The challenges and results of 29 years of publication of Acta Paulista de Enfermagem

The Editorial published by Acta Paulista de Enfermagem (APE) in 1988 expressed its purpose of being a strong and dynamic journal for Brazilian nurses to publish their scientific manuscripts. Along the years, APE began to publish contributions to the health field as well. When APE completed 17 years of age, it assumed the mission of improving the publication of scientific quality articles thus favoring professional education. In the beginning of the XXI century, APE has assumed the demands of indexed globalization, highlighting the SciELO collection and the Institute for Scientific Information (ISI), SCIMAGO, and SCOPUS databases. In addition, APE has innovated in order to meet the urgent need to publish exclusively in the digital version, with a high demand for submissions, aiming to achieve a greater audience, visibility, publication speed, and universal free access. The digital form of APE made possible to provide both ahead-of-print publication and interactivity among authors.

In 2013, the editorial project of APE was to be among the best nursing journals in the world. With this challenge, APE has professionalized its editorial office and adopted the ScholarOne, an international reference system, which allows authors to submit their manuscripts online and follow the flow of reviews by the editor-in-chief, associated editors, and ad-hoc reviewers. Thus, the layout of articles began to be arranged in the editorial office where the smart labeling in the XML format was adopted, as required by the PubMed Central. The APE also adopted a policy of awareness and information about intellectual property, with specific procedures to avoid plagiarism practices. The purpose of this policy is to inform authors about acceptable writing practices, thus defining a quality standard for publication of peer-reviewed articles. Thus, APE began to be considered a rising journal, under stringent quality criteria in the scientific, technical, and administrative areas.

Thus, APE completed 25 years of life, with the following quality criteria: i. open access, ii. App available for iPad (in Portuguese and English), iii. support from Universidade Federal de São Paulo (UNIFESP) and the Brazilian Council for Science and Technology (CNPq); iv. editorial board composed of researchers from Brazil and abroad; v. indexation in national and international databases (including Web of Science, ISI, SCOPUS, CUIDEN, CINAHL, SciELO, and LILACS); and vi. classification in the QUALIS/CAPES index (stratum A2), which is used to evaluate the academic graduate programs.

As the editor-in-chief of APE, I am privileged to make a historical clip of the Editorials of my predecessors. Some previous decisions allowed APE,
a technical-scientific electronic publication of *Escola Paulista de Enfermagem* (EPE, UNIFESP), to come to be a rising scientific journal, with multimedia interface. Once more, APE has innovated with a necessary change to keep trying to be among prominent journals in the nursing and health areas of the national and international scenarios. In 2015, APE was submitted to evaluation by PubMed Central (National Institute of Health, NIH, and National Library of Medicine, NLM), and later by MedLine, aiming at both its indexation in these important data networks of the health area in the world and availability in the open-access text bases of the biomedical and life sciences. Finally, APE has joined the RevEnf Portal as a strategy to strengthen the scientific nursing journals published in Brazil.


Janine Schirmer

*Editor-in-Chief of Acta Paulista de Enfermagem*

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Patient safety in the surgical environment: translation and cross-cultural adaptation of validated instrument

Segurança do paciente no ambiente cirúrgico: tradução e adaptação cultural de instrumento validado

Daniela Campos de Andrade Lourenção
Daisy Maria Rizatto Tronchin

Abstract

Objective: To translate and adapt the Safety Attitudes Questionnaire/Operating Room Version into Portuguese.

Methods: Methodological research of cross-cultural adaptation which applied the stages: translation, synthesis, back-translation, expert panel evaluation, pretest, submission and evaluation of the reports by the authors of the original instrument. The content validation was performed using the semantic, idiomatic, conceptual, experiential and content equivalence. A total of 12 experts participated and the agreement index corresponded to ≥ 80%.

Results: The stages of translation and back-translation were considered adequate and in the synthesis evaluation by the experts, changes were indicated in 41 items from the total of 137. Regarding the equivalence of the validation process carried out by the experts, the general consensus of the instrument obtained 84.1% equivalence, 9.3% of non-equivalence and 6.6% undecided. In the pretest, the mean time to fill in the questionnaire corresponded to 16.5 minutes.

Conclusion: The process of translation and adaptation presented adequacy as to the validity of content through the indices obtained in equivalences and understanding for the subjects, and it was approved by the authors.

Keywords
Patient safety; Translating; Questionnaires; Operating room nursing; Perioperative nursing; Nursing service, hospital

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Resumo

Objetivo: Traduzir e adaptar o Safety Attitudes Questionnaire/Operating Room Version para a língua portuguesa.

Métodos: Pesquisa metodológica de adaptação transcultural que empregou as etapas: tradução, síntese, retrotradução, avaliação por comitê de juízes, pré-teste, submissão e avaliação dos relatórios pelos autores do instrumento original. A validação de conteúdo foi realizada mediante as equivalências semântica, idiomática, conceitual, experiencial e de conteúdo. Participaram 12 juízes e o índice de concordância correspondeu a ≥ 80%.

Resultados: As etapas de tradução e retrotradução foram consideradas adequadas e na avaliação da síntese pelos juízes foi indicada alteração em 41 itens, do total de 137. Em relação ao processo de validação das equivalências realizado pelos juízes, o consenso geral do instrumento obteve 84.1% de equivalência, 9.3% de não-equivalência e 6.6% de indecisos. No pré-teste, o tempo médio de preenchimento correspondeu a 16,5 minutos.

Conclusão: O processo de tradução e adaptação apresentou adequação quanto à validade de conteúdo mediante os índices obtidos nas equivalências e compreensão pelos sujeitos, e foi aprovado pelos autores.

Conflict of interest: the authors declare that there are no conflicts of interest
Introduction

During the last decade, patient safety became a constant concern for the health sector in all its dimensions. This topic is currently intensely debated due to the evidence of the impact of errors and adverse events in health systems.

Among the challenges imposed by the health sector in order to provide quality and safe care, surgical environments are highlighted. In this scenario, the activities are complex, interdisciplinary and with heavy reliance on individual performance in a high risk environment for the occurrence of adverse events. (1,2)

Thus, monitoring and assessing the safety culture in healthcare organizations allows the identification and management of patient safety in the surgical environment; this assessment can be used for the purpose of benchmarking and trend analysis. It should be added that it may provide a basis for the situational diagnosis, continuing education programs, implementation of care protocols and monitoring of adverse events. (1,2)

The literature emphasizes the distinction between culture and safety climate and emphasizes that safety culture has been assessed using psychometric questionnaires that measure the climate of safety attitudes and perception of health professionals on patient safety in hospital organizations. (3) In this perspective, safety culture represents the organization’s values and actions related to safety and safety climate focusing on perceptions of professionals on safety management in the institution. (4)

In this sense, research instruments require translation and adaptation between cultures and countries, in order to keep the content, the psychometric characteristics and their validity to be used in different populations. (5) It is noteworthy that the advantage of the process of adaptation of an existing instrument is to allow comparison of data from different populations and contexts with greater equity, and also enable us to understand their similarities, differences and common characteristics. Other advantages include the anonymity, the lowest cost and time savings in the construction of instruments that assess the same construct. (5)

The literature regarding the translation and adaptation of psychometric instruments recommends the use of six stages, defined as follows: Translation, synthesis of translation, back translation, expert panel evaluation, pretest, submission and evaluation of the reports by the instrument’s authors. (6)

Among the questionnaires available to measure safety climate, we may cite the Safety Attitudes Questionnaire (SAQ). (4) The questionnaire was translated and validated for various countries such as Germany, Denmark, Greece, China, Sweden, Turkey, New Zealand. (7-13) Different versions of SAQ were designed to be applied in various scenarios such as intensive care units, medical and surgical clinics, operating rooms, emergency services, outpatient and primary care, among others. (14,15)

Considering the surgical environment and the lack of instruments capable of measuring the safety climate in operating rooms, in the perception of health professionals, in the Brazilian context, we decided to translate and adapt the version of the Safety Attitudes Questionnaire/Operating Room Version.

The Safety Attitudes Questionnaire/Operating Room (SAQ/OR) is a modified version of the Safety Attitudes Questionnaire (SAQ) developed by researchers at the University of Texas in the United States of America (USA), and has the same properties of SAQ generic version, in relation to patient safety construct adapted to the surgical environments and the scale of answers. (15) It should be noted that the SAQ/OR was translated and adapted for Sweden and Japan, maintaining its psychometric properties. (2,16,17)

Other versions of the instrument have been developed through research to relate the results of the SAQ/OR with patient safety in the surgical environment. In this sense, a study evaluated the impact of the implementation of the checklist in health professionals attitudes towards safety in a surgical center in Japan. (17) Another study, conducted in the USA used the SAQ/OR to identify differences in communication and collaboration between nurses and surgeons. (18)

From a structural point of view, the questionnaire is divided into three parts: the first is related to the quality of communication and collaboration among professionals working in the operating...
room, where the subject must answer about the relationship they have with each of the professional categories. The second part consists of 58 items with assertions designed to measure the perception of the professional towards safety and to verify that the subject completed the first part of the instrument. And finally, the third part, composed of socio-demographic information (gender, ethnic group, professional category, length of experience, shift operations, etc.), at the end there is a space for three possible recommendations for improving patient safety in the operating room. The assertions are answered by a five points Likert scale with valuation and an item “it does not apply”. (15)

We believe that the translation and cultural validation of SAQ/OR will allow the measurement, through the perception of the professionals, of the safety climate in the operating room in the Brazilian reality, contributing to safe and quality of care in hospitals. Thus, this aims to describe the process of translation and cross-cultural adaptation of the SAQ/OR for the Brazilian context.

**Methods**

This is a methodological study of translation and cross-cultural adaptation of the SAQ/OR, used to measure the health professional safety climate in the operating room to the Brazilian reality.

Considering the various methods described in the literature for translation and cross-cultural adaptation of measuring instruments, in this study we opted for the model proposed by Beaton. (5)

The recommendations of this model include six stages, namely: translation, synthesis of translations, back translation, experts panel evaluation, pretest, submission and evaluation of the reports by the authors of the instrument. (5)

**Translation**

This first stage of the cross-cultural adaptation process occurred through the translation of the instrument by two independent translators, fluent in English and who had as their native language, Portuguese. It should be noted that only one of the translators knew the objectives of the study as well as the concepts of the questionnaire.

The following versions were analyzed and compared by the researchers and the inconsistencies or doubts were clarified with the translators. At that time, a synthesis of the translation was carried out.

**Back translation**

At this stage, two back-translation were performed, the synthesis version in Portuguese returned to the English language, with the participation of two independent translators, whose native language was English and who did not know the original instrument. Again, there was the synthesis of these back-translations by the authors, resulting in the two versions. At the end of this research stage, we produced the final version and all reports were inserted into a spreadsheet for evaluation of equivalence by the experts.

**Experts Panel Evaluation**

The final Portuguese version was submitted to the expert panel in order to make the equivalences: semantic, idiomatic, conceptual, experiential and content.

Thus, according to the model adopted the semantic equivalence considers the adaptation of words according to the grammar and vocabulary of the language into which the adjustment occurs; idiomatic equivalence refers to colloquialisms, informal or slang used in the country of origin, which present translation difficulties. At this point, the expert panel may suggest similar expressions to the final version. The conceptual equivalence is whether the words are conceptual connotations are appropriate to the context of the Brazilian health services; experiential equivalence refers to identify the adapted version expresses the experience of the daily services in the Brazilian cultural context; and finally, the content equivalence to evaluate the items of the instrument in relation to the understanding, clarity and redundancies.

The experts received an invitation letter and guidance for completing the equivalence using an electronic spreadsheet. The total assessed items corresponded to 137. It was established validity index ≥ 80% of consensus among the experts for each item.
evaluated. The spreadsheet, nominated form (Figure 1) contained: the items of the original instrument (English), the two translations (T1 and T2) to the Portuguese spoken in Brazil, the synthesis of the translations made, the two back-translations (BT1 and BT2) and synthesis of the two back-translations performed by the researcher and the supervisor.

In figure 1, we can observe the spreadsheet with the items and equivalents, so by clicking on the corresponding cell of equivalence spaces emerged for experts score. This spreadsheet provided the visualization of all translations, back translations, synthesis and evaluation of the five equivalence of the 137 items of the instrument.

Finally, each expert found that the translated version was entirely understandable, considering their concepts and their meanings for the Brazilian culture, comparing the original instrument and the translated one.

The experts panel was composed by 12 professionals presenting at least one of three criteria, namely: being fluent in English language; having experience in the area of patient safety; having experience in the translation and validation of research instruments.

The items that did not get this consensus were discussed in a face-to-face/virtual meeting with the experts, with the personal attendance of five Experts and participation by videoconference of three experts from various regions of Brazil, the researcher, the supervisor, two people to support registration and one for technical support for online meetings, lasting five hours.

**Pretest**

After that, we carried out the pretest with 30 health professionals, who work in operating rooms in a private hospital in southern Brazil, applying a Portuguese version of the SAQ/OR. The report covered all steps and it was approved by the American authors.

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 19332613.4.0000.5392.

![Validation form of SAQ/OR and equivalence for the Portuguese version](image-url)
Results

The cross-cultural adaptation process of SAC/OR was carried out at all stages satisfactorily.

From the 12 experts who joined the panel of this study, 9 (75%) were nurses, 2 (16.7%) were physicians and 1 (8.3%) was a translator. Their ages ranged between 33 and 72 years, with a mean of 51.5 years (SD±10.85). As to the mean time of graduation, it corresponded to 28.1 (SD±10.91). Regarding the legal nature of the participants’ institution, 9 (75%) worked in the public sector and 3 (25%) in the private sector. Regarding the last titration, 50% of specialists had a PhD, 25% were full professors, 8% had a Master’s degree in Political Science and another 8% had a Master’s degree in Nursing and 9% were specialists in Operating rooms, Sterilized Material Center and Post-Anesthesia Recovery in Nursing, showing the participants’ experience with teaching and research.

In relation to the equivalence of the validation process carried out by the experts, the general consensus instrument was 84.1% of equity, 9.3% of non-equivalence and 6.6% undecided.

Regarding the semantic equivalence, this corresponded to 85.2% of equity, 8.4% of non-equivalence and 6.4% undecided. The idiomatic equivalence was 85.5% of equity, 7.6% of non-equivalence and 6.9% undecided. Concerning the validation of conceptual equivalence, data showed that there were 85% equivalence, 8.5% of non-equivalence and 6.5% undecided. The experiential equivalence was 82.8% of equity, 11.5% of non-equivalence and 5.9% undecided. Finally, the content equivalence presented 82.8% of equivalence, 10% of non-equivalence and 7.2% undecided. It is noteworthy that the experiential validity was 12% of non-equivalence and content validity was 10% of non-equivalence and the instrument was a total 84% of consensus among the experts.

However, 41 items did not reach consensus ≥ 80% in at least one of the equivalencies. Of these 12 (8.7%) items referred to the statements about patient safety, 10 (7.2%) to the health professions, in the first part of the questionnaire, 8 (5.8%) to the third part of the health professions questionnaire, as these items referred to the same professions, they were grouped. Finally, 11 (8.0%) items related to sociodemographic data.

Chart 1 describes the items related to professions that did not reach consensus and which were discussed at the meeting with the experts, which made up the final version of the instrument. Since the item with the highest discrepancy between the experts concerned the Nurse Anesthetist.

Other issues that have raised questions related to items such as: resident, intern of surgery and anesthesia resident or intern, which resulted in the option surgical resident and intern and resident of anesthesia. Along the same lines, another word which caused debates referred to the preceptor of surgery and anesthesia, which were defined as surgeon/surgeon assistant and anesthesiologist assistant.

The questions related to patient safety item “26. I am provided with adequate, timely information about events in the hospital that might affect my work.” had the highest percentage of disagreement.
and discussed, especially as the word event, which was replaced by occurrences.

The other changes were related to the order of composition of the statements, punctuation and grammar (Chart 2).

The other 11 items that did not reach consensus refer to sociodemographic data, the third part of the questionnaire. It is noteworthy that in the face-to-face/virtual meeting they were defined using the table of the Brazilian Institute of Geography and Statistics (IBGE) for the classification of Brazilian ethnic groups that composed the instrument.

In the face-to-face/virtual meeting 41 items reached 100% consensus and the suggestions were accepted and incorporated into the final version of the instrument, resulting in the Portuguese version of the questionnaire, which was subjected to pretest with 30 operating room professionals in a Brazilian private hospital.

Professionals who answered the questionnaire were 10 surgeons, 10 anesthesiologists, five nurses and five surgical technician/attending.

**Pretest**
The objective of the pretest is to assess the understanding of the items and the time taken to fill the questionnaire, so each participant was interviewed by the researcher on the understanding of each item and the time taken to fill the instrument was recorded. In this study, the mean filling time was 16.5 minutes.

Participants reported no difficulty in understanding the questionnaire items. However, four respondents indicated that the font size made it difficult for them to read the items, and they also identified difficulties with the instrument layout regarding the assertion of the response on the same line, this was solved accentuating the colors between the lines.

Both the original instrument as the Brazilian version contains two pages, only one subject in the pretest showed that the questionnaire was extensive and another participant pointed out that there were similar questions. However, as the average completion time is in accordance with the guidelines of the authors of the original questionnaire, we chose to keep the formatting and all instrument items.

**Submission to the authors of the questionnaire**
All reports produced, the final version of the questionnaire and the pretest results were sent to the...
authors of the questionnaire at the University of Texas, USA, who approved the Portuguese version of the SAQ/OR and authorized the questionnaire validation.

This version of the instrument was referred to as: Questionário de Atitudes de Segurança (Versão Centro Cirúrgico) However, the international literature and the original questionnaires adopt the SAQ nomenclature for translated and adapted instruments, so we adopted the abbreviation of SAQ/VCC for the Brazilian instrument.

**Discussion**

Considering that the performance of a translation cannot be effective due to cultural differences and language, and therefore, when adapting a research instrument we should consider the technical, linguistic and semantic aspects. This investigation was conducted in a rigorous process of cross-cultural adaptation and the stages have been fulfilled according to the proposed model.

The cross-cultural adaptation process SAQ/OR for the Portuguese language and the context of the Brazilian surgical centers has been completed properly, meeting all purposes in all steps described in the method adopted.

Studies that performed the transcultural adaptation of the SAQ in generic version and in versions of SAQ/OR adapted to Switzerland and Japan also followed the international recommendations of adaptation processes.

Due to the complexity of the instrument and of equivalence evaluated the use of spreadsheet provided a visualization of all stages of the translation process, offered participants flexibility in the assessment of items and their observations and also favored the quantitative analysis of the responses.

The content validation performed by a multidisciplinary expert panel and the participation of a translator involved in the process, as recommended in the literature, enriched the discussion of the terms and their translation into Portuguese.

In this context, the analysis by the expert panel regarding the evaluation of equivalence involved qualitative and quantitative procedures. Among the items that did not reach consensus and involved complex questions, we highlighted the items related to the health professions who work in the operating room. We emphasize that the original instrument context of the professions and the legislation governing the health professions are different in Brazil, especially in the surgical environments, an example is the function of nurse anesthetist, that in Brazil is exercised by the anesthesiologist, a medical professional.

Understanding the items was identified in the pretest, with no exclusion, only layout changes were necessary in the original instrument. Thus the three dimensions were kept as the original instrument, the first part concerning communication and collaboration among health professionals, 58 questions that assess the safety climate and the personal information, also the question about the previous instrument filling and the open question referring to the three recommendations for improving patient safety in the operating room.

Researches that deal with cross-cultural adaptation of the SAQ/OR in the Japanese and Swedish languages indicated minor changes due to cultural differences. However, adaptation to the Swedish context indicated deleting an item on patient safety.

Another matter pointed out in the pretest was the font size. However, since the questionnaire has two pages, increasing the size of the letters would result in the addition of a page, so we chose to preserve the format.

Regarding questions about the safety of the patient, out of the 58 questions that compose the questionnaire, only 12 did not reach consensus and were discussed at the meeting, it corroborates the methodological rigor of the translation and back-translation processes. When considering the complexity of the questionnaire, it is worth noting that small adjustments were necessary on questions related to patient safety and that they concerned the experiential and content equivalence.

Thus, considering the gap of instruments available to measure the perception of health professionals across the patient safety in the surgical environment, the SAQ/VCC can contribute as a
management tool and support strategies for both the assessment of the safety climate as the quality of communication and collaboration among the team of professionals working in the operating room and corroborate for the assessment of safety culture in health care.

**Conclusion**

This study performed the translation and cross-cultural adaptation of the questionnaire SAQ/OR, an instrument which assesses the safety climate in the surgical environment. The process was carried out rigorously as recommended in the literature reaching the objectives, besides that, the original version was approved by the authors of the original instrument.

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**Collaborations**
Lourenção DCA and Tronchin DMR collaborated with the study design, data collection, analysis and interpretation of data, writing, critical review of the intellectual content and approved the final version to be published.

**References**

Prevention of varicose ulcer relapse: a cohort study

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Abstract

Objective: Determine the relapse rate of varicose ulcer and check the association between relapse and prevention measures adopted.

Methods: Cohort study involving 50 patients over 18 years of age post-healing of varicose ulcer monitored over ten years. Relapse was assessed through direct inspection during the clinical assessment, and the preventive measures used were informed by the patient. Pearson’s chi-square test was used with p ≤0.05.

Results: Relapse of varicose ulcer corresponded to 62.2%, mostly in women, followed by elderly, illiterate and retired people. The following combination was effective to prevent relapses: use of compressive stockings, rest and application of moisturizer.

Conclusion: The relapse rate of varicose ulcer was high and the main combination of preventive measures applied was the use of compressive stockings, rest and application of moisturizer.

Keywords
Nursing care; Clinical nursing research; Recurrence; Varicose ulcer/prevention & control

Descritores
Cuidados de enfermagem; Pesquisa em enfermagem clínica; Recidiva; Úlcera varicosa/prevenção & controle

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Conflicts of interest: no conflicts of interest to declare.
Introduction

Different pathological conditions or health problems can cause the appearance of a leg or foot ulcer, which can become chronic when not healed within four to six weeks. Its main etiology has been associated with peripheral vascular disease of lower limbs, mainly venous insufficiency, leading to the formation of varicose ulcer, also called stasis ulcer or phlebostatic ulcer. (1,2)

Varicose ulcer is important in the public health context because it affects people of different age ranges and causes socioeconomic problems. It affects the patient’s lifestyle due to the need for outpatient visits for dressing change, chronic pain and unpleasant smell due to the exudate the wound produces. The patient need health care frequently, causing absence from work, early retirement and economic burden for the institutions, due to the drop in productivity. (3,4)

The varicose ulcer problem involves multiple aggravating factors, characterized as recurrent. These include low socioeconomic conditions to maintain the preventive practices, difficult access to specialized services and patients’ low education. The relapse rate of varicose ulcers is around 30% in the first year after the cure, and increases to 78% after two years. (5)

In the United States, varicose ulcers also constitute one of the main health problems, because they affect the quality of life and come with high costs and extended treatment. The estimated treatment cost ranges between US$1.9 and 3.5 billion, and each patient demands approximately US$40 thousand for treatment. An estimate published in 2007 appoints that about seven million people around the world presented chronic venous problems in the lower limbs, three million of whom evolved to venous ulcers. (6)

In Brazil, epidemiological prevalence and incidence data related to this problem are scarce and no official estimates are found in the national or regional context. Nevertheless, scarce research data exist, like in the city of Botucatu, State of São Paulo, where a prevalence of 1.5% of cases of active or healed varicose ulcer was found. (7)

The findings by Finlayson et al. on varicose ulcer relapse evidenced a median monitoring period of 24 months (interval between 12 and 40 months) and a relapse rate of 68%. This study also demonstrates that a history of cardiac illness is a risk factor for recurrence, while raising the leg, physical exercise and compressive stockings can prevent it. (8) Recurrence rates of varicose ulcers, even after several years, still tend to increase, indicating the need for new strategies after the varicose ulcer is cured.

To prevent relapse, it is important for the patient to be knowledgeable and skilled and to receive support for the adoption of effective self-care measures. In the recent publication by the Wound, Ostomy and Continence Nurses Society® (WOCN®), the recommendations to prevent varicose ulcer relapse include compressive therapies, adjuvant therapies (surgery), medication and educative actions, particularly: dressing compressive stockings before getting out of bed; change the stockings regularly, every three to six months; the use of stockings that correspond to the leg diameter and length, verified by a professional or trained person; not smoking; adopting a healthy diet and controlling one’s body weight; avoiding mechanical traumas in the injured leg and raising the legs above the level of the heart several times per day. (9)

Deepening the knowledge on relapse-related aspects and adopting preventive measures are essential to support health services’ elaboration of protocols and guidelines, in a contextualized manner, within the patients’ historical and social reality. Therefore, this study was developed to determine the relapse rate of varicose ulcers and to verify the association between relapse and the adopted preventive measures.

Methods

A retrospective cohort was conducted between 2003 and 2013 at a dermatology outpatient clinic of a large teaching hospital in Belo Horizonte, the state capital of Minas Gerais, Brazil. The
data were collected between August and December 2013, when all patients who were discharged up to 2003, after the cure of the varicose ulcer, were interviewed.

Relapse is defined as the reappearance of a disease after a period of convalescence or an asymptomatic interval as a result of an external reinfection or a new exposure to the causal agent. In this study, the emergence of a varicose ulcer after complete healing was considered as relapse.

The participants’ eligibility criteria were: being over 18 years of age; attending the dermatology outpatient clinic of the university hospital and having been discharged from this service up to 2003 with a healed varicose ulcer and having received guidelines according to the service protocol to prevent relapse based on the recommendations of the *Wound, Ostomy and Continence Nurses Society* (WOCN)(9); and attending the service during the data collection period. All patients who were discharged from the service up to 2003 with a healed varicose ulcer agreed to participate in the study and signed the Free and Informed Consent Form.

As a dependent variable, the varicose ulcer relapse was selected and, as independent variables, the professional activity and the relapse prevention measures (daily use of class 2 stockings with compression of 30 to 40mmHg up to the region of the kneecap; stocking change every six months; daily rest of two hours in the morning and afternoon, keeping the legs raised 15cm above the heart level; daily application of moisturizer on the lower limbs after removing the stockings), as recommended by the WOCN®.(9)

A form was used to characterize the participants (age, sex, marital status, education and retirement) and relapse (duration of occurrence and location of the ulcer). The data on the wound and measures adopted to prevent relapse were collected through a conversation between the researcher and the patient. The existence of the varicose ulcer was confirmed through direct inspection. It took between 20 and 40 minutes to collect data from each patient.

The data were analyzed using *Statistical Package for the Social Sciences* (SPSS), version 16.0. Descriptive analyses were developed with absolute and relative frequencies, means, besides the analysis of combinations of the preventive measure variables. To identify the factors associated with the prevention of varicose ulcer relapse, for statistical analysis, Pearson’s chi-square test was used. Significance was set as p-value ≤0.05.

The study was reported in the Research Ethics Committee (COEP), Universidade Federal de Minas Gerais under number - 6908.

**Results**

Among the 50 patients, 31 (62.2%) presented relapse of the varicose ulcer. The majority (76.0%) was female; ages ranged between 26 and 85 years and the median was 69 years; 54.0% were elderly people (60 years or older), 40.0% were married and the remainder (60.0%) widowed, single or divorced; 60.0% were functionally illiterate. Retired people were predominant (42.0%). Patients with ulcer relapse were mostly (71.0%) female, over 59 years of age (54.9%), with a predominance of married people (38.7%). The majority (80.6%) was functionally illiterate, and almost half (45.2%) of the people were retired (Table 1).

No statistical association was found between the variables sex, age, marital status, instruction level, professional activity and retirement and relapse. Each participant presented a single relapse of varicose ulcer during the investigated period and the length of occurrence varied between one and more than 24 months (mean 7.9 months) after being discharged with a cured injury. Five (16.1%) patients had a relapse after one month, and relapse two years after the discharge (32.2%) was predominant. The predominant region (45.2%) of the relapse cases was the medial and lateral malleolus (Table 2) and the left leg was the most affected (70.0%) by the relapse.

Most patients used compressive stockings daily (62.0%), rested (62.0%) and applied moisturizer to the lower limbs (74.0%). Among the 31 partici-
Prevention of varicose ulcer relapse: a cohort study

Table 1. Demographic characteristics of patients at the time of the data collection and association with ulcer relapse

<table>
<thead>
<tr>
<th>Variables</th>
<th>Varicose ulcer relapse</th>
<th>Total (n=50)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (n=31)</td>
<td>No (n=19)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9(29.0)</td>
<td>3(15.8)</td>
<td>12(24.0)</td>
</tr>
<tr>
<td>Female</td>
<td>22(71.0)</td>
<td>16(84.2)</td>
<td>38(76.0)</td>
</tr>
<tr>
<td>Age range (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-39</td>
<td>-</td>
<td>1(5.2)</td>
<td>2(10.5)</td>
</tr>
<tr>
<td>40-59</td>
<td>10(32.3)</td>
<td>4(21.1)</td>
<td>14(28.0)</td>
</tr>
<tr>
<td>60-79</td>
<td>15(48.4)</td>
<td>8(42.1)</td>
<td>23(46.0)</td>
</tr>
<tr>
<td>&gt;80</td>
<td>2(6.5)</td>
<td>2(10.5)</td>
<td>4(8.0)</td>
</tr>
<tr>
<td>No information</td>
<td>4(12.9)</td>
<td>4(21.1)</td>
<td>8(16.0)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td>0.131</td>
</tr>
<tr>
<td>Single</td>
<td>6(19.4)</td>
<td>4(21.1)</td>
<td>10(20.0)</td>
</tr>
<tr>
<td>Married</td>
<td>12(38.7)</td>
<td>8(42.1)</td>
<td>20(40.0)</td>
</tr>
<tr>
<td>Widowed</td>
<td>11(34.5)</td>
<td>6(31.6)</td>
<td>17(34.0)</td>
</tr>
<tr>
<td>Divorced</td>
<td>2(6.5)</td>
<td>1(5.2)</td>
<td>3(6.0)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td>6.469</td>
</tr>
<tr>
<td>Illiterate</td>
<td>5(16.1)</td>
<td>3(15.8)</td>
<td>8(16.0)</td>
</tr>
<tr>
<td>Functionally illiterate</td>
<td>20(64.5)</td>
<td>10(52.6)</td>
<td>30(60.0)</td>
</tr>
<tr>
<td>Primary education</td>
<td>4(12.9)</td>
<td>3(15.8)</td>
<td>7(14.0)</td>
</tr>
<tr>
<td>Secondary education</td>
<td>-</td>
<td>2(10.5)</td>
<td>2(4.0)</td>
</tr>
<tr>
<td>Higher education</td>
<td>-</td>
<td>1(5.2)</td>
<td>1(2.0)</td>
</tr>
<tr>
<td>Not informed</td>
<td>2(6.5)</td>
<td>-</td>
<td>2(4.0)</td>
</tr>
<tr>
<td>Professional activity and retirement</td>
<td></td>
<td></td>
<td>2.049</td>
</tr>
<tr>
<td>Retired</td>
<td>14(45.2)</td>
<td>7(36.8)</td>
<td>21(42.0)</td>
</tr>
<tr>
<td>Housewife</td>
<td>4(12.9)</td>
<td>2(10.5)</td>
<td>6(12.0)</td>
</tr>
<tr>
<td>Domestic servant</td>
<td>8(25.8)</td>
<td>6(31.6)</td>
<td>14(28.0)</td>
</tr>
<tr>
<td>Others</td>
<td>5(16.1)</td>
<td>4(21.1)</td>
<td>9(18.0)</td>
</tr>
</tbody>
</table>

Table 2. Length and location of the varicose ulcer relapse

<table>
<thead>
<tr>
<th>Variables</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of relapse (months)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>5(16.1)</td>
</tr>
<tr>
<td>1.1-3</td>
<td>26(85.0)</td>
</tr>
<tr>
<td>3.1-6</td>
<td>15(49.0)</td>
</tr>
<tr>
<td>6.1-12</td>
<td>9(30.0)</td>
</tr>
<tr>
<td>12.1-18</td>
<td>5(16.1)</td>
</tr>
<tr>
<td>18.1-24</td>
<td>5(16.1)</td>
</tr>
<tr>
<td>24.1-36</td>
<td>2(6.5)</td>
</tr>
<tr>
<td>36.1-48</td>
<td>3(10.0)</td>
</tr>
<tr>
<td>48.1-60</td>
<td>3(10.0)</td>
</tr>
<tr>
<td>60.1-72</td>
<td>-</td>
</tr>
<tr>
<td>72.1-84</td>
<td>3(10.0)</td>
</tr>
<tr>
<td>84.1-90</td>
<td>3(10.0)</td>
</tr>
<tr>
<td>Total</td>
<td>31(100.0)</td>
</tr>
<tr>
<td>Relapse location</td>
<td></td>
</tr>
<tr>
<td>Lower third</td>
<td>12(38.7)</td>
</tr>
<tr>
<td>Middle third</td>
<td>5(16.1)</td>
</tr>
<tr>
<td>Medial malleolus</td>
<td>9(29.1)</td>
</tr>
<tr>
<td>Lateral malleolus</td>
<td>5(16.1)</td>
</tr>
<tr>
<td>Total</td>
<td>31(100.0)</td>
</tr>
</tbody>
</table>

Table 3. Influence of preventive measures adopted in cases of varicose ulcer relapse

<table>
<thead>
<tr>
<th>Preventive measures recommended by WOCN®</th>
<th>Patient with relapse</th>
<th>Total (n=50)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (n=31)</td>
<td>No (n=19)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n(%)</td>
<td>n(%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of class 2 compressive stockings (30-40 mm Hg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>21(68.0)</td>
<td>10(52.6)</td>
<td>31(62.0)</td>
</tr>
<tr>
<td>No</td>
<td>10(32.0)</td>
<td>9(47.4)</td>
<td>19(38.0)</td>
</tr>
<tr>
<td>Change stockings every six months (n=31)*</td>
<td>14(45.0)</td>
<td>6(19.0)</td>
<td>20(66.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>2(6.5)</td>
<td>2(10.5)</td>
<td>4(8.0)</td>
</tr>
<tr>
<td>No</td>
<td>7(30.0)</td>
<td>4(21.1)</td>
<td>11(22.0)</td>
</tr>
<tr>
<td>Total</td>
<td>21(68.0)</td>
<td>10(32.0)</td>
<td>31(100.0)</td>
</tr>
<tr>
<td>Rest</td>
<td>17(58.0)</td>
<td>14(28.0)</td>
<td>31(62.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>14(45.0)</td>
<td>5(10.0)</td>
<td>19(38.0)</td>
</tr>
<tr>
<td>No</td>
<td>13(42.0)</td>
<td>15(31.5)</td>
<td>28(56.0)</td>
</tr>
<tr>
<td>Application of moisturizer to lower limbs</td>
<td>22(71.0)</td>
<td>15(78.9)</td>
<td>37(74.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>22(44.0)</td>
<td>15(30.0)</td>
<td>37(74.0)</td>
</tr>
<tr>
<td>No</td>
<td>9(18.0)</td>
<td>4(8.0)</td>
<td>13(26.0)</td>
</tr>
<tr>
<td>Use of stockings and rest</td>
<td>12(38.0)</td>
<td>6(12.0)</td>
<td>18(36.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>19(38.0)</td>
<td>13(26.0)</td>
<td>32(64.0)</td>
</tr>
<tr>
<td>No</td>
<td>9(18.0)</td>
<td>5(10.0)</td>
<td>14(28.0)</td>
</tr>
<tr>
<td>Use of stockings, rest and application of moisturizer to lower limbs</td>
<td>22(44.0)</td>
<td>14(28.0)</td>
<td>36(72.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>9(18.0)</td>
<td>5(10.0)</td>
<td>14(28.0)</td>
</tr>
<tr>
<td>No</td>
<td>22(44.0)</td>
<td>14(28.0)</td>
<td>36(72.0)</td>
</tr>
</tbody>
</table>

*In total, 31 patients used compressive stockings; WOCN® - Wound, Ostomy and Continence Nurses Society®

Patients who used stockings, 65.0% changed their stockings every six months at most and 19 patients who did not use compressive stockings affirmed that they did not do this because this product was not available (Table 3). The influence of preventive measures on the varicose ulcer relapse was analyzed (Table 3): use of compressive stockings (p=1.142), stocking change...
every six months (p=0.132), rest (p=1.776) and application of moisturizer to lower limbs (p=0.390). The influence of combining these measures was also analyzed: use of stockings and rest (p=0.260), use of stockings, rest and application of moisturizer on lower limbs (p=0.043).

**Discussion**

WOCN® recommends changing stockings every three to six months to guarantee an excellent compression level. In this study, relapse occurred in patients who reported changing their compression stockings every six months. Nevertheless, few randomized clinical trials have specifically assessed the impact of compression therapy on the risk of ulcer relapse. In a randomized study developed in a sample of 153 patients whose varicose ulcer was cured after two weeks, distributed in two groups, the reduction of ulcer relapse was associated with the use of compressive stockings. The first group included patients who used compressive stockings (34 to 46mmHg), while the second consisted of patients who did not use compressive stockings. In the assessment, after six months of monitoring, it was verified that the use of the stockings was determinant for the prevention of relapse.

Another factor that interferes in the relapse rate of varicose ulcer is the patient’s compliance with the use of stocking. High compression stockings (40 to 50mmHg) are less accepted when compared to the medium compression type (30 to 40mmHg). Consequently, the relapse rate can be higher when the use of high compression stockings is indicated, due to their intolerance. Nevertheless, in a randomized study involving 100 patients after the cure of a varicose ulcer, 50 of whom were using class 1 compressive stockings (20 a 30mmHg) and the remainder class 2 (30 to 40mmHg), it was concluded that, after 12 months of monitoring, the ulcer relapse rate corresponded to 16.1%, without a statistically significant difference in the relapse rate between classes 1 and 2, despite the higher number of relapses in the group of patients using class 1 compressive stockings.

Based on the systematic review with meta-analysis about the compressive modalities and the healing of the varicose ulcer, it was verified that the compressive effect on the varicose ulcer relapse is still based on low-quality evidence. The ideal pressure measure of the stocking to prevent relapse remains undefined, in view of difference between the levels in the literature.

Venous insufficiency in the lower limbs is frequent in the general population, in Western countries, and is more common in women and elderly people. In the present study results, ulcer relapse was predominant in female patients, at a rate of 2.5:1.0, without any association between sex and relapse though. Studies suggest a higher prevalence of chronic venous insufficiency and varicose ulcers in women, observing that this disparity decreases with age. The common risk factors for chronic venous insufficiency include family history, multiparity, obesity, history of profound venous thrombosis or thrombophlebitis and others, such as diabetes, heart failure, hypertension, kidney disease and rheumatoid arthritis.

