Cogitare Enfermagem

ORIGINAL ARTICLE

CONSTRUCTION AND VALIDATION OF A NURSING CONSULTATION TOOL FOR PEOPLE WITH HEMOPHILIA

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ABSTRACT

Objective: to construct and validate a nursing consultation instrument for people with hemophilia.
Method: methodological study conducted from February 2017 to February 2018, in a hematology reference service in Northeast Brazil. The Delphi technique was used for validation, by three groups of nurse judges (n=29): hemophilia specialists (n=nine) from nine blood centers in the country; Hematology Residency (n=eight); Service Nurses (n=12). Inter-rater agreement was checked by Likert scale and Fisher's exact test.
Results: 89.6% had no difficulty in understanding the instrument. As for the degree of relevance, the characteristics 'credibility' and 'scientificity' showed higher percentages of extremely relevant (90%). Fisher's exact test was significant in the degree of satisfaction of 'clarity of statements' (p<0.05).
Conclusion: the instrument was considered valid, providing autonomy, technical support, and ethical support to the nurse, contributing to the improvement of the quality of care.

DESCRIPTORS: Office Nursing; Validation Study; Hemophilia A; Hemophilia B; Protocol.

CONSTRUCCIÓN Y VALIDACIÓN DE UN INSTRUMENTO DE CONSULTA DE ENFERMERÍA PARA PERSONAS CON HEMOFILIA

RESUMEN:

Objetivo: construir y validar un instrumento de consulta de enfermería para personas con hemofilia. Método: estudio metodológico realizado de febrero de 2017 a febrero de 2018, en un servicio de referencia de hematología del Nordeste de Brasil. Para la validación se utilizó la técnica Delphi, por parte de tres grupos de enfermeras jueces (n=29): Especialistas en hemofilia (n=nueve) de nove hemocentros del país; Residencia en Hematología (n=ocho); Enfermeras del Servicio (n=12). La concordancia entre las jueces se verificó mediante la escala Likert y la prueba exacto de Fisher. Resultados: 89,6% não apresentaram dificuldade para compreender o instrumento. Quanto ao grau de relevância, as características 'credibilidade' e 'cientificidade' apresentaram maiores percentuais de extremamente relevante (90%). O teste exato de Fisher foi significativo no grau de satisfação de 'clareza das afirmações' (p<0,05). Conclusão: o instrumento foi considerado válido, proporcionando autonomia, apoio técnico e respaldo ético ao enfermeiro, contribuindo na melhoria da qualidade da assistência. DESCRITORES: Enfermagem no Consultório; Estudo de Validação; Hemofilia A; Hemofilia B; Protocolo.

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INTRODUCTION

Hemophilia is a rare, genetic, bleeding disorder with recessive inheritance linked to the X chromosome. It is characterized by a deficiency or abnormality in the coagulation activity of factor VIII (hemophilia A) or factor IX (hemophilia B). From a clinical point of view, hemophilia A and B are similar, presenting with hemorrhagic conditions depending on the plasma levels of the deficient factor. Hemophilia can be classified as severe, when the circulating factor level is less than 1%; moderate, between 1% and 5%; and mild, from 5% to 40% [1-2].

In 2017, Brazil (n=12,432) had the world's fourth largest population of Persons with Hemophilia (PwH), behind India (n=18,966), the United States (n=17,750) and China (n=14,390), and it is the most prevalent disease among hereditary coagulopathies [3].

The nursing consultation (NC) is a fundamental part of PwH care, being considered an important technological strategy that offers numerous advantages in the care provided [4-5]. In this context, the nurse is one of the main protagonists of care, because he/she provides health education to the patient and family members [1,4-6], provides training for self-infusion of the factor at home [7-9], monitors treatment progress, improving quality and safety, including treatment adherence [9-10].

To ensure the reliability of nursing care through safe procedures based on scientific evidence, it is essential to build protocols. There are established principles for the construction and validation of care protocols, such as a clear definition of the focus, the intended population, who performs the actions, the literature review strategy, analysis of the evidence used, the form of peer validation, implementation strategies, and the construction of expected results [11-12].

