ABSTRACT
Objective: to perform the transcultural adaptation of the tool Ontario Protocol Assessment Level (OPAL).
Method: methodological research that will be developed in two stages: transcultural adaptation and validation of the adapted version of the tool Ontario Protocol Assessment Level (OPAL), which will measure the workload of the nurse who is clinical study coordinators based on the complexity of the clinical protocols of the National Cancer Institute - Instituto Nacional de Câncer (INCA). The transcultural adaptation process will be supported on the recommended content by Beaton and collaborators. Expected results: with the calculation of scores per protocol through Ontario Protocol Assessment Level (OPAL), we hope to verify the applicability of this tool in assessing the workload of the of study coordinator, both individually and the team as a whole, and, therefore, to map possible discrepancies in the workload among the coordinators.

Descritores: Clinical Protocols, Clinical Research; Workload.

RESUMO
Objetivo: realizar a adaptação transcultural da ferramenta Ontario Protocol Assessment Level (OPAL).
Método: pesquisa metodológica que será desenvolvida em duas etapas: adaptação transcultural e a validação da versão adaptada da ferramenta Ontario Protocol Assessment Level (OPAL), a qual mensurará a carga de trabalho do enfermeiro coordinador de estudos clínicos baseada na complexidade dos protocolos clínicos do Instituto Nacional de Câncer (INCA). O processo de adaptação transcultural será respaldado no preconizado por Beaton e colaboradores. Resultados esperados: com o cálculo dos escores por protocolo pelo Ontario Protocol Assessment Level (OPAL), espera-se verificar a aplicabilidade deste instrumento na avaliação da carga de trabalho do coordenador de estudos individualmente e da equipe como um todo e, com isso, mapear possíveis discrepâncias na carga de trabalho entre os coordenadores.

Descritores: Protocolos Clínicos; Pesquisa Clínica; Carga de Trabalho.
INTRODUCTION

Clinical research in Brazil had significant growth in the last few years and, thus, also increases concerns about the qualification of professionals involved in conducting clinical studies before the importance of generating reliable and qualitative data. From this viewpoint, the building of indicators stands out as a relevant tool for obtaining the quality of work processes.

Faced with the increasing demand for clinical protocols in the clinical research center of the Brazilian National Cancer Institute - Instituto Nacional de Câncer (INCA) and the difficulty of measuring the workload of clinical trial coordinators, there was interest in conducting this current study in an attempt to help in the management of their performances, thus seeking to improve the quality of data generated by them.

Due to the wide role of the study coordinators of INCA and the great number of clinical protocols in progress, the development of performance and quality indicators by means of an instrument that enables the assessment of the workload of coordinators, without compromising the quality of its data, will be very relevant to the institution. The improvement of the quality standard of services provided to patients is a motivational factor for the healthcare team to perform studies that point out the indicators that enhance the care process, patient safety and quality of the research center.¹

In reviewing the literature on this issue, it was found the results of a paper that was written by a group of Canadians who built and validated a tool in the research centers of Ontario, which assesses the workload generated by oncology protocols based on complexity. Before this tool that, apparently, responds to the needs of the Clinical Research Center of INCA, there was interest in conducting this study.

OBJECTIVES

- To perform the transcultural adaptation of the tool Ontario Protocol Assessment Level (OPAL)
- To verify the validity of the tool Ontario Protocol Assessment Level (OPAL) at the Clinical Research Center of the National Cancer Institute (INCA)

METHOD

Previous note designed from the research project in development at the Professional Master Program in Assisitential Nursing from Escola de Enfermagem Aurora de Afonso Costa (EEAAC/UFF), 2012. Niterói, RJ/Brazil.

It is a methodological type study, since it mentions the investigations of methods for obtaining, organizing and analyzing data, by dealing with the development, validation, and assessment of the instrument in its transcultural adaptation.²

The study will be conducted in two stages: the transcultural adaptation of the instrument OPAL to Portuguese language and validation thereof, by means of its application in the Clinical Research Center of INCA.

The process of transcultural adaptation will be based on the following steps, which will guide the development of this study:³

A. Translation: this step must be performed by, at least, two translators, who are, preferably, Portuguese native speakers. Both versions must be analyzed, giving rise to a new version that will be submitted to the next stage.