More than half of the patients were elderly. This data is similar to other authors’ findings, who obtained an annual prevalence of varicose ulcer corresponding to 1.69% among the elderly. This health problem is considered significant for these people and for the health sector, considering that the life expectancy is rising and that, in the next 40 years, the number of elderly people is expected to double.

Although no association was found between the instruction level and relapse or the emergence of a new ulcer, patients with a lower level of instruction (illiterate and functional illiterate) were predominant in terms of relapse and the development of a new injury, while patients with secondary and higher education did not present such events. This result can be related to the better understanding of the orientations and the greater adherence to preventive care, such as the habitual use of compressive stockings and moisturizer for example.
Sedentariness or standing or seated work, without alternating with walking, impairs the venous return, influencing the emergence of varicose ulcers. In a Brazilian study undertaken in Fortaleza, the State capital of Ceará, in the Brazilian Northeast, 52% of the participants with varicose ulcer quit working or studying because of the lesion, and about 70% affirmed having experienced losses in daily and leisure activities. These results differ from the present findings as, at the time of the data collection, among the 50 participants, 58% were professionally active and, among the remainder (42%), although retired, many continued working informally.

Knowledge about the pathogenesis of varicose ulcers has permitted the development of new treatment modalities. Nevertheless, the challenge of impeding their relapse remains. Some authors affirm that most cases of relapse occur within three months after the healing of the wound. In this study, 80.6% of the patients experienced a relapse in the same period. Five patients relapsed within 30 days, possibly due to the non-adoption of preventive care to avoid the occurrence of edema and, consequently, relapse.

Lower relapse rates were observed in people using stockings with a higher degree of compression. It was also observed that patients who used moderate compression presented better compliance, while 42% of patients who used class 3 compressive stockings abandoned the treatment and 28% in class 2. The ongoing use of the therapy is emphasized, with the highest level of compression the patient can bear, in order to guarantee the reduction of venous hypertension in the lower limbs, permitting the patient’s greater adherence and the reduction of the risk of varicose ulcer relapse.

The ideal pressure of the compressive stockings varies according to different factors, such as the severity of the patients’ vascular conditions, the patient’s body weight and length (size) of the affected limb. In practice, it is observed that incorrect stocking pressure can cause skin necrosis, also in the talocrural region, provoking cellulitis or erysipela. As a daily intervention, it should be acknowledge that the use of compressive stocking is not free from potential risks and, therefore, demands correct application and professional accompaniment, especially in patients with frail skin, diabetics, with low immunity and at greater risk of skin damage.

In this study, a group of patients was identified who did not use the compressive stockings. The high cost of the stockings can influence the patient’s non-compliance with the compressive therapy, in combination with the forgetting of the health professionals’ instructions and the difficulty to use the stockings. As regards compliance or not with the use of compressive stocking, among patients with healed ulcers, the perception that the stockings prevent relapse contributed to their use.

In the literature, recommendations are found for patients with venous insufficiency of the lower limbs to rest with or without using stocking, raising the legs above the height of the heart for two to four hours; raising the lower part of the bed 10 to 15 cm; and flex the ankles five to ten times every 30 minutes during the day. Among these recommendations, 62% of the patients in this study mentioned resting, obtaining 45% of patients without relapse. The analysis of the association between varicose ulcer relapse prevention measures showed a significant difference when a combination of the three measures was adopted: using compressive stockings, resting and applying moisturizer to the lower limbs. Nevertheless, no statistical difference was found between the groups when two associated measures or one isolated measure were applied.

A study proves that to avoid standing for long periods and raising the legs when the patient is sitting can help to improve the venous ulcer and
consequently reduce the edema.\textsuperscript{(18)} No randomized clinical trials were found that compare ulcer relapse with and without limb raising. A prospective longitudinal study indicated that raising the legs for at least one hour was associated with a smaller number of relapses. In this study, the function of the compressive stockings, the high levels of personal independence and the existence of social support were also associated with the reduction of the relapse rate.\textsuperscript{(22)}

The results about compliance with ulcer relapse preventive care may have been limited by subjective factors what lifestyle changes are concerned. In this study, these changes referred exclusively to: daily use of compressive stockings, including change; rest; and application of moisturizer. Another limitation was the restriction of the study to a single service. Nevertheless, the results indicated the importance of periodically monitoring the patient after discharge as a result of cure.

The health professionals need theoretical and practical support for them to effectively recommend specific care to patients for the prevention, treatment and relapse of venous ulcer. It is important to continuously train the professionals who take care of patients with varicose ulcers and provide access to the material resources needed, aiming to reduce the existing gap between care practice and scientific evidence.\textsuperscript{(23)}

The study results should contribute to encourage professionals to develop research, as questions on the theme are not exhausted. The results should also support the nurses responsible for the prevention and treatment of patients with varicose ulcer. It should be highlighted that the preventive measures should be adopted in combination, and not only in isolation, when they are not effective.

\textbf{Conclusion}

The relapse rate of varicose ulcer was high and the main measures to prevent varicose ulcer applied in combination were the use of compressive stockings, rest and application of moisturizer. The use of one of these measures alone did not produce the desired result.

\textbf{Collaborations}

Borges EL, Ferraz AF and Carvalho DV contributed to the conception of the study, analysis, interpretation of the data, writing of the paper, relevant critical analysis of the intellectual content and final approval of the version for publication. Matos SS and Lima VLAN contributed to the writing of the article, relevant critical review of intellectual content and final approval of the version for publication.

\textbf{References}

Prevention of varicose ulcer relapse: a cohort study


Patient satisfaction according to the form of hospital stay at a teaching hospital

A satisfação dos pacientes segundo a forma de internação em hospital universitário

Karine Lorenzen Molina
Gisela Maria Schibella Souto de Moura

Abstract

Objective: To analyze the patients’ satisfaction according to the form of hospital stay at a teaching hospital.

Methods: Cross-sectional study involving 366 patients over 18 years of age, hospitalized at clinical and surgical wards between January and June 2014, whose outcome was discharge within 15 and 30 days. The Mann-Whitney test was applied to analyze independent samples for intergroup comparison.

Results: In total, 99.4% of the patients hospitalized through the emergency service and 98.4% of the inpatients were satisfied and highly satisfied, with mean satisfaction rates of 5.66 and 5.55, respectively. The mean satisfaction score was higher on all attributes for the emergency group. The intergroup comparison of the Nursing team attributes and general satisfaction did not demonstrate statistical significance.

Conclusion: The patients’ high level of satisfaction with the health service evidenced the quality of care at the teaching hospital from the patient’s perspective. The same high assessment of the satisfaction with nursing was found between the groups.

Keywords
Patient satisfaction; Mecanismos de avaliação da assistência à saúde; Nursing service, hospital; Nursing audit; Quality of health care

Descritores
Satisfação do paciente; Health care evaluation mechanisms; Serviço hospitalar de Enfermagem; Auditoria de Enfermagem; Qualidade da assistência à saúde

Resumo

Objetivo: Analisar a satisfação dos pacientes de acordo com a forma de internação em hospital universitário.

Métodos: Estudo transversal realizado com 366 pacientes com mais de 18 anos, internados em unidades clínicas e cirúrgicas no período de janeiro a junho de 2014, cujo desfecho tenha sido a alta entre 15 e 30 dias. Teste Mann-Whitney foi realizado para analisar amostras independentes para comparação entre os grupos.

Resultados: Estiveram satisfeitos e muito satisfeitos com o atendimento recebido 99,4% dos pacientes internados pela emergência e 98,4% dos internados pela admissão, apresentando médias de satisfação de 5,66 e 5,55, respectivamente. A média de satisfação foi mais elevada em todos os atributos para o grupo da emergência. A comparação entre grupos dos atributos da equipe de Enfermagem e satisfação geral não demonstrou significância estatística.

Conclusão: O elevado nível de satisfação dos pacientes com o serviço de saúde evidenciou a qualidade assistencial prestada no hospital universitário, na perspectiva do paciente. Destacou-se igual e elevada avaliação da satisfação com enfermagem entre os grupos.

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1Universidade Federal do Rio Grande do Sul, Porto Alegre, RS, Brazil.

Conflicts of interest: no conflicts of interest to declare.
Introduction

The increasing life expectancy of the population and the higher morbidity and mortality due to cerebrovascular and coronary diseases, for example, are factors that have contributed to the growth in the demand rates for health services. Thus, the quality of health services has been a constant concern in the health management area, fomenting the discussion on the need to adopt new care models for the delivery of more complex and lengthier care.

Different problems exist in the health system that need to be reconsidered. One of them is the patients’ entry door for inpatient services. The overcrowded emergency services and long waiting times for elective inpatient services at the admission sector evidence this problem. Therefore, based on professional Nursing experience at a hospital, knowledge on the patients’ profile is relevant and the service need to prove the quality of the care they deliver, considering patient satisfaction as one of the assessment criteria.

Emergency care is characterized as the “bottleneck” of the Brazilian health system. It attends to patients in acute health situations and/or at imminent risk of death, but also low-complexity patients. This sector’s installed capacity is frequently surpassed as the patients spend a long time waiting for a bed, including many patients per health professional. In an international study, the emergency sector was differentiated from fast-care services, so that patients in acute health situations would not await care. In addition, they emphasized that having physicians and expert nurses is an excellent model for the quality of patient care.

At the hospital where this study was undertaken, after the conclusion of emergency care, the patients who need inpatient services are forwarded to clinical or surgical wards, depending on the availability of a bed. These hospital areas are characterized by having a defined number of beds whose occupation does not surpass the installed capacity. The areas have a preset nursing staff, dimensioned to favor an appropriate proportion of patients per professional, aiming for high-quality care. The services also attend to stable patients from elective services who were hospitalized through the admission sector, characterizing an entry process into the system through planned care that was programmed in advance. This context means that, at an inpatient service, patients will be present who entered the hospital in two different ways, arousing questions that the entry form may influence the perceived service quality.

The definition of quality includes the level of professional excellence, efficient use of resources and high degree of patient satisfaction. Patient satisfaction is defined as an individual’s reaction to the most noteworthy aspects of his hospital care. This behavioral response occurs when an individual’s cognitive assessment of care aspects corresponds to or surpasses personal subjective standards. It should be highlighted that the hospital management already acknowledged that the bad quality of health services is closely related with low satisfaction rates and, consequently, with the rise in the institution’s costs.

Some studies support that the main bond between the user and the hospital occurs through the Nursing service, constituting the main group of health professionals, which maintains uninterrupted contact with the patient, promoting the maintenance, recovery and rehabilitation of health through care. The nurses are ideal professionals to inform about the characteristics of the organizations where they work, due to their proximity with the users.

This assessment favors a better planning of care, identifying the attributes that contribute or not to the patients’ satisfaction. Care delivery at the inpatient services has attributes that stand out during the hospitalization through the admission sector, the medical, nursing, nutrition, cleaning and hospital discharge teams. The nurse, articulating the sequence of these different professionals’ actions, naturally takes charge of administering the appropriate functioning of the services.
In Brazil, as from 1990, the health system stood out by the proposal to open the institutions’ doors for all citizens (or individuals) to be attended to without any type of discrimination. (9) Quality research developed with the advent of the health system, including the community’s participation in the assessment and planning processes. (8,9) Although this participation has not been formally structured in the hospital institutions, patient satisfaction research is used as an important indicator. In addition, the ombudsman, the sector that mediates situations between the users and the health institution, can also represent an incipient strategy to include the users’ opinion in the planning of health actions.

Characterizing the patients attended at the health services is fundamental to set priorities and plan the managers’ actions in view of the quality of care. (10) Studies highlighted variables that can interfere in the patients’ satisfaction, demonstrating that age predicts satisfaction. (11,12) Younger users presented lower satisfaction levels with care. In addition, sex is the variable that can also be related with satisfaction, as women reported higher levels of satisfaction than men. (11)

In view of the above aspects, the objective in this study was to analyze the patients’ satisfaction according to the form of hospitalization - emergency care and inpatient care - at a teaching hospital.

Methods

A cross-sectional survey with a quantitative approach was undertaken between January and June 2014, as part of the seminal project entitled Satisfaction with care in public hospitals: a social commitment to the user. The users were contacted when they were no longer at the hospital.

The study was developed at the Hospital de Clínicas de Porto Alegre, a public, general teaching hospital affiliated with the Unified Health System (SUS). This was the first public teaching hospital in the country to receive the international accreditation seal of the Joint Commission International (JCI). (13)

The emergency sector of the Hospital de Clínicas de Porto Alegre could accommodate 49 adult and 9 pediatric patients, but attended almost 120 patients daily, surpassing its capacity. The emergency Service delivered care to more than five thousand patients per month, coming from different places in Rio Grande do Sul and other States.

The clinical and surgical inpatient services in this study were located in the South and North wings, and attended to adult patients. The services in the North wing consisted of 15 three-bed wards each, totaling 45 beds. In the South wing, there were private and semi-private rooms, totaling 34 beds each.

The population consisted of patients hospitalized at clinical and surgical inpatient services. The sample consisted of two groups according to the hospitalization form (through the emergency service and the admission). The estimated sample size was calculated based on the patients discharged from each service, adding 10% for possible losses, resulting in 312 users. For the emergency group, 148 users were estimated and, for the admission group, 164 users.

The inclusion criteria were: users over 18 years of age, who were hospitalized for more than 48 hours and were discharged less than 30 days earlier. When the patients were unable to answer the interview, it was held with a legal responsible who had accompanied the hospitalization.

Users who left or were transferred to another hospital, who died or who were hospitalized again at the time of the telephone contact were excluded.

In the research, a tool was used with two sets of data: sociodemographic variables and patient satisfaction attributes. The sociodemographic variables were nine items related to the patient, such as: age, sex, marital status, years of study, health insurance, whether the patient was staying in the room alone, number of patients in the room and hospitalization period.

The satisfaction was verified through a tool elaborated in an earlier study to measure the users’ satisfac-
Patient satisfaction according to the form of hospital stay at a teaching hospital

It was adapted and tested in the phase called pretest and applied as a pilot tool in the seminal project. The satisfaction attributes in the original tool were produced based on interviews and subject to statistical analysis; significant attributes were selected for inclusion in the final version: two related to the admission, two to the discharge; two to the medical team; four for the nursing team; four for the nutrition team; two for the cleaning team and one to assess the general satisfaction. The satisfaction measure for each attribute used a six-point Likert scale, ranging from highly dissatisfied (1 point), dissatisfied (2 points), somewhat dissatisfied (3 points), somewhat satisfied (4 points), satisfied (5 points) and highly satisfied (6 points) for each attribute.

The study received help from scientific initiation grantees, who were trained and followed a data collection protocol. The research consisted of three steps, according to figure 1.

The patients were selected in multiples of five, avoiding a selection bias and respecting the proportionality of the discharges from each service. A specific database was created for this study in an Excel® 2011 worksheet, which was analyzed using the software Statistical Package for Social Sciences®, version 19.0, for the operating system IOS®, between January and June 2014.

For the categorical variables, the relative and absolute frequencies were calculated and, for the continuing variables, the mean (standard deviation) or median (interquartile interval), depending on the distribution of the variable. The chi-square test was applied to analyze the difference between the two groups (emergency and inpatient). The Shapiro-Wilk tests were used to test the normality of the sample. To compare the satisfaction of the users hospitalized through the emergency and inpatient services, the Mann-Whitney test was used. Significance was set at \( p \leq 0.05 \).

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 07948212.1.0000.5327.

**Results**

The research subjects were 366 patients, 174 hospitalized through the emergency services and 192 through

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*Figure 1. Collection and construction phases of the database*
the inpatient service. The patients' sociodemographic characteristics for the two groups have been demonstrated in table 1. The variables admitted through the emergency service, alone in the room, marital status, health insurance and years of study obtained 1, 1, 16, 4 and 21 losses, respectively, due to the non-completion of these data in the tool. These variables did not interfere in the results because 10% was added in the calculation of the sample size.

Considering the outcome user satisfaction according to the hospitalization form, it was observed that 99.4% of the patients hospitalized through the emergency service and 98.4% of the patients hospitalized through the inpatient service answered they were satisfied or highly satisfied with the care received. For the emergency group, the mean satisfaction rate was higher for all attributes when compared to the admission group (Table 2).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Total n(%)</th>
<th>Emergency n(%)</th>
<th>Inpatient n(%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>176 (48.0)</td>
<td>84 (48.3)</td>
<td>91 (47.4)</td>
<td>0.676</td>
</tr>
<tr>
<td>Female</td>
<td>190 (52.0)</td>
<td>90 (51.7)</td>
<td>100 (52.6)</td>
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</tr>
<tr>
<td>Total</td>
<td>366 (100.0)</td>
<td>174 (100.0)</td>
<td>192 (100.0)</td>
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</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td>0.251</td>
</tr>
<tr>
<td>18-39</td>
<td>75 (20.4)</td>
<td>33 (19.0)</td>
<td>42 (21.9)</td>
<td></td>
</tr>
<tr>
<td>40-59</td>
<td>112 (30.5)</td>
<td>48 (27.6)</td>
<td>64 (33.3)</td>
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<tr>
<td>&gt;60</td>
<td>179 (49.0)</td>
<td>90 (51.7)</td>
<td>89 (42.7)</td>
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<tr>
<td>Total</td>
<td>366 (100.0)</td>
<td>174 (100.0)</td>
<td>192 (100.0)</td>
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<tr>
<td>Marital status</td>
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<td></td>
<td></td>
<td>0.748</td>
</tr>
<tr>
<td>With partner</td>
<td>188 (51.2)</td>
<td>86 (49.4)</td>
<td>102 (53.1)</td>
<td></td>
</tr>
<tr>
<td>Without partner</td>
<td>163 (44.4)</td>
<td>77 (44.3)</td>
<td>86 (44.3)</td>
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</tr>
<tr>
<td>Total</td>
<td>351 (95.6)</td>
<td>163 (93.7)</td>
<td>187 (97.4)</td>
<td></td>
</tr>
<tr>
<td>Years of study</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>&lt;8</td>
<td>175 (47.7)</td>
<td>97 (55.7)</td>
<td>78 (40.6)</td>
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</tr>
<tr>
<td>&gt;8</td>
<td>171 (46.6)</td>
<td>61 (35.1)</td>
<td>109 (56.8)</td>
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<tr>
<td>Total</td>
<td>346 (94.3)</td>
<td>158 (90.8)</td>
<td>187 (97.4)</td>
<td></td>
</tr>
<tr>
<td>Health insurance</td>
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<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
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<td>SUS</td>
<td>285 (77.7)</td>
<td>161 (92.5)</td>
<td>124 (64.6)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>78 (21.3)</td>
<td>10 (5.7)</td>
<td>67 (34.9)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>363 (99.0)</td>
<td>171 (98.2)</td>
<td>191 (99.5)</td>
<td></td>
</tr>
<tr>
<td>Respondent</td>
<td></td>
<td></td>
<td></td>
<td>0.02</td>
</tr>
<tr>
<td>Patient</td>
<td>261 (71.1)</td>
<td>114 (65.5)</td>
<td>147 (76.6)</td>
<td></td>
</tr>
<tr>
<td>Family member</td>
<td>510 (28.9)</td>
<td>60 (34.5)</td>
<td>450 (23.4)</td>
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<tr>
<td>Total</td>
<td>366 (100.0)</td>
<td>174 (100.0)</td>
<td>192 (100.0)</td>
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<tr>
<td>Single room</td>
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<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Yes</td>
<td>62 (16.9)</td>
<td>17 (9.8)</td>
<td>44 (22.9)</td>
<td></td>
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<tr>
<td>No</td>
<td>304 (82.8)</td>
<td>156 (90.7)</td>
<td>148 (77.1)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>366 (99.7)</td>
<td>173 (99.5)</td>
<td>192 (100.0)</td>
<td></td>
</tr>
<tr>
<td>Patients in room</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Alone</td>
<td>61 (16.9)</td>
<td>18 (10.3)</td>
<td>43 (22.4)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>130 (37.1)</td>
<td>54 (31.0)</td>
<td>76 (40.1)</td>
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<tr>
<td>2</td>
<td>155 (42.2)</td>
<td>91 (52.3)</td>
<td>64 (33.3)</td>
<td></td>
</tr>
<tr>
<td>3 or more</td>
<td>14 (3.8)</td>
<td>11 (6.4)</td>
<td>3 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>366 (100.0)</td>
<td>174 (100.0)</td>
<td>192 (100.0)</td>
<td></td>
</tr>
<tr>
<td>Hospitalization period**</td>
<td>13.6 (2.231)</td>
<td>17.8 (2.231)</td>
<td>9.82 (2.83)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Chi-square test; **mean (minimum, maximum); SUS - Unified Health System
The lowest mean satisfaction levels were found for the attributes of the nutrition and cleaning teams, when compared to the other attributes for the two groups, showing a statistically significant difference.

Discussion

The limitations in this research were: the analysis of a single place of study; the short duration of the interview; and the possible bias of gratitude for users hospitalized through the emergency sector. This study contributed by demonstrating the quality of care delivery at a teaching hospital from the patient’s perspective and discussing it based on the use of updated references in the light of the international literature.

Concerning the characteristics of the patients' profile, it was observed that, for the admission group, the results are in accordance with studies that indicated the predominance of women (52%) and adults (50.9%) in the hospitalizations. For the group hospitalized through the emergency sector, however, the highest hospitalization frequency was for elderly patients (51.7%). The health needs of elderly people are complex and need to be known and addressed in the health services. These are users who truly need hospitalization through the emergency sector as, from the management perspective, there is a clear weakness in the health system to prevent elderly people's diseases. The only support the elderly at the emergency service received from the primary care network was medication distribution; other services, such as home visits, consultations with the health team and groups were not offered. This fact possibly suggested that the type of support received is more related to punctual actions than to professional care - probably due to the higher problem-solving ability of the emergency service in punctual actions.

These study findings are in accordance with a cross-sectional study that affirmed that SUS users (77.7%) with low education levels (47.7%) are predominant at the emergency sector. The elderly at the emergency sector of the Hospital...
de Clínicas de Porto Alegre, that is, who exclusively use the SUS, had 4.4 years of study. This aspect directly affects the users’ satisfaction with the health services. It was demonstrated that higher educational levels are associated with lower user satisfaction levels. This was actually evidenced in the admission group’s satisfaction results, with lower mean satisfaction rates than in the emergency group.

In 71.1% of the cases, the patients themselves answered the research tool. These results were similar to a research that used the same data collection method (by telephone), indicating that, in 68.6% of the interviews, the patient answered, without any statistically significant difference between the companions and the patients’ satisfaction.

The hospitalization period was shorter for the admission group (9.8 days) than for the emergency group (17.8 days). The hospitalization period of the users forwarded by the emergency service was similar to the mean 18 days of hospitalization at a surgical inpatient service of a teaching hospital in Ancara, Turkey. In addition, that group demonstrated higher mean satisfaction with care. This finding – longer hospitalization and higher satisfaction – differs from the results of an international study that associated a correlation model, identifying that, when the quality of care is high, the hospitalization is shorter and the satisfaction results are better.

Developing satisfaction research some time after the care was provided or at the patients’ homes is related to the “late satisfaction” effect, that is, with the satisfaction with care. People tend to be more critical over time and, to the extent that their expectations are surpassed, new expectations arise, making them more demanding. The development of the research by telephone was one of the advantages of the selected method and also captured more respondents.

The applicability of the patient satisfaction research results in Nursing practice demonstrated these professionals’ concern with the quality management of care delivery from the patients’ perspective. When hospital have nurses who understand the context of the health services, they can perform their activities focused on care quality. Hence, they assist the users in a broader sense, working to get to know them and attend to their expectations regarding care and available services.

The nursing team spends most of the time with the patient and often serves as a reference framework. Nevertheless, the acknowledgement of Nursing work from the user’s perspective is extremely relevant for this team. The comparative analysis of the results obtained by each of the patient groups in the study - emergency and admission - evidenced no statistically significant difference between the groups, revealing that the patients acknowledge the same care pattern concerning the Nursing team attributes and the assessment of the general satisfaction.

The study demonstrated that the patients showed a higher mean satisfaction level for the attributes of the Nursing team and for general satisfaction. Highly similar results were found in Brazilian studies, in which 99% of the patients demonstrated they were satisfied with the Nursing services provided in the hospital context, highlighting high satisfaction levels (92%) with Nursing care at a teaching hospital. International studies also appoint that the satisfaction results with the Nursing team are high.

It should be highlighted that the Hospital de Clínicas de Porto Alegre has a systemized and solid Nursing process, serving as an example for the other university hospitals and implementing individual Nursing care for all users. The systemization of nursing care is a tool capable of guiding the professionals in the conscious and technical and scientifically competent care.

This study supported others that have demonstrated high user satisfaction levels at gastroenterology, inpatient and hospital services. The group of patients hospitalized through the emergency service demonstrated a higher satisfaction level on all attributes when compared to the group hospitalized through the admission service. This can be related to a bias of gratitude and to the feeling that certain patients can present when they get care, making possible problems in care move to the background.
Nevertheless, high satisfaction levels can be explained by the fact that the hospital characteristics are associated with users’ high general satisfaction levels. As a large and high-complexity university hospital with a high technological level, which conquered recognition in the users’ community, they feel satisfied.\(^{(21)}\)

This study demonstrated that most of the hospitalized users came from the admission sector. This also covers the discussion on the overcrowding of the emergency sector as a result of the inefficiency of the management processes in the health network, leading to a deficient quality of care in this sector. It should be highlighted that measuring the quality of care in the emergency sector should be an indicator of the Brazilian health services, as it was demonstrated in the international sector that, in Australia for example, this already stands out as one of the most important indicators in the health services.\(^{(22)}\)

Concerning the satisfaction attributes, a study developed in public and private hospitals in Ethiopia refers that cleaning is one of the determinants of satisfaction at public hospitals.\(^{(23)}\) In this study, the patients’ satisfaction with the cleaning team attributes obtained lower means in relation to the other attributes for the two groups analyzed, with statistically significant differences between them.

It was demonstrated in a research that the only attribute with the lowest satisfaction level was the food. This supports the findings in this study, in which the lowest mean satisfaction level referred to the quality of the meals for the admission group.\(^{(11)}\)

**Conclusion**

This study revealed that, differently from the admission group, elderly people are the group that most need hospitalization through the emergency sector. Thus, they face problems like overcrowding and long waiting times, revealing the weakness of the health system for this population. Nevertheless, the patients were satisfied with the care received at the teaching hospital. The only satisfaction attributes that did not obtain statistical significance in the comparison of the two groups’ results were the Nursing services provided and the general satisfaction, revealing that both emergency patients and inpatients agreed on the quality of Nursing care, emphasizing its acknowledgement from the patients’ perspective.

**Collaborations**

Molina KL and Moura GMSS declare that they contributed to the conception of the project, analysis and interpretation of the data, writing of the article, relevant critical review of intellectual content and final approval of version for publication.

**References**


Cross-cultural adaptation of safety culture tool for Primary Health Care

Adaptação transcultural de instrumento de cultura de segurança para a Atenção Primária

Márcia Timm¹
Maria Cristina Soares Rodrigues¹

Abstract
Objective: Translate, adapt and validate the Medical Office Survey on Patient Safety Culture (MOSPSC).

Methods: Methodological study for the cross-cultural adaptation of the MOSPSC, elaborated by the Agency for Healthcare and Research in Quality. The following steps were undertaken: translation, back-translation, expert analysis, target population group and pretest, in a sample of 37 professionals.

Results: In the expert analysis, the tool reached a general content validity score of 0.85. Six professionals performed the assessment by the target population group, and the adaptation suggestions were analyzed and modified by consensus. The pretest involved 37 professionals, who assessed the tool as easy to understand. Cronbach’s alpha coefficient corresponded to 0.95.

Conclusion: The tool was translated and adapted to Brazilian Portuguese with a satisfactory content validity and high reliability.

Keywords
Nursing research; Primary care nursing; Public health nursing; Patient safety; Organizational culture

Descritores
Pesquisa em enfermagem; Enfermagem de atenção primária; Enfermagem em saúde pública; Segurança do paciente; Cultura organizacional

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Conflicts of interest: no conflicts of interest to declare.
Introduction

The importance of discussing the patient safety culture and establishing safer care that does not cause harm is beyond doubt, with a view to establishing a safety culture at health institutions and offering quality care. Patient safety is neither an individual’s nor a professional category’s problem, but a process that involves an institutional transformation.

The patient safety culture is a multifactorial structure, intended to promote an approach of the system to prevent and reduce damage for the patients, essentially referring to a culture in which all stakeholders are aware of their role and contribution to the organization, being responsible for the consequences of their actions. The frailty aspects include the existence of the culture of fear that errors are registered in their job records, the clear lack of communication and the reporting culture of adverse events.

Adverse event management involves identification, registering, analysis, discussion and prevention, in a culture of accountability instead of blame. Cultural transformation is thus a complex process with multiple factors that influence its success.

The assessment of the safety culture is considered the starting point to understand the current scenario and start the planning of actions aimed at changes to reduce the incidence of adverse events. It permits the identification and prospective management of relevant safety issues in the work routines, aiming to guarantee safe health care in general practice.

It is important for the organizational culture to support learning and development since, if it is based on punishment and guilt, it can cause the omission of adverse events, hampering the construction of an institutional culture aimed at patient safety. The careful analysis of error triggers evidences a series of incidents that, even in a safe practice, when influenced by the work environment and organizational culture, can produce bad results. Hence, human error should be faced in two different ways: the individual mode and the organizational mode. The factors that knowingly affect the patient safety outcomes include the number of nurses at a service, the nurses’ level of education and a favorable work environment.

Thus, it is fundamental to adopt solutions applicable to all members of the organizations, which should be easily integrated in the routine and workflow, in order to increase the adherence and sustainability. Teamwork should be strengthened as a basic core, since it may contain a decisive potential for the efficacy of the current Primary Health Care model. The institutions should critically reflect on the role the managers should play, as their strategic decisions include personnel management, demanding professional encouragement and training for the effective prevention, reporting and management of these risks during the performance and assessment of the care delivered, the planning of the facilities, the elaboration of the operating procedures, the choice of the equipment and all other decisions that define the structure of the system.

In recent years, patient safety research in primary care has considerably evolved. Adverse events are common also in Primary Care, where most services are provided. Therefore, there has been increasing interest in patient safety factors also beyond the hospital context. Thus, the safety culture needs to be explored from the perspective of the multidisciplinary teams, inserted in an organizational context, to constitute a body of knowledge, identifying the professionals’ view on patient safety and, thus, arousing debate and reflection on the theme to support the implementation of actions that improve the safety culture and the quality of care at Primary Health Care services.

The qualification of Primary Care in the Unified Health System (SUS), adopted by the Brazilian government, intends to rescue the universal tone of the Declaration of Alma-Ata, emphasizing the re-orientation role of the care model towards a universal and integrated health care system. In that sense, the Family Health Strategy is one of the proposals for the reorganization of Primary Care, being considered an alternative action to achieve the objectives of universalization, equity and integrality.
(MOSPSC) to assess the patient safety culture in Primary Health Care in Brazil.

**Methods**

A methodological study was undertaken for the translation and cultural adaptation of the MOSPSC,(12) an assessment tool the Agency for Health Care Research and Quality (AHRQ) developed in 2007. This tool has shown its usefulness as a form of scientific research. The cross-cultural adaptation and validation was undertaken for use in Primary Health Care in Spain.(13) It was also validated in Arabic and recently applied in a study in Al Mukalla, Yemen.(14) In a study developed by the LINNEAUS project, published in November 2015, in which 15 experts from the United Kingdom, the Netherlands, Denmark, Germany, Poland and Austria analyzed the tool, the results show that it is useful and applicable to assess the patient safety culture at Primary Health Care services in Europe.(15)

The original assessment tool consists of 51 questions that measure 12 dimensions of the patient safety construct, including: (1) open communication; (2) error communication; (3) information exchange with other sectors; (4) work process and standardization; (5) organizational learning; (6) general perceived patient safety and quality; (7) management support in patient safety; (8) follow-up of patient care; (9) aspects of patient safety and quality; (10) team training; (11) teamwork; and (12) pressure at work and rhythm.

To achieve the study objective, initially six steps were followed (Figure 1), strictly monitored and registered in reports, according to a guideline for validation studies in health, which are: Step 1 – translation of original tool to target language by two independent translators, (versions T1 and T2), native speakers of Brazilian Portuguese and bilingual in English/Portuguese, experienced in this method and knowledgeable about the research objective; Step 2 - in synthesis I, versions T1 and T2 were compared with the original version of the tool and summarized; Step 3 – back translation by two independent translators (R-T1 and R-T2), bilingual native North Americans, who were unfamiliar with the original version of tool and not knowledgeable about the study objectives; Step 4 - in Synthesis II, the cross-cultural adaptations were undertaken after assessing for discrepancies; Step 5 - Content validity and semantic analysis undertaken in two phases.

In Phase 1 of Step 5, the expert analysis was undertaken. Six experts participated, selected based on the following criteria: be a researcher (M.Sc. or Ph.D.) and author of scientific research on the theme patient safety or methodological advice for tool adaptation. Curricula were analyzed on the Lattes Platform of the Brazilian Scientific and Technological Development Council and, beyond the criteria established, five out of six experts have expertise in collective health.

The invitation and instructions were forwarded to the experts by e-mail. For the sake of analysis, the research program SurveyMonkey was used, which contained the items for individual assessment in terms of clarity, pertinence and content form, using a Likert scale with the following scores: 1 unclear, 2 hardly clear, 3 clear and 4 very clear. At the end of each item, there was space for suggestions and observations.

![Figure 1. Steps of the method; CVI – Content Validity Index; IRA – inter-rater agreement; PHC – Primary Health Care](image-url)
To measure the proportion or percentage of inter-rater agreement, the collected data were analyzed concerning the Content Validity Index,\(^{16,17}\) according to the following formula:

- **Number of “3” and “4” answers divided by total number of answers.**

In addition, the inter-rater agreement level was calculated for each section, using the following formula:

- **Number of items with Content Validity Index ≥80% divided by total number of items in each section.**

The inter-rater agreement serves to assess the extent of the experts’ reliability in the assessments of the items in view of the study context.\(^{18}\) Finally, the Content Validity Index of the tool was calculated by adding up the Content Validity Indices, divided by the total number of items.

Phase 2 of Step 5 referred to the assessment by a group from the target population, aiming to verify whether all items were understandable to the target population of the tool. In this phase, six professionals from the target population participated, representing the main professional categories active in Primary Health Care, ranging from the lowest to the highest education level. Each item was assessed interactively and its understanding was analyzed during a brainstorming.\(^{19}\) For the questions whose interpretation aroused doubts, suggestions were requested for adaptations, which were registered in a report and later analyzed.

In Step 6, the pretest was applied, which was aimed at assessing whether the questionnaire was understandable to a larger number of people in the target population and the reliability analysis of the tool was processed.

The data were collected in March and April 2005 in a sample of 37 multidisciplinary team professionals from three health centers and one family clinic (service with eight family health teams) in a regional health department of the State Health Secretary in the Federal District. The understanding was scored on a five-point Likert scale, as follows: 1 I did not understand; 2 I hardly understood; 3 I understood more or less; 4 I understood; and 5 I fully understood. To analyze the reliability, Cronbach’s alpha coefficient was used.

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 31787314.0.0000.5553. Initially, the AHRQ was consulted, which authorized the study.

**Results**

The adaptations of the assessment tool started with the title, “Medical Office Survey on Patient Safety”, originally translated as “Pesquisa de Consultório Médico sobre Segurança do Paciente”. The goal was to adapt a tool that could be used in the different forms of Primary Health Care. Therefore, the title was modified to “Pesquisa sobre Cultura de Segurança do Paciente para Atenção Primária” (“Research on Patient Safety Culture for Primary Health Care”). In addition, the term “medical office” was changed to “health service”, and the term “provider” to “physician”. The professionals included in the health team were also adapted, as there is no equivalent for some professional categories in Brazil.

Attachment 1 displays the final version of the translation and cross-cultural adaptation applied in the pretest.

**Expert analysis**

The items in the assessment tool that received more than 20% of score 1 (unclear) or 2 (hardly clear) were considered unsatisfactory. They were then modified based on the suggestions while maintaining the general concept. Hence, the minimum inter-rater agreement level was set at 80% to avoid any need for adaptations.

In section A, only three items (questions 1, 3 and 8) reached a Content Validity Index of 0.8; questions 4, 5 and 6 reached index 0.7 and the remainder below 5. In section B, the Content Validity Index was unsatisfactory because the alternative answers were maintained in a single question. In Section C, most items reached an index between 0.8 and 1.0; the index was inferior to 0.7 in only three items (questions 3, 12 and 14), requiring adaptations. In section D, only one item (question 6) did
not reach a satisfactory Content Validity Index; the remainder continued between 0.8 and 1.0. In sections E, F, G and H, all questions obtained indices superior to 0.8.

As regards the inter-rater agreement, the coefficients obtained in sections A (0.3) and B (0.0) were unsatisfactory, demanding further adaptations. In section C, the inter-rater agreement corresponded to 0.8; in D, 0.9; and the remaining sections reached a score of 1.0.

Although some sections required further adaptations, the calculation of the Content Validity Index for the general tool was satisfactory, corresponding to 0.85.

**Assessment by target population group**

In this phase, six professionals participated in the research, one from each category: nurse, physician, dentist, nursing technician, community health agent and oral health technician. As for education, one held a secondary education degree, one was taking a higher education program and one held a higher education degree, two held a specialization degree and one a Master’s degree.

The researchers analyzed the group’s suggestions and the items considered relevant were modified by consensus. In Section A, question number 8 was included, suggested by the group and accepted, so that this section consisted of ten questions (Attachment 1).

**Pretest**

Fifty-two questionnaires were distributed, 37 of which were returned (71%). In the distribution by professional category, the collection was done to include the widest possible range, as follows: nursing technicians (n=11; 29.7%), nurses (n=7; 19.0%), physicians (n=4; 10.8%), dentists (n=3; 8.1%), administrative team (n=3; 8.1%), laboratory technicians (n=2; 5.4%), nutritionist (n=1; 2.7%), oral health technician (n=1; 2.7%), administrator (n=1; 2.7%), manager (n=1; 2.7%), head nurse (n=1; 2.7%), head of registration sector (n=1; 2.7%), and community health agent (n=1; 2.7%).

The Portuguese version of the MOSPSC showed a Cronbach’s alpha coefficient of 0.95, expressing high reliability.

