

Data collection instrument for hematological diseases in an outpatient setting: a validation study

Instrumento de coleta de dados para doenças hematológicas em ambulatório: estudo de validação
Instrumento de recolección de datos para enfermedades hematológicas en ambulatorio: un estudio de validez

Silvana Maria Nunes Rodrigues^I

ORCID: 0000-0002-6147-1485

Andrea Bezerra Rodrigues^{II}

ORCID: 0000-0002-2137-0663

Luilma Albuquerque Gurgel^I

ORCID: 0000-0003-0998-8070

Leidy Dayane Paiva de Abreu^I

ORCID: 0000-0001-8895-1481

Gabriela Lacerda Souza^I

ORCID: 0000-0001-5112-1017

^IUniversidade Estadual do Ceará. Fortaleza, Ceará, Brazil.

^{II}Universidade Federal do Ceará. Fortaleza, Ceará, Brazil.

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Corresponding author:

Silvana Maria Nunes Rodrigues
E-mail: biasilvana2011@hotmail.com



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ASSOCIATE EDITOR: Alexandre Balsanelli

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ABSTRACT

Objectives: to build and validate a data collection instrument for onco-hematological patients undergoing outpatient chemotherapy. **Methods:** methodological study that aimed to build a scientifically consistent data collection instrument to evaluate hematological patients. There were five stages: identification of empirical indicators, evaluation of empirical indicators by focus group, construction of the instrument, content validation by judges and clinical validation. Built based on the Theory of Basic Human Needs of Horta, adjusted by Garcias and Cubas. **Results:** the built instrument contains data on patient identification, perception and expectations related to the disease, assessment of psychobiological, psychosocial and psychospiritual needs. It reached 95% CVI, ensuring the instrument's content validity and Cronbach's alpha test with a reliability of 0.93. **Conclusions:** the instrument is a valid technology to assist nurses in data collection and may serve as a tool for onco-hematological nursing care, teaching and research.

Descriptors: Nursing Process; Validation Studies; Chemotherapy; Neoplasms; Hematology.

RESUMO

Objetivos: construir e validar um instrumento de coleta de dados para pacientes onco-hematológicos em tratamento quimioterápico ambulatorial. **Métodos:** estudo metodológico que objetivou construir um instrumento de coleta de dados consistente cientificamente para avaliar pacientes hematológicos. Foram cinco etapas: identificação dos indicadores empíricos, avaliação dos indicadores empíricos por grupo focal, construção do instrumento, validação de conteúdo por juízes e validação clínica. Construído com base na Teoria das Necessidades Humanas Básicas de Horta, ajustada por Garcias e Cubas. **Resultados:** o instrumento construído contém dados de identificação do paciente, percepção e expectativas relacionadas à doença, avaliação das necessidades psicobiológicas, psicossociais e psicoespirituais. Atingiu IVC de 95%, assegurando a validade de conteúdo do instrumento e teste alfa de Cronbach com confiabilidade de 0,93. **Conclusões:** o instrumento constituiu-se em uma tecnologia válida para auxiliar o enfermeiro na coleta de dados e poderá servir como ferramenta para a assistência, ensino e pesquisa em enfermagem onco-hematológica.

Descritores: Processo de Enfermagem; Estudos de validação; Quimioterapia; Neoplasias; Hematologia.

RESUMEN

Objetivos: construir y validar instrumento de recopilación de datos para pacientes oncohematológicos en tratamiento quimioterápico en ambulatorio. **Métodos:** estudio metodológico objetivó construir un instrumento de recopilación de datos consistente científicamente para evaluar pacientes hematológicos. Fueron cinco etapas: identificación de indicadores empíricos, evaluación de esos por grupo focal, construcción del instrumento, validez de contenido por jueces y validez clínica. Construído basado en Teoría de las Necesidades Humanas Básicas de Horta, ajustada por Garcias y Cubas. **Resultados:** el instrumento construído contiene datos de identificación del paciente, percepción y expectativas relacionadas a la enfermedad, evaluación de necesidades psicobiológicas, psicossociales y psicoespirituales. Atingió IVC de 95%, asegurando la validez de contenido del instrumento y test alfa de Cronbach con confiabilidad de 0,93. **Conclusiones:** el instrumento se constituye en una tecnología válida para auxiliar el enfermero en la recopilación de datos y podrá servir como herramienta para la asistencia, enseñanza e investigación en enfermería oncohematológica.