B. Assessment of initial translation (back-translation): once translated, the paper must be reversed to the original language and the result compared to the original instrument. This step must be performed by two other translators who are, preferably, native speakers of the language in which the original instrument was written.

C. Review by an expert committee: this committee must be formed by a multidisciplinary team, which are knowledgeable about the researched issue, the purpose of the instrument and the concepts to be analyzed. At this stage, the presence of bilingual participants is essential. The committee aims to prepare the final version of the instrument based on translations and back-translation and in the comparison of results with each other, by basing on the analysis of semantic, idiomatic, cultural or conceptual equivalences.³

1. Semantic equivalence: adequacy of the meaning of words according to vocabulary and grammar.
2. Idiomatic equivalence: adequacy of colloquial and idiomatic expressions.
3. Experimental equivalence: description of mistaken situations which are not consistent with the cultural context.

This step may be repeated as many times as necessary in order to obtain a fully understandable version.
Pre-test: The pre-final version is submitted to a pre-test to analyze the understandability of the questionnaire by a sample of the target population, in this case, the study coordinators of INCA.

The expert committee aims to examine the routed translation reports - original, translation and back-translation, to identify discrepancies or found doubts, according to the dimensions described below and to make suggestions. This process aims to reach a consensus of a final version of the instrument, which will be tested with the clinical study coordinators from the three units of the Clinical Research Center of the National Cancer Institute.

This committee will comprised of three nurses, two doctors, one pharmacist, all of them with experience in oncology and clinical research.

The assessment of the measurement properties is another essential step in the transcultural adaptation process, which search for the compatibility between the version to be produced and the original instrument, regarding reliability and validity, and this is embedded in the pre-test.1

At the step of assessment of the measurement properties, embedded in the pre-test, the following variables will be assessed:

The inter-observer reliability or equivalent, the test-retest reliability or stability, content validity and construct validity.

Data will be collected and entered into an Excel spreadsheet, version 2000. Data will suffer descriptive statistical analysis and will be presented in tables, according to their absolute and relative frequencies, to be discussed afterward. After these steps, the document is considered transculturally adapted to the targeted language.

During the validation phase of the instrument, the final version thereof will be applied to the study coordinators of the Clinical Research Center of INCA and research protocols that have different characteristics will be selected (study phase, study type, treatment line, etc.) and, therefore, different complexities to be assessed.

All study coordinators of INCA will be included in this review, which are allocated in the three hospital units already mentioned in this paper, totalling a population of 13 nurses will be verified, where a variation of up to 1.5 points between them will be considered as acceptable.

**Ethical Considerations**

In compliance with Resolution 196/96 from the National Health Council - Conselho Nacional de Saúde (CNS), this research project was submitted to the Ethics Research Committee - Comitê de Ética em Pesquisa (CEP) of the National Cancer Institute for approval with regard to the ethical implications of the proposed research, CAAE 070066-12.5000.5274.

**EXPECTED RESULTS**

Arising from the above mentioned, the implementation of strategies that allow assessing the quality of care in the healthcare services has been raised in the current setting, and the construction of indicators has been mentioned by health professionals as a necessity in the pursuit of efficiency and effectiveness of organizational results. Every institution, whose core mission is to assist the human being, should be concerned with the constant improvement of care, aiming to achieve a harmonious relationship among areas: administrative, technological, economic, healthcare, education and research.4

The Nursing’s role in conducting clinical studies is increasingly extensive. The clinical study coordinators passed from a phase, usually, characterized by data collection and recruitment of participants for studies, to another one that is featured by activities related to the ability to observe and understand the context of their research center, also acting in the care management.5

With the calculation of scores per protocol through OPAL, we can verify the applicability of this tool in assessing the workload of the study coordinator, both individually and the team as a whole. Thus, we hope to map possible discrepancies in the workload among the coordinators, to signal training needs and when they are not in meetings / gatherings outside the laboratories or in medical offices advising patients.

The same protocols will be assessed by all the nurses and they will use the final version of the assessment tool for clinical protocols OPAL to give scores to thereof, by seeking to assess the workload generated by each research protocol.

Subsequently, a comparison will be made and the correlation between the scores given to the identical protocols by distinct nurses will be verified, where a variation of up to 1.5 points between them will be considered as acceptable.
to enable a better distribution of protocols among them.

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