**Discussion**

This study was limited by the fact that, to reach a satisfactory level with only six experts in the calculation of the Content Validity Index, five experts had to assess the item with a minimum score of 3 (clear) or 4 (very clear). Another aspect was that, in section B, the subitems were maintained in a single question, which interfered in the assessment, because the experts suggested that the answered should be divided. Despite these limitations, the Content Validity Index of the general tool reached a satisfactory level (0.85). To check the validity of new tools in general, some authors suggest a minimum agreement coefficient of 0.80.(17)

In the internal consistency analysis, Cronbach’s alpha coefficient corresponded to 0.95, similar to the coefficient found in the validation of the tool for Spanish (0.96).(13)

The use of a consistent method for the translation, cross-cultural adaptation and validation of a research tool is essential.(12) In this study, the steps were carefully monitored, analyzed and documented to achieve a better consistency level. A robust and well-developed tool, with validity and reliability of the data in the original version, strictly adapted and translated in different languages, permits the comparison of the results on an international scale, in different cultures.(20)

The research steps were used to support the conceptual, semantic and content equivalence of the tool to be translated. Experts performed the content analysis step. According to the methodological framework used, six experts are sufficient to obtain content validity.(13,19) Therefore, they were carefully selected to guarantee the quality of the evaluation.

The semantic analysis was undertaken through the target population group, assessing the understanding and face validation. The items were reviewed and modified to enhance the understanding and clarity in accordance with the suggestions. A project to translate, adapt and validate a cross-cultural research tool can take several years and is normally developed based on more than one study as
A methodological framework. The initial target can be defined as the translation, adaptation and validation of a tool using steps 1 to 5, followed by the full psychotechnical test of the prefinal version of the translated tool in a sample of the target public.\(^{(16)}\)

The largest number of suggested adaptations were related to section A, in the expert analysis phase as well as in the assessment by the target population. One factor that contributed to reduce the Content Validity Index of the section was one expert’s assessment, who scored all items as “hardly clear”, not related to the question, but to the answer frequency. Replacing the alternative answers “weekly” or “monthly” by “at least once a week” and “at least once a month” was suggested, respectively.

In section H, the professional categories active at Primary Health Care services in Brazil were adapted, considering that the theme covers the organizational structure and the multiprofessional team. Similarly, another instrument translation and validation study for use in hospitals developed this adaptation.\(^{(6)}\)

None of the items was excluded from the assessment tool; on the opposite, item 8 was added in section A, suggested by the target population group. The item refers to the access to medical exams as, in the Brazilian reality, the necessary exams are not always offered to the patients freely and in due time. Access is defined as the user’s capacity to obtain health care whenever necessary, easily and conveniently,\(^{(11)}\) and this dimension of quality in health interferes directly in the safety, as it makes appropriate diagnosis and treatment impossible. The large number of questions in the tool may interfere in the adherence to the research and, in another study, it was equally suggested that a lesser number of items would be more appropriate.\(^{(13)}\)

Hence, the challenge of adapting a tool cross-culturally, and the limitations of assessing a complex theme like the patient safety culture, containing items that target managers, the administrative team and the multiprofessional team, its reliability can be confirmed. Nevertheless, subsequent steps need to be pursued, aimed at the operational and measuring equivalence, in order to prove its psychometric properties.\(^{(6)}\) The application of a validated questionnaire in studies compared among different contexts in the country and among other countries from different continents will permit understanding the multifaceted phenomenon of safety culture at several Primary Health Care services.

### Conclusion

The research tool Medical Office Survey on Patient Safety Culture was translated, cross-culturally adapted and validated, including the semantic analysis and assessment of the clarity and understanding of the items. In the expert analysis, the results demonstrated satisfactory content validity. In the pretest, the Brazilian Portuguese version showed high reliability, according to Cronbach’s alpha, and was considered easy to understand by the target population.

### Collaborations

Timm M and Rodrigues MCS declare that they contributed to the conception of the study, analysis, interpretation of the data, writing of the article, relevant critical review of the intellectual content and final approval of the version for publication.

### References


Attachment 1. Adapted and validated tool

Research on Patient Safety Culture for Primary Health Care

RESEARCH INSTRUCTIONS

Think about the way things are done in your health service and provide your opinions on issues that affect the safety and quality of the care provided to patients.

If a question does not apply to you or you don’t know the answer, please check “Does Not Apply or Don’t Know.”

If you work in more than one health service, when answering this survey, answer only about the location where you received this survey—do not answer about your practice in general.

If you work in a building with other health services, answer only about your own place of work.

SECTION A: List of questions on patient safety and quality

The following items describe things that can happen at health services that affect patient safety and quality of care. According to you, how often did the facts listed below happen at your place of work OVER THE PAST 12 MONTHS?

<table>
<thead>
<tr>
<th></th>
<th>Daily</th>
<th>At least once a week</th>
<th>At least once a month</th>
<th>Several times in the past 12 months</th>
<th>Once or twice over the last 12 months</th>
<th>Did not happen over the past 12 months</th>
<th>Does not apply or I don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A patient was unable to get an appointment within 48 hours for an acute/serious problem.</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
<td>☐ 6</td>
<td>☐ 9</td>
</tr>
<tr>
<td>Patient identification</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
<td>☐ 6</td>
<td>☐ 9</td>
</tr>
<tr>
<td>2. When attending a patient, a chart/medical record from another patient was used.</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
<td>☐ 6</td>
<td>☐ 9</td>
</tr>
<tr>
<td>Charts/medical records</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
<td>☐ 6</td>
<td>☐ 9</td>
</tr>
<tr>
<td>3. The chart/medical record of a patient was unavailable when necessary.</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
<td>☐ 6</td>
<td>☐ 9</td>
</tr>
<tr>
<td>4. Clinical information from one patient was filed, scanned or entered into the chart/medical record of another patient.</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
<td>☐ 6</td>
<td>☐ 9</td>
</tr>
<tr>
<td>Equipment</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
<td>☐ 6</td>
<td>☐ 9</td>
</tr>
</tbody>
</table>
SECTION A: List of questions on patient safety and quality (continued)

How often did the facts listed below happen at your place of work OVER THE PAST 12 MONTHS?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Daily</th>
<th>At least once a week</th>
<th>At least once a month</th>
<th>Several times in the past 12 months</th>
<th>Once or twice over the last 12 months</th>
<th>Did not happen over the past 12 months</th>
<th>Does not apply or I don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. The patient returned to the health service to clarify or correct a prescription</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. The health professional did not review the medication a patient used during his/her appointment.</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostics &amp; tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. The lab or imaging tests were not done when necessary.</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. The lab or imaging test results were not available when needed.</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. An abnormal result of a lab or imaging test was not followed up in due time.</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION B: Information exchange with other institutions

Over the past 12 months, how often has this health service had problems exchanging accurate, complete, and timely information with:

<table>
<thead>
<tr>
<th>Problems daily</th>
<th>Problems at least once per week</th>
<th>Problems at least once per month</th>
<th>Several problems over the past 12 months</th>
<th>One or two problems over the last 12 months</th>
<th>No problem over the last 12 months</th>
<th>Does not apply or I don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Imaging centers/labs from the health care network?</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Other health services/physicians from the health care network?</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Pharmacies?</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Hospitals?</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others? Please specify:</td>
<td>□1 □2 □3 □4 □5 □6 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION C: Working at this health service

How much do you agree or disagree with the following statements?

<table>
<thead>
<tr>
<th>Statements</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
<th>Does not apply or I don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. When someone in this service gets really busy, other colleagues help out</td>
<td>□1 □2 □3 □4 □5 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. In this service, there is a good working relationship between the physicians and other professionals</td>
<td>□1 □2 □3 □4 □5 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. In this service, we often feel rushed when taking care of patients</td>
<td>□1 □2 □3 □4 □5 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. This service trains the team when new processes are put into place</td>
<td>□1 □2 □3 □4 □5 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. In this service, we treat each other with respect</td>
<td>□1 □2 □3 □4 □5 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. We have too many patients for the number of physicians in this service</td>
<td>□1 □2 □3 □4 □5 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. This service makes sure the team gets the training they need for care delivery</td>
<td>□1 □2 □3 □4 □5 □9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. They aren't investing enough resources to improve the quality of care in this service.


2. In this service, there are procedures in place to check that work in this service was done correctly.


3. The professional in this service are asked to do tasks they haven't been trained to do.


4. We have enough professionals to handle the number of patients.


5. This service monitors patients who need follow-up.


6. The team at this service believes that its errors can be used against the team.


7. The team in this service follows standardized processes to get its activities done.


8. This service is more disorganized than it should be.


9. Employees are willing to report bugs to observe this service.


10. In this service we discuss ways to prevent errors from happening again.


11. We have problems with workflow in this service.


12. This service values teamwork in taking care of patients.


13. This service follows up when it does not receive an expected report from another service.


14. The team is encouraged to express other points of view.


15. The team in this service follows standardized processes to get its activities done.


How often do the following facts happen in this service? Never Rarely Sometimes Almost always Always Does not apply or I don't know


1. The physicians at this service are open to the ideas of the other team members on how to improve the work processes.


2. At this service, the team is encouraged to express other points of view.


3. At this service, the patients are warned when they need to make an appointment for preventive or routine care.


4. At this service, the team is afraid to ask questions when something does not seem right.


5. This service keeps records of how chronic patients follow the treatment plan.


6. This service follows up when it does not receive an expected report from another service.


7. The team at this service believes that its errors can be used against the team.


8. The team talks openly about problems at this service.


9. This service monitors patients who need follow-up.


10. At this service it is difficult to express different opinions.


11. In this service we discuss ways to prevent errors from happening again.


12. Employees are willing to report bugs to observe this service.


SECTION E: Management/administration/leadership support

A. Are you a manager/administrator or do you have a leading function with responsibility to make financial decisions for the service?

☐ 1 Yes → Move on to Section F

☐ 2 No → Continue below

How much do you agree or disagree with the following statements about the managers/leaders of your service? Strongly disagree Disagree Neither agree nor disagree Agree Strongly agree Does not apply or I don't know


1. They aren’t investing enough resources to improve the quality of care in this service.


2. They overlook patient care mistakes that happen over and over.


3. They place priority on improving patient care processes.


4. They frequently make decisions based on what is best for the office instead of what is best for patients.
SECTION F: Your health service

How much do you agree or disagree with the following statements?

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>Does Not Apply or Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. When there is a problem in our service, we assess whether the way we do things needs to change.</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
<td>☐9</td>
</tr>
<tr>
<td>2. Our work processes are appropriate to prevent errors that could affect the patients.</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
<td>☐9</td>
</tr>
<tr>
<td>3. At this service, mistakes happen more often than they should.</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
<td>☐9</td>
</tr>
<tr>
<td>4. It is just by chance that we don’t make more mistakes that affect our patients.</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
<td>☐9</td>
</tr>
<tr>
<td>5. This service is good at changing work processes to make sure that problems do not happen again.</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
<td>☐9</td>
</tr>
<tr>
<td>6. At this service, how much work is done is more important than the quality of the care provided.</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
<td>☐9</td>
</tr>
<tr>
<td>7. At this service, after making changes to improve the patient care process, we check to see whether they work.</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
<td>☐9</td>
</tr>
</tbody>
</table>

SECTION G: Overall assessment

Overall quality assessment
1. In general, how would you rank this health service in each of the following health care quality areas?

<table>
<thead>
<tr>
<th>Area</th>
<th>Bad</th>
<th>Reasonable</th>
<th>Good</th>
<th>Very good</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Patient centered:</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
</tr>
<tr>
<td>b. Effective:</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
</tr>
<tr>
<td>c. Punctual:</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
</tr>
<tr>
<td>d. Efficient:</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
</tr>
<tr>
<td>e. Impartial:</td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
</tr>
</tbody>
</table>

Overall patient safety assessment
2. Overall, how would you rank the systems and clinical processes this service uses to prevent, identify and correct problems that may affect patients?

<table>
<thead>
<tr>
<th>Area</th>
<th>Bad</th>
<th>Reasonable</th>
<th>Good</th>
<th>Very good</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐1</td>
<td>☐2</td>
<td>☐3</td>
<td>☐4</td>
<td>☐5</td>
</tr>
</tbody>
</table>

SECTION H: Questions about professional practice

1. How long have you worked at this service?
   - ☐ a. Less than 2 months
   - ☐ b. Between 2 months to less than 1 years
   - ☐ c. Between 1 years to less than 3 years
   - ☐ d. Between 3 years to less than 6 years
   - ☐ e. Between 6 years to less than 11 years
   - ☐ f. 11 years or more
2. Normally, how many hours per week do you work at this service?

- [ ] a. 1 to 4 hours per week
- [ ] b. 5 to 16 hours per week
- [ ] c. 17 to 24 hours per week
- [ ] d. 25 to 32 hours per week
- [ ] e. 33 to 40 hours per week
- [ ] f. 41 hours per week or more

3. What is your function at this service? Check ONE category that best applies to your job.

- [ ] a. Physician
- [ ] b. Nurse
- [ ] c. Management
  - Administrator
  - Nurse Manager
  - Laboratory Manager
  - Another manager ________
- [ ] d. Administrative team
  - Medical records
  - In charge of scheduling (appointments, exams, surgery etc.),
  - Reception
  - Another administrative function: ________________________
  - Receptionist
  - e. Nursing Technician
- [ ] f. Other clinical staff:
  - Laboratory Technician
  - Oral Health Technician
  - Odontologist
  - Pharmacist
  - Social Worker
  - Another function. Please specify: ________________________
  - Physiotherapist
  - Nutritionist
  - Psychologist
  - Occupational Therapist
  - Community Health Agent

SECTION I – Your comments

Please feel free to write any comments you may have about safety and quality of care at the service where you work.

THANK YOU FOR COMPLETING THIS RESEARCH.
Efficacy of an educative intervention on knowledge related to cardiovascular diseases among men

Efetividade da intervenção educativa no conhecimento de doenças cardiovasculares

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Abstract

Objective: Compare the knowledge about risk factors for cardiovascular diseases before and after an educative intervention involving male metal workers.

Methods: Intervention study involving 135 metal workers between 18 and 70 years of age. The knowledge on cardiovascular diseases was determined by means of the Heart Disease Fact Questionnaire (HDFQ-2). Student’s t-test for independent samples was used and Mann-Whitney’s test for intergroup comparisons, and Student’s t-test for dependent samples and Wilcoxon’s test for the paired assessment.

Results: In the intervention group as well as in the control group, a statistically significant increase by 1.4 points was found in the mean knowledge between baseline and follow-up.

Conclusion: The educative intervention, undertaken in group, at the workplace and at lunchtime, was a possible and effective strategy to increase men’s knowledge on risk factors for cardiovascular conditions.

Descritores
Educação em enfermagem; Enfermagem em saúde pública; Conhecimento; Doenças cardiovasculares/educação; Fatores de risco; Saúde do homem; Indústria metalúrgica

Keywords
Education, nursing; Public health nursing; Knowledge; Cardiovascular diseases/education; Risk factors; Men’s health; Metalmechanic Industry

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Introduction

Cardiovascular diseases (CVD) still prevail as the main cause of death and disability in Brazil and around the world. According to the World Health Organization (WHO), in 2008, 17.3 million people died due to this group of diseases. Estimates appoint that these data will increase to 23.3 million in 2030. Therefore, health promotion and CVD prevention actions are fundamental for the sake of modifications in this epidemiological profile.

Among these actions, activities aimed at increasing the population's knowledge on risk factors for chronic conditions stand out, as this empowers them for lifestyle changes and, consequently, can be useful to improve the quality of life, avoid the emergence of a problem and influence the search for treatment when the disease has already established.

In this context, the work environment can serve as a favorable scenario for health promotion, because it constitutes a privileged space for health promotion in the 21st century, since it directly influences the workers' physical, mental, economic and social wellbeing and, consequently, the health of their families, community and society as a whole.

Educative and intervention actions in the work environment have demonstrated promising results, particularly regarding the modifiable risk factors of CVD, such as lack of physical exercise, smoking, hypertension, dyslipidemia, inappropriate diet, hyperglycemia and high stress. Thus, the occupational health professionals and owners of large companies in the territory of their health services should be trained for health promotion in the work environment, considering that this place offers an ideal scenario and infrastructure to support these activities, which target a large public at the same time.

Finally, it should be highlighted that, in the specific case of the male public, the strategy of undertaking health promotion in the work environment is relevant because many men allege that the opening hours of the health services coincide with their work hours, impeding their search for care.

Thus, in view of the importance of health education for male workers at the place of work, the objective in this study was to compare the knowledge about risk factors for cardiovascular diseases before and after an educational intervention involving male metal workers.

Methods

A randomized and controlled before-and-after intervention study was undertaken, involving 135 workers from a metal industry located in Maringá (PR), a State in the South of Brazil.

The population consisted of male workers in the iron and steel sector. The inclusion criteria were: working in the company when the data collection started and being 18 years of age or older. The exclusion criteria were: being on leave and/or holiday and not having participated in at least 80% of the educative activities or in the assessment at the end of the educative intervention.

According to company data, 230 male workers were active at the company. Based on this figure, a stratified sample (n=135) was calculated, divided between an intervention group (n=6) and a control group (n=68), considering an estimation error with 1% reliability and 95% sample precision, with an expected prevalence of 50%.

The data were collected between November 2013 and June 2014, divided in three phases (Phases I, II and III).

In Phase I, the 230 workers were interviewed to identify their knowledge on cardiovascular diseases, using a semistructured sociodemographic questionnaire and the Heart Disease Fact Questionnaire (HDFQ-2), developed in the United States. This questionnaire consists of 25 questions with three alternative answers: “true”, “false” and “I don’t know”. A score was attributed to each correct answer and zero to incorrect answers, with total scores ranging from zero to 25 points.

The answer “I don’t know” was considered wrong. After the translation of the HDFQ-2 by
three experts, the word “gardening” was replaced by “housework”, considering that gardening is rarely a physical exercise in the Brazilian population. Thus, the reliability of the questionnaire was tested using Cronbach’s alpha (0.74).

The knowledge was calculated as a continuous variable, using the total score of each individual.

In Phase II, a random sample of 135 participants was obtained among the 230 metal workers. This sample was randomized for the intervention and control groups through random drawing, being 67 allocated to the intervention group and 68 to the control group. The workers from the intervention group were invited to participate in a health education program and, after they had accepted to participate, they were also subdivided using random drawing into four subgroups, so that the small number of participants in each group would guarantee that all individuals were considered at the same time during the activities. (12)

The health education program was developed in the form of operative groups, (13) which are characterized by the conversation wheel, the interaction among its members, the commitment to the group, the establishment of bonding and of tasks for the members to perform, as well as the mutual experience exchange. This activity model favors the participants’ engagement and, consequently, the practice of healthy habits. (14)

The theoretical framework adopted to discuss the themes was supported self-care, more specifically the premises of levels 1 and 2, which incorporate the health promotion interventions related to changes in the behaviors and lifestyles of the Care Model for Chronic Conditions in Primary Health Care. (15)

The themes discussed during the meetings were determined in advance and in group between the mediating nurse and the participants during the first meeting and, for the following meetings, during the conversation wheels. They included topics like arterial hypertension, diabetes mellitus, cerebrovascular accident, stroke, prostate cancer, healthy eating, physical exercise, posture at work, cholesterol, smoking and alcohol consumption, overweight and obesity. Different health professionals were invited to contribute to the health education actions: nutritionists, physiotherapists, physician, physical educator and nurses.

The groups met weekly for three months on fixed weekdays and times. Each meeting took 50 minutes and, to facilitate the workers’ participation, the meetings were held soon after lunchtime, during the rest period, in a room the company made available. These meetings took the form of dialogued lectures as well as conversation wheels and dynamics especially prepared for each theme/encounter. Before starting the discussion of the theme programmed, among the participants, the knowledge and experience concerning the theme were verified, within a perspective based on Paulo Freire’s pedagogy of autonomy, in which the student’s background knowledge is valued, to the detriment of education solely based on scientific contents. (16)

The researcher conducted, mediated and recorded the meetings with the help of a nurse who participated as an observer, registering non-verbal behaviors during the meetings, besides helping to check blood pressure, capillary glucose and weight before the start of the group activity. At the end of each meeting, the group of participants set tasks and/or targets to be achieved during the week together with the researcher, by some specific individuals or by the entire group. During the next week, before starting to discuss the programmed theme, a conversation wheel was held to exchange experiences on the tasks set during the previous meeting, when each participant presented his difficulties and conquests, providing feedback on the learning/knowledge gained.

Also regarding the conduction of the educative activity, it should be informed that the same professionals participated in the meeting during the four intervention groups, and were surprised by the direction the activity took in each group. That was so because, despite having a basic script related to their activity area and in line with the themes of interest initially established by the
four group participants’ expectations, the general and individual interests that emerged during the activity were always valued. It should also be highlighted that the participants demonstrated interest in the group meetings, as they normally arrived before the scheduled time and, in addition, they commonly brought their own and even their wives’ doubts to the meeting, concerning how to prepare certain foods to make them healthier for example. Another example of this interest was one participant’s presence during a medical leave because of a forearm fracture.

The 68 workers in the control group did not receive any orientation on risk factors for cardiovascular diseases in the baseline of the study. Nevertheless, blood pressure and capillary glucose verification were offered upon the metal worker’s request. In addition, educative activities were guaranteed to all workers after the end of the data collection.

In the final phase, after the end of the intervention period, the HDFQ-2 was again applied to verify the efficacy of the health education program for knowledge on risk factors of cardiovascular diseases. Thus, the outcome variable in this study was the knowledge the participant had gained after the intervention in comparison with his background knowledge.

The data were typed through double entry in Microsoft Excel® 2010 worksheets and later analyzed in statistical software R, version 3.0.1(17)

The descriptive and normality analysis of the data was undertaken based on the Shapiro-Wilk test. When the normality parameters were satisfactory, the analysis was based on Student’s t-test for two dependent samples, comparing two means (before and after) of the same group, and Student’s t-test for two independent samples when comparing the means for two different groups at baseline and follow-up. When the distribution of the variables was asymmetrical, Wilcoxon’s test was used in the paired assessment and Mann-Whitney’s test in the independent assessment. The proportions were compared using Pearson’s chi-square tests. Significance was set at 5% for all tests.

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 25517913.9.0000.0104.

Results

Sixty-seven metal workers started the intervention, but only 35 (52.2%) concluded it, as 14 workers did not participate in at least 80% of the weekly meetings in educative group activities or did not participate in the final assessment, and 18 left the organization before the end of the intervention period. Among the 68 men included in the control group, 37 (54.4%) participated in the second assessment, as six workers refused to answer the questionnaire again and 25 left the company (Figure 1).

In general, the study participants’ mean age was 40.3 years (standard deviation ±12.3). The majority was mulatto/black (62.5%), lived with a partner (76.4%) and had eight or more years of education (61.1%). The mean knowledge on risk factors for cardiovascular diseases was 16.6 points (data not included). These characteristics, according to the group the participants were allocated to, are displayed in table 1. No statistically significant differences were found between the groups, guaranteeing their comparability.

In table 2, the comparison between the participants’ knowledge levels on risk factors for cardiovascular diseases is presented according to the group they were allocated to (before (time 1) and after (time 2) the intervention. As observed, in both groups, a statistically significant increase (p<0.05) by 1.4 points was found in the mean HDFQ score at time 2. A similar result was found for the median, which increased significantly in the intervention group (p=0.028) as well as in the control group (p=0.008).

Additional analysis showed that, although the median of the control group (2 points) increased more than in the intervention group (1 point)
Efficacy of an educative intervention on knowledge related to cardiovascular diseases among men

**Figure 1.** Flow chart of the study; BP - Blood pressure; WC - Waist circumference; WHR - Waist-hip ratio; BMI: Body Mass Index; T - Time

- Total workers in the company, n=285
- Eligible workers for the research, n=230
  - Eligibility criteria:
    - Active in the company;
    - Male;
    - over 18 years of age
- Excluded from the study, n=55
  - 26 female
  - 9 under 18 years of age
  - 20 on holiday or leave
- Random sampling, n=135
- Intervention group, n=67
- Control group, n=68
  - Sub-groups:
    - Group 1: n=17
    - Group 2: n=17
    - Group 3: n=17
    - Group 4: n=16
- Operative Groups
  - 1x/week
  - Length: 50min
  - Duration: 3 months (13 meetings)
  - Multiprofessional (4 nurses, 1 physical educator, 2 physiotherapists, 2 nutritionists, 1 physician)
- Baseline measures:
  - BP, Capillary glucose, Weight, height, WC, WHR, BMI, semistructured and structured questionnaire
- T=3 months – Measures:
  - BP, Capillary Glucose, Weight, Height, WC, WHR, BMI, semistructured and structured questionnaire
- Excluded from the study, n=55
  - 26 female
  - 9 under 18 years of age
  - 20 on holiday or leave
- Baseline measures:
  - BP, Capillary glucose, Weight, height, WC, WHR, BMI, semistructured and structured questionnaire

- T=3 months
  - 3 months of pressure and capillary glucose verification when requested;
  - Supply of health education at the end of the intervention
- T=3 months, n=37
  - 6 refusals,
  - 25 resignations.
- T=3 months, n=35
  - 14 drop-outs;
  - 18 resignations.
mathematically, this difference was not statistically significant (p=0.131) for the Mann-Whitney test, data not included).

**Discussion**

Among the limitations in this research, the possibility of information exchange between the participants in the two groups is highlighted, as the participants shared common spaces, such as the lunchroom and the leisure area, working at the same company, although in different sectors. This can easily happen with educational interventions in the work environment, as the participants naturally share/disseminate information with other colleagues, which can threaten the internal validity of results. In addition, this type of situation is unwanted to assess an intervention, as it reduces the differences observed between the intervention and control groups. Nevertheless, from a Public Health perspective, the fact that the control group benefited from the intervention due to the information exchange is something positive, as these participants also increased their knowledge about the risk factors for CVD, enhancing the prevention of these outcomes.

Other limitations are some factors inherent in this type of study, such as the length of the intervention for example, as three months may not have sufficient for the workers to be able to translate information into knowledge learned; the short interval between the intervention and the assessment of its impact; the low generalizability of this kind of study results, with esti-
mates that are only valid for the population actually studied and, finally, the losses related to the initial and final number of participants in the two groups, due to not only drop-outs, but also workers who left the company, which may have influenced the results somehow.

Despite the limitations, it should be highlighted that this was a controlled and randomized intervention, that is, ranking higher on the scientific evidence scale, and its results appointed a significant increase (p<0.05) by 1.4 points in the mean knowledge on cardiovascular diseases among metal workers between time 1 (baseline) and time 2 (follow-up). This signals promising perspectives for nursing professionals to reach this specific kind of population.

In that sense, this study presents fundamental information to plan health actions focused on man’s health, as they appoint knowledge that is to be considered when addressing male cardiovascular health needs. In addition, it is highlighted that knowledge on the disease is one of the pillars for the development of self-care actions in cardiovascular diseases. Despite the influence of beliefs and values, improving the population’s knowledge seems to be fundamental to strengthen their capacity and confidence to develop self-care actions, contributing to improve the disease management and prevention.

A quasi-experimental study in the job context in Italy, involving a predominantly male population, aimed at reducing the cardiovascular risk through educative intervention, found that even 12 months after the end of the intervention, its effect on the reduction of the cardiovascular risk were still observed.(18) Studies that assessed the knowledge on the cardiovascular risk using different types of questionnaires(20,21) and with interventions that took between six(20) and 12 (21) months found a significant increase in the mean knowledge scores. Also, a study in the United States, involving 2,787 participants, showed that the educative intervention can be effective to change knowledge on cardiovascular diseases, even when undertaken for only three months, and that the benefit for knowledge can last beyond 12 month after its end. (22)

The interest in research involving workers, aiming to help them improve the health condition and efficiency at work has increased especially in groups from the private sector, (18) and the educative intervention has been appointed as a feasible alternative in the work environment. Hence, the importance of this type of study is highlighted, as the concept of health promotion in the workplace is increasingly gaining relevance, to the extent that both public and private organizations acknowledge that success in the job market can only be achieved with a healthy, qualified and motivated workforce. (6)

Despite the increased interest in this kind of studies, however, not many reports are found in the literature because, when the studies are developed in the work environment, they can be impaired by the existence of a research bias, which interferes in the internal validity of its results. (18) It is highlighted that, like in this study, the possibility of information exchange between the groups is a very frequent bias when the study is developed in industrial companies/services. (19)

Independently of whether information was exchange between the groups, another aspect that should be considered in the comparison of the results with other studies is the difference between the populations, as this study only involved men, while most other studies, mainly international research, which have identified a significant increase in knowledge on risk factors for cardiovascular diseases, were developed with female populations(2,24) or populations with a large share of female participants. (21,24)

Despite acknowledging the efficacy of the educative intervention based on the increased knowledge score in both groups, it is important to emphasize that knowledge alone may not be sufficient to change health behaviors, especially among male individuals, as studies show that women are more prone to behavioral changes. (2,24) Thus, assessing and also stimulating knowledge in these populations may be the most efficient forms of developing culturally appropriate messages to encourage and/or pro-
mote acceptance of simpler behavioral changes, besides setting the first step towards a healthier life.\(^{(24)}\) Assessing the baseline knowledge as part of an educative intervention and health promotion during the intervention can make this kind of programs relevant.

**Conclusion**

The educative intervention in group, at the workplace and during lunchtime, showed to be feasible and effective strategy to increase men’s knowledge on risk factors for cardiovascular diseases.

**Acknowledgements**


**Collaborations**

Ganassin GS and Silva EM contributed to the conception of the project, execution of the research, writing of the paper and final approval of the version for publication. Pimenta AM and Marcon SS collaborated with the conception of the project, relevant critical review of the intellectual content, development of the research and interpretation of the data.

**References**

22. McKinley S, Dracup K, Moser DK, Riegel B, Doering LV, Meischke H, et al. The effect of a short one-on-one nursing intervention on knowledge,
Efficacy of an educative intervention on knowledge related to cardiovascular diseases among men


Sexual and emotional experiences of women with urinary incontinence secondary to HTLV

Vivência sexual e afetiva de mulheres com incontinência urinária secundária ao HTLV

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Evanilda Souza de Santana Carvalho³

Abstract

Objective: To understand the sexuality experience of women with urinary incontinence secondary to human T-cell lymphotropic virus (HTLV).

Methods: Qualitative study using oral thematic history and data collection through in-depth interview and, for analysis, the content and gender analysis technique.

Results: Ten women participated and four categories emerged: understanding sexuality; experiencing conflict and violence; experiencing sexuality without pleasure; and experiencing urinary losses during intercourse. Knowledge about sexuality and exercise was limited. Living with incontinence and the virus contributed to conflicts in marital and emotional relationships, surrounded by renunciation, limitation, gender-based violence, as well as life changes and adaptations to learning how to live with the disease.

Conclusion: Women had difficulty in performing their sexuality, and needed to change their lifestyle and empower themselves to live better.

Resumo

Objetivo: Aprender a vivência da sexualidade das mulheres com incontinência urinária secundária ao vírus linfotrópico de célula T humana (HTLV).

Métodos: Pesquisa qualitativa, utilizando-se história oral temática e coleta de dados por meio da entrevista em profundidade e para análise, a técnica de análise de conteúdo e gênero.

Resultados: Participaram dez mulheres e emergiram quatro categorias: Compreensão da sexualidade; Vivenciando conflitos e violência; Vivenciando a sexualidade desprovida de prazer; e Vivenciando as perdas urinárias na sexualidade. O conhecimento sobre sexualidade e seu exercício foram limitados. Viver com a incontinência e o vírus contribuiu para uma relação conjugal e afetiva conflitantes, cercada de renúncias, limitações, violências de gênero, além de modificações e adaptações na vida, para aprender a conviver com a doença.

Conclusão: As mulheres apresentaram dificuldade em exercer a sexualidade, e precisaram modificar seus estilos de vida e se empoderarem para viver melhor.

Keywords

Nursing care; Nursing research; Sexuality; Urinary incontinence; Deltaretrovirus infections

Descritores
Cuidados de Enfermagem; Pesquisa em Enfermagem; Sexualidade; Incontinência urinária; Infecções por deltaretrovírus

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Introduction

The word “sexuality” refers to multiple meanings and interpretations. Initially it is related to sex, intercourse, and reproduction; however, there is the involvement of the whole body associated with the five senses, the symbolic attributes, and the human capacity to imagine and fantasize.\(^{(1)}\)

The construction of sexuality involves social and cultural beliefs and ideologies.\(^{(2)}\) In a broader dimension, this experience can be altered by the presence of a deficiency and/or a disease. Then there is a bigger issue regarding sexual performance, which is influenced by prejudice, stigma, body changes, and the fear of transmission.\(^{(3,4)}\)

Among the sexually transmitted infections, we approached the human T-cell lymphotropic virus (HTLV). The most prevalent is type I, which is associated with the presence of adult T-cell leukemia/lymphoma and with HTLV-associated myelopathy/tropical spastic neurological paraparesis disease that causes muscle and neuromotor symptoms.\(^{(5)}\) Neurological changes can compromise bladder performance, leading to a neurogenesis state, which causes urinary disorders such as nocturia, urgency, dysuria, hesitation and effort to urinate, the feeling that bladder-emptying is incomplete, and urinary incontinence.\(^{(5,6)}\)

HTLV seropositivity is more pronounced in women than in men and increases after the age 40. The most probable explanation for this difference is sexual transmission, which is more efficient from men to women, and blood transfusions, which is more frequent in women.\(^{(6)}\)

During the service, it was clear that this vulnerability influenced affective relationships, and to what extent it damaged sexuality. During the rehabilitation sessions, a high expectation of solving the complications arising from HTLV was evident, in terms of having the hope of again having a sexual life without any interference from urinary incontinence.

Women with incontinence secondary to HTLV differ from others who have other types of incontinence once they present, in addition to urinary symptoms, other myelopathy derivatives, such as perineal hypersensitivity, vaginal palpation pain, and hypertonia of pelvic floor muscle. These are added to neuromotor changes that impair their autonomy and mobility, such as march changes, patellar hyperreflexia, and lower limb hypertonia that affect daily activities, including sexuality, self-care, sleep, and willingness,\(^{(5,6)}\) which constitute an aggravation of sexual performance.

Thus, the motivation for this study came from the clinical care experience of one of the authors of the study, who realized that women often expressed their dissatisfaction about changes in their sexuality following the urinary incontinence caused by HTLV. This question led the authors to enquire: How do women with urinary incontinence secondary to HTLV experience sexuality? Moreover, how does the gender relationship develop? To answer these questions, we defined the objective of understanding the sexual experiencing of women with urinary incontinence secondary to HTLV.

The importance of this study is emphasized as it explores the experiences of a specific group of women whose illness is poorly studied, and the obscurity of the problems experienced by them implies the quality of provided care. This study contributes to nursing professionals’ understanding of how these women experience sexuality, given the limitations imposed by the incontinence and the virus, and support the planning of a specialized care. However, we do not intend to establish a generalization about sexuality, but rather to initiate a discussion based on the interpretations of narratives from women that live in a society with little clarification on this issue.

Methods

This is a qualitative study developed with patients addressed by services of the Bahia State to a public hospital with a specialized unit for infectious disease, in Salvador (Bahia) that cares for adults with HTLV.
The subjects were women who met the following inclusion criteria: adult; registered in the specialized service of infectious diseases; with confirmed HTLV diagnosis; presenting urinary incontinence; and able to answer the interview questions.

The subjects’ participation was voluntary, free, and spontaneous, and their identities were preserved. There was no disruption to the care provided to the patients during data collection, and they were advised that they could cease their participation at any time, even after they had signed the Consent Form.

The approach to the participants was in the ambulatory. In a preliminary talk, they were invited to participate in the investigation. This kind of screening was used because frequently the information about urinary incontinence or other urinary abnormalities was not described in medical records.

For empirical data, we used oral thematic history, which put the discussion around a defined central issue, that being the narrative of a fact that was part of a whole life context, enabling participants to tell their history according to the way it is lived and experienced.\(^7,8\)

The collection of testimonies was done through in-depth interview, which is recommended when access to the perceptions and behaviors is required, once it allows those interviewed to talk about their experiences, complaints, and concerns.\(^7,8\) Associated with this, a semi-structured script served as the interviewers’ guide, and the interviewers did not limit the patients to the narrated histories.

The interviews, recorded on a digital recorder, were completely transcribed later.

For data analysis, the collected narratives were submitted to the content and gender analysis technique, as an analytical tool for the content related to women’s issues in the face of the men; on their role in the society, in the private media, in family and in public; how they saw themselves; and how they behaved according to their principles, values, beliefs and social norms.

The study follows the 196/96 determinations and has no ethical repairs its approval.

**Results**

We interviewed 10 women with a mean age of 46 years (from 23 to 70 years) and a mean time of six years after a virus-positive diagnosis. However, even before the disease diagnosis, they already had neurological symptoms resulting from virus infection. One woman presented with congenital HTLV; another one had a yet-unconfirmed diagnosis, and the remaining eight patients had acquired the virus through sexual intercourse. Eight of them self-reported as black race, Catholic, with elementary education, and with an income of one minimum salary on average. They lived in 10 different cities in the Bahia State.

Regarding marital relations, five women said they currently had a good marital relationship and remained married; the other five were divorced after they were discovered to be contaminated by the virus, after the symptoms emerged, and after suffering physical, emotional, and psychological violence from their consorts.

**Sexuality comprehension**

During the nursing appointment, the interviewers asked what the interviewed women understood about sexuality and the answers were usually preceded by a moment of reflection and apparent difficulty in explaining something they either had no rule about or something they had no preconception about. In addition to modesty and shame, there was also a lack of knowledge on the issue. Some women reported a limited understanding of urinary incontinence as a binary relationship and necessarily linked to sexual intercourse and penetration. Only one interviewed woman, who had a higher level of education, described the concept of sexuality as something that involved not just sexual intercourse, but sensuality, pleasure without necessarily penetration, and not just done between a woman and a man, but also by people of the same sex or even
alone. She reported sexuality as the way someone dressed, felt, saw him/herself, and felt alive.

**Experiencing changes in sexual behavior after HTLV diagnosis**

There was low sexual interest. The lack of respect in the relationships associated with the consorts’ betrayal, with the transmission of HTLV viruses, with situations of domestic violence, and with the disappointment over their consorts, contributed to the discredit of the affective relationships and the male figure, discouraging women from investing in their existing relationships or in a new one. In addition to the emotional and psychological disturbances, there were also physical and anatomical changes of the vagina and vaginal canal due to neuropathy caused by the virus and, in some women, caused also by menopause.

Another condition that contributed to decreasing sexual interest was the fear of virus transmission to the uninfected partner. There was the women’s sense of altruism and respect in the face of their consort, a kind of feeling these women have not experienced with a partner that betrayed them.

**Experiencing conflicts and violence**

It was observed that men exerted power, hierarchy, and domination over the woman, who remained passive to male desires and to their psychological, emotional, and physical violent acts, in that it was common to have sex without the women’s consent. The constant use of alcohol by some consorts also contributed to strengthen the aggressiveness of their violent acts and to keep women’s feeling fear. However, the women that had suffered from this were able to empower themselves and become free from these violent relationships, choosing to remain alone.

**Experiencing sexuality without pleasure**

Women who remained married and had a good marital relationship reported that most of the time they had sex without pleasure, as if it was a wife’s obligation just to satisfy her consort, and they rarely reached orgasm. They credited the lack of libido to the HTLV, the incontinence, and the pain they commonly felt in their bodies and during sexual penetration.