Descriptorios: Proceso de Enfermería; Estudios de Validez; Quimioterapia; Neoplasias; Hematología.

INTRODUCTION

Currently, antineoplastic chemotherapy (CTX) remains an indispensable therapeutic option, which has the best cure results for many types of tumors, increasing the survival of cancer patients⁽¹⁻²⁾. It is a systemic treatment of cancer administered at regular intervals, which vary according to therapeutic regimens⁽³⁾.

Oncological patients are exposed to several sources of physical and psychological suffering and, to prevent and reduce it, several interventions can be implemented. However, the formulation of such interventions is done by assessing the human needs presented by the patient⁽⁴⁾. Individualized care is associated with quality of care. Thus, personalization of care is one of the means for improving nursing care for cancer patients⁽⁵⁾.

Regarding the quality of care, the systematization of nursing care has brought great advances in recent years, and is configured as a valid tool for obtaining positive results for patients and nursing professionals⁽⁶⁾. Therefore, knowing that the nursing process is made up of interrelated and dynamic stages, and that the initial stage of building the patient's history is essential for the development of the others, there is a need to use complete data collection instruments and easy to understand, which allows obtaining relevant data for the nurse⁽⁷⁾.

Once validated, this tool is considered to bring contributions to the outpatient care of patients with onco-hematological diseases undergoing antineoplastic treatment, given the lack of similar technology published in journals in the area.

OBJECTIVES

To build and validate a data collection instrument for onco-hematological patients undergoing outpatient chemotherapy.

METHODS

Ethical aspects

The ethical precepts established by Resolution No. 466/2012 of the National Health Council followed, so that the study was approved by the Research Ethics Committee of the Federal University of Ceará.

Design, study location and period

Methodological study guided by the tool Consolidated Criteria for reporting qualitative research (COREQ), referenced on the Equator network, which presents a checklist of 32 items to provide subsidies to studies using focus groups⁽⁸⁾. The study was developed according to the methodological framework of the Theory of Basic Human Needs, by Wanda de Aguiar Horta⁽⁹⁾, from February to October 2017.

Population and sample

It was carried out in a focus group, by a specialist nurse coordinator, from a CTX outpatient clinic, who is trained in leading a focus group, and with four nurses from a chemotherapy outpatient clinic of a teaching hospital, belonging to the Hospital

Complex of *Universidade Federal do Ceará* (UFC). And it aimed to evaluate the grouping of the empirical indicators found and their relationship with altered BHN in the onco-hematological patient, through analysis of the interviews with content analysis of the participants' responses. The choice of participants was for convenience, and they were approached in person, considering the experience of nurses in the care of this public. There were no withdrawals from participation. The interviews were recorded and transcribed shortly after their end, in addition to field notes taken during the group. There were two meetings, considering that the data obtained in the first meeting were returned to the participants for possible corrections and validation.

After the elaboration of the instrument, it was validated in terms of content by seven judges with experience in onco-hematology and systematization of nursing care. Jasper's criteria⁽¹⁰⁾ were used to recruit the judges: possess specialized skill/knowledge, which makes the professional an authority on the subject; possess skill and knowledge acquired by experience; have skill in the type of study; pass a specific test to identify judges; have a high rating, assigned by an authority. Emphasizes that at least two of these criteria should be met.

The criteria proposed by Pasquali⁽¹¹⁾ were adopted to choose the number of participating judges, which considers a number between six to twenty specialists. The selection of judges was carried out by sampling a net or snowball, which is used when the population is composed of people with characteristics that can be difficult to find.

In the process of clinical validation, of the 40 patients in the referred outpatient clinic, 31 agreed to participate, who followed the following inclusion criteria: presenting onco-hematological disease; be guided and in clinical condition to be interviewed; be at least 18 years old.

