliação em enfermagem; Auditoria em enfermagem; Transplante; Estudos de validação; Doação dirigida de tecido; Tradução

doi: http://dx.doi.org/10.1590/1982-0194201400012

1Hospital Santa Isabel, Blumenau, SC, Brazil.
2Escola Paulista de Enfermagem, Universidade Federal de São Paulo, São Paulo, SP, Brazil.
Conflict of interest: Roza BA is an associate editor of Acta Paulista de Enfermagem and was excluded from the evaluation process of the manuscript.
**Introduction**

In recent times, the number of patients enrolled in the transplantation list has grown significantly. However, the donation rates have not grown at the same rate, so that approximately one third of patients die while waiting for an organ. (1-3)

Great disparity can be identified between the number of potential deceased donors and donations performed. (2,3) Brazil has an estimated rate of 70 potential donors per million inhabitants (per million population - pmp) per year. From these, only 43.6 pmp/year are reported to the Notification, Procurement and Distribution Centrals of Organs and Tissues and only 12.6 donors (pmp/year) came into effect in 2012. There was a potential donor loss of 29.5 pmp/year. From these, 38.9% corresponded to family refusal; 14% to cardiac arrest and 10% to medical contraindications. (4) However, the reasons that lead to family refusal to donate, as well as the cardiac arrest reasons and medical contraindications are unknown. (4-7)

Brazil does not have a quality program in organ donation and transplantation that can determine the causes of losses by underreporting, maintenance and family refusal, as a result of the care process. (4-6)

The need to increase the number of donors is a worldwide problem. (4-6) Spain, Portugal, Italy and the United States, among other countries, have significantly changed this situation. (8) Spain stands out in this context, (8,9) in which the rate of notifications of potential organ donors has changed significantly, from 14.8 pmp/year effective donors in 1989 to 36.2 pmp/year in 2012. (9) The change in this reality is related to the organizational improvement of the transplantation process and the implementation of the Quality Assurance Program. (8,9)

The Quality Assurance Program allows the National Transplantation Organization to identify factors that influence the loss of potential donors. These data are transformed into indicators, which admit the analysis of non-reported Brain Death, the causes of the maintenance problems and the reasons of medical contraindications and family refusals, year by year. (8,9)

Thus, the main objective in this study is to carry out the cross-cultural translation of quality instruments in the organ donation process from the National Transplantation Organization of Spain. The specific objectives were: to apply the quality instruments of the organ donation process from the National Transplantation Organization of Spain in pilot hospitals in Santa Catarina and to evaluate the reliability of these instruments.

**Methods**

This is a methodological, cross-cultural translation research, developed according to recommendations from the literature, carried out in three reference hospitals in Neurosurgery in the South of Spain. (10-12)

The instruments of the Quality Assurance Program were developed by professionals from the National Transplantation Organization, with extensive experience in the quality area and in the donation process, using Avedis Donabedian. (8,9) The objective of the instruments is: to define the capacity of organ donation according to the type of hospital; to detect the loss of potential donors and to analyze the causes of the losses as a tool to identify points of improvement in the donation process, and to discover the hospital factors that impact this process. To use these instruments, the National Transplantation Organization elaborated an orientation guide.

The Quality Assurance Program uses an orientation guide, which describes the stages to analyze the records of deceased patients at the critical patient units step by step. For this analysis, two instruments are used. Instrument I is used in the first analytic stage of the records, called stage of internal review. This analysis is performed by the transplantation hospital coordinators from the institution. Instrument II is used in the second review of medical records (by sampling), called external evaluation. This analysis is carried out by transplantation hospital coordinators from another institution. To participate in the
second stage, the institution must be developing the first step for a year. Instrument I presents eight items for analysis and instrument II six items.