**Experiencing urinary losses in sexuality**

The urine loss, the moisture in the clothes, the unpleasant odor and the constant need to use absorbent denounced the inability of these women to control themselves, especially in such private and personal moment as courtship, the moment of caresses, the touch time, and the penetration. The bladder catheterization relief procedure has also been reported as something that discouraged their sexuality, but at other times, it was a support to maintain continence. Women’s positions for sexual intercourse were also expressed as a limiting factor, because they were afraid of losing urine depending on the effort they made, and the act of penetration sometimes contributed to a full bladder feeling and the urgency to urinate.

Due to incontinence, some women had low self-esteem, had lost their confidence in themselves, and therefore refused sexual relations. In addition, they showed an inability to establish a marital relationship.

**Discussion**

Understanding, through in-depth interview, the sexuality experiences of HTLV-positive women with urinary incontinence was satisfactory to learn about the reflections on the issue. There is a limitation on the number of women interviewed, but there was a convergence regarding the talks, with a great deal of information on the study’s purposes and the construction of a matrix of analysis from the narrated stories with well-structured meaning cores.

It is known that the dialogue about sexuality may be embarrassing, and decency prevents free thought without prejudice. In addition, the lack of knowledge on the issue also contributes to reductionist definitions, because sexuality is pleasure in doing anything, such as to be at the side of someone, talking, touching, living.
Vaginal changes such as atrophy, lack of lubrication, and dyspareunia arising from HTLV and from changes in hormone levels contribute to decrease the frequency and even suspend sexual relations, mainly when restricted to penetration, limiting the possibilities of female pleasure.

The psycho-emotional changes such as feelings, interpersonal relationships, and self-esteem greatly influence sexuality. All of these things are interconnected, and it becomes worse when the woman has a disease, in terms of domestic violence and low self-esteem.

In sexually transmitted diseases with little information, such as HTLV, the fear of viral transmission is real. The lack of discussion on the issue is an aggravating factor that moves the consort away and frightens people who have the virus with the fear of transmitting it, restraining new affective relationships. Additionally, after suffering violence, abandonment, and discrimination, loneliness becomes a woman’s haven. Once she realizes all she has suffered, being alone may be her best option.

Regarding this psychological aspect, the lack of libido and sexual denial could be managed in order to seek other alternatives for pleasure and personal satisfaction, reducing women’s complaints and denials. Sensuality, the vanity, the care of her own body, the woman’s relationship with her illness, the search for appreciation for herself and her body appearance, empowerment in the face of the consort and the construction of a balanced gender relation are socio-cultural elements for the performance of sexuality.

Regarding gender analysis, sexuality, seen as a biological and instinctive impulse, is found mainly in men’s talk, justifying the domination and sex impulse. The idea that male sexual desire is uncontrollable, and that men have a “biological” need to having sex, makes women suffer even more at the time to perform “their role as wives,” even if they are sick and with no desire.

This concept contributes greatly to women’s passiveness in the face of male desires. In this way, gender identity reflects the active and virile behavior of men, and the passive behavior of women who do not have the feeling belonging to their own bodies, and consequently they are violated in favor of their partner’s wishes.

The male power, represented by physical and psychological strength and sexual desires, imposes an unequal emotional relationship in which gender issues are not worked through in order to balance the mutual interests between men and women. Conversely, there is an oppressor just because there is an oppressed one. Then it is essential for women to empower themselves in their relationships and decide what is best for them.

Given this social and emotional context, there is also an impact of the incontinence in these women’s lives. The smell, the fear of getting wet in public, the need for catheterization, and the lack of control over their own bodies leads them to feelings of weakness, low self-esteem, social isolation, sexual repression, and a shortened sexual life. Thus, it is believed that if health professionals, once meeting these women with the virus, have a more cautious view of incontinence symptoms and implement management techniques, these would not be experiencing incontinence associated with odor and shame.

Implementing strategies to prevent incontinence, such as behavioral therapy, the use of products for urine restraint instead of using cloths, doing exercises for pelvic strengthening, knowing urination habits and, in some cases, using electrical stimulation and doing biofeedback with a specialized nurse, may considerably change the way women live and get along with their own sexuality.

### Conclusion

Women who have the HTLV virus and urinary incontinence develop several social-affective and emotional conflicts, which hamper the performance of sexuality, resulting in losses to their satisfaction. However, when they empower and place themselves in the face of difficulties, these women can have a freer and happier life.
Acknowledgements
To the Coordination for the Improvement of Higher Education Personnel (CAPES) for the scholarship granted to Rayssa Fagundes Batista Paranhos.

Collaborations
Paranhos RFB, Paiva MS and Carvalho ESS state that they contributed to the study design, analysis and data interpretation, manuscript writing, relevant critical review of the intellectual content, and approval of the final version of this manuscript.

References
Comparison between the accredited and non-accredited public hospital working environments

Comparação entre ambiente de trabalho de hospitais públicos acreditado e não acreditado

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Cleide Carolina da Silva Demoro Mondini³

Objective: To compare and identify the working environment of accredited and non-accredited public hospitals.

Methods: A quantitative approach with two cross-sectional studies in parallel, with 106 nurses from the hospitals, conducted between January and September of 2014. Hospital A was not accredited, and Hospital B was accredited. Data collection used a questionnaire with sociodemographic labor information and the Nursing Work Index - Revised - Brazilian version (B-NWI-R), with 57 items and four domains. The reliability of the instrument was measured using Cronbach’s alpha.

Results: The participants included 50 nurses of Hospital A and 56 of Hospital B. Hospitals were compared; there were statistically significant wage satisfaction (Hospital A showed greater salary satisfaction) and working hours (30-36 hours per week in Hospital B; 40 hours in Hospital A). The environment was favorable to the four domains of B-NWI-R in both hospitals, regardless of accreditation status.

Conclusion: The administration of the instrument showed that hospital accreditation did not affect the nurses’ work environment.

Keywords
Practice management; Working environment; Accreditation; Quality of health care; Job satisfaction

Descritores
Gerenciamento da prática profissional; Ambiente de trabalho; Acreditação; Qualidade da assistência à saúde; Satisfação no emprego

Submitted
August 18, 2015
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Keywords
Practice management; Working environment; Accreditation; Quality of health care; Job satisfaction

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Conflicts of interest: there are no conflicts of interest to declare.

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Conflicts of interest: there are no conflicts of interest to declare.
Introduction

Health organizations have sought to improve quality of care for patients, which imply the continuous improvement of their practices that are mainly related to people and their development in the work process.

The environment is closely related to job satisfaction of health professionals, among these, nurses and their team, and the quality of care.\(^{(1)}\)

In addition to influencing patient outcomes, the work environment also influences nursing outcomes due to work overload, poor working conditions, conflicting interpersonal relationships, lack of professional expectation, minimal professional autonomy, and ambiguity of functions that can compromise the work process as a whole.\(^{(2)}\)

The evaluation of the quality of the work environment is a key indicator to support the practice of nurses who, as team leaders, need to have knowledge of the pillars that organize their practice in order to ensure quality of care.\(^{(3)}\)

Therefore, an appropriate work environment is fundamental, not only for optimum results in terms of patient care, but also to provide an innovative climate for health staff, as a healthy work environment has a positive impact on the effectiveness of their own work.\(^{(4)}\)

One of the possibilities for identifying the work environments of health organizations is the use of instruments that can measure objective aspects present in those environments.

The use of scales contributes to innovation and creation of new models, functions and changes, which can be identified and which contribute to the work of nurses, through the exploration of new ideas.\(^{(4)}\)

For emphasizing the importance of this subject, studies were conducted with the prospect of identifying and analyzing the work environment of nurses and how this can affect the quality of care.\(^{(1,3-8)}\)

Among the instruments developed, the Nursing Work Index - Revised (NWI-R) has been used in different cultures and professional nursing practice environments.\(^{(7,8)}\) It is an instrument that consists of 57 items, whose “objective is to measure the presence of certain characteristics of the work environment that favor the professional nursing practice”\(^{(8)}\) The total number of items has four subscales: autonomy, control over the work environment, relationship between nurses and physicians, and support of organizations.\(^{(8)}\)

This instrument was adapted and validated for the Brazilian culture, and the final version of the instrument was titled Nursing Work Index - Revised. - Brazilian version (B-NWI-R)\(^{(7,8)}\) For the cultural adaptation of the instrument, some phases were followed: translation of the instrument to the Portuguese language, back translation of the instrument to the original language, evaluation of translated version by a group of experts, and pre-test.\(^{(9)}\)

The B-NWI-R consists of 57 original items and the same subscales that contribute to assessing the presence of certain features in the nursing work environment may interfere with the level of professional satisfaction, perceptions of quality of care, turnover staff and burnout levels.\(^{(8)}\) The challenge to optimize the safety and quality of care provided to patients in health institutions is present around the world. The quality of the nursing work environment interferes with the quality and safety of care provided.\(^{(10)}\)

Therefore, the environment in which the working processes are developed is a fundamental aspect of quality, because this may be related to the context of evidence-based practice (EBP), due to its stressors, whether physical or psychological.\(^{(11)}\)

Quality certification processes have contributed to health organizations’ aiming toward excellence, having as principles scientifically grounded standards and the achievement of involving the organization as a whole.

The National Accreditation Organization (Organização Nacional de Acreditação - ONA) is a nonprofit, non-governmental entity, responsible for coordinating the entire system of accreditation, certifying the existing health organizations in the
The standards are based on the principles of quality, involving structure, process and outcome. The result of accreditation is reflected in the concepts: non-accredited, accredited (level 1), fully accredited (level 2), and accredited with excellence (level 3).

Scientific production has increased significantly, making methodological approaches necessary that include the synthesis of the best scientific evidence to enable incorporation into health care practice, supporting the diagnostic, therapeutic and management decisions.

Considering the importance of this subject, the lack of studies in Brazil using scales to measure the work environment, and the recognition that the use of instruments contributes to decision-making grounded in evidence justifies this research, which has as its questions: a) how do nurses assess their working environment according to the subscales: autonomy, control over the work environment, relationship between nurses and physicians, and organizational support? b) what is the correlation between two public institutions, one accredited and another nonaccredited, with regard to the work environment?

Thus, the aim of this study was to identify and compare the nursing environment of public hospital A (nonaccredited) and B (accredited), by means of the B-NWI-R.

Methods

A quantitative approach was adopted to make the comparison between hospitals, regarding the characteristics of the work environment that favor professional nursing practice. The experiment consisted of two cross-sectional studies.

The survey was conducted in two public hospitals in the area of the Regional Health Department - VI (DRS-VI), which were named hospital A and B. Hospital A serves patients exclusively originating of the Unified Health System (SUS), and is a tertiary hospital, with an estimated population of 1.8 million people; it currently has 529 active beds. Hospital B is a public institution linked to the SUS, which has a level 1 accreditation certificate from ONA. It has 318 operating beds, and 63 additional beds.

The target population constituted of clinical nurses working in adult inpatient units of Hospitals A and B, working between January of 2014 to September of 2014. There was no sampling, because all the nurses (n = 185) who were working in the adult units met the inclusion criteria and were invited to participate. Of these, 106 (57.3%) agreed to participate (50 of Hospital A and 56 of Hospital B).

The B-NWI-R instrument uses a Likert scale, whose score ranges from one to four points. The participant was asked to answer whether they agreed or disagreed with the statement, “this factor is present in my daily work” with the options: totally agree (one point); partially agree (two points); partially disagree (three points), and totally disagree (four points), thus, the lower the score, the greater the presence of favorable attributes. Values below 2.5 represent favorable environments for professional practice, and above 2.5 points, unfavorable environments.

Each score was calculated by averaging the responses given for the items.

The independent variable was Hospital A (non-accredited) or B (accredited). The potential confounders listed were: nurse’s academic level; weekly work hours (30, 36, 40); double or triple duty (no/yes); shift (day/night); work in long-term patient unit (no/yes); promotion in the last 12 months (no/yes); negative evaluation on the last administrative review (no/yes); satisfaction with remuneration (no/yes).

The dependent variable had the score of the four sub-scales related to B- NWI-R: - Score of the subscale “Autonomy” (range 1-4). This sub-scale was captured by five items of the B-NWI-R instrument: (items 4, 6, 17, 24 and 35) and measured how much autonomy favored nurses’ activities. Score of the subscale “Control over the environment.” This sub-scale was captured by seven items of the B-NWI-R instrument: (items 1, 11, 12, 13, 16, 46 and 48) and measured how the control of the environment favored the nurses’
activities. Score of the subscale “Relations between physicians and nurses.” This subscale was captured by three items of the B-NWI-R instrument: (items 2, 27 and 39) and measured how the relationship between physicians and nurses was favorable to the nurses’ activities. Score of the subscale “Organizational Support”. This subscale was captured by ten items of the B-NWI-R instrument: (items 1, 2, 6, 11, 12, 13, 17, 24, 27 and 48) and measured how organizational support favored nursing activities.

The scores of the B-NWI-R subscales were measured by direct administration of the questionnaire to nurses from each of the units of Hospitals A and B.

The variables with the potential confounding effect were provided by nurses when they answered the questionnaire.

Statistics were used to analyze the data in two stages. Phase 1 addressed the identification of potential confounders, using the nonparametric chi-square and Fisher’s exact test. In Phase 2, the environment was compared to B-NWI-R scores using the non-parametric Mann-Whitney test.

The relationships were considered significant if p <0.005. Analyses were performed using the Statistical Package for the Social Sciences software (SPSS), version 15.0 and R.v2.11.0.

The Cronbach’s alpha coefficient was performed, as a statistical tool to evaluate the questionnaire’s reliability through internal consistency.

There was no systematic error selection, because it was population-based research, namely, the nurses who worked in Hospitals A and B.

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 23304713.4.0000.5411.

Results

The research sample included 106 nurses from the two hospitals studied, with 50 from Hospital A; 41 (82%) were women, and nine (18%) men, with the predominant age group being between 20 to 35 years. Hospital B had 56 subjects, and of these, 52 (93%) were female and four (7%) male, showing the same age group as Hospital A.

The majority of the participating nurses from hospital A were white, 44 (88%), married 13 (26%), and had children, 12 (24%). From Hospital B, 40 (71%) were white, 26 (46%) were married, and 28 (50%) had children.

Regarding the academic level in Hospital A, only one (2%) nurse had a doctoral degree; three (5%) from Hospital B had doctorates. With regards to the long-term patient unit, 45 (80%) of the Hospital B were working in those units, and from Hospital A, there were 34 (68%). Of the 50 nurses of Hospital A, 20 (40%) worked at night and 12 (24%) had other formal employment; while in Hospital B, 14 (25%) practiced at night, and 16 (28%) nurses had another job.

Regarding the evaluation of professional performance, in Hospital A, 2% of study participants were evaluated negatively, and two (4%) had a promotion in the previous three months. In Hospital B, ten (18%) received a promotion and three (5%) had a negative evaluation.

There was statistical significance in relation to the salary satisfaction and work hours. The nurses of Hospital A showed greater satisfaction with their salary (44%) when compared with Hospital B (14%), and the scheduled work of 30-36 hours per week was predominant in Hospital B (80%), while in the other institution, the schedule was equivalent to 40 hours or more per week.

Table 1 compares the two institutions in regard to demographic characteristics and labor.

Table 1 shows the relationship between environment and sociodemographic variables and some work variables; such variables were not considered to be confounding, because they were not related to the B-NWI-R score in any subscale.

Therefore, the comparison between the work locations relative to the B-NWI-R score was performed without the need for correction for any confounding effect (Table 2).
Table 1. Comparison of environment in relation to sociodemographic and work-related variables (n = 106)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Place of work</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A (n=50)</td>
<td>B (n=56)</td>
</tr>
<tr>
<td>Male sex</td>
<td>n(%)</td>
<td>n(%)</td>
</tr>
<tr>
<td>Age</td>
<td>9(18)</td>
<td>4(7)</td>
</tr>
<tr>
<td>20-35 year old</td>
<td>45(90)</td>
<td>38(68)</td>
</tr>
<tr>
<td>36-50 years old</td>
<td>5(10)</td>
<td>18(32)</td>
</tr>
<tr>
<td>White ethnicity</td>
<td>44(88)</td>
<td>40(71)</td>
</tr>
<tr>
<td>Married</td>
<td>13(26)</td>
<td>26(46)</td>
</tr>
<tr>
<td>Had children</td>
<td>12(24)</td>
<td>28(50)</td>
</tr>
<tr>
<td>Doctoral degree</td>
<td>1(2)</td>
<td>3(5)</td>
</tr>
<tr>
<td>Working in a long-term patient unit</td>
<td>34(68)</td>
<td>45(80)</td>
</tr>
<tr>
<td>Promoted in the last three months</td>
<td>2(4)</td>
<td>10(18)</td>
</tr>
<tr>
<td>Negative evaluation</td>
<td>1(2)</td>
<td>3(5)</td>
</tr>
<tr>
<td>Satisfied with salary</td>
<td>22(44)</td>
<td>8(14)</td>
</tr>
<tr>
<td>Work schedule</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-36 hours/week</td>
<td>25(50)</td>
<td>45(80)</td>
</tr>
<tr>
<td>&gt;40 hours/week</td>
<td>25(50)</td>
<td>11(20)</td>
</tr>
<tr>
<td>Working night shift</td>
<td>20(40)</td>
<td>14(25)</td>
</tr>
<tr>
<td>Another job</td>
<td>12(24)</td>
<td>16(28)</td>
</tr>
<tr>
<td>Scheduled work shift hours (?)</td>
<td>1(2)</td>
<td>6(11)</td>
</tr>
</tbody>
</table>

p < 0.005; * Fisher exact test; ** chi-square

Table 2. Comparison between environment and the B-NWIR subscales (n = 106)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Place of work</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A (n=50)</td>
<td>B (n=56)</td>
</tr>
<tr>
<td>Autonomy</td>
<td>2.0(1.0-4.0)</td>
<td>2.0(1.0-4.0)</td>
</tr>
<tr>
<td>Control over the environment</td>
<td>2.0(1.0-3.7)</td>
<td>2.2(1.1-3.7)</td>
</tr>
<tr>
<td>Relationships between physicians and nurses</td>
<td>2.0(1.0-4.0)</td>
<td>2.3(1.0-4.0)</td>
</tr>
<tr>
<td>Organizational support</td>
<td>2.2(1.0-3.9)</td>
<td>2.2(1.1-3.8)</td>
</tr>
<tr>
<td>General</td>
<td>2.3(1.1-3.7)</td>
<td>2.3(1.1-3.3)</td>
</tr>
</tbody>
</table>

p < 0.005; Mann-Whitney

Table 3. Reliability of the B-NWI-R

<table>
<thead>
<tr>
<th>B-NWI-R Subscale</th>
<th>Cronbach’s Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autonomy</td>
<td>0.71</td>
</tr>
<tr>
<td>Control over the environment</td>
<td>0.71</td>
</tr>
<tr>
<td>Relationships between physicians and nurses</td>
<td>0.73</td>
</tr>
<tr>
<td>Organizational support</td>
<td>0.82</td>
</tr>
<tr>
<td>General</td>
<td>0.95</td>
</tr>
</tbody>
</table>

The reliability of the scale was analyzed using Cronbach’s coefficient that was calculated for each subscale and the total instrument items. Table 3 shows the results.

Discussion

This study had as a limitation the lack of participation of all nurses, of both Hospital A and B, that were working during the study period and also the lack of involvement of other accredited and non-accredited public hospitals, for better coverage and comparability.

The contribution of the study was to understand, from the perspective of clinical nurses, the public hospital work environment and the differences and similarities of that environment between accredited and nonaccredited hospitals. The administration of this instrument in the nursing work context supports managers in improving that environment.

In the current study, the sample characteristics of the nurses was similar to that in other studies conducted, and the profile of the workers were predominantly young, female adults, which is justified by the historical character of the profession. (7,17,18)

The competitiveness of the market and the need to seek technological innovations in care practice through direct care or quality managers, educators, researchers, have been shown to trigger stress in the nurse. (19)

A statistical significance was observed between the ratio of nurses at the two hospitals in relation to their satisfaction with their salary, in which the nurses from Hospital A proved more satisfied when compared to those who work in Hospital B. In addition to the high competition, lack of contentment with the salary level can lead to stress, which when added to other factors leads to burnout syndrome. In this view, this syndrome comes from chronic occupational stress, absorbing negative consequences related to the individual, profession, family, society and institution, which leads the employee to lose the ability to reorganize and find fulfillment in existing demands. (20-22) This situation is also explained considering the features of nursing work, such as extended shifts, multiples jobs, in addition to domestic work that is characteristic with women, leading to a double or even a triple workday. (23)

Work overload, an extensive schedule, limited technical skills, conflict management, lack of social support at work, and failures in problem-solving can lead the professional to exhibit mood disorders. (24) In another study, depression was associated with...
burnout syndrome, including emotional exhaustion, which can lead to depersonalization and result in job dissatisfaction.\(^{(25)}\)

Most participants reported not having other employment, a finding also obtained in other studies conducted in the country.\(^{(7,8)}\)

With regard to the reliability of the scale, the Cronbach’s alpha coefficient was satisfactory and similar to the study that validated this scale for use in Brazil.\(^{(17)}\) A study that administered this scale to nurses working in intensive care units (ICU) demonstrated that the scale measures what it proposes to measure.\(^{(3)}\)

The application of B-NWI-R in this study revealed that the sample of nurses from Hospital A and B had autonomy and control over their environment, respect between physicians and nurses and favorable organizational support, as values presented below 2.5, regardless of where they worked.\(^{(7)}\) This finding was similar to the study, cited earlier, conducted in the ICU of public and private hospitals in Brazil, since there was no significant difference related to the four sub-items of B-NWI-R mentioned.\(^{(3)}\)

The hospital accreditation process did not interfere by providing a more favorable working environment in the accredited hospital. This finding leads to the conclusion that other factors are involved in the work environment.

The work environment consists of physical and social spaces. Regarding the social environment, interpersonal relationships supported by self-knowledge and knowledge of others may be strategies that favor the quality of work life, humanizing the process.\(^{(26)}\)

The organizational context is critically important to the impact of nursing actions and the use of this instrument can capture the environment, thus contributing to the nursing management process.\(^{(27)}\)

**Conclusion**

This research allowed for the analysis of the nursing work environment of two public hospitals, showing, through the use of the B-NWI-R instrument, that the environments were favorable in the dimensions of autonomy, control over the environment, respect between physician and nurses, and organizational support. There was no significant difference in relation to the work environment in the dimensions mentioned above between the accredited and non-accredited hospital. The differences were presented in relation to work hours and satisfaction with salary, as in the nonaccredited organization nurses had fewer work hours and were more satisfied with their salary.

**Collaborations**

Oliveira PB and Spiri WC declare that they contributed to the study design, relevant critical review of the intellectual content, analysis, data interpretation, article writing, and final approval of the version to be published. Dell’Acqua MCQ and Mondini CCSD collaborated with the relevant critical review of the intellectual content, and final approval of the version of the article to be published.

**References**

Refractory schizophrenia: quality of life and associated factors

Esquizofrenia refratária: qualidade de vida e fatores associados

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Fernanda Daniela Dornelas Nunes¹
Andreia Roberta Silva e Souza¹
Richardson Miranda Machado¹

Abstract

Objective: To analyze the quality of life of people with refractory schizophrenia using clozapine, and its associated factors.

Methods: A cross-sectional study, conducted in the extended western region of Minas Gerais, which included patients with refractory schizophrenia using the antipsychotic, clozapine. For the measurement of quality of life, the Quality of Life Scale was used, specific for patients with schizophrenia. Univariate and multivariate analyses were performed.

Results: A total of 72 patients with a mean age of 42.9 years was part of the study. The overall score of the Quality of Life Scale indicated compromised quality of life, with a greater impairment in the social network domain (median = 2.36). The logistic regression analysis showed factors associated with a better quality of life.

Conclusion: Low quality of life in patients with refractory schizophrenia was found. Physical activity, family income over three times the minimum wage, and having children were associated with a better quality of life.

Keywords
Schizophrenia/drug therapy; Quality of life; Clozapine/therapeutic use; Metabolic syndrome X

Descritores
Esquizofrenia/quimioterapia; Qualidade de vida; Clozapina/uso terapêutico; Síndrome X Metabólica

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February 1, 2016
Introduction

Quality of life is related to subjective well-being and includes biological and psychological components, such as emotional well-being, awareness of one's own abilities and disabilities, possibility of adequate sleep and rest, vitality, and overall satisfaction with one's life.(1) It is a comprehensive and multifaceted concept, which also includes the complex relationship of the individual with society and his environment. In conditions of chronic diseases, including schizophrenia, the question of quality of life is more evident and complex, and is influenced by the length and severity of the disorder, the side effects of medications, as well as stressful events that interfere with the evolution of the problem. In addition, people who have schizophrenia are culturally stigmatized, which further compromises their social functioning.(2)

The importance of evaluating the quality of life in people with schizophrenia became more prominent in the last decade, as the recovery of patients also includes their reintegration in the family, workplace and social life.(3) In addition, efforts should not only be restricted to the transition to the community, but should also provide support for the maintenance of life.(4) Therefore, understanding the quality of life in schizophrenic individuals should refer to the full human experience: biological, psychosocial and environmental.

Paradoxically, the group of patients who have the most severe form of schizophrenia, known as refractory or resistant, is an uncommon focus of studies on quality of life and associated factors. Although there is not a single and globally accepted consensus, refractory schizophrenia can be characterized if there is no improvement in the main symptoms of the disease after treatment with two different classes of antipsychotics (at least one atypical), in suitable doses for a given period of time (four to six, or six to eight weeks).(5) Approximately 30% of the patients had the resistant form, and the treatment of choice is the use of the atypical antipsychotic, clozapine.(6)

Clozapine is considered a gold standard in the treatment of patients with refractory schizophrenia, and demonstrates a reduction in acute symptoms and the risk of suicide.(6) However, its use is not free of side effects, especially metabolic: weight gain, increased central adiposity, dyslipidemia, glucose intolerance, insulin resistance and high blood pressure, which characterize the metabolic syndrome. (7) Although these are the main and most common symptoms, there are also others associated with the use of clozapine, but without relevance to the metabolic syndrome.

Identifying factors that influence the quality of life in schizophrenia is therefore of fundamental importance, because it can help to define services and propose interventions to improve the life of these people.(8) In addition, antipsychotic medications, although representing a breakthrough in the treatment of this disorder, when they mitigate the negative symptoms, can trigger side effects or adverse reactions, which often influence the individual’s functional capacity.(9) Thus, measuring the quality of life as a criterion of the treatment effect is especially important for patients who have refractory schizophrenia, considering that this disorder can cause an overall interference in many aspects of life.(3)

The analysis of the quality of life of people with refractory schizophrenia taking clozapine, with regard to the identification of associated factors, is scarce in the literature, especially in studies conducted in Brazil. Also, identifying and correlating clinical factors, such as the presence of metabolic syndrome, is of fundamental importance because this disorder is considered to be one of the main risk factors for cardiovascular disease in people with schizophrenia, and may be associated with a worsening quality of life.(10)

Thus, this study is expected to fill part of this gap in the Brazilian literature on the subject, and provide information for the improvement of the practices of health professionals, particularly those from mental health and primary care.

Thus, the aim of this study was to analyze the quality of life of people with refractory schizophrenia taking clozapine, and its associated factors.

Methods

This was a cross-sectional analytical study, conducted at the extended western region of Minas Gerais,
with patients with refractory schizophrenia using the antipsychotic, clozapine. The inclusion criteria were: medical diagnosis of refractory schizophrenia; use of the atypical antipsychotic, clozapine; older than 18 years of age; both sexes; and capacity for understanding the questions. The exclusion criteria of the study were: pregnant women; participants who were not fasting; and those with any condition that might interfere with the data collection and measurement, for example, presence of any disability that would compromise the assessment of anthropometric characteristics. The need for fasting was related to the need for laboratory tests to identify the presence of metabolic syndrome.

The sample size calculation was performed using the OpenEpi program, version 3.03a, considering a population of 169 individuals for an expected event ratio of 50%, a significance level of 5%, and a 10% margin of error, estimating a sample of approximately 62 individuals. The final sample consisted of 72 participants.

The data collection period occurred during the months of December of 2014 to June of 2015. The patients with refractory schizophrenia in the extended western region of Minas Gerais were previously invited through letters and telephone contact, at which time they received all necessary information on the research. Data were collected at the Psychosocial Care Center Type III in the extended western region of Minas Gerais, according to the date and time indicated.

The instrument used to measure and evaluate the quality of life of the participants was the Quality of Life Scale. It is considered one of the main specific instruments for measuring the quality of life in schizophrenic patients. This scale was properly adapted and validated for use in the Brazilian context, receiving the QLS-BR acronym. Its dimensional structure has a total of 21 items, divided into three areas (social, occupational, and intrapsychic and interpersonal relationships), which include subjective and objective information relating to the functioning and symptoms of the patient in the three weeks preceding the interview. Scores of five and six reflect an unchanged quality of life; scores of two to four show a moderate involvement; and scores of zero and one indicate a very impaired quality of life. It is also important to note that the blunted affect on quality of life was not assessed in this study, considering that this is the first study that specifically evaluated patients with refractory schizophrenia taking clozapine, as well as to avoid overlapping of the items of the Quality of Life Scale with other instruments that measure negative symptoms.

The categorization of the quality of life variable was based on the rating obtained by the scores, using the median value, and was divided into: unchanged, compromised, and very compromised quality of life. However, because of the almost insufficient amount of participants who presented with an unchanged quality of life, it was decided, for statistical reasons, to group the unchanged and compromised quality of life categories, which indicated better quality of life. The very compromised quality of life category was maintained.

For the collection of sociodemographic and clinical data, a semi-structured, pre-coded, and standardized questionnaire developed by the authors was used. For measuring the high-density lipoprotein cholesterol (HDL-C), triglyceride levels and glucose, which are criteria for metabolic syndrome classification, venous blood samples from the ulnar vein of the forearm were taken after 12 hours of fasting. The analysis was performed in the biochemical laboratory of the Federal University of Sao Joao del Rei / Midwest Campus Dona Lindu.

Metabolic syndrome was defined using the criteria of the National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP-III) when three or more of the following risk factors are present: abdominal obesity (waist circumference >102 cm in men or > 88 cm in women); high blood pressure (> 130/85 mmHg) or on antihypertensive treatment; hyperglycemia (fasting blood sugar >100 mg/dL) or on hypoglycemic treatment; high concentration of triglycerides (> 150 mg/dL) or on medication to reduce this; low HDL-C (<40 mg/dL in men and <50 mg/dL in women), or on medication to treat low HDL-C. The processing and data analysis were performed using the Statistical Package for the Social Scienc-
es, version 20.0. To describe the results, tables for frequency distribution were used in the analysis of categorical variables and measures of central tendency, position and variability in the analysis of numerical variables. The chi square tests and Fisher’s exact test were used in the analysis of categorical variables, and Mann-Whitney test, the analysis of numerical variables with asymmetric distribution, was used to evaluate the factors associated with the results of the QLS-BR scale in univariate analysis. For multivariate analysis, the binary logistic regression model was used. For input of the variables in the model, a p-value <0.20 in the univariate analysis was considered. The forward criterion was used and the 5% level of significance was adopted. The odds ratio (OR) was evaluated, adjusted with a respective 95% confidence interval (95%). The calibration of the model was assessed using the Hosmer-Lemeshow statistic.

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 19436213.6.0000.5545.

Results

A total of 72 patients with refractory schizophrenia taking clozapine were evaluated, unintentionally found in both sexes in the same proportion (50%). The mean age was 42.9 years, and most were single (72.2%).

The overall score of the QLS-BR scale showed compromised quality of life. Regarding the distribution of scores on the scale, a greater commitment in the social network domain was found. The item affective-sex factor intrapsychic functions and interpersonal relationships presented a median <2, indicating severe impairment. There was no rating compatible with unchanged quality of life in any of the investigated items (Table 1).

Table 2 shows the relationship between the sociodemographic and clinical variables with the results of the global scale of the QLS-BR. Having children, family income above three times the minimum wage, and physical activities were associated with a better quality of life (p <0.05).

Table 1. Descriptive analysis of the results of the Brazilian version of the Quality of Life Scale (QLS-BR). Items, factors and global scale (n = 72)

<table>
<thead>
<tr>
<th>Item</th>
<th>Factors</th>
<th>Mean±SD</th>
<th>Median*</th>
<th>Interquartile range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interpersonal Relationships</td>
<td>Household</td>
<td>2.5±1.2</td>
<td>2.36</td>
<td>1.71</td>
</tr>
<tr>
<td>2</td>
<td>Friends</td>
<td>4.00</td>
<td>2.00</td>
<td>5.00</td>
</tr>
<tr>
<td>3</td>
<td>Acquaintances</td>
<td>2.00</td>
<td>1.00</td>
<td>4.00</td>
</tr>
<tr>
<td>4</td>
<td>Social activity</td>
<td>2.00</td>
<td>1.00</td>
<td>2.00</td>
</tr>
<tr>
<td>5</td>
<td>Social network</td>
<td>2.00</td>
<td>2.00</td>
<td>4.00</td>
</tr>
<tr>
<td>6</td>
<td>Social initiative</td>
<td>2.00</td>
<td>1.00</td>
<td>3.00</td>
</tr>
<tr>
<td>7</td>
<td>Withdrawal</td>
<td>2.00</td>
<td>2.00</td>
<td>4.00</td>
</tr>
<tr>
<td>Instrumental Role</td>
<td>Occupational role</td>
<td>3.1±1.4</td>
<td>3.00</td>
<td>2.20</td>
</tr>
<tr>
<td>10</td>
<td>Work functioning</td>
<td>2.00</td>
<td>1.00</td>
<td>2.75</td>
</tr>
<tr>
<td>11</td>
<td>Work level</td>
<td>2.00</td>
<td>0.00</td>
<td>2.75</td>
</tr>
<tr>
<td>12</td>
<td>Work satisfaction</td>
<td>4.00</td>
<td>4.00</td>
<td>9.00</td>
</tr>
<tr>
<td>17</td>
<td>Time use (aimless activity)</td>
<td>2.00</td>
<td>2.00</td>
<td>4.00</td>
</tr>
<tr>
<td>Intrapsychic Foundations and Interpersonal Relationships</td>
<td>Socio-sexual relationship</td>
<td>2.8±1.3</td>
<td>2.86</td>
<td>1.89</td>
</tr>
<tr>
<td>8</td>
<td>Sense of purpose</td>
<td>1.00</td>
<td>1.00</td>
<td>2.00</td>
</tr>
<tr>
<td>13</td>
<td>Curiosity</td>
<td>2.00</td>
<td>1.00</td>
<td>4.00</td>
</tr>
<tr>
<td>15</td>
<td>Objects</td>
<td>4.00</td>
<td>3.00</td>
<td>6.00</td>
</tr>
<tr>
<td>19</td>
<td>Activities</td>
<td>4.00</td>
<td>2.00</td>
<td>4.00</td>
</tr>
<tr>
<td>20</td>
<td>Empathy</td>
<td>2.50</td>
<td>2.00</td>
<td>4.00</td>
</tr>
<tr>
<td>21</td>
<td>Emotional interaction</td>
<td>4.00</td>
<td>2.00</td>
<td>6.00</td>
</tr>
<tr>
<td>Common Objects &amp; Activities</td>
<td>Motivation</td>
<td>2.8±1.2</td>
<td>2.55</td>
<td>2.02</td>
</tr>
<tr>
<td>14</td>
<td>Anhedonia</td>
<td>2.00</td>
<td>2.00</td>
<td>4.00</td>
</tr>
</tbody>
</table>

* Scores zero to 1.99 indicated very compromised quality of life; Scores 2 to 4.99 indicated compromised quality of life; Scores 5-6 indicate unchanged quality of life; SD - Standard Deviation
In contrast, other sociodemographic variables such as gender, age, marital status and employment status did not show significant association. In relation to clinical variables, none was associated with quality of life, nor with the presence of metabolic syndrome.

The results of the multivariate analysis of factors associated with a better quality of life are arranged in table 3. The family income (OR: 15.98), the practice of physical activity (OR: 25.24), and having children (OR: 24.92) have been associated (p <0.05) with a compromised or unchanged quality of life, or a better quality of life. The variable related to the frequency of psychiatric medical care was not included in the final model.