Study protocol

The study was carried out in five stages⁽¹²⁾. 1) Integrative review of the scientific literature. The search occurred in the databases of Medical Literature Analysis and Retrieval System Online (MEDLINE/Pubmed), Latin American and Caribbean Literature in Health Sciences (LILACS), Nursing database (BDENF) and Scopus, using the Health Sciences Descriptors and Medical Subject Headings (DeCS/MeSH): "nursing" ("*enfermagem*"), "nursing diagnosis" ("*diagnóstico de enfermagem*"), "chemotherapy" ("*quimioterapia*") and "adverse effects" ("*efeitos adversos*"). The controlled descriptor used was "hematologic neoplasms" ("*neoplasias hematológicas*") associated through the Boolean operator AND to the aforementioned descriptors. Primary studies in full, published from 2012 to 2017, in English, Portuguese or Spanish were included. 2) Evaluation of empirical indicators through a focus group. This research technique, when used in the construction of indicators, aims to acquire consensus on the data found, which will later be analyzed by the researcher and transformed into instruments or devices⁽¹³⁾. This process took place from January to February 2018; 3) Construction of the data collection instrument; 4) Content validation by teaching and assisting judges; 5) Clinical validation with the target population.

The seven judges and four nurses received and delivered the signed Free and Informed Consent Form (ICF). The judges were

sent via email the instrument to be evaluated and a script with the evaluation items, in addition to the instructions on how to complete it. This phase occurred from May to December 2018.

In the structuring of the instrument, the international Nursing Minimum Data Set (NMDS) was used, to obtain a concise, clear instrument with sufficient and necessary information for the initial assessment of the patient's health status⁽¹⁴⁾. The International Nursing Minimum Data set (NMDS) divides it into three categories, namely: patient demographic items, nursing care items and service items, which aim to obtain a concise, clear instrument with sufficient and necessary information to the initial assessment of the patient's health status⁽¹⁴⁾. However, psychobiological, psychosocial and psycho-spiritual needs were classified, based on the Theory of Basic Human Needs of Horta (TBHN)⁽⁹⁾.

The relevance of the items was scored using a Likert scale, containing four levels of valuation: 1 - irrelevant; 2 - not very relevant; 3 - relevant and 4 - extremely relevant, in addition to space for suggestions. The first version of the instrument consisted of data from the institution, identification data, perceptions and expectations related to the disease and the set of SI distributed in the BHN classifications of Horta.

Regarding the collection with patients, they were invited to participate at the time of the nursing consultation. This process took place from May to December 2019. Two nursing assistants from the outpatient unit participated in the application of the nursing consultation instrument, as well as two researchers trained for this purpose, who are already working on extension projects in that clinic. During the interviews, notes of comments, opinions, and suggestions from nurses about the instrument were recorded.

Analysis of results and statistics

The data obtained in the focus group were coded, as recommended by COREQ⁽⁸⁾, into empirical indicators necessary to be included in the instrument. These empirical data were separated by the classification of Horta's nursing theory into psychobiological, psychosocial and psycho-spiritual needs⁽⁹⁾.

To determine the level of agreement between the judges in a quantitative way, the Content Validity Index (CVI) was calculated for each of the items and for the total set of items of the instrument. It should also be noted that all suggestions made by the judges were considered and analyzed in a descriptive manner. The data were analyzed in the Statistical Package for the Social Sciences (SPSS), version 20.0, and presented in tables.

The analyzed items were considered validated when the judges presented an agreement index $\geq 78\%$ ⁽¹⁵⁾. Therefore, the item that did not reach this percentage was revised or deleted. At the same time, the reliability of the instrument was assessed by Cronbach's α test, considering the following values >0.90 - excellent, >0.80 - good, >0.70 - acceptable, >0.60 - questionable; >0.50 - poor and <0.50 unacceptable⁽¹⁶⁾.

In the process of applying the instrument to the target population, for each item, the option to disagree or agree was considered. And in case of disagreement, a space to propose suggestions. This process allowed the verification of the pertinence and applicability of the proposed instrument.

RESULTS

1st stage: Identification of empirical indicators

The search resulted in a sample of 27 articles, in which 83 IE related to human needs were identified, being distributed according to each level of need described by Horta, equivalent to 60 in psychobiological needs, 22 in psychosocial needs and one in psycho-spiritual need.