In instruments I and II, for three items, YES or NO answers are used. To get to one of these answers, the professional must conduct detailed evaluations in the first and final evolution of the health team in the records. For the other five items of instrument I and the other three items of instrument II, there are at least three possible answers. To indicate one of the answers, the professional needs to obtain information on the evolutions of the healthcare team and help from the orientation guide.

The first stage of the cross-cultural translation was performed by two health professionals, including one physician and one nurse. After translation, the synthesis stage was developed, checking for any inconsistency between the translated information versions. After reaching a consensus between translators and researchers, Version I was reached and documented as the synthesis of the translations, which was submitted to backtranslation.

The second stage consisted of backtranslation, performed by two nurse translators, independently. One of the translators was a native from Spain and the other came from Uruguay, and both resided in Brazil. After the consensus in the backtranslation, Version II was reached and evaluated by the authors of the instruments. Afterwards, it was submitted to the evaluation of the expert committee.

The fourth stage was the pre-test, developed in three high-complexity hospitals that were references in Neurosurgery in Santa Catarina. The choice of these institutions took into account the demand of neurosurgical patients and the average of 25 reports of potential donors (pmp/year) to the Notification, Procurement and Distribution of Organs and Tissues Central.

Data collection was carried out from the medical records of patients who died in Critical Patient Units by two nurses, a physician and researchers between May and June 2011. A week before the start of data collection, those professionals received an orientation guide.

The pretest was carried out in two distinct stages: In the first stage, it was carried out in hospitals number 1, 2 and 3, between March 1st and May 31st, 2010, with a total of 119 records, by using instrument I, which intended to identify the following items: the cause of death, if brain death has been identified by the Transplant Hospital Coordinator; the reason why the Transplant Hospital Coordinator did not detect brain death, medical contraindication to donation, the cause of medical contraindication; if surgery to remove the organ was initiated, the cause of the non-removal of organs; if the family interview was conducted.

In the second stage, the pre-test was conducted only in hospital number 3, between March 1st, 2010 and March 1st, 2011, with a total of 259 records, by using instrument II, which in-
tended to identify the following items: if it corresponds to a report of brain death; if there is information indicating a brain death; if it was possible to know the causes of loss of the potential donor; causes of the potential donor losses; if the losses were considered appropriate or inappropriate; and what were the causes of losses considered inappropriate.

After evaluating the medical records, the researchers finalized a table, so that the professionals involved in data collection could indicate the degree of understanding of each item in the instruments. We used a Likert Scale,\(^{(13)}\) and the values were represented: -1 = no understanding, zero = partially understood, +1 = fully understood. When responses were zero or -1, they were requested to indicate suggestions for the item and, as a result, the proposed changes in the instruments were made.

At the end of the pretest, the analysis of psychometric properties was carried out. To measure the reliability of the instruments, equivalence was used by means of interobserver evaluation, and the stability was obtained by means of the test and retest.

89 records were evaluated.

For the interobserver equivalence, each of the Transplantation Hospital Coordinators analyzed all medical records. For the stability test and retest, they reevaluated two or three records, at an interval of 5 days.

Data analysis of the psychometric properties occurred through descriptive and statistical analysis. Statistical analysis evaluated the degree of concordance between the results of different observers. The test used for comparisons was the multiple Kappa, which evaluates the correlation between the answers. For this analysis, a significance level of 5% was considered. The hypothesis tested was that the Kappa index was equal to zero, which would indicate agreement or null, if it was greater than zero, the correlation would be greater than by chance. For this study, a Kappa value of 0.70 was considered.

The study development followed the national and international standards of ethics in research involving human beings.

**Results**

In the committee evaluation stage, ten judges participated, five of them evaluated instrument I and five evaluated instrument II.

The committee evaluations results showed that there was 100% equivalence for all the judges on 89% of items and 11% of the items were considered as not equivalent. From the items that did not show equivalence (11%), 80% were related to semantic evaluation and 20% due to conceptual evaluation.