Table 2. Comparison of sociodemographic and clinical variables with the results of the Brazilian version of the Quality of Life Scale (QLS-BR) (n = 72)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Global Scale QLS-BR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>QL VC (n=15)</td>
<td>QL C/U (n=57)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
<td>28</td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
<td>29</td>
</tr>
<tr>
<td>Age</td>
<td>Mean ± standard deviation</td>
<td>43.9±16.0</td>
</tr>
<tr>
<td>Median (Minimal – Maximal)</td>
<td>44 (30-52)</td>
<td>43 (22-59)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>14</td>
<td>42</td>
</tr>
<tr>
<td>With partner</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>Educational level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary</td>
<td>10</td>
<td>30</td>
</tr>
<tr>
<td>High school or above</td>
<td>4</td>
<td>26</td>
</tr>
<tr>
<td>Children</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>13</td>
<td>36</td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
<td>21</td>
</tr>
<tr>
<td>Are you currently working?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>No</td>
<td>15</td>
<td>50</td>
</tr>
<tr>
<td>Do you get retirement benefits?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10</td>
<td>35</td>
</tr>
<tr>
<td>No</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>What is your current household income?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 2 times the MW</td>
<td>13</td>
<td>26</td>
</tr>
<tr>
<td>3 times the MW or more</td>
<td>1</td>
<td>26</td>
</tr>
<tr>
<td>Where do you receive psychiatric treatment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public network</td>
<td>13</td>
<td>38</td>
</tr>
<tr>
<td>Private network</td>
<td>2</td>
<td>19</td>
</tr>
<tr>
<td>How long have you been receiving psychiatric treatment?*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 10 years</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td>More than 10 years</td>
<td>10</td>
<td>35</td>
</tr>
<tr>
<td>How often do you go to the psychiatrist for consultation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At least once every six months</td>
<td>3</td>
<td>32</td>
</tr>
<tr>
<td>Semiannually or annually</td>
<td>10</td>
<td>22</td>
</tr>
<tr>
<td>Have you ever been hospitalized in a psychiatric hospital?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12</td>
<td>44</td>
</tr>
<tr>
<td>No</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>How long have you used clozapine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 5 years</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>More than 5 years</td>
<td>7</td>
<td>38</td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>12</td>
<td>46</td>
</tr>
<tr>
<td>Yes</td>
<td>3</td>
<td>11</td>
</tr>
</tbody>
</table>

*to be continued
Variables | Global Scale QLS-BR | p-value
---|---|---
QL VC (n=15) | QL C/U (n=57) | |

### Diabetes
- No: 15, 46 | 0.105***
- Yes: 0, 11

### How many medicines do you take per day?
- Up to 3 medications: 2, 18 | 0.704***
- 4 or more: 7, 32

### Do you think the medication that you take affects you?
- No: 10, 37 | 0.313***
- Yes: 2, 20

### Do you smoke?
- No: 12, 42 | 0.746***
- Yes: 3, 15

### Do you currently consume alcohol?
- No: 0, 2 | 0.999***
- Yes: 15, 54

### Do you practice any physical activity?
- No: 11, 32 | 0.044***
- Yes: 1, 24

### Metabolic syndrome
- No: 9, 29 |
- Yes: 6, 28

*p-value Hosmer-Lemeshow test = 0.999; IC95% - Confidence interval - 95%; OR - Odds Ratio; MW - minimal wage

### Table 3. Multivariate analysis (binary logistic regression) to evaluate the factors associated with a better quality of life (compromised or unchanged) according to the Brazilian version of the Quality of Life Scale (QLS-BR)

<table>
<thead>
<tr>
<th>Factors</th>
<th>p-value*</th>
<th>OR</th>
<th>CI95% for OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Household income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 2 times MW</td>
<td>-</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>3 times MW or higher</td>
<td>0.020</td>
<td>15.98</td>
<td>1.55</td>
</tr>
<tr>
<td>Physical activity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>-</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>Yes</td>
<td>0.006</td>
<td>25.24</td>
<td>2.48</td>
</tr>
<tr>
<td>Children</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>-</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>Yes</td>
<td>0.007</td>
<td>24.92</td>
<td>2.43</td>
</tr>
</tbody>
</table>

Discussion

The limitations of this study were related mainly to the cross-sectional design, which allows the establishment of a cause and effect relationship. For example, one cannot say that a better quality of life is a direct consequence of having children, or that it transcends it. Another important question referred to the need for caution when comparing the results of this study with others that have used different measurement instruments than the QLS-BR, considering that they are less close to the event. However, different perspectives to assess quality of life were used in this investigation, considering the lack of recent studies using this scale validated in Brazil. Thus, it is important to remember that generic measurement instruments are useful in comparing the population, while specific, such as the one used here, better evaluate the effects of schizophrenia treatment. It is also important to note that, in this investigation, it was not possible to specifically assess negative symptoms such as affective blunting, nor the possible side effects related to clozapine and other psychotropics used, except those related to metabolic syndrome.
The results of this research have important implications for patient care with refractory schizophrenia patients taking clozapine. The change in the health care model with the consequent institutionalization of patients points to the need for community care, especially in the context of primary health care. In this regard, the assessment of quality of life is an important indicator for the establishment of care plans and policies related, particularly, to the group of critically ill patients, who are the most disadvantaged and stigmatized. Moreover, the results indicate factors that may be involved in a better quality of life in this group, which can be an important tool for planning actions based on the real needs of these people, with a focus on psychosocial rehabilitation.

The measurement of quality of life in people with schizophrenia reinforces an alarming result, considering that a significant portion of these studies indicate an impaired quality of life, to a lesser or greater degree. This research shows that the assessment of quality of life showed compromise in all areas and items on the QLS-BR scale, which is corroborated by other studies. However, it is remarkable that only one item (affective-sexual relationships), of 21 evaluated, showed marked impairment (very compromised quality of life), taking into consideration that this research involved critically ill patients. Probably the fact that the patients were stable, receiving outpatient treatment during the research influenced this finding. People presenting a refractory form of schizophrenia usually has some substantial impair related to affection and sometimes even in cognition, which does not mean that they are unable to understand what it is good for them, taking decisions according to their relationship context.

Regular physical activity, current family income, and having children were associated with better quality of life in the multivariate analysis. These findings may be related to the fact that the social domain presented the greatest loss, which indicates impasses on issues involving interpersonal relationships and other social problems derived, possibly, from their own mental framework. Thus, it is essential to promote stimulation and social support for these patients, with the support of the entire health care network.

Physical activity showed a relationship with an improved quality of life (OR: 25.24). Regular exercise aimed at patients with schizophrenia can help to reduce body mass index, improve psychiatric symptoms, and lead to feelings of accomplishment and therefore provide an impact on quality of life. In this sense, managers and professionals who work with this population should support the need for planning and implementation of initiatives to promote and encourage this practice in the routine of health services, including seeking of intersectoral partnerships.

Income was another variable that was associated with quality of life. The results indicate that family income above three times the minimum wage is a favorable indicator to the outcome in question (OR: 15.98). It is possible to infer that a reasonable minimum financial condition can provide more adequate living conditions through access to basic services, health and leisure facilities, increasing the feeling of well-being. The literature suggests that the financial condition is related directly to the quality of life in patients with schizophrenia, including the refractory form. In view of this, it is important that these patients are referred to programs and strategies for income generation and psychosocial rehabilitation, a barrier that prevents access to a productive and independent life. It indicates their integration into workshops to generate employment and income or other social initiatives organized in a participatory manner. The customer needs to be attended along with his family, in an indispensable partnership with assistance from social services.

Having children was also an indicator that can influence the quality of life. Note that this variable is poorly documented in the literature. A study in Rio de Janeiro had the opposite result, since children were associated with lower quality of life. In another study, this variable was not associated with quality of life. It is believed that patients considered the most serious,
who had children, have stronger network support, and are more stimulated and receive more care, including follow-up treatment.

Other demographic factors such as age, sex, marital status and occupation, were not associated with quality of life in this study. Regarding sex, despite being controversial, women generally showed a higher level of quality of life.\(^{(7,25)}\) Concerning the marital status, some studies indicate that being single is associated with worse quality of life, while married people show more satisfactory results.\(^{(23,24)}\) However, occupational activity, which is important for the autonomy and development of interpersonal skills, appears to be associated with quality of life in some investigations.\(^{(14,16)}\)

Regarding metabolic syndrome, the possibility of its association with quality of life was tested, and the result denied such questioning. The issue that surrounds this condition in the patient who has schizophrenia, especially in refractory form, is considered worrisome, as these changes can dramatically increase the risk of cardiovascular disease and diabetes mellitus type II.\(^{(26)}\) A longitudinal study pointed to a high prevalence of metabolic syndrome in people who use clozapine.\(^{(6)}\) Important and recent studies that assessed the relationship between this syndrome and the quality of life also did not show significant association, despite the high prevalence of metabolic syndrome and low quality of life of patients.\(^{(8,9,27)}\) Thus, the planning and implementation of strategies to minimize the risk of metabolic disorders and therefore improve treatment adherence and quality of life, should be a major focus of individual treatment plans for these patients.

The use of three or more medications was present in 77.8% of patients with impaired quality of life, although without reaching statistical significance. It is difficult to establish a precise relationship between these variables, given that more severe patients generally use a higher number of medications, which may reflect poorer quality of life. It is also important to consider that the amount of medication used, according to some investigations, often relates to increased side effects and worse perceived health status, especially in those using clozapine.\(^{(28,29)}\)

**Conclusion**

People with refractory schizophrenia taking clozapine have impaired quality of life in all areas and across all items of the Brazilian version of the *Quality of Life Scale* (QLS-BR). Physical activity, family income and having children were factors associated with a better quality of life. The presence of metabolic syndrome, although prevalent, was not related to quality of life. The evaluation of quality of life in these patients may help in the design of care and policies, as well as the measurement of treatment effects.

**Acknowledgements**

We thank the Regional Health Superintendency of extended western region of Minas Gerais (Superintendência Regional de Saúde da Região Ampliada Oeste de Minas Gerais - SRS-MG), municipality of Divinópolis, for supporting the research.

**Collaborations**

Pinto JAF, Nunes FDD and Souza ARS contributed in the project execution, data analysis and final editing. Freitas PHB collaborated with the design and implementation of design, analysis and interpretation of data, and review of the final content. Machado RM contributed with the project design, critical review and approval of the final version.

**References**

Development of a course in the Virtual Learning Environment on the ICNP®
Desenvolvimento de um curso no Ambiente Virtual de Aprendizagem sobre a CIPE®

Carolina Costa Valcanti Avelino
Fernanda Ribeiro Borges
Camila Mitiko Inagaki
Marcos de Abreu Nery
Sueli Leiko Takamatsu Goyatá

Abstract
Objective: To develop and evaluate a course on a Moodle Platform on diagnoses, interventions, and nursing outcomes according to the International Classification for Nursing Practice.

Methods: A quantitative, descriptive, cross-sectional study conducted with 51 nursing students and practicing nurses. The course evaluation was done using a COLLES Survey. A multiple linear regression model was used to analyze the variables.

Results: The course was developed in accordance with the instructional objectives defined using various technological resources: activities map, coffee with prose forum, virtual library, personalized teaching support material, discussion forum, Wiki, and animation video. There were significant associations among four COLLES Survey sub-items and the variables images, Wiki resource, time available for the activities, and group.

Conclusion: The proposal for creating this course proved to be effective and consistent for innovation in vocational training and continuing education in nursing.

Keywords
Nursing informatics; Educational technology; Education, distance; Education, nursing; Education, nursing, continuing

Resumo
Objetivo: Desenvolver e avaliar um curso na Plataforma Moodle sobre diagnósticos, intervenções e resultados de enfermagem, de acordo com a Classificação Internacional para Práticas de Enfermagem.

Métodos: Estudo quantitativo, descritivo, de corte transversal realizado com 51 graduandos de enfermagem e profissionais enfermeiros. A avaliação do curso foi realizada por meio do Inquérito COLLES. Utilizou-se o modelo de regressão linear múltipla para análise das variáveis.

Resultados: O curso foi desenvolvido de acordo com os objetivos instrucionais definidos, utilizando diversos recursos tecnológicos: mapa de atividades, fórum café com prosa, biblioteca virtual, material de apoio didático personalizado, fórum de discussão, Wiki e o vídeo de animação. Houve associações significativas entre quatro subitens do Inquérito COLLES e as variáveis imagens, recurso Wiki, tempo disponibilizado para as atividades e grupo.

Conclusão: A proposta de criação desse curso mostrou-se efetiva e consistente para a inovação na formação profissional e educação permanente em enfermagem.

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Conflicts of interest: there are no conflicts of interest to declare.
Introduction

Using information technology for learning in nursing has intensified recently. New technological possibilities are being incorporated into teaching practices, especially in initiatives with universities, whether to support the classroom teaching or for developing distance activities. Furthermore, the Brazilian government is investing in distance learning by using new technologies as a way to raise the teaching quality standard in the country.

In this context, it is the role of higher education institutions to create opportunities for learning mediated by computer technology and the use of the internet. These changes, which occur at a national and international level, have required the development of new pedagogical and educational methodologies, especially in nursing.

A study conducted in São Paulo with the objective to identify the cognitive and social skills developed by graduate students of the discipline Didactic-Pedagogical Training in Health, through the Moodle platform, showed that students processed and problematized information in the form of thoughts and knowledge built from the collective dimension of learning. It also showed that 81% of participants had no previous experience with Moodle. However, the students felt like they had a positive experience and considered Moodle to be a friendly environment that promotes collaborative learning. The positive points they brought up were the possibility of accessing different didactic materials, continuous editing and revising of the messages posted, spatial and time flexibility, exchange of information made easy, coupled with the possibility to interact with different people.

Thus, the development of courses in the Virtual Learning Environment should be planned beforehand and based on methodologies and educational theories, using different technological resources that enable motivating, interactive, and reflective learning.

The option to use the Moodle platform is justified because it is a Virtual Learning Environment that can be used for free, and also because of the possibility of incorporating various technological and media resources to process information.

The decision to use the International Classification for Nursing Practice (ICNP®) is also justified since this nursing classification is little known and used in the clinical practice of nurses. Furthermore, there is resistance on the part of nurses to work with methods that lead to clinical reasoning, which in most cases occurs due to the lack of knowledge of these methodologies.

This study was aimed to develop and evaluate a course in the Virtual Learning Environment using the Moodle platform on diagnoses, interventions, and nursing outcomes according to ICNP®, directed to training nursing students and for the continuing education of practicing nurses.

Methods

A quantitative, descriptive, cross-sectional study was conducted at the School of Nursing of the Federal University of Alfenas with 51 participants, divided into two groups (25 nursing students and 26 practicing nurses) aged 19 to 55 years old. The study was carried out in two stages. The first stage was the development of a course on the Moodle Platform on diagnoses, interventions, and nursing outcomes according to ICNP®. The second stage was the evaluation of this course by the participants.

The process of developing the course took place in four phases: analysis, design and development, implementation, and evaluation. The contextualized instructional design model was adopted to carry out these stages. In this model the development process phases do not occur in a linear fashion; rather, these phases are carried out recursively throughout the entire process, making the selection of the educational objects and technological resources more flexible and accessible. Because of this, even if the course has already started, it is possible to make the necessary adjustments in accordance with the needs of the students and educational objectives. Below are the actions presented for each phase according to Filatro.
In the analysis phase the learning needs are identified and the instructional objectives defined according to the learner’s characteristics and to the economic, human resources, administrative, technical, and time constraints that are raised for the course.

The design and development phase involves the production and adaptation stage of the didactic and digital resources, which means building the course’s design through the Virtual Learning Environment. It is in this stage that the planning of the instruction takes place and the production of the educational materials, which determined the degree of interaction between the students and the professor, the interactivity provided by the technological capabilities of the Virtual Learning Environment, and the level of technical support and from the tutor.

In the implementation phase, the students are trained to use the technological resources developed, which is when they get used to the Virtual Learning Environment and when teaching-learning is carried out when the social organization of learning, the form of evaluation, and the feedback given by the professor are checked.

In the evaluation phase, a review is made of the problems detected, of the errors that can be corrected, and to what extent the instructional design can be improved. At this stage, 51 participants were selected through simple random sampling to evaluate the Virtual Learning Environment in relation to its visual formatting, access to the Moodle Platform, to the web browsing, as well as the hypertext and images.

The course’s evaluation was also done by means of the COLLES Survey, which is a questionnaire that is validated and available on the Moodle Platform. For statistical analysis, we used the program Statistical Package for Social Sciences, version 17.0. The internal consistency analysis of the set of items in the COLLES Survey for the study was given a Cronbach’s alpha of 0.87, demonstrating significant internal consistency.

The multiple linear regression model was used to explain the relationship between the independent variables and the dependent variables of the COLLES Survey. Significance was set at 10% for the regression model’s parameters.

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 30802714.8.0000.5142.

Results

The development phase consisted in defining the course’s instructional objective with the use of technologies for the dissemination of knowledge about the ICNP for the professional practice. As for the course’s sequence, it was decided to provide the structure of the Virtual Learning Environment in stages according to the Contextualized Instructional Design Model to make it easier for the student on the platform and the evaluation of all the stages.

Next, the resources and the media to be used were defined: activities map, coffee with prose forum, virtual library, personalized teaching support material, discussion forum, Wiki, and animation video.

- Activities map: this was a resource used for the students to gain a view of the course as a whole, such as the themes of the units, specification of the activities and the period to carry them out, description of the assessments, and information about the classroom times together. It was developed in Google Drive using a “Google Presentation” tool in the form of slides and made available on the Moodle Platform. It should be pointed out that the course’s resources were made available on the map in the form of a link so as to make it easier for the students to access the activities.

- Coffee with prose forum: this was the medium of communication of the tutors with the students and for feedback about the activities developed.

- Virtual Library: this was the place where all the support material was made available to the student, and it could be downloaded.

- Teaching support material: it was produced by the authors and evaluated by a post-doctorate professor with experience in this subject. All
suggestions were considered and the final version was converted to a PDF format and made available on the virtual library so that the students could download them. It was also made available on the Virtual Learning Environment in the format of a virtual book to encourage reading. A free Digital Publishing Platform that does this conversion was used (Figure 1).

- Discussion Forum: this took on the form of questions and answers and was intended to encourage discussion and interaction among participants based on the teaching support material and further reading. The topic of discussion was “Getting to know the stages of the nursing process and using the ICNP®.”

- Wiki: this was a feature of the Moodle Platform that made it possible to build collaborative texts, which means that the text editing was not done by only one author, but by many, whether students or professors, all of whom participated in the teaching-learning process. Three Wiki resources were built on the platform. On Wiki 1, a fictitious case study was prepared directed to chronic conditions, which was evaluated by three experts with experience in the subject. The items evaluated were clarity, readability, content, and changing of items. In this activity, the questions were directed toward building the students’ clinical reasoning without specifying any type of nursing classification in order to evaluate their knowledge on the subject. On Wiki 2 the Arc Method proposed by Charles Maguerez was used as a pedagogical strategy for the troubleshooting stages (questioning). This method was applied by the reasoning process of diagnoses, interventions, and nursing outcomes according to the ICNP®. This way, based on the observation of the reality of clinical nursing practice, problem situations were identified such as case studies raised at the clini-
ic, at home, among other areas. Data collection was performed from the case study raised. After this, a careful, critical, and reflective analysis of the client’s case was carried out, identifying the relevant data (key points), which were grouped and submitted to theoretical analysis (theorizing). This phase, which corresponded to clustered relevant data, needed to be compared to the normal standards or explanatory theories of the factors related to the occurrence of the injury. The hypotheses of solutions by the Magueretz method corresponded to hypotheses of nursing diagnoses established by the ICNP®. Finally, the application to reality corresponded to the implementation of the nursing process through interventions and outcomes for the client. On Wiki 3 a case study was prepared in the form of an animated video. The production of the animated video included the following steps: preparation and examination of the case study, writing of the script, preparation of the storyboard, and development of a short video. This case study was drawn from reality and adapted for educational purposes. It was then evaluated by three doctor experts with experience in prenatal care, childbirth, and postpartum care, which were the subjects addressed in this case. The items evaluated were clarity, readability, content, and changing of items. The final case study was turned into a script and reviewed by an animation designer with an academic background in cinema animation. This script was based on a prenatal nursing check-up at a Family Health Unit of a pregnant woman with social problems. The characters were the nurse, the receptionist, the pregnant woman, and her baby. In the third stage, a storyboard was drawn up by the same professional who reviewed the script. The storyboard is the tool used as a first viewing of a short or long video, which is required for the production of a film and is used from its preparation all the way to the showing. In the last stage, the animated video was finally developed by the same designer. The animated film was intended to give “life” or movement to the drawings, photos, objects, cutouts, and puppets through computer animation. In the process, the actors only added their voice as narrators or by dubbing characters. The animated video was entitled Case Study: a pregnant woman at a prenatal consultation at a family health unit and featured three actors to narrate the characters. The length of the video was 5 minutes and 58 seconds (Figure 2).

After the end of building the course on the Moodle Platform, an evaluation was done by 51 participants, which showed that almost all the participants succeeded in all the aspects evaluated. When asked about the educational objectives proposed by the survey, 96.1% considered the visual formatting of the page to be appropriate, 100% considered access to the Moodle Platform page and to the hypertext as appropriate, and 98% considered the internet browsing and images appropriate.

According to the multiple linear regression model, 10 to 25% of the variance in the sub-items of the COLLES Survey was explained by the models adjusted with the independent variables (Table 1).

Significant associations occurred to explain the behavior of four sub-items on the COLLES Survey (relevance, critical reflection, support from tutors, and support from peers), which had the following independent variables involved: appropriateness of images, using the Wiki resource, time available for doing the activities, and group.

The mean scores of the answers to the sub-item “relevance” increased for those who considered the images of the Virtual Learning Environment and the use of the Wiki resource as very adequate for the educational objectives. The mean scores of the answers to the sub-item “critical thinking” increased for those who considered using the Wiki resource as very adequate for the educational objectives. For the sub-item “support from tutors,” the mean scores of the answers decreased for time, which means that the more the time was appropriate to carry out the activities, the lower the need for support from tutors was; and it increased for those who considered the Wiki resource as very adequate. For the sub-item “support from peers”, the mean scores of the answers was higher for the group of professionals.
Discussion

Despite the course being developed on the Moodle Platform and the educational materials used being highly rated by the participants and validated by the linear regression modeling, a limiting factor for its realization was the financial investment made available for developing virtual learning objects such as the animation video. This may hinder the democratic access of nursing students and healthcare professionals to new educational technologies, especially in public higher education institutions where there is neither technical staff nor budget funds for such activities.

The development of virtual environments for education should be planned beforehand and based on educational principles that allow a dialogical learning and that contribute to the formation of opinions and reflections by the learners. Because of this, the most important stages for the development of a distance learning course are: setting objectives, producing adequate teaching materials, and building an efficient

Table 1. Distribution of the sub-items on the COLLES Survey and other variables studied according to the estimate of the parameters of the multiple linear regression models

<table>
<thead>
<tr>
<th>Variables</th>
<th>Relevance</th>
<th>Critical reflection</th>
<th>Support from tutors</th>
<th>Support from peers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>p-value</td>
<td>B</td>
<td>p-value</td>
</tr>
<tr>
<td>Intercept</td>
<td>8.486</td>
<td>0.000</td>
<td>9.583</td>
<td>0.000</td>
</tr>
<tr>
<td>Images</td>
<td>4.917</td>
<td>0.008</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Wiki</td>
<td>1.171</td>
<td>0.016</td>
<td>1.783</td>
<td>0.004</td>
</tr>
<tr>
<td>Time</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Group</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>R²</td>
<td>0.255</td>
<td>-</td>
<td>0.155</td>
<td>-</td>
</tr>
</tbody>
</table>

B - estimate of the parameters that make up the model
and organized script. Furthermore, a well-planned and friendly Virtual Learning Environment must contain various technological resources as an educational strategy and be dynamic, while also allowing necessary adjustments and adaptations.\(^{(5,9)}\)

The study carried out at a public university that aimed to evaluate the Virtual Learning Environment in the teaching of the nursing process to students of the discipline Basic Fundamentals of Nursing I revealed the importance of a previous planning of this discipline, whose educational objectives were achieved: 95.2% considered the format and the hypertexts adequate, 92.9% considered the navigation to be adequate, 100% considered the access adequate, and 97.6 considered the images adequate.\(^{(3)}\)

As for the digital teaching support material, it is different from printed material due to the possibility of using different media. Therefore, the construction of the digital teaching material should consider technical, graphic, and pedagogical aspects with support from appropriate equipment and software. However, human support is essential, from qualified professionals for the area that material needs to be created for, in accordance with the purpose of learning, since the use of technology by technology is insufficient to devise a new educational concept.\(^{(10)}\)

The animated video simulating a clinical situation was an innovative and different approach from those to which the participants were used to. The use of resources that simulate common situations of professional nursing practice is essential to the process of teaching and learning about skills, abilities, and decision making by nurses.\(^{(5)}\) Furthermore, the learning styles of the students should be considered when proposing a course because each one has a different way of processing information, of reasoning, and of solving problems. Some prefer concrete facts and data while others process better visual information such as videos, images, and diagrams, while still others prefer written forms. Knowing these different forms of learning contributes to the planning and allocation of resources in order to achieve the educational objectives that distance education will target. The competence of professors in the choice of methods and resources to be used depends in most cases on knowing how to balance these different styles.\(^{(11)}\)

Therefore, it is necessary to select technological resources that are adequate to the educational objectives proposed for developing a discipline or a course. The results show that among the resources available on the Moodle Platform, Wiki is certainly one of the most applicable to higher education for training nursing students and for the continuing education of practicing nurses and it serves as an important resource toward building collaborative knowledge. Wiki can facilitate the creation, planning, and development of clinical case studies, which favors building the critical and reflexive view of students.\(^{(12)}\)

**Conclusion**

The quantitative assessments done by the participants made it possible to conclude that the course developed on the Moodle Platform from a contextualized instructional design provided a more friendly, motivating, and interactive environment for the process of training nursing students and for the continuing education of practicing nurses. Among the resources used were Wiki, which has important characteristics such as the possibility of building a collaborative text, inclusion of active methodologies, and different media tools. Thus, it can be said that the objective proposed for this study was successfully achieved because the course developed was considered an effective and consistent technological strategy since it allowed access to information and built knowledge about the ICNP®.

**Acknowledgements**

We would like to thank the Coordination for the Improvement of Higher Education Personnel for the financial support of a stricto sensu graduate scholarship, for a master’s degree in nursing.

**Collaborations**

Avelino CCV and Goyatá SLT collaborated in the design stages of the study, analysis, data interpreta-
tion, writing of the article, critical review on the intellectual content, and final approval of the version to be published. Inagaki CM, Nery MA, and Borges FR declare to have contributed with writing the article and doing a critical review of the intellectual content and final approval of the version to be published.

References

Adaptation and validation into Portuguese language of the HIV Antibody Testing Attitude Scale

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Maria Margarida Santana Fialho Sim-Sim¹
Maria Antónia Fernandes Caeiro Chora¹
Ermelinda do Carmo Valente Caldeira¹

Abstract

Objective: To culturally adapt and validate a version in European Portuguese language of the HIV Antibody Testing Attitude Scale.

Methods: Study conducting a methodological investigation for the adaptation and validation of an attitude measurement instrument. The instrument translation and back-translation were performed. Then, a pre-test was conducted. The study used a sample of 317 subjects from the academic community: students, professors and other professionals - who were contacted in the campus. Ethical principles were observed.

Results: Three analyses were conducted using the method of principal component analysis (PCA) with five, four and three factors. A three-factor solution was achieved, which presents 50.82% variance. In the analysis of inter-item correlation, values between -0.018 and 0.749 were observed. Internal consistency shows Cronbach’s alpha coefficients of 0.860 overall and between 0.865 and 0.659 in the three factors.

Conclusion: The instrument version shows psychometric properties that allow its use in Portuguese-speaking countries.

Keywords
Primary care nursing; Community health nursing; HIV; HIV infections; Validation studies

Descritores
Enfermagem de atenção primária; Enfermagem em saúde pública; HIV; Infecções por HIV; Estudos de validação

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Resumo


Métodos: Estudo referido a investigação metodológica, para adaptação e validação de instrumento de medida atitudinal. Realizou-se a tradução, retrotradução. Seguiu-se pré-teste. Amostra de 317 sujeitos que pertencendo à comunidade académica na qualidade de estudantes e funcionários docentes e não docentes que foram abordados no campus. Foram observados os princípios éticos.

Resultados: Realizaram-se três ensaios de análise fatorial de componentes principais a cinco, quatro e três fatores. Redundou numa solução a três fatores que explica 50,82% da variância. Na análise da correlação inter-itens observaram-se valores entre -0,018 e 0,749. A consistência interna revela coeficientes de alfa de Cronbach de 0,860 no global e entre 0,865 e 0,659 nos três fatores.

Conclusão: a versão do instrumento mostra propriedades psicométricas que permitem a sua aplicação em países lusófonos.

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Conflict of interest: there are no conflict of interest to declare.
Testing for seropositivity for the human immunodeficiency virus (HIV) is important for the health of individuals and the community. The identification of HIV antibodies is possible through tests conducted in conventional laboratories and rapid tests. The protocol of rapid tests includes, besides the blood sample, a questionnaire about behaviors, emotional support and specific guidance. The group of activities involving rapid tests is commonly referred to as Voluntary Counselling and Testing (VCT). The World Health Organization (WHO) recommends it to health centers, programs or campaigns. In Portugal, rapid tests are conducted under the National Program of HIV/AIDS Infection Control and Prevention 2012-2016. Despite the rapid test benefits for HIV/AIDS status awareness, stigmatization may occur. Insufficient information is an obstacle to rapid tests, as well as beliefs of invulnerability to HIV infection, thus justifying additional education. HIV/AIDS rapid tests in a university environment are performed in projects conducted in Africa, India, and the United States, contextualized in educational policies. Attitudes towards HIV/AIDS rapid tests show the predisposition to the test and are analyzed in clinical studies, among the general population, groups of homosexual orientation, ethnic minorities or emigrants, and university students via application of scales. The use of foreign instruments, if any, should be encouraged, concentrating efforts, improving versions, and comparing different samples. However, instrument validation requires a detailed process, as complying with lexical rules does not ensure an identical meaning. Despite the methodologies defined for the translation, adaptation and validation of instruments, a great variation occurs in this type of study. Some authors define guiding lines, from the first translation to psychometric analysis, maintaining linked, consistent, and rigorous processes.

Although the bibliography of this study was extensively analyzed, no instruments were found in Portuguese to evaluate the attitudes towards HIV/AIDS rapid tests, which will be a useful tool, considering that 203 million people in 12 countries speak Portuguese. In view of the broad interest in studying HIV/AIDS and the benefits of instrument accessibility, the objective of this study was to validate the HIV-Antibody Testing Attitude Scale in the Portuguese language.

This study was conducted to validate the HIV Antibody Testing Attitude Scale (HTAS). The instrument was translated in the literary dimension by an English teacher and in the conceptual dimension by a health psychologist, both from Portugal and fluent in English. After an analysis conducted by a bilingual individual, who corrected inconsistencies, the first translated version was obtained. Another bilingual collaborator performed the back-translation. Consent was obtained via email from one of the original authors (Peltzer), when he also agreed to participate as the judge of the reverse translation. A pre-test was then conducted with 30 students, who confirmed the understanding of the items after cognitive debriefing. The participants were chosen by convenience, confirmed their availability and consent and were recruited from the seven departments of the university campus. The inclusion criterion required participants to belong to the academic community. The sample size was based on the rule that suggests 300 subjects in validation studies. In total, 372 subjects were contacted, and 317 completed questionnaires were returned.

This study was conducted under the HIV/AIDS Project in the Academic Community, registered in the Investigation Center in Health Sciences and Technology (CICTS) from the University of Évora. HTAS is an instrument initially developed with 32 variables. A psychometric study with a multinational sample (that is, Nigeria, South Africa, Uganda, and Zimbabwe) rearranged the construct in 22 items. Prior studies showed HTAS organized in four factors in the first version and five factors in subsequent versions.
This instrument uses a five-point Likert scale ranging from 1 “strongly disagree” to 5 “strongly agree”. The score is obtained by a sum after reversing negative items. Higher scores indicate more favorable attitudes. It takes about 8 minutes to fill it.

Data were collected in a single episode, replacing the retest with the split-half method, and later analyzed with IBM SPSS Statistics®, version 20. The significance value for this study was $p<0.05$.

Study obtained positive opinion of the ethics committee for research in the areas of Human Health and Welfare of the University of Évora under No. 13009.

## Results

The mean age of the 317 participants was 21.214 years (SD = 2.176), ranging between 18 and 30 years, 122 (38.50%) were male and 195 (61.50%) female.

Data sustainability was observed for factor analysis. The Kaiser-Meyer-Olkin index (KMO = 0.860) showed sample adequacy. Bartlett’s test showed statistical significance ($X^2=2599.885; gl=231; p=0.000$). Commonalities ranged from 0.318 to 0.818. The initial solution without rotation presented 57.93% variance, explained by five factors of Eigenvalues above one, assuming the construct multidimensionality.

With a declivity plot as illustrated in figure 1, and because the authors of HTAS studies identified different factors, a principal component analysis (PCA) was conducted with five, four and three factors.

The PCA with varimax rotation, using five factors and retaining those with factor loading of 0.4 or above showed the first factor presents 28.93% variance, with Eigenvalue 6.366, and containing 5 items referred to as “fear” regarding the HIV/AIDS test. This factor includes item 12, which, in the original scale is in the dimension of “general concerns” about the rapid test. The second factor (Eigenvalue 2.132) accounts for 9.68% of total variance and includes six items related to “trust and support” regarding the HIV test. It does not include item 6 of the original scale, but it includes item 19, which, in the instrument of the authors was located in the dimension of “concerns about confidentiality”. The third factor of Eigenvalue 1.758 accounts for 7.98% of total variance. It includes five items reported as “friends’ concerns” and two items which, in the original scale, were in other dimensions: item 9, located in “general concerns”, and item 6, located in “trust and support”.

![Figure 1. Declivity plot](image-url)

<table>
<thead>
<tr>
<th>Eigenvalue</th>
<th>Component Number</th>
</tr>
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<tbody>
<tr>
<td>6.366</td>
<td>1</td>
</tr>
<tr>
<td>2.132</td>
<td>2</td>
</tr>
<tr>
<td>1.758</td>
<td>3</td>
</tr>
<tr>
<td>1.421</td>
<td>4</td>
</tr>
<tr>
<td>1.016</td>
<td>5</td>
</tr>
</tbody>
</table>
regarding the HIV test. The fourth factor, Eigenvalue 1.282, accounts for 5.82% of total variance and its two items refer to “confidentiality”. When compared to the original scale, it does not have item 19. The fifth factor, Eigenvalue 1.208, represents 5.48% variance and refers to “general concerns” about the HIV test; it is comprised of four items. This dimension does not include item 9, which is present in the original scale.

The second analysis with PCA was conducted, with varimax rotation and four factors. Two items lost their factor validity (item 7 and item 22). Total variance was 52.44%. The first factor had eight items that accounted for 28.93% of total variance and Eigenvalue 6.36%. The items referred to a mix of “concerns about friends and family and revelation of personal acts”. The second factor (Eigenvalue 2.132), accounted for 9.68% of total variance and included seven items related to “trust and support” regarding the HIV test. The third factor, with two items, referred to “confidentiality of health professionals”, Eigenvalue 1.758, accounted for 7.98% of total variance. The fourth factor, Eigenvalue 1.282, accounted for 5.82% of total variance and had three items related to a mix of “confidentiality and alienation from the test importance and intrusion in personal life”.

The third analysis was conducted using three factors. Two items lost their factor validity (items 8 and 22), loading under 0.4, and item 19 was present in two factors with almost similar factor loadings (i.e. 0.477 and 0.425) and the total variance was 46.61%. After removing items 8, 19, and 22, the last study was conducted with three factors, now with total variance of 50.82%.

Regarding the nature of the items, the organization grouped meanings of “fear”, “trust”, and “confidentiality”. The first factor gathered ten variables that expressed fear regarding the HIV rapid test, presenting 30.89% of total variance and Eigenvalue 5.870. The second factor, including six items, expressed trust in the decision to be tested for HIV and showed 10.72% variance and Eigenvalue 2.038. The third factor, with three items, referred to confidentiality and presented 9.20% variance and Eigenvalue 1.749. The factors were organized as indicated in table 1.

Considering the three-factor model, which does not include items 8, 19, and 22 of the original scale, the adequacy of items was observed in each subscale. In the first factor, related to the dimension of “fears”, the item-subscale correlation ranged between 0.329 and 0.733; in the second factor, regarding the dimension of “trust”, it ranged from 0.325 to 0.635; and in the third

<table>
<thead>
<tr>
<th>Items</th>
<th>Factor 1</th>
<th>Factor 2</th>
<th>Factor 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>0.790</td>
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</tr>
<tr>
<td>14</td>
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</tr>
<tr>
<td>12</td>
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<tr>
<td>13</td>
<td>0.719</td>
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<td></td>
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<tr>
<td>21</td>
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<td></td>
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<tr>
<td>15</td>
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<td></td>
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<tr>
<td>16</td>
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<td>11</td>
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<td>9</td>
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<td>7</td>
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</tr>
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<td>2</td>
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<td>3</td>
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<td>6</td>
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<tr>
<td>10</td>
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<td>0.475</td>
<td></td>
</tr>
</tbody>
</table>

Extraction Method: Principal Component Analysis, Rotation Method: Varimax with Kaiser Normalization a. Rotation converged in 4 iterations Note: Eigenvalues below 0.40 were omitted
factor, related to “confidentiality”, from 0.280 to 0.604.

Inter-item correlations in the three-factor model ranged from -0.018 to 0.736. Item 7 presented correlations with the other items, all below 0.30, which does not contribute to the main measurement. These items did not present correlations of 0.80 or above; thus, they were not redundant. Regarding the scale homogeneity, and after removing item 7, corrected item-total correlations ranged between 0.286 and 0.697.

Regarding correlations between subscales and overall scale, item 7 was removed from subscale “fears”. Correlations between the total scale and the subscales presented the following values: total scale versus subscale “fears” $r=0.900$, versus subscale “trust” $r=0.746$ and versus subscale “confidentiality” $r=0.539$.

Construct validity: the split-half method was used to analyze the construct validity. The first group of items presented a Cronbach’s alpha coefficient of 0.766 (items: 1, 3, 5, 9_r, 11_r, 13_r, 15_r, 17, 19, and 21_r) versus 0.750 from the second group (items 2, 4, 6, 10_r, 12_r, 14_r, 16_r, 18, and 20_r). The correlation between both forms presented $r=0.819$, with Spearman-Brown correction coefficient of 0.901.

Table 2 shows the descriptive statistics for the overall scale and subscales. In the overall scale and subscale “fears”, Cronbach’s alpha coefficients are strong, in “trust”, they are acceptable, and in “confidentiality”, they are insufficient.

In the Mann-Whitney test, no significant difference was observed when comparing the values of male and female participants, when using the overall HTAS ($U(317)=12.866; Z=1.224; p=0.221$), or in subscales “trust” ($U(317)=12.684; Z=1.002; p=0.316$), “fears” ($U(317)=12.235; Z=0.431; p=0.666$) or “confidentiality” ($U(317)=13.199; Z=1.664; p=0.096$).

Discussion

In face of the lack of a bilingual population, the instrument was translated and back-translated, with the agreement of the authors. The judgment of the original author ensured security when reproducing the instrument in the Portuguese language. The items are simple, which allows easy linguistic procedures and content validation.

When observing the scree plot, it was not possible to conclude with objectivity if the model should use three factors. Indeed, it is not always easy to assign a number of factors based on the point of the line where it starts to become horizontal, then PCA was used. As the instrument was still unknown in Portuguese, after the initial solution, it started with a number of dimensions identified in prior studies. The orthogonal rotation was justified by the multidimensional perspective of the construct, as it intended to maximize high correlations and minimize low correlations. The varimax rotation emphasized the loadings and evidenced the independence of factors. After successive analyses, the interpretation resulted in three dimensions.

The PCA of three-factor model showed, in the nature of variables presented, an explicit organization, leading to the interpretation of a dimension of “fears” regarding the decision to get tested and the opinion of friends and family and exposure of private life; a dimension of “trust”, related to the support from friends and family; a dimension of “confidentiality”, regarding the roles involving secrecy of health professionals. The three-factor interpretation was selected, because, besides the mathematical aspects of the PCA, the results from four- and five-factor models are dispersed in the variables presented. The selection of successive PCAs, extracting different numbers of factors and rotating them, in an intuitive interpretation, fa-
vored diversity and suggested a clear three-factor solution. Then, the results did not support the same number of dimensions found in African universities, but the interpretation based on three-factors makes sense, as it names the dimensions after the organization of variables presented.\(^{(12,18)}\) Variance based on three factors, after removing items 8, 19, and 22 (50.82%) was near the value obtained with the five-factor model (51%), and above the value from the four-factor model (44%) obtained in a previous study.\(^{(12,18)}\) Explained variance, even not ideally reaching 75%, could reach the minimum of 50%.\(^{(20)}\) In the validation of instruments in a foreign language, the PCA is a justified procedure, as it standardizes the way local participants perceive the original construct, but applied to another one.