2nd stage: Evaluation of empirical indicators by the focus group

The nurses who made up the focus group were aged between 39 and 51 years, among whom, one was a master and three specialists, with experience in the area of oncology nursing between four and 20 years. The changes and suggestions were recorded on a form and, after obtaining the consensus opinion, a summary of the discussions was presented.

According to the suggestions, four IE were repositioned, inserted in the psychobiological needs (psychological stress, insomnia, hyperglycemia and fatigue). The items insomnia and fatigue were reallocated to the need for sleep and rest. The item psychological stress was reallocated to the need for emotional security and the item hyperglycemia to the need for hormonal regulation. There was an addition of 20 IE related to 10 classifications of psychobiological needs and nine indicators referring to five classifications of psychosocial needs. There was also a change in the writing of some IE and addition of items referring to the institution's data, identification data and perceptions/expectations related to the disease. These recommendations followed the principles outlined in COREQ.

3rd stage: Construction of the data collection instrument

The built instrument had 146 items and was organized by topics, namely: data from the institution; identification data, perception and expectations related to the disease; assessment of psychobiological needs; assessment of psychosocial and spiritual needs, all with their respective items (indicators).

4th stage: Validation of the instrument with judges

All the judges who evaluated the instrument were female, predominantly in the age group 41 to 50 years old (42.8%), 21 to 30 years of professional training (57.1%) and with degrees from doctors and masters (42, 8% each). Regarding the length of experience in the oncology field, judges with experience between 17 and 21 years old (42.8%) prevailed, with the majority (42.8%) exercising teaching and assistance activities. The consent of the responses remained between 86 to 100%. Of the 146 items evaluated, 143 obtained agreement above 78% of the judges. The instrument's CVI as a whole reached 95% CVI, thus ensuring content validity and the representativeness of the instrument for collecting nursing data in the target population. In addition, Cronbach's α test was 0.93, which demonstrated excellent instrument reliability.

Regarding psychosocial needs, the items “number of rooms in the residence, number of family members and privacy at home”, belonging to the need for space, obtained CVI equal to 71%, therefore being excluded from the instrument.

Despite the satisfactory results obtained, it was decided to consider the suggestions for inclusion, exclusion and repositioning of items proposed by the judges, in order to improve the instrument.

Table 1 - Distribution of instrument items that obtained 100% Content Validity Index, Fortaleza, Ceará, Brazil, 2017

		CVI
ASSESSMENT OF PSYCHOBIOLOGICAL NEEDS		
Oxygenation	Respiratory rate, Dyspnea Cough, Sputum Secretion characteristic	1.0
Nutrition	Weight/Height/BMI, Weight Loss Malnutrition, Obesity Anorexia, Odynophagia Dysphagia, Xerostomia, Nausea, Type of diet/number of meals/day, Appetite	1.0
Elimination	Urinary and Intestinal (frequency / characteristic) Dysuria, Hematuria Anuria, Oliguria Polyuria, Urinary incontinence Diarrhea, Constipation Vomit, Melena	1.0
Sleep and rest	Sleep Habit/Period/Duration Insomnia, Drowsiness Fatigue: frequency/time of greatest fatigue	1.0
Physical activity	Exercise, Physical limitation	1.0
Physical integrity	Whole skin, Bruises Petechiae, Mucositis Skin infections Pallor, Hives Adenomegalies, Other skin lesions	1.0
Cell growth and functional development	Neutropenia, Thrombocytopenia Anemia, Alopecia Neutrophil/platelet/hemoglobin values	1.0
Thermal regulation	Temperature, Cold/Chills	1.0
Neurological regulation	Consciousness Confusion, Anxiety Depression, Drowsiness Tingling, Numbness Muscle weakness	1.0
Hormonal regulation	Glycemic levels, Excessive thirst Frequent urination, severe hunger Easy tiredness	1.0
Sensoperception	Pain, Dysgeusia	1.0
Therapy and prevention	Emotional support, Information support Family support, Social support Economic support, Form of treatment adherence	1.0

To be continued

Table 1 (concluded)