Content validity is the determination of the representativeness of items that express a content, based on the judgment of experts in a specific area, determining whether the content of a measurement instrument effectively explores the requirements for measuring a particular phenomenon to be investigated [12].

This article aims to describe the construction and content validation of a nursing consultation instrument for PwH, in a reference hematology service in Northeast Brazil. The scarcity of NC instruments for patients with coagulopathies, and the great complexity of information needed for the consultation, in order to ensure that no aspect is neglected, justify the importance of this study.

METHOD

Methodological study conducted in the hereditary coagulopathies' outpatient clinic of a hematology reference service of Northeast Brazil, located in Recife-PE. Data collection was performed from February 2017 to February 2018.

The theoretical framework followed in the study [13] suggests a four-step script to guide the process of instrument construction and validation: 1. planning (objective, target population, instrument items); 2. construction (content, content validity assessment by a panel of experts); 3. validation (test application to a significant number of judges for content and appearance validity). 4. final evaluation of the instrument (application of the pilot version in an appropriate experimental group).

1st Step: Planning

In this step, empirical indicators (sociodemographic and clinical variables) and affected human needs of PwH were identified through the randomized observation of NCs in the outpatient clinic of the service. A literature search was also performed with the descriptors "validation studies" combined with "nursing in the clinic", "hemophilia A" and "hemophilia B" using the Boolean operator 'AND', in the databases BDENF, BIREME/BVS, LILACS, MEDLINE/PubMed, Brazilian Ministry of Health, SCIELO and World Federation of Hemophilia.

2nd Step: Construction of the Instrument

The first version of the instrument was built according to the Hemovida Web-Coagulopathies model of the Brazilian Ministry of Health [14], because the literature search did not find articles on NC instrument for hemophilia. Thus, the instrument was developed by two nurses of the service with 10 years dedicated exclusively to PwH, with an average of 110 attendances/month. Later, the instrument was analyzed by the focus group technique, by a multi-professional team of 12 outpatient specialists (one social worker, two nurses, two psychologists, one physiotherapist, one dentist, one pharmacist, and four physicians).

3rd Step: Validation of the instrument

In this step, the instrument was evaluated by nurse judges through the Delphi technique [15], which consists in evaluating a given topic through the judgment of experts on the subject, based on the convergent opinion of the evaluators, emphasizing the need for group consensus. We also used the appearance validation, even though it is considered a subjective technique [12], however we consider it important because the evaluation was performed by experts from nine Brazilian states, providing greater reliability to the instrument.

The sample size of the female judges was defined by the formula $n=Z\alpha^2.P.(1-P)/d^2$, where $Z\alpha$ refers to the confidence level (95%), P is the proportion of individuals who agree with the relevance of the concepts (85%), and d is the difference in proportion considered acceptable (15%) [16]. The final calculation was determined by $n=1.95^2.0.85.0.15/0.15^2$ and with this, a sample of 22 judges was obtained, adding 20% for losses or refusals, totaling 26 judges.

The selection criteria for the judges were: 1. hemophilia specialists (HS, n=nine) from nine blood centers in the country (Campinas, Ceará, João Pessoa, Maceió, Manaus, Natal, Minas Gerais, Recife and Rio de Janeiro) defined by snowball sampling (17), in which the selected participant indicates other participants, it is a convenience sample, being sent by e-mail the invitation letter and the evaluation form; 2. Nurses with Hematology Residency (RN, n=8); 3. Service Nurses (SN, n=12), all with more than three years' experience in PwH care. Nurses away on medical leave, premium and vacation were adopted as exclusion criteria.

The judges were invited to participate in the study, oriented about the objectives, and signed the Informed Consent Form. All the nurses agreed to participate in the study, and the HS group sent the answers via e-mail. It was possible to obtain a sample of 29 judges, giving more confidence to the validation performed, meeting the recommended quantity of a sample of 25 to 50 experts to perform the validation [15].