Regarding the overall scale, most items showed a good measurement reliability, observed in the internal consistency, indicating the variables presented in the three dimensions are correlated.\(^{(21)}\) The first and the second factors, when addressing items of opposed nature, solidly discriminated the dimensions. The third factor, with a Cronbach's alpha coefficient of 0.659, showed insufficient consistency, but still acceptable in social sciences.\(^{(21)}\) The relative fragility of internal consistency of the factor may be interpreted by the small number of items.\(^{(16)}\) Perhaps, the nature of items may not be strange, as the guaranteed confidentiality of health professionals is a measurement of broad spectrum at the level of agreement of all subjects. Other studies also consider it a determinant when choosing a health service, constituting a relevant concern.\(^{(6)}\) The results from the dimension “confidentiality” suggest greater variability of intra-subject responses and lower inter-subject variability. In this study, despite the homogeneous inter-item variance, the corrected values of item-total correlations, precisely for the three variables that constitute the third factor, were the lowest.

With no chance of test-retest or procedure of parallel forms, as the subjects were contacted only once in the university campus, the split-half method evaluated the instrument precision. The values of correlations between the two halves were satisfactory.\(^{(16)}\) The strategy of ordinance of items for the analysis considered odd items versus even items, as proposed by Spearman.\(^{(21)}\) Thus, the effect of the position of items on correlations between the two halves is reduced. The split-half method provided a response to the assumption that the two parts are equivalent forms and shows the HTAS has global coherence. Regarding the test-retest, the split-half method offers the advantage of not biasing the results, either through the memory of subjects when answering the same questionnaire for the second time or through alterations in the interval between applications. It occurs in particular in psychological variables, such as attitudes, opinions, as it is the case in this study.\(^{(13)}\)

Overestimation or underestimation of the number of factors is a risk, perhaps leading to limitations. It is seen in the response and justifies the factor analysis in a future study. Despite these limitations, the scree plot observation method is the best option considering the Kaiser’s criterion which tends to remove an excessive number of factors.\(^{(13)}\)

Considering the study was developed in an academic community, whose mission is to promote knowledge, provide clarification and education in health, it is assumed the interviewees reduced the stigmatization of getting tested for HIV. At the same time, providing a chance to give an opinion, in the academic dimension, about a subject that is typically discussed in clinical areas, conditioned some subjects. Thus, some level of social desirability was admitted in this study.

### Conclusion

The current version of the HTAS is a valid measurement that evaluates attitudes towards the HIV/AIDS rapid test. The factor-based organization supports a three-factor model that does not coincide with the original model, but it was the result of interpretation of the local population. The current validation is useful in Portugal, and it may be of interest to Portuguese-speaking communities around the world. Attitudes towards HIV/AIDS rapid tests should be known urgently to promote the test and start therapeutic solutions.
Collaborations
Frias A and Sim-Sim M collaborated in the phases of study conception, analysis, data interpretation, article writing, relevant critical review of the intellectual content and final approval of the version to be published. Chora M and Caldeira E contributed to article writing, relevant critical review of the intellectual content and final approval of the version to be published.

References
Abstract

Objective: To analyze the complications deriving from the use and type of peripheral venous catheter in adults.

Methods: Randomized clinical trial; undertaken at a teaching hospital between 2012 and 2015; 169 adults were included who were hospitalized at clinical and surgical services and needed peripheral venipuncture with an expected dwelling time of more than 96 hours. Through systemized randomization, 90 participants were allocated to the trial group (complete safety catheter) and 79 to the control group (short flexible catheter).

Results: The general complications rate was 55.62%, with 18.34% of phlebitis, 11.83% infiltration, 11.24% obstruction and 9.47% traction. No significant difference was found between the groups for the occurrence of complications, phlebitis, obstruction and traction.

Conclusion: The complication rate in peripheral venous catheterization was high but, when compared, without a statistically significant difference, the complete safety catheter showed lower complication rates after the fourth day of survival.

Resumo

Objetivo: Analisar as complicações decorrentes do uso e tipo de cateter venoso periférico em adultos.

Métodos: Ensaio clínico randomizado; realizado em um hospital de ensino, no período de 2012 a 2015; incluiu-se 169 adultos internados em unidades clínicas e cirúrgicas que necessitaram de punção venosa periférica e com permanência prevista de mais de 96 horas. A randomização aleatória sistematizada alocou 90 participantes no Grupo Experimental (cateter de segurança completo) e 79 no Grupo Controle (cateter curto flexível).

Resultados: A taxa geral de complicações foi 55,62%, houve 18,34% de flebite, infiltração 11,83%, obstrução 11,24% e tração 9,47%. Não houve diferença significativa entre os grupos para a ocorrência de complicações, flebite, obstrução e tração.

Conclusão: A taxa de complicações no cateterismo venoso periférico foi alta, mas quando comparados, sem diferença estatisticamente significativa, o cateter de segurança completo teve taxas menores de complicações após o quarto dia de sobrevivência.

Keywords
Catheterization, peripheral/adverse effects; Cateterismo/efeitos adversos; Endovascular procedures/adverse effects; Adult

Descritores
Cateterismo periférico/efeitos adversos; Cateterismo/efeitos adversos; Procedimentos endovasculares/efeitos adversos; Adulto

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Introduction

Intravenous therapy is widely used in hospital contexts, mainly through the placement of peripheral venous catheters. Most catheters are removed due to the occurrence of complications, the end of the treatment or lack of use.\(^1\) The following local complications are associated with the use of peripheral intravenous catheter: hematoma, thrombosis, phlebitis, thrombophlebitis, infiltration, extravasation, local infection and venous spasm.\(^2\) More than 70% of inpatients need a peripheral venous catheter. In the United States (USA), about 200 million catheters are used each year.\(^3\) In Spain, about 50% of the inpatients receive an intravenous catheter, 95% of which are peripheral.\(^4\) Other studies appoint usage rates of peripheral venous catheters in 86.4%\(^5\) and 80.6%\(^6\) of the patients.

Thus, the nurses and nursing team's technical-scientific knowledge about intravenous therapy guarantee the treatment efficacy and the quality of care delivery, making it fundamental to know the best technologically and evidence-based care practices. That justifies the importance of this research for daily nursing care practice, as it produces knowledge and scientific evidence to support the nursing professionals' decision making on the most appropriate peripheral venous catheter for patients submitted to intravenous therapy. Hence, the objective in this research was to analyze the complications deriving from the use of peripheral venous catheters in adults.

Methods

A randomized, controlled clinical trial was undertaken at clinical and surgical services of a large teaching hospital. The randomization was achieved through systematic random sampling, in which two groups were set up: complete safety catheter (Trial Group) and short flexible catheter (Control Group). The complete safety catheter consists of a silicon needle with biangular and three-faceted bezel connected to the spindle through a metallic guide and knob; made out of polyurethane biomaterial; has a complete needle protection device; activated after the puncture; wings with grooves; transparent vinyl extension tube; bioselective reflux chamber filter lid; rapid cut clamp; two access routes consisting of a female connector in “Y”, being one Luer-Lok® connector and another with a removable male plug device. The short flexible catheter is of the over-the-needle type, with an internal safety device (passively activated) and flip, single use and disposable, needs to be coupled to an extensor for the infusion to take place; the extensors used at the research institution included cannulas, simple equipment and intermediary extensors with two or four access routes. The variable local complication of peripheral venous catheterization was the primary outcome and covered the occurrence of phlebitis, thrombophlebitis, extravasation, infiltration, obstruction, accidental catheter traction and local infection, assessed according to international guidelines.\(^2\)

The participants were adult patients over 18 years of age, hospitalized that inpatient services, who needed peripheral intravenous therapy. The study objects were the peripheral venous catheters installed. The inclusion criteria were: patients who needed peripheral venous access for intravenous therapy; expected length of stay more than 96 hours for clinical and/or surgical treatment; no previous inclusion in the research and use of already randomized catheter. The exclusion criteria were: impossibility of peripheral venipuncture due to capillary weakness, clinical conditions that contraindicated the venipuncture, specified by the responsible physician, as well as local changes that made the venipuncture impossible.

The data were collected between August and November 2014, when the number of participants proposed in the sampling calculation was reached (5% significance and 0.80 test power). Before the collection, the researchers were trained through meetings to standardize the collection and the concepts addressed (approximately 30 hours) and during the execution of the pilot test in pairs. The collection took place daily, in pairs, when material was replaced, the list of inpatients was updated and authorization was requested (free and informed consent form), analysis of inclusions and random-
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ization, reading of registers, active search for participants, direct observation of catheter puncture in patients and control for complications.

The nursing teams at the investigated services also participated in training. Thirty-four meetings were held, taking 40 to 60 minutes, involving 109 collaborators, through dialogued lectures (concepts standardized according to an international guideline),(2) watching a video and a puncture workshop.

The data were collected through a structured tool that contained sociodemographic, clinical, catheter and outcome variables. The patient was monitored daily from the inclusion in the research until the withdrawal of the catheter.

In the descriptive analysis of the data, absolute and percentage frequencies and central trend and dispersion measures were determined (means and standard deviations). In the univariate analysis, the characteristics of the catheter groups were compared, using chi-squared, Fisher, William’s G, Mann-Whitney’s U and the binomial test of proportions. In all tests, significance was set at 5%. A survival curve was established for each group, from the puncture date until the appearance of complications, using Kaplan-Meier’s product limit estimate. To compare the obtained curves, Mantel-Haenzel’s test (log-rank) was used with 5% significance.

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 30398914.9.0000.0102.

Results

In total, 193 participants were eligible for inclusion in the research, 23 of whom were excluded from the data analysis, one dropped out and 169 participants were included (90 from the trial group and 79 from the control group); only one catheter was assessed per patient; all uninformed registers were excluded from the statistical analyses.

The sample was homogeneous and mostly characterized as Caucasian, approximately 50 years of age, unfinished primary education, retired, non-smokers and non-drinkers, with a family history of systemic arterial hypertension. Men were the majority in the control group and women in the trial group. Hospitalization at the male medical clinic, clinical diagnosis of digestive diseases, no associated comorbidity, no surgical procedures during the hospitalization, absence of infection and discharge as the outcome were predominant. The length of the hospitalization was longer (in days) in the control group (Table 1).

The predominant catheter caliber in the two groups was number 20; location in upper left limb, forearm region and successful puncture during first attempt. Regarding the use of the devices, in the two groups, the prevalent drugs used were solutions and schedules with serum, sedatives and analgesics and other drugs (which were not part of the classifications considered) (Table 1), but a minority used antimicrobial agents, electrolytes, anticoagulants, vesicant drugs and corticosteroids.

Most catheters were inserted for two days. When referring to the dwelling time in hours, most catheters were inserted for 72 hours or longer (Table 1). The catheter in the experimental group was inserted without complications for an average 3.73 (±2.25) and a maximum of 10 days, while the catheter in the control group remained for 3.28 (±1.66) and a maximum of seven days. Among the motives for withdrawal, discharge was predominant, followed by phlebitis. A significant difference was found between the groups for the variables: puncture location (p=0.0236) and number of puncture attempts (p=0.0047), that is, the proportion of catheters in the trial group punctured in the upper left limb was significantly larger than in the control group when compared to the upper right limb and the proportion of successful puncture upon the first attempt was higher in the two groups.

Complication rates have been described in table 2, considering the two catheter groups, i.e. trial and control. No statistically significant difference was found between both groups regarding complications.

When considering only catheters that developed complications (n=94; n=50 Trial Group; n=44 Control Group), the upper right limb revealed more prone to the development of complications in the trial group and the upper left limb in the
control group (p=0.0234). Successful first puncture attempts were statistically significant (p=0.0289) in both groups.

Regarding the catheters that developed phlebitis, the caliber 20 gauge (G) was predominant, puncture in the upper left limb, in the forearm region, use of other drugs and dwelling time 72 hours or longer, as well as non-infusion of electrolytes, anticoagulants, vesicant drugs and corticosteroids. In the trial group, the use of analgesics and sedatives, solutions and serum schedules stood out, as well as the non-administration of antimicrobial agents.

In the control group, the infusion of solutions and schedules and the non-administration of analgesics and sedatives stood out. No statistically significant differences were found between the research variables and the occurrence of phlebitis.

Phlebitis was present in different grades, predominantly grade I, followed by grade II. Only the trial group presented grade III. Grade IV phlebitis was not developed in any of the groups analyzed.

In the comparison between the catheter groups that developed infiltration, in the two groups, the most used caliber was 22G, punct-
tured in the forearm region, with infusion of electrolytes, anticoagulants and vesicant drugs in a minority of cases, and administration of other drugs. In the trial group, the most punctured site was the upper left limb, with a predominance of no use of antimicrobial drugs, infusion of analgesics and sedatives and solutions and serum schedules, dwelling time 72 hours or more. Infilt-ration was significant (p=0.0379) for punctures in the upper left limb in the trial group and in the upper right limb in the control group.

Among the catheters that developed obstruction, the following stood out in the two groups: caliber 22G; inserted in the forearm region; absence of infusion of: antimicrobials, sedatives and analgesics, electrolytes, anticoagulants, vesicant drugs and corticosteroids; use of solutions and serum schedules and other drugs. In the trial group, puncture in the upper right limb and dwelling time shorter than 72 hours were predominant. In the control group, the upper left limb and dwelling time 72 hours or longer stood out. No significant difference was found between the variables analyzed for obstruction.

The comparison between the catheter variables and the complication traction for both groups was similar. The caliber 20G was predominant, as well as insertion in the upper left limb, in the forearm region, use of catheter for infusion of sedatives and analgesics, solutions and serum schedules and other drugs, minimal use for infusion of electrolytes, vesicant drugs, anticoagulants and corticosteroids, dwelling time less than 72 hours. No statistically significant differences were found between the variables.

The survival was estimated for all complications, as well as for the four most frequent complications in this research: phlebitis, infiltration, obstruction and traction. No significant difference was found between the curves. Nevertheless, for the development of complications (p=0.0650), survival was longer in the trial group after the fourth day of the catheter dwelling time. When comparing the groups concerning the occurrence of phlebitis, the survival function in the trial group was only shorter on the third dwelling day of the catheter (p=0.2900). Sur-

vival was similar for infiltration up to the second day. After the third, it was longer in the trial group when compared to the control group (p=0.1650). For the occurrence of obstruction, survival in the experimental group was shorter between the second and fifth day of the dwelling time (p=0.9510). Traction obtained longer survival for the trial group as from the second day (p=0.3950) (Figure 1).

**Discussion**

Regarding the results, the population was homogeneous, predominantly Caucasian, age range 50 years, similarity between the sexes, absence of reported smoking and drinking, history of systemic arterial hypertension and absence of comorbidities, in line with different studies that assessed the peripheral venous catheters.\(^4\_7\_13\)

Concerning the catheter characteristics, studies appoint that caliber 20G is the most used,\(^10\_14\) location in upper left limb\(^3\_10\) and forearm region,\(^1\_4\_8\_9\_13\) success-ful puncture upon the first attempt,\(^1\_4\) and dwelling time superior to 72 hours,\(^8\_10\_13\_15\) similar to the present findings. The use of antimicrobials in this research differed from studies that appoint frequent use.\(^1\_3\_4\_14\_15\)

Similar complication rates in peripheral venous catheterization are found in 52%\(^7\) and 51.1%\(^4\) of the catheters. Data appoint a larger proportion of complications in peripheral venous catheters in women (p=0.0300), patients aged 85 years or older, when compared to participants younger than 65 years of age (p=0.0500), puncture in the forearm region when compared to other puncture regions (p≤0.0001) and other regions punctured. When compared to the hands or wrist (p=0.0300)\(^9\) in that region, however, no significant relations were found for any of the variables analyzed. As regards the dwelling time, the literature does not recommend programmed catheter change, but when clinically indicated, as this is safe, makes the patient more comfortable and reduces costs for the institution.\(^16\_18\)

When considering the phlebitis rate, similarity was found when compared to other studies,
with 17.58% (n=148); 15.4% (n=13) and 16.9% (n=101). In this research, no significant associations were found between phlebitis and catheter-related variables. Independent analyses appointed significant relations for the development of phlebitis, including: lower limb puncture (p=0.015) and use of antimicrobials (p=0.009); puncture site in cubital fossa was vulnerable to more severe phlebitis when compared to the forearm (p<0.05); regions of flexion or great mo-

Figure 1. Survival functions per catheter group in complications
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bility contribute to traumatic phlebitis; \(^{12}\) closed infusion systems reduce phlebitis rates by 29\% (\(p=0.004\)); \(^{4}\) age (between 60-100 years), smoking (\(p=0.030\)), hospitalization at clinical, geriatrics and cardiology wards, emergency admission, use of intravenous antimicrobial drugs, catheter inserted in the back of the hand, calibers 22 and 24 gauge and other catheter materials different from polyurethane; \(^{13}\) diabetes (\(p=0.003\)), 18 gauge caliber (\(p=0.031\)), punctured in antecubital fossa region (\(p=0.001\)), dwelling time longer than 49 hours (\(p=0.0000\)), continuous infusion (\(p=0.039\)), use of antimicrobials (\(p=0.002\)); \(^{21}\) hospitalization time longer than 18 days (\(p=0.002\)) and dwelling time longer than 72 hours (\(p<0.001\)). \(^{10}\) A study that related the catheter dwelling time with phlebitis identified its development in 28\% of the catheters between fourth and fifth day of the dwelling time (\(p=0.03\)). \(^{22}\) In line with the research findings, a study appointed grade I phlebitis as the most frequent in 94.4\% of the catheters and grade III was the most severe. \(^{13}\) Other studies appoint that grade I predominates in 77.66\%, \(^{22}\) 46.2\% \(^{10}\) and 41.6\% \(^{8}\) followed by 22\% grade II, \(^{22}\) 40\% \(^{10}\) and 37.5\% \(^{8}\) Grade III, only found in the trial group, was appointed with 12\%, \(^{22}\) 16.7\% \(^{8}\) 19.3\%, \(^{23}\) 18.3\%, \(^{10}\) 9.9\% \(^{15}\) and 7.2\%. \(^{12}\) As opposed to the present data, in which no grade IV phlebitis was developed, these cases did occur in studies, with rates of 4.2\% \(^{8}\) 2.2\% \(^{12}\) and 22.8\%. \(^{23}\) When relating the dwelling time with the grades of phlebitis, the results appoint grade I and II phlebitis for catheters inserted for up to 72 hours and grade III and IV after 72 hours of dwelling time, with a statistically significant difference (\(p=0.006\)), as well as a significant relation (\(p=0.0130\)) for grade I in the back of the hands and grades II, III and IV in the forearm region. \(^{23}\)

The rates of infiltration were similar to the literature, measured at 12.5\% \(^{24}\) and 13\%. \(^{12}\) In this research, no significant difference was found between the variables analyzed for obstruction, but a study involving surgical patients appointed that the 22 gauge caliber, used in 8.1\% of the participants, presented more cases of obstruction, with a prov-}

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**Conclusion**

The complication rate in peripheral venous catheterization was high but, when compared, the complete safety catheter obtained lower complication, obstruction and traction rates, without a statistically significant difference after the fourth day of survival.

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Collaborations
Danski MTR contributed to the conception of the project, execution of the research, relevant critical review of the intellectual content and final approval of the version for publication. Johann DA cooperated with the conception of the project, execution of the research, analysis and interpretation of the data, writing of the article and final approval of the version for publication. Vayego SA cooperated with the analysis and interpretation of the data and relevant critical review of the intellectual content. Oliveira GLR contributed to the conception of the project, execution of the research, analysis and interpretation of the data, writing of the article and final approval of the version for publication. Lind J participated in the execution of the research, writing of the article and final approval of the version for publication.

References


Transcultural adaptation of the Infiltration Scale into the Portuguese culture

Adaptação transcultural da Infiltration Scale para o português

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Abstract

Objective: To translate, adapt and evaluate the psychometric properties of the Infiltration Scale for the Portuguese culture.

Methods: A methodological study of trans-cultural adaptation to evaluate the psychometric properties of the Infiltration Scale, conducted in a cohort study with 110 adults undergoing intravenous therapy.

Results: In the translation and cultural adaptation, language adjustments were discussed by researchers and a panel of experts, achieving an agreement of 85.71% for clinical criteria, except for “Possible numbness”. The scale identified infiltration in 48 patients (60% prevalence). Edema was the most evident sign in the insertion site and areas adjacent to the venous catheter. The internal consistency, determined by Cronbach’s alpha, was 0.85.

Conclusion: The scale adapted to the Portuguese culture presented linguistic equivalence to the original, proved valid and reliable, with good internal consistency for assessing infiltration. The systematic evaluation of infiltration using the scale can support decision-making and the implementation of preventive measures.

Keywords
Extravasation of diagnostic and therapeutic materials; Nursing, practical; Validation studies; Nursing research; Scales

Resumo

Objetivo: Traduzir, adaptar e avaliar as propriedades psicométricas da Infiltration Scale para a cultura portuguesa.

Métodos: Estudo metodológico de adaptação transcultural com avaliação das propriedades psicométricas da Infiltration Scale em uma coorte com 110 adultos submetidos à terapia intravenosa.

Resultados: Na tradução e adaptação cultural, as adequações linguísticas foram discutidas pelos investigadores e um painel de especialistas, havendo concordância em 85,71% dos critérios clínicos, exceto “Possible numbness”. A escala captou infiltração em 48 pacientes (prevalência de 60%). O edema foi o principal sinal evidenciado na inserção e áreas adjacentes ao cateter venoso. A consistência interna, determinada pelo alfa de Cronbach, foi de 0,85.

Conclusão: A escala adaptada para a cultura portuguesa apresentou equivalência linguística em relação à original, mostrou-se válida e fidedigna, com boa consistência interna para avaliar a infiltração. A avaliação sistemática da infiltração com recurso a escala poderá subsidiar a tomada de decisão e implementação de medidas preventivas.

Keywords
Extravasation of diagnostic and therapeutic materials; Nursing, practical; Validation studies; Nursing research; Scales

Descritores
Extravasamento de materiais terapêuticos e diagnósticos; Enfermagem prática; Estudos de validação; Pesquisa em enfermagem; Escalas

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Introduction

Infiltration is a complication related to intravenous therapy, and has been a major cause for removal of peripheral venous catheters prior to completing treatment.\(^{(1-3)}\) It is defined as the inadvertent administration of solutions and non-vesicant medications into tissue close to the venous catheter insertion, due to breakage or perforation of the vein. A leakage is an infiltration that occurs due to inadvertent administration of solution or vesicant medication, which represents a risk for progressive tissue damage, and which may become apparent within days or weeks after exposure.\(^{(4-7)}\) Regardless of the causal mechanism of tissue injury, the intervention is determined by the pharmacological characteristics of the infused solution, and involves an interdisciplinary team of nurses, physicians and pharmacists.\(^{(7,8)}\)

Some problems hamper the process of infiltration management, such as failure to identify the problem, due to insufficient number of professionals, high staff turnover and lack of knowledge about effective treatments, related to limitations of research, among others.\(^{(7)}\)

However, in order to reduce the risk of infiltration, best practices for intravenous therapy must be implemented. Among these, the following stand out: monitoring the catheter insertion site, implementing guidelines and protocols for prevention, early detection of the first signs and symptoms, and properly intervening on the problem, to limit damage and prevent serious adverse effects.\(^{(4-6,8-11)}\)

A rating scale is recommended for assessing and determining the extent, standardizing the description of the infiltration, documenting the severity of the problem, and evaluating the degree and prevalence of infiltration.\(^{(5,6,9,10)}\) Currently, scales have also been used as indicators to assess the outcomes of care and to support the implementation of interventions.\(^{(12)}\) This same logic is proposed by the American Nurses Association, in the safety aspects related to intravenous therapy, especially in the evaluation of the infiltration rate of peripheral venous catheters in pediatrics, and the catheter-related infection rate.\(^{(13)}\)

The Infusion Nurses Society\(^{(5)}\) published the Infiltration Scale, organized into four levels, to classify infiltration. Level zero represents the absence of infiltration, and level four represents the most severe. The scale describes the clinical criteria to be evaluated for each level of infiltration, such as skin color, skin temperature to touch, pain, extent and depth of edema, abnormal sensitivity, circulatory impairment and infiltration of blood, irritant solution or vesicant. The identification of one clinical criterion is sufficient to characterize the level of infiltration, and the recommendation for the removal of a peripheral venous catheter.\(^{(5)}\)

An investigation assessed the psychometric properties of the Infiltration Scale based on the following dimensions: feasibility, acceptability, reliability and concurrent validity. It was found that the scale was easy to administer, with rapid implementation (mean of 1.3 minutes), and was clinically appropriate.\(^{(14)}\) The authors also indicated the need to make other psychometric studies to assess the validity and reliability of the scale.

To date, studies have not been identified on the transcultural adaptation of the Infiltration Scale for the Portuguese population. Thus this investigation was conducted, in order to translate, adapt and evaluate the psychometric properties of the Infiltration Scale to the Portuguese culture.

Methods

A methodological, transcultural adaptation study of the Infiltration Scale\(^{(5)}\) to the Portuguese of Portugal was conducted, to evaluate psychometric properties and to assess its validity and reliability in clinical practice.

The process of translation and transcultural adaptation met international guidelines,\(^{(15,16)}\) following five phases: translation into Portuguese; version synthesis; back translation; preliminary version in Portuguese; proposal for a final version by panel of
experts. This process followed the authorization of the Infusion Nurses Society.\(^{(5)}\)

**Phase I and Phase II**

The Infiltration Scale was independently translated from the original language into the Portuguese of Portugal by two bilingual translators, whose native language was Portuguese. The translations obtained were compared and the items that did not reach consensus on translation regarding the terms were discussed by the research team (two professors with doctorates in nursing, with experience in research on vascular trauma; two professors, with doctorates in nursing with experience in the process of scale validation, and one master’s-prepared professor, who was a doctoral student in nursing, with experience in intravenous therapy) and the translators. After achieving linguistic appropriateness, the first version of the Infiltration Scale translated into Portuguese (synthetic version) was developed. Two bilingual translators (English as native language) back-translated this version into English, independently. The translations and back-translations were analyzed by the same research team to evaluate ambiguities and discrepancies; to achieve cross-cultural equivalence of the scale into the Portuguese context; and to achieve consensus; a draft was developed.

**Phase III and IV**

The preliminary version in Portuguese, and the original in English, were analyzed and compared by a panel of seven experts (three nurses from a medical clinic service, with between 10 and 20 years experience in the venipuncture process; one Brazilian nursing professor and one professor of Portuguese, both doctorally prepared, with experience in vascular trauma research; a doctorally prepared professor of Portuguese, with expertise in management and research, and one of the translators, who participated in the back translation phase, and who had a nursing degree) for semantic, idiomatic, experimental and conceptual verification into the Portuguese. The final version of the “Portuguese Infiltration Scale” achieved a level of agreement of 85.71% from the panel.

**Phase V and VI**

The final version was applied in a cohort of 110 patients of a medical service in the central region of Portugal. The study included patients older than 18 years with intravenous therapy for peripheral venous catheter; those with central venous catheter or who refused to participate were excluded. The patients were followed from admission into the service until the end of intravenous therapy (July-September, 2015).

The data were organized and analyzed using the Statistical Package for the Social Sciences, version 21.0. A descriptive and factor analysis were performed of main components to assess the dimensionality and analysis of the internal consistency of the scale for determining the Cronbach’s alpha. The significance level for the tests was 5% (\(\mu = 0.05\)).

The study was approved by the Hospital and University of Coimbra (C.H.U.C.) Under the registration number 4907 PCA - University of Coimbra.

**Results**

Two translators performed the Infiltration Scale translation process into the Portuguese of Portugal. Both translations approached the literal Infiltration Scale sense except on four criteria, requiring evaluation and adjustments by the research team, namely: “No symptoms”, “Gross edema > 6 inches in any direction,” “Possible numbness and” Moderate-severe pain”. This step produced the synthesized version, which was approved by the translators and submitted to back translation. Of the 16 clinical criteria, only the criterion “Possible decreased sensitivity” (“Possible numbness” and “Possible reduction in sensitivity”) required reassessment.

The research team and one translator examined the original version, the summary version in Portuguese, the back translation, and approved the translation of “Possible numbness” to “Possível dormência”.

Consensus on the draft was obtained following these steps. This version was analyzed for conceptual, semantic, idiomatic, experiential and operational equivalence, by a panel of seven experts with
clinical experience in the venipuncture process. All items of the scale were analyzed and compared with the Infiltration Scale. Because of clinical judgment, the translation of “Possible numbness” was changed to “Possible decreased sensitivity”. Chart 1 presents the proposed version of the Portuguese scale infiltration.

The Portuguese Infiltration Scale version was subjected to evaluation in clinical settings with 110 patients receiving intravenous therapy, who used 517 peripheral venous catheters. The sample consisted predominantly of people over 60 years (95.5%), with a mean age of 80 years and mode of 79 years (range 18-96 years). The mean length of stay of the 517 catheters was 2.5 days (range 1 to 16 days).

The observation performed of the catheter insertion site and surrounding areas, using the Portuguese Infiltration Scale, enabled the identification and removal of 80 peripheral venous catheters due to infiltration (prevalence of 15.7%) in 48 patients (prevalence of 60% infiltration per patient). Sixty-seven infiltrations were documented as Grade One (83.8%), and 13 as Grade Two (16.2%). There were no Grade Three or Four infiltrations. The 48 patients presented between one to six infiltrations throughout the intravenous treatment; 28 patients had only one infiltration, 15 had two infiltrations, two had four infiltrations, one had five infiltrations, and another had six infiltrations.

The length of stay of the catheter in the patient, beginning with the insertion of the venous catheter until the identification of infiltration, was a mean of 1.7 day (from less than a day, to 8 days), the mode was one day (40%), with a standard deviation of 1.5. Almost half of the catheters remained at least one day, or 24 hours, in the patient (55%); only 32.5% remained two or three days.

Edema was the clinical sign that differentiated the degree of infiltration (edema < 2.5 cm, or from 2.5 - 15 cm in any direction); it was present in all assessments and was the essential condition to characterize the infiltration. The other clinical criteria alone did not characterize infiltration without the presence of any amount of edema.

In the evaluation of the psychometric properties of the Portuguese Infiltration Scale, the analysis of the adequacy of the sample was performed using the Kayser-Meyer-Olkin Measure of Sampling Adequacy (KMO) test, obtaining a value of 0.72 (considering a mean value between 0.7 - 0.8) with a Bartlett sphericity test ($X^2 (6) = 1066.64$, p < 0.000), which was statistically significant. Next, a solution with Varimax rotation was generated. Items with commonalities > 0.30 and loadings ≥0.45 were accepted, and it was not necessary to eliminate any items. The extracted solution was one-dimensional and explained 69.13% of the total variance. Thus, it was possible to state that the scale is valid and reliable for assessing the degree of infiltration (Table 1).

<table>
<thead>
<tr>
<th>Clinical criteria of the Portuguese Infiltration Scale</th>
<th>Factors, % explained variance and commonalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edema &lt; 2.5 cm or between 2.5 and 15 cm in any direction</td>
<td>F1 71.2% $h^2$ 0.804</td>
</tr>
<tr>
<td>Pele pálida</td>
<td>0.90</td>
</tr>
<tr>
<td>Frio ao toque</td>
<td>0.87</td>
</tr>
<tr>
<td>Dor</td>
<td>0.84</td>
</tr>
<tr>
<td>Cronbach’s alpha</td>
<td>0.73</td>
</tr>
</tbody>
</table>

Table 1. Loadings, percentage of explained variance, commonalities ($h^2$) and internal consistency of the Portuguese Infiltration Scale

F1 - nurse assessment
Discussion

The limitation of this study is the lack of an evaluation strategy by two independent professionals, in order to confirm the judgment of the degree of infiltration. The sample size may also have influenced the results, as the sample (n) may have been low and have not captured the Grade Three and Four infiltrations. In addition, this is the first study on the translation and adaptation of the Infiltration Scale in Portugal, and few studies on the subject were available in the literature, particularly on the method of assessment and documentation of infiltration. This fact limits the comparison of results and restricts the discussion.

The process of transcultural adaptation of the scale required grammatical adjustments, due to the cultural context and use in clinical practice, to ensure repeated measurement and to preserve the meaning of the original version. In this sense, the clinical criteria should be self-explanatory without generating doubts or ambiguities. In this regard and in accordance with the consensus reached by the research team and the expert panel, the criterion “No symptoms” was translated as “Sem sinais e sintomas”. It facilitates the understanding regarding the absence of signs and/or symptoms of infiltration, while “Assintomático” refers to the absence of symptoms of a disease, and did not make sense when translated.

For the criterion “Moderate-severe pain”, the terminology used by nurses in clinical practice to characterize the intensity of pain supported the translation to “Dor moderada a severa”, excluding the “grave” term, which does not characterize pain intensity.

The clinical criterion “Deep pitting tissue” was translated as “Edema depressível dos tecidos profundos.” According to the analysis of the research team and the translators, the word “profundo” was not appropriate. According to one of the translators, “Deep pitting edema” is an idiom referring to the depression created in the tissues when evaluating the depth of edema. From this discussion, the “profundo” word was then excluded.

The analysis of the scale by the panel of experts enabled the necessary adjustment in the translation of the criterion “Possible numbness” to “Possível diminuição da sensibilidade”. For the remaining items of the scale, 100% agreement in semantic, idiomatic, conceptual and experimental equivalence of the terms was achieved.

The participation of a translator with knowledge of the technical health terms, nurses and nursing professors/researchers with expertise in intravenous therapy was extremely important to make changes or eliminate insignificant terms, during the process of trans-cultural adaptation of the Infiltration Scale to the Portuguese culture.

A scale translated and adapted to the Portuguese context that characterized the infiltration as relevant is important, in particular due to the risk that inadvertent administration of medications or solutions in the tissues may generate. Therefore, the use of valid and reliable scales based on well-designed clinical criteria should be the strategy followed to monitor, assess, measure and document the degree of infiltration, in addition to supporting the implementation of interventions, as infiltration may lead to more serious consequences such as tissue necrosis, when irritating and/or vesicant solutions are infused.

The use of a scale enables early identification of the first signs and symptoms of infiltration, and a quick approach to the initiation of treatment and prevention of damage. The first intervention when identifying any degree of infiltration must be immediate removal of the catheter.

The evaluation of the venous catheter insertion site and adjacent areas should not be confined to the catheter utilization period, but should be extended for at least 96 hours after its removal, because the signs and/or symptoms may appear within three weeks, and may require surgical intervention or assessment/treatment by the wound team. It is important, as well, to evaluate catheter patency with 0.9% saline solution before the administration of medications, to identify possible signs of infiltration and prevent inadvertent infusion of medicinal products into the tissues. In case of doubt about the presence or absence of infiltration, the removal
of the catheter and its replacement by another in a distant region is recommended, preferably in the opposite limb.

The evaluation of the psychometric properties of the scale for construct validity of the study showed that the clinical criteria of the scale measured what one wanted to measure. The internal consistency, determined by a Cronbach’s alpha of 0.85, indicated that the scale was valid and reliable for assessing the degree of infiltration, but studies in other realities are needed, since this is the first study in the Portuguese scenario.

The main components exploratory factor analysis found that the scale consisted of a single factor, and was one-dimensional, with high loadings, particularly for the item “edema”. The increase of edema was the sign most identified by nurses at the catheter insertion site or in the surrounding areas during all infiltration assessments, and was supported by the literature.\(^{(19)}\)

The use of the Portuguese Infiltration Scale in the clinical setting found inconsistency in the analysis and interpretation of the degree of infiltration. As described below, only the presence of clinical criteria to characterize infiltration generated ambiguity and doubt on the record of the degree of infiltration when “Edema” was not associated with one or more clinical criteria, as in the presence of “Pele pálida” only, or “Frio ao toque”, or “Com ou sem dor”, which may be present both in Grade One as well as Grade Two, and the degrees of infiltration differ depending on the extent of edema (< 2.5 cm, between 2.5 - 15 cm). The same applies to the criteria “Pele pálida, translúcida” and “Edema extenso > 15 cm em qualquer direção”, which, when not associated with other clinical criteria, can be interpreted as Grade Three or Four; or the criterion “Frio ao toque” alone can characterize Grade One, Two, or Three. However, the clinical criterion of Grade Four, “Infiltração de qualquer quantidade de produtos derivados do sangue, irritantes, ou vesicantes”, is unique to this level and does not depend on the extent of edema, and other signs and symptoms to be categorized on the scale.

Thus, the Escala Portuguesa de Infiltração (Chart 2), with the inclusion of the words “podendo associar-se a”, was proposed for Grades 2, 3 and 4. It could support the interpretation of the degree of infiltration, considering that the identification of edema at the insertion site or in the surrounding areas is an important condition to characterize the infiltration in these Grades. There is an exception for the clinical criteria “Infiltração de qualquer quantidade de produtos derivados do sangue, irritantes, ou vesicantes” in Grade 4, which alone determined this degree of infiltration, but can be associated to one or more clinical criteria.

**Chart 2. Portuguese scale Infiltration**

<table>
<thead>
<tr>
<th>Grau</th>
<th>Critérios clínicos</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Sem sintomas</td>
</tr>
<tr>
<td>1</td>
<td>- Pele pálida</td>
</tr>
<tr>
<td></td>
<td>- Edema &lt; 2.5 cm em qualquer direção</td>
</tr>
<tr>
<td></td>
<td>- Frio ao toque</td>
</tr>
<tr>
<td></td>
<td>- Com ou sem dor</td>
</tr>
<tr>
<td>2</td>
<td>Edema entre 2.5 e 15 cm em qualquer direção podendo associar-se a:</td>
</tr>
<tr>
<td></td>
<td>- Pele pálida</td>
</tr>
<tr>
<td></td>
<td>- Frio ao toque</td>
</tr>
<tr>
<td></td>
<td>- Com ou sem dor</td>
</tr>
<tr>
<td>3</td>
<td>Edema extenso &gt; 15 cm em qualquer direção, podendo associar-se a:</td>
</tr>
<tr>
<td></td>
<td>- Pele pálida, translúcida</td>
</tr>
<tr>
<td></td>
<td>- Frio ao toque</td>
</tr>
<tr>
<td></td>
<td>- Dor leve a moderada</td>
</tr>
<tr>
<td></td>
<td>- Possível diminuição da sensibilidade</td>
</tr>
<tr>
<td>4</td>
<td>Infiltração de qualquer quantidade de produtos derivados do sangue, irritantes ou vesicantes podendo associar-se a:</td>
</tr>
<tr>
<td></td>
<td>Ou</td>
</tr>
<tr>
<td></td>
<td>Edema extenso &gt; 15 cm em qualquer direção podendo associar-se a:</td>
</tr>
<tr>
<td></td>
<td>- Pele pálida, translúcida</td>
</tr>
<tr>
<td></td>
<td>- Pele tensa, com perda de fluidos</td>
</tr>
<tr>
<td></td>
<td>- Pele descorada, com hematoma e edema</td>
</tr>
<tr>
<td></td>
<td>- Edema depressível dos tecidos</td>
</tr>
<tr>
<td></td>
<td>- Comprometimento circulatório</td>
</tr>
<tr>
<td></td>
<td>- Dor moderada a severa</td>
</tr>
</tbody>
</table>

**Conclusion**

The scale adapted to the Portuguese culture presented linguistic equivalence to that published by the Infusion Nurses Society; it proved to be valid and reliable, with good internal consistency to assess infiltration in the clinical setting. The inclusion of the expression “podendo associar-se a” has made it a self-explanatory scale, as it facilitates the assessment process and allows for greater discriminative capacity in the assessment of the degree of infiltration.