		CVI
EVALUATION OF PSYCHOSOCIAL AND PSYCHOSPIRITUAL NEEDS		
Communication	Speech disorders Difficulty understanding what professionals say	1.0
Gregaria	Feel support from the family/ Social relations Receives financial support from family for treatment	1.0
Recreation and leisure	Participates in recreation and leisure activities	1.0
Emotional security	Anguish/Stress/Hopelessness, Concerns/Uncertainty/Fear of the spread and/or recurrence of cancer/Suffering/Despair	1.0
Love, acceptance	Feels rejected and stigmatized by people Problems in the relationship with your partner after diagnosis and treatment	1.0
Self-esteem, self-confidence and self-respect	Decreased self-esteem, Shame Altered body image	1.0
Religiosity/spirituality	Has religion, belief or faith	1.0

Note: CVI – Content Validity Index; BMI – Body Mass Index.

Chart 1 - Suggestions for changes to items in the data collection instrument, according to the analysis of the judges, Fortaleza, Ceará, Brazil, 2017

INSTRUMENT ITEM CHANGES SUGGESTIONS	
Data identification	
Replace “age” with “date of birth”, include “sex”, “race” and “number of cycles of the chemotherapy protocol”, include the “initial, relapse, palliative” treatment phase and “previous treatments”; include “hematopoietic stem cell transplantation: type, date and complications”	
Perceptions and expectations related to the disease	
Include “drug intolerance”	
Assessment of psychobiological needs	
Include “type of liquid ingested” in the need for hydration; include “fatigue level” in the need for sleep and rest; exclude the items “increased risk of complications and increased risk of mortality” in the need for physical security and the environment; include “change in temperature in the last week” in the need for thermal regulation; include “dizziness and vertigo” in the need for hormonal regulation	
Assessment of psychosocial needs	
Replace “exercise paid activities” with “have a fixed income source” in the need to self-realization; include “face the disease positively” in the need for security emotional	
Assessment of psycho-spiritual needs	
Including “are you a practitioner?” in need of religiosity	

The changes suggested by the expert judges are organized and presented in Chart 1. 13 suggestions for changes were accepted, these suggestions referring to items of the instrument that presented CVI greater than 0.78%.

5th stage: Validation of the instrument with the target population

After the stage of validation by judges, validation was carried out with the target population. Through the application of consultation instruments, it was possible to characterize 31 onco-hematological patients treated at a chemotherapy outpatient clinic. Their average age was 50.94 years, along with this, 54.1% were female, 60.7% were married and 36% had finished high school. The most frequent medical diagnoses were Non-Hodgkin's Lymphoma (48.4%), in its various subtypes; Hodgkin's lymphoma (19.4%); Multiple Myeloma (16.1%).

The item Knowledge about the disease and treatment was removed, belonging to the segment "Perceptions and expectations related to the disease". The change is justified, as this information was included in other items of the instrument.

In the Psychobiological needs segment, the items "weight loss" and "obesity" were eliminated, since the items weight, height and BMI were already included in the Nutrition domain, making the data repetitive. The item "dysgeusia", which used to be in the Sensoperception domain, was reallocated to the Nutrition domain, since, at the time of the nursing consultations, it was found that it was more appropriate to ask the patient along with similar questions, such as xerostomia and dysphagia.

In the Regulation domain: cell growth and functional development, the terms "neutropenia", "anemia" and "thrombocytopenia" were replaced by items with space to record the hemogram values (neutrophils, hemoglobin, and platelets), as the value of these parameters in oncohematology is more relevant than just the classification⁽¹⁷⁾.

In the field of Therapeutics and prevention, the following items were relocated: "need for emotional support", "need for information support", "need for family support". These changes are justified, as they are obtained in other items of the instrument referring to psychosocial needs, such as Gregaria, Emotional security and Education for health and learning, facilitating the approach by the interviewer at the time of the interview.

In the emotional security domain, it was observed that patients tended to limit their report of coping with the disease to religious issues. In view of this, the Religiosity/Spirituality domain was reallocated, preceding the Emotional Security domain, to allow the interviewer to address other aspects of coping with the disease. The question "How did Mr./Mrs. Do you face the disease?" to allow an opening by the researcher to address the subject. The items "concern" and "suffering" were also removed, as it was assessed that they did not characterize a way of coping with the disease, as well as the item "avoidance", for observing patients who did not like to talk about the subject. In the domain Education for health and learning, the item Coping, previously discussed, was removed, becoming repetitive at the time of the nursing consultation.