The content validation index results showed that the average interobserver rate in all comparisons was higher than 0.8, as recommended value for this study and in accordance with other consulted authors.\(^{(12-14)}\)

**Pre-test results**

The results of the pre-test revealed that all the professionals who carried out the data collection fully understood 89% of the items of the instruments, while there was partial understanding in 8% and no understanding by all professionals in 3%. Each professional took an average 20 minutes to evaluate each report.

From the 378 medical records evaluated in the pre-test, 125 (33%) were medical records of patients who had clinical signs of brain death. From the 125 records, 20 (16%) did not have sufficient information to identify a possible brain death and were discarded. From the 105 remaining, there was loss of potential donors in 45 (42.8%), and the losses were considered inappropriate in 26 (57.7%).

Table 1 shows the results of the pre-test related to the main causes of potential donor losses.

**Results of psychometric properties**

Twenty-four Transplantation Hospital Coordinators participated, with an average work experience in the area of 42 months. Nurses were 65% and physicians 35%.

The interobserver Kappa equivalence in the two instruments (Table 2) almost corresponds to a perfect agreement.
Cross-cultural translation of quality instruments in the organ donation process

Table 1. Causes of potential donor losses

| Items                                                                 | Possible answers                   | n*(%)
|----------------------------------------------------------------------|------------------------------------|--------
| Instrument I                                                                                           |                                    |
| Reasons why the Transplantation Hospital Coordinator did not detect brain death | Incorrect medical contraindication | 3(37.5) |
|                                                                        | Due to instability to start the diagnosis of brain death | 2(25) |
|                                                                        | Due to the Critical Patient Unit staff’s inability to identify clinical criteria for brain death | 1(12.5) |
|                                                                        |                                    | 2(25) |
| Total                                                                                                        | 8(100) |
| Family refusal reasons                                                                                     | Opposition from family to donation without a specific reason | 5(23.8) |
|                                                                        | Health care team problems          | 5(23.8) |
|                                                                        | Opposition from donor when alive   | 4(19) |
|                                                                        | Family wanted the body intact      | 3(14.4) |
|                                                                        | Other                             | 4(19) |
| Total                                                                                                        | 21(100) |
| Instrument II                                                                                              |                                    |
| Causes of the potential donor losses                                                                       | Encephalic deaths unidentified     | 12(26.6) |
|                                                                        | Maintenance problems               | 8(17.7) |
|                                                                        | Family refusal to donate           | 21(46.6) |
|                                                                        | Logistical problems               | 3(6.7) |
|                                                                        | Other                             | 2(4.1) |
| Total                                                                                                        | 45(100) |

Source: Medical records of the critical patients units of the hospitals numbers 1, 2 and 3. *n is the number of times the item was appointed

Table 2. Kappa and simple agreement of the stability of instruments I and II

<table>
<thead>
<tr>
<th>Items</th>
<th>Instrument I</th>
<th></th>
<th>Instrument II</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cause of death</td>
<td>0.62</td>
<td>98.6</td>
<td>0.95</td>
<td>98.4</td>
</tr>
<tr>
<td>Identified brain death</td>
<td>1.00</td>
<td>100.0</td>
<td>1.00</td>
<td>100.0</td>
</tr>
<tr>
<td>Medical contraindication</td>
<td>1.00</td>
<td>100.0</td>
<td>1.00</td>
<td>100.0</td>
</tr>
<tr>
<td>Cause of medical contraindication</td>
<td>1.00</td>
<td>100.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cause of non-removal of organs</td>
<td>0.72</td>
<td>93.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The interview was conducted for donation</td>
<td>1.00</td>
<td>100.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The interview was conducted for donation</td>
<td></td>
<td></td>
<td>1.00</td>
<td>100.0</td>
</tr>
<tr>
<td>It was possible to identify the causes of losses</td>
<td></td>
<td></td>
<td>0.71</td>
<td>95.0</td>
</tr>
<tr>
<td>Causes of loss of potential donors</td>
<td>0.86</td>
<td>93.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Causes of losses considered adequate or inadequate</td>
<td>0.51</td>
<td>92.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Kappa</td>
<td>0.89</td>
<td>97.7</td>
<td>0.83</td>
<td>95.9</td>
</tr>
</tbody>
</table>