The results with the use of the scale in clinical context allowed for the finding of a 60% prevalence of infiltration by patient, which would not have been possible to identify without such a scale. The
systematic evaluation of infiltration with the use of this scale can support nurses’ decision-making and the implementation of preventive measures.

It is suggested that studies should be conducted to validate the Portuguese Infiltration Scale in other clinical settings, with larger samples and interobserver evaluators, since the Grade Three and Four infiltrates were not identified in this study.

Acknowledgements
Our acknowledgment to the Coordination for the Improvement of Higher Education Personnel (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - CAPES, PhD student scholarship to Luciene Muniz Braga - Process 0867/14-4); to the professionals who performed the translation and back translation, and to the nurses of the Medicine Service of Centro Hospitalar e Universitário de Coimbra, who participated in the panel of experts.

Collaborations
Braga LM, Parreira PMSD, Salgueiro-Oliveira AS and Henriques MAP contributed to the project design, literature review, analysis and interpretation of data and writing of the article. Arreguy-Sena C contributed to the project design, data analysis and writing of the article. All authors approved the final version to be published.

References
Burnout Syndrome among master’s and doctoral students in nursing
Síndrome de Burnout entre mestrandos e doutorandos em enfermagem

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Júlia Trevisan Martins²
Maria do Carmo Fernandes Lourenço Haddad²
Maria Lucia do Carmo Cruz Robazzi³
Marcela Maria Birolim²

Abstract
Objective: To investigate the occurrence of burnout syndrome and to identify its predictors in master’s and doctoral students of graduate nursing programs.

Methods: A cross-sectional, descriptive, analytic study performed with 129 master’s and doctoral students from three public universities. The research instruments were a semi-structured questionnaire to characterize the participants, and the Maslach Burnout Inventory™ - Student Survey. Data were analyzed using descriptive, inferential statistics and multiple linear regressions.

Results: It was found that 11.6% of postgraduate students had signs of burnout. The variables related to their perception about the course and its requirements were those that contributed most to the occurrence of the dimensions of the syndrome. The main predictors were: dissatisfaction with the study topic, lower perceptions of social support, and leisure opportunities.

Conclusion: There were signs of burnout syndrome occurring in the studied sample; the course’s requirements played a relevant role among the syndrome predictors.
Introduction

Burnout syndrome is characterized as a process of response to workplace overload that results in exhaustion. Therefore, deterioration occurs in the fundamental relationship of a person with her occupation, leading to reduced work performance, interpersonal relationships, organizational commitment, and a decline in health.\(^1\)\(^2\)

Burnout syndrome has been exclusively related to the work process for a long time, especially among professionals with high interpersonal contact. However, with the expansion of studies on this phenomenon, the concept has been found to be applicable to other occupational contexts; in this case, students experience the academic environment, as they are integrated into an organizational structure whose activities are established and guided in a compulsory way for the specific purpose of acquiring an academic degree.\(^3\)

Among students, burnout syndrome is defined as a process which includes three dimensions: emotional exhaustion, understood as the feeling of being drained due to study demands; depersonalization, characterized by attitude of distancing oneself from scholarly work; and, reduced academic effectiveness, explained by the perception of being incompetent as a student.\(^4\)

In the nursing area, the syndrome has been reported in professional qualification activities, in undergraduate and residency courses, due to the variety of stressors inherent in the academic environment.\(^5\)\(^-\)\(^8\) However, studies on this syndrome in \textit{stricto sensu} graduate students are incipient, although there are effectively stressful situations in researchers’ educational program.\(^9\)

Causes of overload and exhaustion in graduate students are related to high levels of academic requirements that are relevant to the complex functions of teaching, research and publishing. These activities require intense mental effort and many hours of study.\(^10\)

When it does not lead to abandoning the course, lack of adaptation to this reality can generate mental suffering, sleeping difficulties, health problems (physical or psychological), substance abuse, and even suicide.\(^10\)\(^11\)

Given the above, the following guiding questions emerged: Does burnout syndrome occur in master’s and doctoral students of graduate programs in nursing (GPN)? What are the predictive characteristics of the syndrome in these students?

Investigating the occurrence of burnout syndrome and its predictive factors in \textit{stricto sensu} graduate students is fundamental for both managers of these programs and the graduate students themselves, in order to adopt strategies to reduce tension, stress, and illness deriving from this academic level.

Thus, this study aimed to investigate the occurrence of burnout syndrome and to identify its predictors in master’s and doctoral students of graduate programs in nursing.

Methods

A cross-sectional, descriptive, analytic study performed with master’s and doctoral students of three GPN of public universities in the state of Paraná, Brazil. The courses included in this study are recognized by the Coordination for the Improvement of Higher Education Personnel (CAPES) and have proposed curricula with a workload ranging from 600 to 1125 hours, divided between theoretical-practical classes and the preparation of the thesis/dissertation. For a graduate student to obtain the academic level of the master’s/doctorate, he must pass a qualifying examination and defense, in addition to completing the minimum workload.

At the time of the survey of potential participants, 165 nurses enrolled in the three GPN were identified. The sample size was calculated by adopting a prevalence of 50% for the presence of the phenomenon, a 95% confidence interval, and a maximum error of 5%, resulting in a minimum of 115 respondents.

To collect the data, a semi-structured questionnaire was developed with socio-demographic, academic, occupational, lifestyle, and health
variables. Three research nursing professors in the area of occupational health previously evaluated the instrument and suggested modifications for its improvement.

To evaluate burnout syndrome, the Maslach Burnout Inventory™ - Student Survey (MBI-SS) was used, a self-administered questionnaire consisting of 15 items, which evaluated three conceptual dimensions on a Likert-type scale (0-6): emotional exhaustion, depersonalization, and academic effectiveness. It is considered indicative of burnout syndrome when a person has both high scores in emotional exhaustion and depersonalization, and low scores in academic effectiveness, according to the cutoff points determined by the authors.\(^{(12)}\)

Data collection was performed from November of 2014 to February of 2015, by means of an electronic questionnaire sent by email with the invitation to participate. During this period, 129 graduate students became participants, with the proportional participation of each subdivision of the population.

Data were analyzed using descriptive statistics, frequency and percentage calculations for categorical variables, and median, minimum, and maximum for continuous variables. The Cronbach’s Alpha was used to evaluate the internal consistency of the MBI-SS. Subsequently, a bivariate analysis was performed comparing the independent (demographic, academic, occupational, lifestyle and health) and dependent (MBI-SS dimensions) variables, using Spearman’s correlation coefficient for quantitative variables and Mann-Whitney for the qualitative variables. Then, a forward selection multiple linear regression was performed for each of the outcomes, including all the variables that were statistically significant (\(p<0.05\)) in the bivariate analysis. The analyses were performed using the Statistical Package for the Social Sciences™, version 20.0.

Licenses to use the MBI-SS were acquired from the company Mind Garden, which manages the instrument copyright. The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 35451514.6.0000.5231.

Results

Regarding the sociodemographic data, it was found that among the 129 participants, ages ranged between a minimum of 22 and a maximum of 61 years, with a mean age of 32.3 years for the master’s students and 35 as the mean age of the doctoral students. Most students were female (89.9%; \(n=116\)), married (58.9%; \(n=76\)) and without children (62.8%; \(n=81\)). The individual monthly income ranged from R$1,500.00 to R$12,000.00, with a mean of R$3,764.00 (corresponding, in February 2015, to US$526.32, US$4,210.53 and US$1,320.70 respectively).

Regard the training profile, graduate students who completed a nursing degree in public schools predominated (73.6%; \(n=95\)), and the time since graduation ranged between one and 34 years, with a mean of 8.6 years. It was found that 12.4% (\(n=16\)) of nurses had no previous professional practice experience in the area.

Regarding the academic characteristics, 61.2% (\(n=79\)) were enrolled in a master’s course, and 38.8% (\(n=50\)) in a doctoral course, spending a mean of 4.8 hours every day to study, with extremes of zero and 15 hours. They considered their relationship with their academic advisors to be excellent or very good (76.7%; \(n=99\)). The mean satisfaction with the study topic was 8.5 points, and the satisfaction with the graduate program was 7.5 points, on a scale of zero to 10. Although most manifested never having the intention to quit the program, it was found that 48.8% (\(n=63\)) of the sample had indeed had this intention.

Regarding occupational characteristics, 35.7% (\(n=50\)) were exclusively dedicated to the graduate program and received grants, while 64.3% (\(n=83\)) balanced study and work. Regarding the type of work activity, 27.1% (\(n=35\)) were professors, 37.2% (\(n=48\)) worked in nursing care, and 13.2% (\(n=17\)) had two or more jobs.

The MBI-SS had satisfactory internal consistency (\(\alpha=0.719\)), characterized as reliable, and having good internal consistency.
Regarding the classification of the MBI-SS dimensions, based on the cut-off points, it was found that 69.8% (n=90) of master’s and doctoral students had high scores of emotional exhaustion, 27.1% (n=35) had high depersonalization, and 24.8% (n=32) had low academic effectiveness. By associating these dimensions, it was found that 11.6% (n=15) of the sample had signs of burnout: 11.4% master’s students and 12.24% doctoral students. Of these individuals, most were women (93.3%), up to 30 years of age (66.7%), and balanced study and work (66.7%). In addition to these graduate students, it was found that 14.7% of participants had high scores of emotional exhaustion and depersonalization, and could be considered prone to burnout.

Regression analyses performed for the syndrome dimensions are shown in table 1. The predictive model of emotional exhaustion consists of seven variables that explain 52.4% of the occurrence, and show that perception of pleasure, satisfaction with the study topic, and social support were inversely associated with that dimension. Thus, the lower the perceptions of leisure opportunities, social support and satisfaction with the study topic, the greater the emotional exhaustion score. Other variables participated directly in the model, namely, the presence of thoughts of withdrawing from the graduate program, anxiety related to studies, the difficulty of reconciling studies and personal life, and the pressure to produce scientific publications related to higher emotional exhaustion. Four predictive variables explained 45.9% of the occurrence of depersonalization. The variable thinking of quitting the graduate course had direct participation, whereas the other variables inversely related to each other: the smaller the perceptions of leisure opportunities, satisfaction with the postgraduate program and the study topic, the higher the score of depersonalization. The variables, social support, satisfaction with the study topic, and relationship with the academic advisor, were positively associated with the academic effectiveness dimension and explained 25.1% of the occurrence of this dimension. Therefore the worse the perceptions of these issues, the lower the scores of this dimension.

### Table 1. Predictors of three dimensions of burnout syndrome among nursing master’s and doctoral students

<table>
<thead>
<tr>
<th>Models</th>
<th>Beta</th>
<th>p-value</th>
<th>R²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional exhaustion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leisure</td>
<td>-0.217</td>
<td>0.004</td>
<td>0.724</td>
</tr>
<tr>
<td>Thinking about withdrawing from the postgraduate course</td>
<td>0.256</td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td>Anxiety related to studies</td>
<td>0.002</td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td>Difficulty reconciling studies and personal life</td>
<td>0.207</td>
<td>0.003</td>
<td></td>
</tr>
<tr>
<td>Pressure for scientific publication</td>
<td>0.264</td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td>Satisfaction with the topic study</td>
<td>-0.174</td>
<td>0.010</td>
<td></td>
</tr>
<tr>
<td>Social support</td>
<td>-0.177</td>
<td>0.016</td>
<td></td>
</tr>
<tr>
<td>Depersonalization</td>
<td></td>
<td></td>
<td>0.677</td>
</tr>
<tr>
<td>Thinking about withdrawing from the graduate course</td>
<td>0.298</td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td>Leisure</td>
<td>-0.345</td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td>Satisfaction with the graduate course</td>
<td>-0.221</td>
<td>0.003</td>
<td></td>
</tr>
<tr>
<td>Satisfaction with the topic study</td>
<td>-0.182</td>
<td>0.011</td>
<td></td>
</tr>
<tr>
<td>Academic effectiveness</td>
<td></td>
<td></td>
<td>0.501</td>
</tr>
<tr>
<td>Social support</td>
<td>0.220</td>
<td>0.012</td>
<td></td>
</tr>
<tr>
<td>Satisfaction with the topic study</td>
<td>0.255</td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td>Relationship with the academic advisor</td>
<td>0.238</td>
<td>0.006</td>
<td></td>
</tr>
</tbody>
</table>

Coefficients of determination: emotional exhaustion R²=0.524; depersonalization R²=0.459; academic effectiveness R²=0.251; *the three models were statistically significant (p=0.000); R² - Multiple correlation coefficient

**Discussion**

The limitations of this study are related to its cross-sectional design, by investigating both the exposure and outcome, and thus it has low generalizability. It must be considered that it was a self-reported assessment and, therefore, responses might have occurred that are congruent with acceptable societal standards. In addition, there is a tendency for self-denial involved in the manifestation of burnout, which is therefore first perceived by colleagues.

This study highlighted important information about the phenomenon under study, indicating the need to implement actions at the institutional level, in order to promote mental health in graduate students and, consequently, prevent health problems from the syndrome.

The participants’ characteristics showed the prevalence of married females with no children, with a mean age of 32 years, who were working while undertaking the graduate program. This preference can be related to an insufficient number of grants offered by programs, as well the grant
values provided within Brazil, which, in this study, represent the minimum value of income.\(^{(9)}\) Therefore, these nurses achieved better financial possibilities by choosing employment over exclusive dedication to graduate school. However, this is an option that may predispose individuals to exhaustion, since the work tasks of nurses are by themselves considered to produce physical and psychological overload.\(^{(13)}\)

The presence of students without professional work experience in the area indicated that some nurses opted to join the *stricto sensu* graduate program after completing undergraduate studies. This choice has proved to be a tendency in these educational levels,\(^{(14,15)}\) even with the professional immaturity that is peculiar to most recent undergraduates, which can cause difficulties in the development of research related to practice.

Although the sociodemographic and occupational variables of graduate students were not statistically significant, and consequently did not compose the predictive models of the burnout syndrome, it should be considered that among students with signs of the syndrome, young women prevailed who balanced studies and work. Research identified that women who reconciled studying with work and household tasks, including care for children, were more likely to experience physical and mental strain, making them more susceptible to illness.\(^{(9,13,16)}\)

Similarly, the type and the period of the program were not predictors. This suggests that master’s and doctoral studies are equally intense and complex during their courses.

Regarding the signs of burnout syndrome, it was present in 11.6% of the study participants. This result differs from those obtained by studies performed with nursing residents and undergraduates, which ranged from 20.8% to 24.7%.\(^{(7,8)}\)

However, it should be noted that 14.7% manifested a predisposition to the syndrome due to high emotional exhaustion and depersonalization, but were not part of the prevalence because they still demonstrated academic effectiveness. Another relevant datum was the presence of a high score of emotional exhaustion in 69.8% of the participants, demonstrating that most were overworked due to the insufficiency of psychological coping resources to deal with academic demands. The presence of emotional exhaustion is worrying because it is the first dimension of the syndrome to emerge, it is the central characteristic and is associated with student absenteeism, chronic fatigue, mental health decline, and memory capacity and concentration, and these conditions can adversely affect the process of educational development.\(^{(6,17,18)}\)

The predictive model of emotional exhaustion revealed that the intention to withdraw from the course, and anxiety, were associated with this dimension. These findings are similar to those obtained with students in other programs of study.\(^{(19,20)}\) Anxiety is an emotional experience derived from the possibility of experiencing unpleasant future situations, and may be related to the fear of not achieving one’s academic expectations.\(^{(21)}\)

Among these tasks that require high mental load and lead to exhaustion, the pressure to produce publishable scientific texts in periodicals with a high impact factor was reported, which requires a lot of time for the graduate student, along with mental, physical and emotional skills and energy. In addition, the pressure to publish is common in higher educational institutions, present in all areas of knowledge worldwide, and publishing has been considered to certify the competence of researchers. Therefore, the presence of the “publish or perish” dilemma is expected in the *stricto sensu* training, taking into account its objectives. Thus, conducting educational activities that aim to encourage, clarify and demystify the article writing can be an essential and effective strategy for publication and, consequently, reduce mental distress and exhaustion of the graduate student.\(^{(11,22)}\)

In a study performed in an Australian university nursing school,\(^{,}\) it was reported that the implementation of a strategic plan to engage students and educators was essential to motivate the production of scientific papers. During 20 months, there were workshops on practical aspects of publication, scientific writing, presentation process and paper format, using search engines, where to publish, and other topics relevant to publication. These work-
shops were conducted by editors of academic journals and experienced researchers, and resulted in an improvement of participants’ skills.\(^{(22)}\)

In addition, considering the reality worldwide,\(^{(11,22)}\) there are aspects related to difficulty and the obligation to publish, which may cause tension in graduate students, such as uncertainty about paper acceptance, the contributions and criticism of reviewers, and the publication costs, among others.

The predictors of few leisure opportunities, and difficulty reconciling personal life and studies, suggest that master’s and doctoral students have insufficient time for life outside the university, prioritizing studies to the detriment of other aspects of their lives. Thus, they may consider that leisure is wasted time given the numerous activities within the graduate course deadlines. By analyzing the predominant characteristics of the sample, it can be stated that they face a triple journey including studies, work and family, which, if unbalanced, contribute to exhaustion.\(^{(6,23)}\)

Perception of social support was inversely related to emotional exhaustion, with suggests that the support provided by family, friends and colleagues to master’s and doctoral students is essential for enduring the difficulties encountered in graduate school.\(^{(23,24)}\)

Depersonalization is a dimension that reflects the distance between study and its explanatory model. It was found that most of the variables also explained emotional exhaustion. This can be understood by the strong relationship between these dimensions in burnout syndrome, as depersonalization is an adaptative psychological response against emotional exhaustion.\(^{(17)}\)

With regard to lesser involvement of students because of dissatisfaction with the graduate program, studies have revealed that graduate students expect a structure from the program that meets all their idealized training needs and fosters minimum conditions for research. Not having those expectations met can contribute to frustration with the program, as well as contribute to the intention to withdraw from the course.\(^{(23,25,26)}\)

Regarding academic effectiveness, a good interpersonal relationship with the academic advisor was positively related to this dimension. It was highlighted that the advisor-student relationship is one of the most exploited aspects by studies, due to being recognized as a facilitator in the production of quality aspects, in the learning process, and in the self-efficacy beliefs of graduate students. Thus, a satisfactory relationship with the academic advisor develops in the graduate student’s exploratory behaviors to improve her skills, and motivates her in the development of the thesis/dissertation. However, lack of support and feedback, differences and disagreements related to the study increase the tension, stress and academic ineffectiveness.\(^{(27-29)}\)

Satisfaction with the study topic was a predictor of all the dimensions of the syndrome, and indicated that the dissatisfaction with this item leads to exhaustion, less involvement in the study, and the sense of academic incompetence. The study topic is the thesis/dissertation focus, and the object of greatest commitment and involvement for the graduate student, thus, it is believed that investigating that to which one does not have much affinity may become a source of psychological distress and stress. The inverse can be also true, namely, studying what is considered attractive and relevant is a protector against the syndrome.\(^{(30)}\) However, it is known that most of the times, this theme is attributed by the academic advisor in order to fulfill a project in her own research line linked to GPN, which may or may not serve the interest of master’s/doctoral students.

**Conclusion**

The study demonstrated signs of the occurrence of burnout in the sample. Variables related to the perception of master’s and doctoral students about the course and its requirements prevailed in predictive models of the syndrome dimensions. Dissatisfaction with the study topic, lower perceptions of social support, and leisure opportunities were the main predisposing factors.
Acknowledgements
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Collaborations
Galdino MJQ and Martins JT contributed to the project concept, analysis and interpretation of data, study writing, critical review of intellectual content and final approval of the version to be published. Haddad MCFL, Robazzi MLCC and Birolim MM collaborated in the analysis and interpretation of data, relevant critical review of the intellectual content, and final approval of the version to be published.

References
Severity of liver disease and quality of life in liver transplantation
Gravidade da doença hepática e qualidade de vida no transplante de fígado

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Clébia Azevedo de Lima³

Abstract
Objective: To analyze the influence of liver disease severity on the quality of life of patients before and after liver transplantation.

Methods: A descriptive study with 150 liver transplant recipients over 18 years of age. Severity was assessed using Child and MELD, and the Liver Disease Quality of Life was administered. The t-test or Mann-Whitney test was used to compare the mean values of the domains, and an ANOVA or Kruskal-Wallis test was used for between group comparison.

Results: Prior to transplantation, patients with Child class C had lower quality of life scores than those with Child class A. Patients with MELD lower than or equal to 15 had a significant increase of mean values in ten domains, whereas patients with MELD scores greater than 15 had increased mean values in 12 domains.

Conclusion: There was a negative influence of severity on quality of life prior to transplantation, according to Child-Turcotte-Pugh. The MELD did not interfere significantly in the post-transplantation outcomes, even though the mean values increased.

Keywords
Liver transplantation; Quality of life; Nursing assessment; Patient acuity; Preoperative period; Postoperative period

Descritores
Transplante de fígado; Qualidade de vida; Avaliação em enfermagem; Gravidade do paciente; Período pré-operatório; Período pós-operatório

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Conflicts of interest: none to declare.
Recognition of the severity of liver disease is crucial to provide the only possible remedy for reversing the terminal situation, which impacts the biological, psychological and social levels. In 2013, Brazil ranked second in absolute numbers for liver transplantation among 30 surveyed countries, second only to the United States. Between 2005 and 2015, 14,817 liver transplants were performed.

General indicators of the severity of liver failure are used in the assessment of candidates for transplantation: Child-Turcotte-Pugh (CTP) and the Model for End-stage Liver Disease (MELD). These indicators are used to establish liver transplantation priority, disease prognosis, prediction of survival and mortality after transplantation, in addition to serving as a parameter for assessing health-related quality of life (HRQOL). The CTP Classification is based on latest results of liver function laboratory tests, including bilirubin, albumin, prothrombin time, and severity of patient symptoms regarding ascites and degree of hepatic encephalopathy. Results are scored on a scale ranging from 5 to 15 points; they are stratified into class A (5-6), B (7-9) or C (10-15), where greater values indicate greater disease severity, providing predictive values of one-to-two year patient survival. Since 2002, the MELD scale has been used by the Organ Procurement and Transplantation Network (OPTN) as a basis for allocation of deceased donor livers for transplantation among adults in the United States. The liver transplant allocation system has followed the criterion of severity of liver disease based on the MELD score since 2006, regardless of the amount of time on the waiting list. The score is based on a formula whose variables are: serum creatinine (Cr), total bilirubin (BT), prothrombin time (PT) and international normalized ratio (INR), ranging from 6 to 40 points; it also considers the disease progression and therapeutic indication, and is able to predict the three-month mortality risk. During the literature review, relevant studies on the impact of using the MELD on patient survival on the waiting list for liver transplantation were identified. However, studies evaluating the relationship between severity criteria and quality of life of patients post-transplantation are still incipient, indicating the need for further studies to more deeply investigate the topic, also considering the risks and high costs related to the procedure.

The quality of life of these individuals can be assessed by generic and specific instruments. Among the generic instruments already validated for the Brazilian population, there are: the Medical Outcomes Study Short-Form 36 (SF-36), the World Health Organization Quality of Life Instrument (WHOQOL), and its abbreviated version WHOQOL-bref. Instruments for the assessment of patients with liver disease include the Hepatitis Quality of Life Questionnaire (HQOLQ), the Chronic Liver Disease Questionnaire (CLDQ), and the Liver Disease Quality of Life (LDQOL) stand out. The LDQOL was selected for this study, due to its ability to identify issues that are more specific than the impact of liver disease and the individual’s response to liver transplant.

From this perspective, the study aimed to analyze the influence of the severity of liver disease on the quality of life of patients before and after liver transplantation.

**Methods**

A quantitative, descriptive study performed in the Liver Transplant Center of Ceará/University Hospital Walter Cantidio (HUWC), a national reference center for liver transplantation.

To determine population size, the number of patients remaining alive, who had transplants between 2002 and 2011, was considered, totaling 439 patients. The calculation for a finite sample was per-
formed, with a 95% confidence level and a sample error of 4%. The following inclusion criteria were used: patients undergoing liver transplantation at least six months prior to the study, eighteen years of age or older, and who were regularly monitored in the transplant service.

Transplant recipients transferred to other states, patients undergoing liver transplantation due to fulminant hepatitis or double liver-kidney hepatitis, patients with hearing loss and mental disability were excluded from the study. In total, 150 patients participated in the survey, which was considered a representative number.

Data were collected from July 2012 to January 2013, by administering an instrument developed by researchers, containing demographic (gender, age, race) and clinical (etiolo gy, CTP and MELD) aspects and the LDQOL questionnaire. The questionnaire included 75 questions about signs and symptoms of the disease and the effect of treatment on daily living, distributed in 12 domains: symptoms related to liver disease, effects of liver disease on activities of daily living, concentration, memory, sexual function, sexual problems, sleep, loneliness, hopelessness, quality of social interaction, health distress, and self-perceived stigma of liver disease. The questions are answered by evaluating the frequency, intensity, or agreement with the statements on a Likert scale, with scores ranging from zero to six points. It is a specific tool for assessment of the quality of life in liver disease, translated and validated for the Brazilian population, in which the questions are answered by evaluating the frequency, intensity, or agreement with the statements on a Likert scale, with scores ranging from zero to six points.

The LDQOL was administered by the researchers through interviews, six months after transplantation, during the postoperative follow-up visits at the liver transplantation clinic. It was administered twice for each patient: the first, considering the pre-transplantation period experienced by the patient, and then considering the current quality of life (after transplantation).

The Statistical Package for the Social Sciences (SPSS) was used for data analysis. The comparison of means before and after transplantation was performed using the Student’s t-test or Mann-Whitney when two means were assessed, and by ANOVA or Kruskal-Wallis when three or more means were assessed. A significance level of 0.05 was adopted.

Patients authorized their participation by signing the Terms of Free and Informed Consent Form. The study was approved according to the standards of the National Health Council - Resolution 196/96 - Protocol: 041.06.12 of the University Hospital Ethics Walter Cantídio Committee, Federal University of Ceará.

### Results

Regarding demographics, among patients undergoing liver transplantation, there was a predominance of males (n=120; 80%); the prevalent age range was 40 to 59 years of age (n=71; 47.3%), followed by 60 to 76 years (n=51; 34%), and finally 18 to 39 years (n=28; 18.7%), with a mean of 52.4 years. The race with the highest proportion was mixed (n=90; 60%), followed by white (n=45; 30%), black (n=14; 9.3%), and indigenous (n=1; 0.7%).

Alcohol abuse was the most prevalent etiology of liver disease in the study group, with a total of 58 (38.7%) patients, followed by hepatitis C (n=42; 28%), and cryptogenic cirrhosis (n=22; 14.7%), in addition to other diseases such as hepatitis B, Wilson’s disease and hepatocellular carcinoma (HCC).

Regarding the criterion of disease severity for allocation in the liver transplantation waiting list before surgery, most (n=116) patients had a MELD equal to or greater than 15, corresponding to 77.3% of the sample; 15 (10%) had a MELD less than 15; and, 19 patients (12.7%) had no MELD charted. Preoperatively, 56 patients (37.3%) were classified as CTP level C, 76 (50.7%) as level B, and only 9 (6%) as level A; 9 (6%) had no CTP documented (Table 1).
Severity of liver disease and quality of life in liver transplantation

The analysis of the influence of the severity of liver disease according to the CTP classification on the quality of life before transplantation showed that patients with Child class C had lower mean values compared to patients with Child classes A and B, in ten of 12 domains, except for sexual function and sexual problems. There was a greater compromise (p<0.05) symptoms related to liver disease, effects of liver disease on activities of daily living, concentration, memory, quality of social interaction, sleep and stigma of liver disease, indicating a significant difference based on multivariate comparison of the Child classes C and A groups in the domains: symptoms (56.9 vs. 80.7; p=0.001), effects of liver disease (51.7 vs. 73.7; p=0.017), concentration (47.6 vs. 77.7; p=0.014), memory (49.3 vs. 78.1; p=0.021), social interaction (62.9 vs. 80.5; p=0.023), sleep (46.6 vs. 67.4; p=0.034) and stigma (49.2 vs. 77.4; p=0.043). The differences between Child classes B and C were significant in the domains: symptoms (56.9 vs. 66.9; p=0.016), concentration (47.6 vs. 64.0; p=0.005), memory (49.3 vs. 64.2; p=0.013), social interaction (62.9 vs. 70.9; p=0.038) and stigma (49.2 vs. 62.5; p=0.050).

The comparison of CTP before and after transplantation was not performed because there was no documentation of the scale after transplantation.

The analysis of the comparison of the LDQOL quality of life domains before and after liver transplantation according to the MELD criterion less than or equal to 15, showed a significant increase in the means in ten of 12 domains, with a higher statistical significance (p<0.0001) in the domains: symptoms (68.0 vs 93.0), effects of liver disease (49.2 vs. 87.2), health distress (53.3 vs. 85.3) and stigma of liver disease (51.1 vs. 95.5), whereas patients with MELD scores greater than 15 showed significant results in all domains.

On the other hand, there were no significant differences in the evaluation of the influence of the severity of liver disease according to the MELD on post-transplant quality of life. The results were homogeneous.

Table 1. Analysis of the influence of CTP on LDQOL quality of life domains before liver transplantation (n=141)

<table>
<thead>
<tr>
<th>LDQOL Domains</th>
<th>Child A Mean ± SD</th>
<th>Child B Mean ± SD</th>
<th>Child C Mean ± SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms related to liver disease</td>
<td>80.7 ± 16.9</td>
<td>68.9 ± 18.5</td>
<td>56.9 ± 23.2</td>
<td>0.001</td>
</tr>
<tr>
<td>Effects of liver disease</td>
<td>73.7 ± 17.3</td>
<td>58.2 ± 21.9</td>
<td>51.7 ± 22.6</td>
<td>0.015</td>
</tr>
<tr>
<td>Concentration</td>
<td>77.7 ± 24.4</td>
<td>64.0 ± 30.3</td>
<td>47.6 ± 29.0</td>
<td>0.001</td>
</tr>
<tr>
<td>Memory</td>
<td>78.1 ± 33.3</td>
<td>64.2 ± 30.0</td>
<td>49.3 ± 28.5</td>
<td>0.003</td>
</tr>
<tr>
<td>Quality of social interaction</td>
<td>80.5 ± 10.7</td>
<td>70.9 ± 17.8</td>
<td>62.9 ± 20.0</td>
<td>0.007</td>
</tr>
<tr>
<td>Health distress</td>
<td>56.6 ± 27.1</td>
<td>57.1 ± 27.3</td>
<td>50.8 ± 30.5</td>
<td>0.459</td>
</tr>
<tr>
<td>Sleep</td>
<td>67.4 ± 20.5</td>
<td>55.5 ± 24.6</td>
<td>46.6 ± 20.6</td>
<td>0.014</td>
</tr>
<tr>
<td>Loneliness</td>
<td>93.4 ± 19.6</td>
<td>89.9 ± 19.1</td>
<td>89.5 ± 19.1</td>
<td>0.851</td>
</tr>
<tr>
<td>Hopelessness</td>
<td>82.5 ± 19.6</td>
<td>76.1 ± 23.6</td>
<td>68.6 ± 23.5</td>
<td>0.099</td>
</tr>
<tr>
<td>Stigma of liver disease</td>
<td>77.4 ± 31.3</td>
<td>62.5 ± 30.5</td>
<td>49.2 ± 34.6</td>
<td>0.013</td>
</tr>
<tr>
<td>Sexual function*</td>
<td>75.0 ± 36.8</td>
<td>58.3 ± 34.1</td>
<td>64.9 ± 29.0</td>
<td>0.511</td>
</tr>
<tr>
<td>Sexual problems*</td>
<td>75.9 ± 41.2</td>
<td>68.0 ± 32.8</td>
<td>76.6 ± 30.2</td>
<td>0.505</td>
</tr>
</tbody>
</table>

*The Sexual function domain had n = 47, and Sexual problems had n = 40

Table 2. Analysis of the quality of life domains of the LDQOL scale before and after liver transplantation in patients with MELD scores lower than or equal to 15 (n=15)

<table>
<thead>
<tr>
<th>LDQOL Domains</th>
<th>Pre-transplantation Mean ± SD</th>
<th>Post-transplantation Mean ± SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms related to liver disease</td>
<td>68.0 ± 13.8</td>
<td>93.0 ± 6.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Effects of liver disease</td>
<td>49.2 ± 21.9</td>
<td>87.2 ± 13.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Concentration</td>
<td>65.7 ± 30.1</td>
<td>93.7 ± 12.0</td>
<td>0.007</td>
</tr>
<tr>
<td>Memory</td>
<td>65.1 ± 32.2</td>
<td>85.2 ± 19.2</td>
<td>0.070</td>
</tr>
<tr>
<td>Quality of social interaction</td>
<td>67.0 ± 19.7</td>
<td>83.8 ± 10.1</td>
<td>0.002</td>
</tr>
<tr>
<td>Health distress</td>
<td>53.3 ± 23.5</td>
<td>85.3 ± 15.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Sleep</td>
<td>51.9 ± 24.6</td>
<td>77.3 ± 16.4</td>
<td>0.002</td>
</tr>
<tr>
<td>Loneliness</td>
<td>84.7 ± 26.0</td>
<td>99.4 ± 2.0</td>
<td>0.046</td>
</tr>
<tr>
<td>Hopelessness</td>
<td>74.3 ± 19.8</td>
<td>92.6 ± 13.7</td>
<td>0.012</td>
</tr>
<tr>
<td>Stigma of liver disease</td>
<td>51.1 ± 32.8</td>
<td>95.5 ± 6.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Sexual function*</td>
<td>68.7 ± 27.6</td>
<td>64.5 ± 39.3</td>
<td>0.895</td>
</tr>
<tr>
<td>Sexual problems*</td>
<td>77.7 ± 25.6</td>
<td>63.8 ± 47.4</td>
<td>0.655</td>
</tr>
</tbody>
</table>

*The Sexual function and Sexual problems domains had n = 4

Table 3. Analysis of the quality of life domains of the LDQOL scale before and after liver transplantation in patients with MELD scores greater than 15 (n=15)

<table>
<thead>
<tr>
<th>LDQOL Domains</th>
<th>Pre-transplantation Mean ± SD</th>
<th>Post-transplantation Mean ± SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms related to liver disease</td>
<td>63.1 ± 21.4</td>
<td>93.5 ± 9.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Effects of liver disease</td>
<td>57.5 ± 22.5</td>
<td>91.6 ± 11.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Concentration</td>
<td>57.7 ± 30.7</td>
<td>91.9 ± 15.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Memory</td>
<td>59.6 ± 30.7</td>
<td>82.3 ± 22.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Quality of social interaction</td>
<td>69.1 ± 18.8</td>
<td>83.7 ± 11.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Health distress</td>
<td>55.0 ± 28.7</td>
<td>88.4 ± 14.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Sleep</td>
<td>53.6 ± 23.5</td>
<td>76.9 ± 16.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Loneliness</td>
<td>91.4 ± 16.9</td>
<td>96.5 ± 12.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Hopelessness</td>
<td>73.8 ± 24.4</td>
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<td>&lt;0.0001</td>
</tr>
<tr>
<td>Stigma of liver disease</td>
<td>59.5 ± 33.1</td>
<td>93.4 ± 12.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Sexual function*</td>
<td>56.6 ± 34.8</td>
<td>88.9 ± 18.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Sexual problems*</td>
<td>65.4 ± 35.9</td>
<td>92.0 ± 21.3</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*The Sexual function and Sexual problems domains had n = 28
Discussion

There was a prevalence of alcoholic liver disease (38.7%) and hepatitis C (28%) as indications for transplantation among the participants. The order of primary disease etiology prevalence differed from the data released by the Organ Procurement and Transplantation Network, including a total 5,805 liver transplants in adults in the United States, in which Hepatitis C was first with 23.5%, followed by alcoholic cirrhosis, with 17.6%.

It should be noted that hepatitis C and alcohol abuse were among the most frequent causes in other international studies. According to data of a study performed at the University of Pittsburgh, including 668 adult patients from Minnesota, Nebraska and California (San Francisco) who received a liver transplant due to non-fulminant hepatic disease, among the patients who survived the first year, the most prevalent causes were primary sclerosing cholangitis (17.8%), hepatitis C (16.4%) and alcohol (11.8%).

The same study evaluated the sustainability of the quality of life benefits by monitoring 381 recipients for 12 years after transplantation according to the diagnosis, using the questionnaire from the National Institutes of Diabetes and Digestive and Kidney Diseases - Liver Transplantation (NIDDK-LTD), and found that patients with an autoimmune disease had a decline in HRQOL in the physical suffering, social role/function, personal function and general health perception domains. Patients with alcoholic liver disease and hepatitis C+ had a consistent reduction in all domains one year after the transplant, with physical functioning and personal functioning worsening significantly over time.

However, in a study that included 353 liver transplant patients with alcoholic cirrhosis in Finland, in which the HRQL 15D instrument was administered, patients with alcoholic cirrhosis, acute liver failure, primary biliary cirrhosis or primary sclerosing cholangitis had similar scores in the HRQL 15D, whereas patients with liver tumors had lower scores that were non-significant. The group of patients with various chronic liver diseases had statistically significant higher HRQL levels than the other groups (p=0.003).

Regarding the MELD assessment of study participants, most patients had a value that was equal to or greater than 15 (77.3%) at the time of the disease. The data showed that patients had more severe disease compared with those in a Brazilian study in which 59% of the transplanted patients had a MELD greater than 15, and 41% had MELD scores less than or equal to 15; another study in London, with 1,032 transplanted adult patients, which measured MELD in the immediate pre-transplant period, found that 45.1% of patients had MELD scores less than 15, 26.7% between 15-25, and 28.2% were higher than 25.

The CTP criterion has previously been the most frequently used in the assessment of disease severity. In recent years, international research has highlighted the positive impact of the implementation of MELD criteria in allocating organs, with a reduction in mortality rates of patients on the transplantation waiting list.