INSTRUMENT FOR DATA COLLECTION FOR ONCO-HEMATOLOGICAL PATIENTS			
UNIVERSITY HOSPITAL WALTER CANTÍDIO CHEMOTHERAPY AMBULATORY			
IDENTIFICATION DATA			
Name:	Date of Birth:	Sex:	
Medical Record:	Origin:	Education:	Race:
Civil status:	Profession:	Clinical diagnosis:	Previous treatment:
Chemotherapy protocol:	No. of cycles:	Treatment phase: () Initial () Relapse () Palliative	Type:
Hematopoietic stem cell transplantation () Yes () No	Date of procedure:		
PERCEPTIONS AND EXPECTATIONS RELATED TO THE DISEASE			
Main complaint:			
Summary/current disease:			
Personal/family medical history, family/cancer history:			
Medicines in use:	Dose:	Usage time:	
Allergies: () No () Yes Type: Intolerance to medicines: () Yes () No			
ASSESSMENT OF PSYCHOBIOLOGICAL NEEDS			
Oxygenation	FR _____ m/rpm () Dyspnea () Cough ()	Expectation Characteristic: _____	
Hydration	Oxygen use: () Catheter () Mask _____	Volume: _____	
	Drink fluids frequently: () Yes () No _____	How many glasses/day: _____	
	Type of liquids: () Water () Natural juice () Artificial juice () Soft drink Other: _____		
Nutrition	Weight _____ Kg Height _____ cm BMI _____	Appetite: () Preserved () Decreased () Increased	
	Type of diet: _____	No. of meals / day: _____	
	() Malnourished () Anorexia () Odynophagia () Dysphagia () Xerostomia () Nausea () Dysgeusia		
Elimination	Urinary (frequency / characteristic): _____		
	Intestinal (frequency / characteristic): _____		
	Presents: () Dysuria () Hematuria () Anuria () Oliguria () Polluria () Urinary incontinence () Diarrhea () Constipation () Hemorrhoids () Melena _____		
Sleep and rest	Sleep habit: Duration: _____ Presents: () Insomnia () Drowsiness () Fatigue		
	Frequency / time of greatest fatigue: _____		
	Fatigue level: () Mild (0 to 2) - Does not interfere with ADL * _____		
	() Moderate (3 to 7) - Interferes, but does not disable the ADL * _____		
	() Intense (8 to 10) - Disable for ADL * _____		
Physical activity	Practices exercises () Yes () No Qual: _____ Frequency: _____		
	Features: () Physical limitation - Which? _____		
Sexuality and reproduction	Sexual activity: () satisfactory () unsatisfactory () has no sexual intercourse		
	Presents: () Erectile dysfunction () Amenorrhea () Vaginal dryness () Reduced libido () Dyspareunia () Use of contraceptive methods - Which _____		
Physical and environmental security	Makes use of: () alcohol () Smoking () Drugs _____		
	House: () Light () City water () Sewer system _____		
Body and environmental care	Deficit in self-care body hygiene: () No () Yes Which _____		
	Deficit in self-care oral hygiene: () No () Yes Which _____		
Physical integrity	Home hygiene: () Adequate () Inadequate _____		
	Presents: () Skin intact () Hematomas () Petechiae () Mucositis () Skin infections () Paleness () Urticaria () Adenomegalies () Other skin lesions _____		
Regulation: Cytic and functional growth	Values: neutrophils _____ platelets _____ hemoglobin _____		
Vascular regulation	PA _____ x _____ mmHg P _____ bpm		
	Presence of: () Arrhythmias () Hypertension () Hypotension () Hypoalbuminemia () Edema () Phlebitis		
	Bleeding: () Gingival () Nasal () Intestinal () Others _____		
	Venous access: () Central () _____ Peripheral Venous network conditions: () Good () Regular () Poor		
Thermal regulation	Temperature: _____ °C Feels: () Cold () Chills _____		
	Temperature change in the last week: () Yes () No _____ °C		
Neurological regulation	() Conscious () Oriented () Confused () Anxious () Depressive		
	Presence of: () Tingling () Numbness () Muscle weakness () Others _____		
Hormonal regulation	Glycemic levels: _____ mg / dL		
	Presents: () Excessive thirst () Frequent urination () Severe hunger () Easy tiredness		
Sensoperception	Pain: () Yes () No Location _____ Type _____ Intensity _____		
Therapy and prevention	Form of treatment adherence: () Completely complies () Completely complies () Does not comply		
EVALUATION OF PSYCHOSOCIAL AND PSYCHO-SPIRITUAL NEEDS			
Communication	Speech disorders: () Yes () No		
	Difficulty understanding what professionals say: () Yes () No		
Gregaria	Do you feel support from the family: () Yes () No Social relationships: () Preserved () Decreased		
	Do you receive financial support from the family for treatment? () Yes No		
Recreation and leisure	Participates in recreation and leisure activities: () Yes () No Which _____		
Religiosity / spirituality	Do you have religion, belief or faith: () No () Yes Which _____ Are you practicing? _____		
Emotional security	Like Mr./Mrs. Do you face the disease? _____ Need emotional support? () Yes No		
	() Anguish () Stress () Hopelessness () Fear of the spread and / or recurrence of cancer () Despair () Avoidance () Sadness		
Love, acceptance	Feels rejected and stigmatized by people: () Yes () No		
	Problems in the relationship with your partner after diagnosis and treatment: () Yes () No		
	Which _____		
Self-esteem, self-confidence and self-respect	Decreased self-esteem: () Yes () No		
	Regarding body image: () satisfied () dissatisfied () ashamed		
Freedom and participation	() Participates in a support group () Knows and exercises the rights of cancer patients		
Health education and learning	Understands about your disease, risks involved and type of treatment: () Yes () No		
Self-realization	Do you need any information? () Yes No		
	Do you feel capable of performing your daily life activities: () Yes () No		
	Has a fixed income source: () Yes () No Restriction and / or leave from work: () Yes () No		
Guaranteed access to technology	You have access to: () Medicines () Exams () Health services		
	Form of access: () SUS () Agreement () Private		
Nurse: _____	COREn: _____ Date: ____/____/____		