Agreement between the judges was verified by the four-point Likert scale [18] and by Fisher's exact test, applied to compare agreement between the experts, to verify homogeneity in the application of the instrument. The evaluation form analyzed: A. Degree of difficulty to fill out (complete difficulty-1, moderate difficulty-2, mild difficulty-3, no difficulty-4); B. Degree of relevance of the characteristics: objectivity, simplicity, clarity,

pertinence, accuracy, credibility and scientificity (not relevant-1, not very relevant-2, relevant-3, extremely relevant-4); C. Degree of satisfaction on the appearance of the instrument: presentation, clarity of questions, ease of reading, interpretation and representativeness (no impact-1, insufficient-2, satisfactory-3, excellent-4).

The score for each item was tabulated with a simple count of the number of responses for each evaluation criterion and the percentage of female judges who agreed with the content of the instrument. Scores one and two were considered indicative of poor quality, and scores three and four were considered indicative of good quality. Items with at least 85% agreement were considered valid.

For statistical analysis of the data, a database was built in Microsoft Excel 2013 spreadsheet, which was exported to SPSS-18 software, where the analysis was performed. All conclusions were drawn considering the significance level of 5%.

4th Step: Final evaluation of the instrument

This stage consisted of a pilot test of the final version of the instrument with 30 adult PwH who attended the NC in the outpatient clinic of the institution, according to criteria established in the literature, which define a sample of 30 to 40 people [19].

The study was conducted in compliance with resolution 466/2012 of the National Health Council of the Ministry of Health and was approved by the Research Ethics Committee of the researched institution under opinion number 1,863,411.

RESULTS

As for the characterization of the judges, all were female. The NR group was younger, with a mean age (30±6.4), HN (47±9.8) and ES (51±12). In the HN group, there was one doctoral degree (11.1%), two master's degrees (22.2%), and three proficiencies in hematology (33.3%); in the NR, all had completed their hematology nursing residency less than five years ago; and in the NS, six had master's degrees (50%) in areas other than hematology.

Considering the suggestions given by the judges (Chart 1), a total of 19 suggestions were found, of which 12 (63.2%) were accepted by the researchers. It was observed that the HN group presented more suggestions 11 (57.9%), followed by NS five (26.3%) and NR three (15.8%).

Chart 1 - List of suggestions from the nurse judges. Recife, PE, Brazil, 2018 (continues)

Items	Judges´ Suggestions		Acceptance by the Researchers
General data	1.	Expand the instrument to all hereditary coagulopathies	No
	2.	Specify all drugs	No
	3.	Insert number of children	Yes
	4.	Remove the item about blood glucose	No

Habits	5.	Insert number of cigarettes / days	Yes
	6.	Carry over to social activities	No
Allergies	7.	Compose Block 1	Yes
Inhibitor Research	8.	Exchange order with item 11	No
	9.	Add self-infusion training	Yes
	10.	Add date of last training	Yes
	11.	Clarify titles: first title, historical peak, general title	Yes
Mobility	12.	Change the term "ambulates with assistance" to "ambulates with difficulty"	No
Sorologies	13.	Insert those of immunization	Yes
Social Activities	14.	Insert sexual activity	Yes
	15.	Insert sports activities	Yes
	16.	Insert family planning	Yes
Infusion diary checking	17.	Insert correct disposal of the material	Yes
Nursing Diagnoses	18.	Exchange order with item 17	No
Immunotolerance	19.	Insert "presence of inhibitor" option	Yes

Source: Authors (2018)

In relation to the degree of difficulty of the judges to understand the instrument, it was verified that the majority did not present any difficulty 15 (51.7%), followed by light difficulty 11 (37.9%) and moderate difficulty three (10.4%). The Fisher's exact test (p=0.358) was not significant, indicating that the degree of difficulty is similar between the analyzed groups.

The analysis of the characteristics of the instrument regarding structure, aesthetics and content showed a similar pattern of response, with a single divergence in the item 'clarity of information', where the HN group showed a lower percentage of 'excellent'; and suggested that the instrument should be extended to all hereditary coagulopathies. However, it was decided to keep the instrument unchanged, because it would be necessary to insert several items referring to women's health in order to meet the female profile of the other hereditary coagulopathies.

The instrument was also considered long by the HN group, even though all the nurses were instructed that it would be implemented in electronic format, and that the complete filling out would only occur in the first consultation, and afterwards, the data would only be updated.