Confirming these data, a study with 154 liver transplant patients in Germany showed an increase in the value of the median MELD score, comparing one year before and two years after its implementation in the service, ranging from 19.1±8.1 to 22.1±10.5, with a statistically significant difference (p=0.007). The mean time on the waiting list decreased from 369 days, in the pre-MELD period, to 238 days one year after the implementation of the MELD (p=0.1), and 247 days two years after its implementation (p=0.17). There was also a significant reduction of mortality on the waiting list, from 18.4% in the period before the adoption of the MELD to 10.4% in the period after one year (p=0.04), and 9.4% after two years (p = 0.015).

In addition, another study showed that the MELD score was an independent risk factor for mortality after liver transplantation (p<0.001).

However, when it comes to the assessment of the impact of the MELD on quality of life, studies are scarce and insufficient, and there is much controversy among the authors. In this study, significant differences were found between mean LD-QOL scores, compared before and after transplan-
Severity of liver disease and quality of life in liver transplantation

tation, indicating a positive impact on quality of life of transplant recipients with different degrees of liver disease severity, assessed by the MELD at the time of transplantation. However, no association was observed between the MELD values on the quality of life areas, considering that there was a great difference in sample groups compared according to the MELD.

This fact can be explained by the considerable number of patients with hepatocellular carcinoma (HCC) participating in the study, a condition in which the calculated MELD is disregarded, and the minimum MELD is 20 points, contributing to the high MELD values found in this study and the difficulty of comparing the findings.

Another study with 126 adults, 65 of whom were awaiting liver transplantation and 61 who had already received a transplant, regularly monitored by the reference transplantation service at Hospital das Clínicas in São Paulo (SP), Brazil, showed better quality of life scores in seven of the 12 areas assessed by the LDQOL in patients eligible for transplantation with a MELD less than or equal to 15, with statistically significant results: memory (p=0.001), social interaction (p=0.008), health distress (p=0.042), loneliness (p<0.001), stigma of liver disease (p = 0.004), sexual function (p = 0.01) and sexual problems (p=0.012). By using the Medical Outcome Study 36-Item Short-Form Study Health Survey (SF-36) scale, differences were observed in eight domains: social aspects (p<0.001), bodily pain (p=0.002), limitations due to physical health (p= 0.001), and general health perception (p=0.043). In the group of transplanted patients, the pre-transplant MELD value did not affect quality of life after transplantation,\(^{8}\) which agrees with the findings of the present study.

In contrast, a similar study performed in the United States with 104 patients on the waiting list and the post-transplant, based on the SF-36 scale, MELD value> 18 had a significant positive effect on the limitations due to physical health domain (p=0.052), and a superficial effect on pain (p=0.072).\(^{15}\)

In a study of 347 liver transplant recipients, 265 from the University of Florida and 95 from a medical center in Massachusetts, also in the United States, patients with MELD scores greater than 25 reported better significant parameters after one year of transplant in functional capacity (p=0.02), limitations due to physical health (p=0.04), general health (p=0.03), vitality (p=0.02) and summarized physical component (p=0.01) when compared to patients with MELD scores of 16-25, indicating that patients with more severe pre-transplantation clinical status achieved higher quality of life scores after the procedure.\(^{16}\)

However, it should be emphasized that although the MELD has already been recognized for its ability to predict mortality, functioning as a current measure for allocating livers for transplantation, there are not enough studies to support the association of MELD values with quality of life, considering that the MELD does not take into account other aspects that directly impact the perception of the patient’s quality of life, such as ascites and encephalopathy.

On the other hand, when analyzing the results of this study before transplant, considering the CTP classification, patients categorized as Child C had worse scores in ten of the 12 domains measured by LDQOL, suggesting a negative influence of the severity of liver disease on patients’ quality of life, with a significant difference (p<0.05) among the three groups in the following domains: symptoms, disease-related effects, concentration, memory, quality of social interaction, sleep, and stigma of the disease.

Similar results were obtained in another study that evaluated the influence of CTP on patients’ quality of life, and decreased levels of HRQOL were found among Class C liver transplantation candidates, compared with class A, with significant differences in eight of 12 domains: symptoms related to liver disease (p=0.08), effects of liver disease (p=0.002), memory (p=0.042), preoccupation (p=0.004), loneliness (p<0.003), hopelessness (p=0.005), sexual function (p=0.010) and sexual problems (p=0.041).\(^{8}\)

These data were further confirmed in a publication about the reliability and validity of the
Spanish version of the LDQOL, with 200 liver transplantation candidates, in which class A patients had better means than those of classes B and C, in nearly all dimensions except for loneliness, with major differences among patients in the following dimensions: symptoms (77.8, 67.1 and 63.9, respectively, p<0.001 between Child classes A and C), liver disease-related effects (65.9, 49.9 and 55.9, respectively, p<0.05 between Child classes A and B), and sexual functioning (75.4, 63.7 and 57.0, respectively, p<0.005 between Child classes A and C).(17)

Another previous study with 150 patients waiting for a transplant at the University of California, Los Angeles center, found a moderate negative correlation between the total value on the SF-36 instrument and CTP classification (r=-0.40), with major differences in the physical dimension, including functional capacity (r=-0.44), limitations due to physical health (r=-0.46) and pain (r=-0.30); and general health (r=-0.20), and a moderate correlation between CTP classes and emotional aspects (r=-0.38) and mental health (r=-0.43). When the Chronic Liver Disease Questionnaire (CLDQ) was administered, a moderate negative correlation was also found between the total score (r=-0.39, p<0.001), with a moderate correlation between the CTP and the abdominal symptoms (r=-0.38), fatigue (r=-0.43), systemic symptoms (r=-0.31), activity (r=-0.35) and emotional functioning domains (r=-0.37); and a weak correlation with the preoccupation domain (r=-0.27).(18)

In the study of development and validation of the Spanish version of the CLDQ, performed with 149 patients with chronic liver disease, the overall CLDQ scores for Child classes A, B, and C, were 5.2, 5.0, and 4.5, respectively (p<0.012) and 5.5 in patients without cirrhosis.(19)

**Conclusion**

The analysis of the influence of the severity of liver disease showed a significant increase in quality of life scores in ten of 12 domains, comparing the stages before and after transplantation among patients with a MELD score less than or equal to 15; and improvement in all domains in patients with MELD scores higher than 15. However, the MELD value did not interfere significantly on the results of the scale after transplant. In contrast, there were significant differences in HRQOL values among the CTP classes before transplantation, indicating a greater impairment of quality of life for patients with more severe disease.

**Collaborations**

Aguiar MIF and Braga VAB state that they contributed to the study design, analysis, data interpretation, article writing, relevant critical review of the intellectual content, and final approval of the version to be published. Almeida PC, Garcia JHP and Lima CA collaborated in writing the article, data analysis, relevant critical review of the intellectual content, and final approval of the version to be published.

**References**


Validation of the defining characteristics of the nursing diagnosis impaired comfort in oncology

Validation das características definidoras do diagnóstico de enfermagem conforto prejudicado em oncologia

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Abstract

Objective: To validate the content of the defining characteristics of impaired comfort nursing diagnosis proposed by NANDA-I in patients under palliative care in oncology.

Methods: Methodological study according to the model of diagnostic content validation of Fehring, in a sample of 53 nursing experts. The Mann-Whitney test and Spearman’s correlation coefficient (P <0.05) were used to check if there were influences on expert judgment.

Results: We validated the contents of seventeen defining characteristics of the nursing diagnosis and seven other defining characteristics developed in this study. Nine defining characteristics were considered major, another twelve were considered minor and three were excluded. The total diagnostic score was 0.74.

Conclusion: To validate the content of the defining characteristics of the nursing diagnosis Impaired Comfort for patients in palliative care in oncology is a way of supporting the clinical nursing practice in their own theoretical knowledge.

Keywords
Nursing diagnosis; Nursing process; Nursing research; Validation studies; Palliative care

Descritores
Diagnóstico de enfermagem; Processos de enfermagem; Pesquisa em enfermagem; Estudos de validação; Cuidados paliativos

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Introduction

Some diseases have stages that lead people to approach death, since they have serious medical conditions with high probability of death. Among them, cancer, understood as a set of cells formed from an uncontrolled growth, invading the tissues and organs of the various regions of the body.(1)

The World Health Organization (WHO) estimates that in 2030, the world will have the incidence of 21.4 million cancer cases and 13.2 million deaths.(2) In Brazil, it is estimated that about 576,000 new cases for the biennium 2014-2015.(3)

In its recommendations for the prevention and control of cancer, WHO establishes the provision of palliative care, involving the assistance promoted by a multidisciplinary team, which aims to improve the patient’s and their families quality of life, before a disease that threatens life through the prevention and relief of suffering, early identification, effective and efficient evaluation and treatment of pain and other physical symptoms, social, psychological and spiritual.(2) Despite the negative or passive connotation of palliative term, the approach and treatment are highly active, mainly in cancer patients in advanced stages.

The Nursing Diagnosis (NDs), as clinical judgements that support the choice of nursing interventions, guide the definition of interest for the research and work of nurses and their team. From the disease and vital processes several diagnostic are chosen and making use of the taxonomy of the North American Nursing Diagnosis Association International (NANDA-I) investigated in this study as the “Impaired Comfort”.

Present in Taxonomy II since 2008, the Impaired Comfort is allocated in the domain 12 (Comfort), it is defined as the “perceived lack of feeling of comfort, relief and transcending the physical, psycho-spiritual, environmental, cultural and social factors”.(4) By broader sense of the concept, one can already expect the alignment of the responses and experiences of patients in palliative care in oncology. However, for diagnoses purposes, the most comprehensive notions are not enough, and what is required is the ongoing effort to validate diagnosis.

Among the required procedures for validation of a Nursing Diagnosis (ND) there is the content validation. This validation seeks to analyze the components of the nursing diagnosis and the adequacy of its definitions supposedly developed with the concept analysis. Each ND is composed of a title (diagnostic statement), definition, defining characteristics and related factors or risk factors. This set of elements, which form the whole or part, will be validated by the content validation.(5)

The defining characteristics (DCs) are observable or reportable signs and symptoms representing the presence of a diagnosis and are of particular interest as the necessary clues to the diagnosis development.(4)

The minimum requirement for a ND to be in NANDA-I taxonomy is its consistent theoretical argument, which means that diagnoses approved for classification must be validated in order to ensure a practical and accurate application. The ND validation describes the degree to which a group of DCs describes a reality observed in the interaction with the patient. These are valid when actually occur and can be identified in a clinical situation.(6,7)

The method of diagnosis content validation proposed by Fehring has received some criticism in particular due to its difficulty of capturing the number of experts needed for more reliable conclusions, and its tendency to give greater weighting expertise to academic training instead of clinical experience. Thus, the characteristics related to the type and duration of academic training and experience in the field can be study variables in validation researches, not just considered methodological criteria.(5)

This study aims to validate the contents of DCs and NDs Impaired Comfort in adult patients under palliative care in oncology, according to the assessment of expert nurses, and verify if the judgement of these nurses was influenced by factors that aligned with the expertise in the
area, namely: age, working time as a nurse, working time in oncology, professional practice time in palliative care, participation in Graduate Studies on Nursing Process (NP), ND and/or palliative care, conducting research on NP, ND and/or palliative care in oncology, performance of ND as a step for NP and use of NANDA-I taxonomy in professional practice.

Methods

This is a methodological study that used the validation model of diagnostic content proposed by Fehring. This model is based on obtaining nurses expert opinions about the degree to which certain DCs are indicative of a diagnosis. Before it is applied, the author recommends the performance of a literature review to provide theoretical support for both the ND and for the DCs, with the possibility that additional DCs could be added to the official list established by NANDA-I during this process. (7)

The DCs of Impaired Comfort diagnosis described by NANDA I include: anxiety, crying, inability to relax, restlessness, irritability, moaning, fear, alteration in sleep patterns, discontent with situation, uneasy in situation, feeling of hunger, itching, feeling hot, feeling cold, feeling of discomfort, distressing symptoms and sighing. (4)

From the literature review on Comfort Theory, proposed by Kolcaba (theoretical basis of the ND), seven other DCs were elaborated, namely: insecurity, physical expressions of discomfort, feelings of disregard, spiritual suffering, feeling limited, discouragement, not feeling comfortable in the environment.

The criteria for selection of nursing experts in this study were adapted from the model proposed by Fehring, based on study criteria proposed by Silva and Gorini. (7,8) Professionals that obtained a minimum score of five points were included in the final assessment criteria, in order to include clinical nurses who provide care to adult cancer patients in palliative care and who have knowledge of NANDA-I taxonomy and researchers in the areas of oncology, palliative care, NP and/or ND.

Thus, PhDs, master’s, specialization in oncology nursing by the Brazilian Society of Nursing Oncology (SBEO), residence in oncology or palliative care, specialization in oncology or palliative care, or the use of diagnostic terminology of NANDA-I in clinical practice totaled three points each.

The current minimum practice of one year with palliative care patients and one research or article published about nursing process, nursing diagnosis or palliative care totaled two points each.

An abstract published about nursing process, nursing diagnosis, palliative care or participation in courses, symposiums and conferences (with minimum workload of 4 hours) on these same topics totaled one point each.

Nurses experts who answered the data collection instrument after the deadline were excluded. We held contact through e-mail or in person, with researchers in the areas of oncology, palliative care, NP and/or ND, with professionals working in hospitals which have a nursing ward for palliative care for cancer patients, alumni of specialization and residence programs in oncology and nurses who have the Certificate of Expert by SBEO inviting them to participate in the research.

The data collection instrument consisted of an electronic form containing, in the first part, questions about the characterization of the sample and, the second part, the Impaired Comfort description followed by a Likert scale for each of the 17 DCs of the diagnosis, and the seven DCs developed in this study, and its conceptual and operational definitions.

The conceptual definition represents the abstract or theoretical significance of the studied concepts. While the operational definition of a concept specifies operations that researchers should do to collect the information, it also indicates how the concept is found in practice, this way it must be congruent to the conceptual definition. (9)

Out of the six steps from the Fehring Content Validation Diagnostic technique, (7) five were developed. At first, the nurses assigned a value from one to five, in Likert scale, every DC towards its conceptual and operational definitions. The value was indicative of the increasing degree of agreement with the adequacy of the
diagnostic characteristic. The second step was optional - the Delphi technique for consensus responses of expert nurses - and it was not performed in this study because the repeated rounds of questions required by the technique could involve the loss of individuals in the sample.

In the third step we calculated the weighted mean (WM) of the grades given by nurses for each of the DCs, considering the weights: 1=0, 2=0.25, 3=0.5, 4=0.75, 5=1. In the fourth step, we discarded the DCs with weighted mean lower than 0.5. In the fifth step, the DCs with weighted mean greater than or equal to 0.8 were considered major defining characteristics. These features must be present to confirm the diagnosis, namely diagnosis state that really exists. Defining characteristics with a weighted mean between 0.5 and 0.8 are classified as minor.

Finally, a total score was obtained by the sum of the scores for each individual DC and divided by the total number of diagnostic characteristics to be tested. This score indicates the validity of a given defining characteristic as valid content of nursing diagnosis. The DCs with lower weighted means and/or equal to 0.5 should be excluded from the total score.

In the data analysis, the characterization of the population was carried out by means of descriptive statistics. Correlations between defining characteristics and possible continuous quantitative variables of age, as the nurse’s working experience, work experience in oncology and length of professional practice in palliative care were estimated using the Spearman correlation coefficient (P value <0.05).

Comparisons involving categorical variables “conducting graduate studies in NP”, “ND and palliative care”, “conducting research or article published on NP”, “ND or palliative care in oncology”, “performance of ND as step of NP and the use of NANDA-I taxonomy professional practice” were carried out using the non-parametric Mann-Whitney test.

In all analysis, a significance level of 5% was considered and the SAS software version 9.4 was used. The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 23173713.0.0000.5404.

Results

Fifty-six nurses participated in the study, three (5.36%) were excluded from the sample, since they did not obtain the minimum score of the inclusion criteria, totaling a sample of 53 nursing experts. Table 1 describes the characteristics of the sample.

The scores of expert nurses in the inclusion criteria ranged from five to 21, mean of 9.49 and standard deviation of 3.84.

The mean working experience as a nurse is 15.98 years (standard deviation of 11.85 years), the mean working experience as a nurse in oncology is 8.77 years (standard deviation of 11.17 years) and the mean working experience in palliative care in oncology was 5.15 years (standard deviation of 7.53 years).

There were nine DCs which were identified as major (WM ≥0.80), they are: physical expressions of discomfort (WM=0.90), anxiety (WM=0.87), feelings of anguish (WM=0.86), fear (WM=0.84), feelings of discomfort (WM=0.83), restlessness (WM=0.82), inability to relax (WM=0.81), alteration in sleeping patterns (WM=0.81), feeling limited (WM=0.80). It is noteworthy that the DCs physical expressions of discomfort (with the highest mean among the DCs) and feeling limited were prepared in this study.

Twelve DCs were considered minor (WM <0.80 and >0.50), they are: discouraged (WM=0.77), crying (0.75), insecurity (WM=0.75), spiritual suffering (WM=0.73), discontent with situation (WM=0.71), irritability (WM=0.68), uneasy in situation (WM=0.68), moaning (WM=0.67), sighing (WM=0.62), feeling of discomfort (WM=0.60), feeling cold (WM=0.52) and feelings of disregard (WM=0.52).

The DCs itching (WM=0.47), feeling hot (WM=0.47) and feeling of hunger (WM=0.44) were excluded as they obtained weighted mean lower than 0.5. The total score was found to be 0.74. Twelve DCs (57.14%), considering the characteristics proposed by NANDA I or by this study, obtained weighted mean above this value.

Table 2 presents the statistically significant correlations found in this study, estimated by the Spearman correlation coefficient between the DCs
of ND in study and age variables, nurse experience time in oncology, and nurse experience time in palliative care. We sought in this analysis, to verify influences of professional experience in the judgement of DCs by expert nurses, especially in the subjective DCs.

As showed in table 2, for the defining characteristics that the statistical significance was found, the correlation was always positive.

Using the Mann-Whitney test, it was found that there were no significant differences between the means of the DCs judgements by the experts who carried out or not a graduate study in palliative care and those who performed or not some research about NP, ND or palliative care.

Table 3 presents the significant comparisons found in this study, between the means of DCs judgment and performing or not graduate studies on NP or ND, the use or not of NANDA I taxonomy in professional practice and the performance or nonperformance of ND as a NP step.

<table>
<thead>
<tr>
<th>Variable</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>50(94.34)</td>
</tr>
<tr>
<td>Male</td>
<td>3(5.66)</td>
</tr>
<tr>
<td>Age groups (years)</td>
<td></td>
</tr>
<tr>
<td>20-30</td>
<td>14(26.41)</td>
</tr>
<tr>
<td>31-40</td>
<td>16(30.19)</td>
</tr>
<tr>
<td>41-50</td>
<td>9(16.98)</td>
</tr>
<tr>
<td>51-60</td>
<td>13(24.53)</td>
</tr>
<tr>
<td>Over 61</td>
<td>1(1.89)</td>
</tr>
<tr>
<td>Title</td>
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<tr>
<td>Graduate studies in Nursing process</td>
<td>8(15.09)</td>
</tr>
<tr>
<td>Graduate studies in Nursing diagnosis</td>
<td>8(15.09)</td>
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<tr>
<td>Graduate studies in Palliative care</td>
<td>13(24.53)</td>
</tr>
<tr>
<td>Certificate in Nursing Oncology SBEO</td>
<td>6(11.32)</td>
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<tr>
<td>Certificate in oncology or palliative care</td>
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<tr>
<td>Residence in oncology or palliative care</td>
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</tr>
<tr>
<td>Master’s degree</td>
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<tr>
<td>PhD-Research and abstract in nursing process or palliative care</td>
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</tr>
<tr>
<td>Abstract</td>
<td>19(35.85)</td>
</tr>
<tr>
<td>Use Nursing Process in their professional practice</td>
<td>50(94.34)</td>
</tr>
<tr>
<td>Use Nursing diagnosis as step of Nursing process</td>
<td></td>
</tr>
<tr>
<td>No</td>
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</tr>
<tr>
<td>Yes</td>
<td>38(71.70)</td>
</tr>
<tr>
<td>Did not answer</td>
<td>4(7.55)</td>
</tr>
<tr>
<td>Know NANDA-I Taxonomy</td>
<td>53(100.00)</td>
</tr>
<tr>
<td>Use NANDA-I Taxonomy</td>
<td>38(71.70)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Defining characteristics</th>
<th>Variables</th>
<th>Age</th>
<th>Working experience time as Nurse</th>
<th>Working experience time in oncology</th>
<th>Professional practice in palliative care</th>
<th>p-value*</th>
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</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.300(0.028)*</td>
<td></td>
</tr>
<tr>
<td>Feelings of discomfort</td>
<td>0.306(0.25)*</td>
<td>0.289(0.035)*</td>
<td>0.365(0.007)*</td>
<td>0.317(0.020)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeling hot</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.337(0.013)*</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Feelings of disregard</td>
<td>-</td>
<td>-</td>
<td>0.410(0.002)*</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Spiritual suffering</td>
<td>0.271(0.040)*</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.291(0.034)*</td>
<td></td>
</tr>
<tr>
<td>Fear</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

*p-value obtained through the Mann-Whitney test
Discussion

The selection of experts is one of the finer points of a diagnostic content validation study and despite Fehring selection proposal is widely described in literature, it is difficult to use in its entirety, which led the authors to implement adjustments to the original model.\(^{(10)}\)

Such modifications were effective in trying to promote expert nurses sampling with care and research profiles with knowledge of NANDA-I taxonomy, meeting the Fehring recommendations to contemplate professionals with Masters’ degree and who have research in the diagnostics studied.

Thus, the findings related to masters’ and PhDs in areas relevant to the present study support the adequacy of the sampling criteria considered as important to validate a nursing diagnosis. The publication in NP, ND or palliative care was also found for a majority of experts as research or abstract. Associated with title data, the publication data allowed us to infer that the experts in continuing education process can maintain a consumption standard of scientific production in the area and produce on it. Whereas the nursing diagnoses are in continuous development, the findings are satisfactory.

In this study, almost all of the sample of experts are female which is compatible with the overall distribution in the profession. The historical and cultural heritage in which care is part is linked to the female image and despite the number of men in nursing is growing over time, it is still possible to observe discrepancies, such as found between the number of women workers compared to men.\(^{(11)}\) However, there is no published evidence that the gender of the Nursing diagnostician can interfere with the content of the prepared diagnosis.

Developing palliative care in Brazil is a challenge that involves the qualification of health professionals, awareness of public service administrators on the importance of this type of care and improvements in public access. It is still common for health professionals and family members of patients to consider such care as applicable at the moment of imminent death, and the transition to this type of care is a continuous, gradual and progressive process.\(^{(2,12)}\)

The low mean years of practice in palliative care compared to working experience in oncology of the expert nurses reflects this difficulty in the national scenario. However, it was found in this study that there is a search for theoretical knowledge that can incorporate palliative care when considering performance of graduate studies (including masters and PhD) and published research on the topic.\(^{(13)}\)

It is also highlighted that only 11.32% of the sample had the Certificate of specialist nurse in oncology given by the Brazilian Society of Oncology Nursing (SBEO), this body was founded in 1988 and aims to represent the scientific, cultural and professional interests of its members representing the oncology nursing in Brazil before national and international bodies.\(^{(14)}\)

In Brazil, the taxonomy of NANDA-I was introduced in a Nursing publication in Portuguese in 1990 by nurses of the Universidade Federal da Paraíba by the professor Dr. Marga Coler. It is noted in this study that although relatively recent, NANDA-I taxonomy introduction in the country was recognized by all nurses experts and applied in the preparation of the nursing diagnosis for a large portion of the sample.\(^{(15)}\)

Nine DCs, considered major (physical expressions of discomfort, anxiety, distressing symptoms, fear, discontent with situation, restlessness, inability to relax, alteration in sleep patterns and feeling limited) validates the ND Impaired Comfort in patients in palliative care and oncology, that is, it is asserted that this diagnosis actually exists in this population.

To understand the nature of these findings, we chose to use the definition of Impaired Comfort as “perceived lack of feeling of comfort, relief and transcending the physical, psycho-spiritual, environmental, cultural and social factors”; which reflects a more comprehensive view of the individual.\(^{(4)}\) Also, guided by the Kolcaba Theory of Comfort, there are situations of patients in palliative care in oncology to contemplate an approximate way the problems that are experienced.\(^{(2,6)}\)

In this nursing theory comfort occurs in four contexts. The first context is the physical, related to the physical conditions of the individual. The
second context is the psycho-spiritual, which combines the mental, emotional and spiritual components of being, and corresponds to everything that gives meaning to life of an individual. It includes self-esteem, self-concept, sexuality and relationships with an order or superior being (e.g. God). The third context is social, corresponds to interpersonal, family, social and cultural relations. It includes finances, education, social support, traditions and language. The fourth context is environmental, referring to the conditions and environmental influences, encompasses light, sound, color, temperature and natural versus synthetic elements.\(^{(16)}\)

It was found that some of the DCs considered major by expert nurses only reflect physical aspects of patient comfort (physical expressions of discomfort, inability to relax, altered sleep patterns). Mahon and McAuley showed in their study on personal perceptions of oncology nurses about palliative care that the main focus of these professionals was the control of physical symptoms, although advanced cancer also brings impairments of psychological, spiritual, cultural and social order.\(^{(17)}\) Maybe such a finding is due to the fact that changes in physical comfort are more evident to third party verification, it does not require the patient to verbalize a lived situation or depends on the sensitivity of the professional in capturing changes in psycho-spiritual, social, environmental or cultural comfort and it is still difficult to be hidden for any reason by the patient.

For the major subjective defining characteristics of “anxiety”, “discontent with situation” and “feeling limited” signal the verbalization of a patient’s feelings and not necessarily a finding of nurses. Thus it shows clearly the presence of impaired comfort, even though it is not based on data that is observable and of physical nature.

“Fear” and “anxiety”, also considered major characteristics, showed a psycho-spiritual aspect of comfort, but also have physical and behavioral expressions that make them easy to be perceived by the nursing professional. Moreover, cancer brings with it awareness of the possibility of death that can be accompanied by anxiety and fears, influencing the dimensions of comfort. The meaning and the meaning of death depends on the stage at which the patient is vital in the development process. This view also considers the life history, their experiences and learning of their physical, psychological, social and cultural conditions interfering with comfort.\(^{(18)}\)

The defining characteristic “physical expressions of discomfort” was developed by the authors and in addition to this study, obtaining the highest weighted mean. It is believed that this result is due to this DC intuitively be characteristic of discomfort as conceptual and operational settings for easy identification, and because it has a semantic proximity and almost common sense accordance between discomfort and impaired comfort. This is due to the high score given by expert nurses.

The DCs also developed in this study, “insecurity”, “feelings of disregard”, “spiritual suffering”, “discouraged” and “feeling uncomfortable with the environment” were developed from literature review, to meet the psycho-spiritual, environmental and social Impaired Comfort diagnosis, however, all of them were considered minor (weighted mean \(<0.80\) and \(>0.50\)) by the experts. They are characteristics that provide a secondary evidence supporting the diagnosis, as well as the characteristics discontent with situation, irritability, unease in situation, moaning and sighting, proposed by NANDA-I.

The characteristics “itching”, “feeling hot” and “feeling of hunger” were excluded due to weight mean below 0.5, that is, they are not indicative of the studied diagnosis.

Feeling of hunger conceptually defined in this study as the desire for food generated by a sense that forms by the lack of food in the stomach and operationally as exposure of desire/need to eat is not a common discourse among cancer patients experiencing terminal illness. The anorexia and cachexia are common in these patients and most often is the natural evolution of the disease.\(^{(2)}\) Thus, excluding this DC makes sense in the context of palliative care in oncology.

Itching in patients with cancer is also uncommon, this symptom is cited as a paraneoplastic manifestation of malignant tumors of the nasopharynx, prostate, stomach, breast and uterus.\(^{(19)}\) Thus, the DC itching report was also rejected.
The twelve defining characteristics considering the characteristics proposed by NANDA-I or the present study obtained weighted mean above the total score that was 0.74. It is evident then, that the DCs are most relevant in the identification possibilities in the Impaired Comfort diagnosis in patients in palliative care in oncology.

The influences of positive correlation between age, working experience time as a nurse in oncology and length of professional practice in palliative care in considering the validity of “anxiety”, “feeling uncomfortable with the environment”, “feeling hot”, “feelings of disregard”, “spiritual suffering” and “fear” for the diagnosis may have several explanations.

The time of experience can be considered a facilitator of interpersonal relationships among patients in palliative care and nursing professionals who have committed to empathic communication as it enhances the ability to listen, perceive, understand, identify needs and then plan actions. However, it is emphasized that the maintenance of this communication capability requires a commitment to improving the professional performance that may decrease due to the increase of the total work environment, as with professionals who are working a long time in the same work environment.

The expertise is acquired as the nurses experience different situations with cancer patients in palliative care. The newly trained nurses tend to be aware of the details, perception reaches a peak tracking a plateau and a conditional decrease, similarly to time. Experts are not infallible and tend to make mistakes related to omission of important information, tunnel vision and tendency to chance, because they have subjectivity and understanding of the cognitive nature of making subjective decision, which leads to taking measures to increase the value of these decisions.

The DCs presented objective and subjective aspects as related to time. For comparison of the variables: conducting research on nursing process, conducting graduate studies in palliative care in oncology, nursing process or nursing diagnosis, making the nursing diagnosis as a step of the nursing process and use of the NANDA-I taxonomy in professional practice, we found significant differences in the DCs judgements.

The experts who did not conduct graduate studies in NDs showed higher mean judgment of DCs insecurity and sighing, statistically significant compared those who had graduate studies. The same happened in the DC judgement of anxiety among experts who did not have a graduate degree in NP. Experts who did not perform the DCs as a step of NP had higher mean in DC judgement of anxiety, crying and physical expressions of discomfort statistically significant compared to the experts who performed ND. Experts using NANDA-I taxonomy obtained higher mean in the judgement of DC irritability compared to nurses who did not use the taxonomy. Although they are considered statistically significant these comparisons would not change the situation of DCs judgement as major, minor or removed.

It stands out in the analysis of the DC “sighing”, nurses who held a graduate degree in nursing diagnosis showed a mean that would determine the exclusion of this DC (0.44), as the characteristic is observed as of liberal experts without training. It is considered that these professionals are more apt to perform a more accurate judgment in relation to the experts who did not have such qualification and therefore, the exclusion of this DC is feasible, proposed by NANDA-I, for the population of patients in palliative care in oncology.

The reverse happens with the DC “feelings of disregard”, nurses who did not have a graduate degree in nursing process had a mean that would determine the exclusion of this DC (0.49), however, the assessment of the experts who carried out this type of specialization such DC had a mean 0.72, ranking it as minor. Classification in
which the DC obtained as final, with the borderline mean 0.52.

This study reveals that variables related to the professional who diagnoses can interfere with her/his consideration of the validity or otherwise of a given defining characteristic. This points to the need to carefully consider the existence of variables related to training, expertise and experience in diagnostic validation studies by experts. It is proposed that consideration of the DCs “physical expressions of discomfort”, “feeling limited” and the disregard of the DCs “itching”, “feeling hot”, “feeling of hunger” and “sighing” from the official NANDA I list of DCs for Impaired Comfort in palliative care in oncology.

**Conclusion**

The defining characteristics validated in this study were as major: physical expressions of discomfort, anxiety, distressing symptoms, fear, discontent with situation, restlessness, inability to relax, altered disturbed sleep, feeling limited; validated as minor: discouragement, crying, insecurity, spiritual suffering, reporting lack of satisfaction with the situation, irritability, feeling of discomfort, mourning, uncomfortable with the environment, feeling cold and feelings of disregard. DC excluded were itching, feeling hot, feeling of hunger and sighing.

The judgment of expert nurses was positively influenced by the factors age, work experience time in oncology, work experience as nurse, professional practice time in palliative care in defining characteristics: anxiety, uncomfortable with the environment, feeling hot, feelings of disregard, spiritual suffering and fear.

Significant differences were verified between the means of DCs judgements and performing or not graduate studies on the nursing process or nursing diagnosis, the use or not of NANDA I taxonomy in professional practice and the performance or nonperformance of the nursing diagnosis as a step of the nursing process in the following defining characteristics: sighing, insecurity, anxiety, crying, physical expressions of discomfort and irritability.

**Collaborations**

Gonçalves MCS and Duran ECM declare that contributed to the study design, analysis, data interpretation, article writing, relevant critical review of the intellectual content and approval of the version to be published. Brandão MAG collaborated in writing, relevant critical review of the intellectual content and final approval of the version to be published.

**References**

Validation of the defining characteristics of the nursing diagnosis impaired comfort in oncology


Opening speech at the IX COBEON*, III CIEON*, and ABENFO* 2015 in Belém, PA, Brazil

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The IX COBEON and III CIEON were organized by ABENFO and implemented by the Pará (PA) Session of ABENFO in the “heart” of the Amazon (Belém City, Pará State, 2-4 Dez 2015). The congress theme was “Obstetric and Neonatal Nursing: impacts, achievements, and challenges for sexual and reproductive health and safe and enjoyable maternity”.

After three decades of existence of ABENFO, we highlight some landmarks: a) the firm defense of human and citizen rights of both women and men in the context of the society and family; b) its engagement in including nursing professionals in the government proposals to defend SUS (which is equitable, has an expanded coverage, unrestricted access, management and care for quality, and participation of all professionals); c) the recognition of Nursing as an applied social science, which is committed to the care, teaching, and research trilogy, and its reciprocal relationship between the practical and academic worlds, and d) its commitment to the social movements including women and the health professional categories, a commitment that is inherent to a humanistic and ecological profession of the art of caring for life.

In addition, we recognize the internal movements that occurred along the professional and ABENFO journeys, such as those of students during their undergraduate courses, specializations in obstetric

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and neonatal nursing, residency in obstetric nursing, women’s health, masters and doctoral students, as well as other professionals in their distinct operation areas. We also recognize the movements that have the COFEN-CORENs system as a driving force, through the action of the Technical Chambers who inspect the professional practice and Nursing Code of Ethics for defense and strengthening of profession and life.

In the opening session, we said what we call an opening prayer, which was constructed with the collaboration of all presidents of ABENFO since it was established. We highlighted the ethical, political, and technical scientific aspects of ABENFO, which has been committed to the philosophy of SUS and operated with focus on the development of the society, especially the health of women and their political and sociocultural training, thus meeting the mission of ABENFO, which is aligned with the defense of the human and citizen rights. Its mission corresponds to its history, which was marked not only by struggles, movements, progress and achievements, but also great challenges of the category and State whose claims it aims to meet.

In this opening prayer in favor of life, we highlight the theme of the “Cobeon of the Amazon”, which is based on three fundamental objectives: 1) safe motherhood, as the guiding principle to chose non-interventionist models in care processes and life of individuals and social groups; 2) (re)visiting conceptual controversies and program deviations imposed by undesirable guidelines; (in this sense, we reaffirm our commitment to improve maternal health and reduce maternal and newborn mortality, although Brazil has not yet reached the MDG Nº 5 (UNO, 2000); and 3) political action of ABENFO, which is an entity legally constituted by nursing professionals, and represents individual (women, men, children, and families) and public health, together with other entities (ABEn, its Regional Sections, COFEN-CORENs system, Nursing Federations & Labor Unions, and others) that represent the movements in the states, governments, societies, and communities.

Concluding this opening prayer, we invite every nursing professional to celebrate the unity of both our category and ABENFO, with the establishment and launch of an Advisory Council of Presidents of ABENFO, which consists of all ABENFO presidents (since 1989), who we cite by their names:

**Administration (1992-1995)**, with Marilanda Lopes de Lima, who was a landmark of the origin of ABENFO and whose administration was characterized by the transition from ABO to the establishment of ABENFO, making concrete the myths and rites of obstetric nursing, including this congress. We point out that the activities of ABENFO (1989-1991) began under her leadership.

**Administrations (1996-1999 and 2000-2002)**, with Maria Antonieta Rubio Tyrrell, who was the first president elected, and characterized her administration with i) institutionalization of ABENFO at the national and international levels, ii) strengthening its articulations with the PAHO and the Brazilian MH and universities, and iii) linking ABENFO to both ABEn and the REHUNA.

**Administration (2003-2005)**, with Rosângela da Silva Santos, who strengthened i) the institutional advances of previous administrations, ii) the spaces conquered at the level of the Brazilian MH and iii) the relationship between ABENFO and JICA for training of obstetric nurses in Japan.

**Administration (2006-2008)**, with Marli Vilela Mamede, who i) strengthened ABENFO and ii) developed the competencies proposed by the ICM with actions proposed by the Brazilian MH and PAHO.

**Administrations (2009-2011 and 2012-2014)**, with Valdecyr Herdy Alves, who i) developed ABENFO in the national and international levels, as well as in its relations with governments, ii) strengthened the relationship between ABENFO and the COFEN-CORENs system, and iii) promoted the first COBENEO.

**Current administration (2015-present)**, with Kleyde Ventura de Souza who, while saying this opening prayer, reaffirms the guiding proposals and actions for a good development of the i) technical-scientific and academic nursing and ii) women’s health in the ethical, political and social aspects, thus consolidating the ABENO trajectory, which is connected to the history of the former presidents here acknowledged.
On behalf of all these people and of the National Board of Directors of ABENFO, I declare the IX COBEON and III CIEON open, and I reaffirm that Nursing, in the specialties of women’s health and obstetric and neonatal nursing, will strengthen the protagonism of those who care and are cared for in the SUS, based on the commitment to a technical-scientific, social, and ethical performance of ABENFO.

Be welcome to the “COBEON of the Amazon, the COBEON of COBEONs”!

*Abbreviations: ABEn (Associação Brasileira de Enfermagem): Brazilian Nursing Association; ABENFO (Associação Brasileira de Obstetrizes e Enfermeiros Obstetrais): Brazilian Association of Midwives and Obstetric Nurses; ABO (Associação Brasileira de Obstetrizes): Brazilian Association of Midwives; CIEON (Congresso Internacional de Enfermagem Obstétrica e Neonatal): International Congress of Obstetric and Neonatal Nursing; COBENDO (Congresso Brasileiro de Enfermagem Neonatal): Brazilian Congress on Neonatal Nursing; COBEON (Congresso Brasileiro de Enfermagem Obstétrica e Neonatal): Brazilian Congress of Obstetric and Neonatal Nursing; COFEN (Conselho Federal de Enfermagem): Federal Council of Nursing; CORENs (Conselhos Regionais de Enfermagem): Regional Councils of Nursing; ICM (International Confederation of Midwives); JICA (Japan International Cooperation Agency); MDG (Millennium Development Goal); MS (Ministério da Saúde do Brasil): Brazilian Ministry of Health; MH: PAHO (Pan American Health Organization); REHUNA (Rede de Humanização do Parto e Nascimento): Network for Humanization of Labor and Delivery; SUS (Sistema Único de Saúde): Unified Health System; and UNO (United Nations Organization).