Figure 1 – Final version of the instrument for data collection for onco-hematological patients, Fortaleza, Ceará, Brazil, 2020

It was also observed the need for more space for effective registration of the evaluated aspects, justifying changes in the instrument's layout. Thus, considering the pertinence of the items added referring to the judges' suggestions and during the clinical validation process, the final version of the instrument was elaborated, which now has 178 items and greater availability of space for recording information (Figure 1).

DISCUSSION

The built instrument, called "Data collection instrument for onco-hematological patients", consists of identification data, perceptions and expectations related to the disease, as well as the assessment of psychobiological, psychosocial and psycho-spiritual needs.

Patient identification data are relevant in the instrument for the first stage of the nursing process, as they belong to the set of essential nursing elements that meet the information needs of various users in the health system⁽¹⁸⁾.

A suggestion by the judges turned to the inclusion and association of the item "drug intolerance" with the item "drug allergy".

These data were evaluated as relevant, since it is essential for nurses to know and register allergies and drug intolerances. The knowledge and recording of this information supports an adequate analysis of prescriptions and nursing care, being listed as good practices in the administration of chemotherapy⁽¹⁹⁾.

The changes recommended by the judges regarding psychobiological needs were focused on the topic of hydration and sleep. In the topic of rest, the importance of measuring the intensity of fatigue was added. The high prevalence of fatigue in this population is highlighted, being disabling and detrimental to the quality of life, in addition to being underestimated and underreported. In addition to being reported as one of the most important and stressful symptoms related to cancer and its treatment⁽²⁰⁾.

Still regarding psychobiological needs, the topic "thermal regulation" was marked by the increase in the presence of fever in the last week. Fever is a warning sign and, when associated with neutropenia, is considered an oncological emergency. The administration of antibiotic therapy in a timely manner is related to better outcomes. Nursing participates in the management of neutropenic fever, acting in the identification of the event and intervening by providing information to the patient, an important part of the management⁽¹⁷⁾.