Source: Medical records of the critical patient units of hospitals number 1, 2 and 3. Kappa perfect agreement = 1.00; simple agreement (%)

Discussion

The translated and adapted instruments proved important to measure the quality in the organ donation process. These instruments pointed out the main cause of potential organ donor losses, and create opportunities to identify strong and weak points and areas of improvement.

The results showed the percentage of brain death in the records evaluated and the real causes of the potential donor losses (Table 1), which were related neither to the non-detection of brain death by the Transplantation Hospital Coordinator nor to family refusal. In these losses, we identified the reasons why the coordinator did not detect brain death and the reasons why families refused to donate (Table 1). These results show that the translated instruments were able to get results according their objectives.

It is expected that this study will be the starting point for the use of these instruments in the donation process throughout the country. Certainly, the use of instruments will permit the identification of potential brain death and potential donors from health institutions and, at the same time, provide real data on the problems that prevent the increase in the number of effective donors.

One of the limitations identified during the study stages was the lack of information in the records. When information existed, this were restricted and difficult to understand.

The final Kappa in the stability test and retest (Table 3) corresponded to 0.97 and 0.94, considered a strong agreement, a value higher than the rate recommended for the study, which was 0.70.
The results revealed an equivalence of 89% and 92% by the expert committee, results approaching previous studies developed in the country. In some of these studies, there was 100% agreement and equivalence of 73%, 80% and 85% by the expert committee.\(^{(12-14)}\) In one study, there was an equivalence percentage higher than 80%.\(^{(15)}\) In another study, 17% of the items were highlighted as hardly altered.\(^{(16)}\)

The content validity of the instruments was considered excellent, with a final average content validation index of 0.9 when compared with other studies, with indexes of 0.67, 0.80, 0.9 and 1.0.\(^{(12,15-19)}\)

The pre-test stage was crucial in this process. In this stage, there was the possibility to use the instruments, to detect possible errors, to confirm that both the presentation of the instruments and all questions are understandable to those collecting the information. In addition, the pre-test helped verify the practical aspects of the application and the time needed to use the instruments in practice.

The results of the psychometric properties of instruments I and II corresponded to an almost perfect agreement. This suggests that the inter-observer agreement of items lies within the levels recommended by other authors, with Kappa values of 0.68, 0.73, 0.80, 0.92, 0.97.\(^{(13-19)}\) Still, in these studies, values of 0.68, 0.86, 0.89 and 0.92 for the tests and re-tests were identified.\(^{(16,17)}\)

The simple agreement average of the interobserver evaluation corresponded to 97.6%, and the mean simple agreement of the test and retest was 97%, indicating an excellent agreement, in line with other studies.\(^{(13-19)}\) The data revealed that the instruments of the Quality Assurance program present equivalence and excellent stability when compared to those from other studies.\(^{(16-19)}\)

We believe that, through these instruments, the managers of the National Transplantation System can encourage hospital managers to use these tools in order to develop indicators, based on concise information obtained from the medical records of patients deceased at Critical Patient Units.

**Conclusion**

The quality instruments in organ donation evaluated in this study were adapted and validated for use by healthcare institutions that carry out the process of organ donation, as well as by the donation system authorities of the country, because they permit identifying the reasons for not reporting the potential donors, the causes of losses, the reasons for losses due to maintenance, losses due to refusal and effective donations.

**Collaborations**

Knihs NS; Schirmer J Roza and BA contributed to the study design, analysis and interpretation of data, critical revision of the important intellectual content, collection and interpretation of data, writing of the manuscript and approval of the final version for publication.

**References**