The indicators "dizziness and vertigo" were also added to the instrument because they are symptoms that suggest changes in blood glucose levels⁽²¹⁾. Vertigo is one of the forms of dizziness, being a hallucination of movement, rotational or translational. Vertigo patients report feeling of movement, even in a static position⁽²²⁾. In acute lymphocytic leukemias, episodes of hyperglycemia may occur during the therapeutic induction protocol, due to the concomitant administration of corticosteroids. Early detection and treatment of hyperglycemia are fundamental steps in the prevention of acute complications, such as non-ketoacidotic hyperglycemic syndrome⁽²³⁾.

In the psychosocial and psycho-spiritual needs, the question of exercising paid activity and / or fixed income were considered relevant by the judges, as well as how the individual coped with the disease.

Coping is nothing more than an adaptive change to the environment, which can be positive or negative, depending on the defense mechanisms employed. Such records add relevance to the instrument, since a person's health is influenced by socioeconomic determinants. Therefore, coping with patients may be focused on emotion, through the search for social support or information, as well as the search for religious practices, assimilating thoughts of hope that serve to assist in coping with cancer⁽²⁴⁾. Knowing this aspect goes against what is recommended for the nurse's work on what to investigate in an outpatient context⁽²⁵⁾. In the validation process with the target audience, avoidance was seen as a way of coping, and for this reason, it was included in the instrument.

The item practice of religion was added to the instrument to have belief or faith, considering that the religious and spiritual aspects differ and must be understood and valued⁽²⁶⁾. The use of religion, spirituality or faith as a coping strategy in the face of unfavorable contexts is called *spiritual/religious coping*. Individuals who have positive coping strategies also have high levels of hope. Thus, in the relationship with the patient and family, the nurse must identify the religious and spiritual needs of the binomial,

providing care focused on spirituality, using their coping strategies in maintaining hope⁽²⁷⁾. This element can contribute to treatment adherence⁽²⁸⁾. It is noteworthy that, during the validation with patients, the religious issue emerged in almost all consultations as a means of coping with the disease/treatment.

The validation with the target audience confirmed the relevance of the items contained in the instrument validated by the judges, and most of the changes made in this process of clinical validation referred to structural changes, reallocation of items in other domains and items that were found, repeated, in a way.

Nursing has an important role of facilitator and mediator for the patient to contemplate his biological, psychological, social and spiritual needs. Therefore, it is believed that the use of the built instrument may contribute to the practice of oncologist nurses who work in an outpatient unit, as it translates items relevant to nursing research.

Study limitations

During the development of the research, limitations were found, such as the difficulty of elaborating a brief instrument so as not to make the application in care practice unfeasible, but that, nonetheless, included minimum essential items to guarantee quality care. Another limitation was the difficulty in defining judges, in view of the difficulty of being conceptualized in its entirety. The criterion used in the study was that of Jasper, who considers items of clinical experience, but there is no guarantee that all prerequisites are, in fact, a guarantee of clinical expertise. Furthermore, failure to perform field validation with nurses is also a limitation of the present study.

Contributions to the field of nursing, health or public policy

It is believed that the elaboration and validation of the nursing data collection instrument, based on BHN and directed to onco-hematological patients, constitutes the first step to assess the real needs of this clientele, enabling the planning and implementation of interventions appropriate and individualized within the outpatient context. Thus, it will be possible to contribute to the nursing process, aiming to share and expand care for the target audience.

CONCLUSIONS

The constructed instrument was submitted to content validation by seven expert judges, in addition to clinical validation with 31 patients. The results showed that the scores attributed by the judges validated most of the items contained in the instrument. The instrument's CVI as a whole reached 95%. Therefore, ensuring content validity and the representativeness of the instrument for collecting nursing data in the target population. In addition, Cronbach's alpha test was 0.93, which demonstrated excellent reliability of the instrument. The clinical validation allowed the improvement of the instrument and obtained a final version with 178 items. Thus, the instrument is a valid technology to assist nurses in data collection and will serve as a tool for onco-hematological nursing care, teaching and research.

Finally, it is hoped that the elaborated and validated data collection instrument will be inserted as a nursing care management tool, since this step, which is essential to the nursing process, when well structured, will provide support for the other steps. In

addition to providing nursing assistants with the development of critical thinking and clinical reasoning in the preparation of nursing diagnoses and in the establishment of appropriate and specific nursing interventions.

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