The relevance of the characteristics evaluated in the instrument is described in Table 1. It was verified that 'credibility' and 'scientificity' presented the highest percentages of "extremely relevant". However, excluding these characteristics, we observed a higher percentage of "extremely relevant" in groups HN (accuracy), NR (objectivity and relevance) and NS (clarity) of the instrument. The comparison test was not significant in all characteristics (p>0.05).

Table 1 - Distribution of the degree of relevance of the characteristics of the instrument evaluated by the nurse judges (n=29), according to professional training/actuation. Recife, PE, Brazil, 2018

Valuated characteristic	Total n (%)	Evaluated group			p-value (*)
		HN n (%) (n=9)	NR n (%) (n=8)	NS n (%) (n=12)	
Clarity					
Relevant	8(28)	3(33)	3(38)	2(17)	0,582
Extremely relevant	21(72)	6(67)	5(62)	10(83)	
Pertinence					
Relevant	9(31)	3(33)	1(12)	5(42)	0,468
Extremely relevant	20(69)	6(67)	7(88)	7(58)	
Accuracy					
Relevant	7(24)	1(11)	3(38)	3(25)	0,407
Extremely relevant	22(76)	8(89)	5(62)	9(75)	
Credibility					
Relevant	3(10)	1(11)	1(12)	1(8)	1
Extremely relevant	26(90)	8(89)	7(88)	11(92)	
Scientificity					
Relevant	3(10)	1(11)	1(12)	1(8)	1
Extremely relevant	26(90)	8(89)	7(88)	11(92)	

Legend: HN - Hemophilia Specialist Nurse; NR - Nurse with Residency in Hematology and Hemotherapy; NS - Service Nurse; (*) Fisher's Exact Test (p<0.05 there is difference of opinion between the groups of specialists).
Source: Authors (2018).

Regarding the degree of satisfaction of the judges about the appearance of the instrument (Table 2), it was found that the characteristic 'representativeness' presented the highest percentages of excellent. The NR group considered all analyzed characteristics as excellent, presenting the highest percentages of satisfaction. The HN group showed a lower percentage of excellent in relation to the characteristic 'clarity of statements', resulting in a significant Fisher's exact test (p<0.05), indicating that there is difference of opinion between the groups.

Table 2 - Distribution of the degree of satisfaction of the nurse judges about the appearance items of the instrument, according to professional training/activity. Recife, PE, Brazil, 2018 (continues)

Valuated characteristic	Total n (%)	Evaluated group			p-value (*)
		HN n (%) (n=9)	NR n (%) (n=8)	NS n (%) (n=12)	
Presentation					

Satisfactory	7(24)	2(22)	1(12)	4(33)	0,664
Great	22(76)	7(78)	7(88)	8(67)	
Clarity of statements					
Insufficient	1(3)	0	1(12)	0	0,035
Satisfactory	8(28)	5(56)	0	3(25)	
Great	20(69)	4(44)	7(88)	9(75)	
Ease of reading					
Insufficient	2(7)	0	1(12)	1(8)	0,434
Satisfactory	5(17)	3(33)	0	2(17)	
Great	22(76)	6(67)	7(88)	9(75)	
Representativeness					
Insufficient	1(3)	1(11)	0	0	0,338
Satisfactory	4(14)	0	1(12)	3(25)	
Great	24(83)	8(89)	7(88)	9(75)	

Legend: HN - Hemophilia Specialist Nurse; NR - Nurse with Residency in Hematology and Hemotherapy; NS - Service Nurse; (*) Fisher's Exact Test ($p < 0.05$ there is difference of opinion between the groups of specialists).
Source: Authors (2018).

The final version of the instrument was composed of two parts, the first (Figure 1) with general data with 19 categories, and the second (Figure 2) with Immunotolerance data.

Figure 1 – Nursing Consultation Instrument for Person with Hemophilia. Recife, PE, Brazil, 2018

Figure 2 – Nursing Consultation Instrument for Person with Hemophilia/ Immunotolerance. Recife, PE, Brazil, 2018

In the pilot test carried out in the outpatient clinic with 30 PwH, it was found that the nurses had no difficulties in applying the instrument. The first consultation was longer, around 30 minutes; subsequent consultations, when the data were only updated, took 10 to 15 minutes. The most time-consuming part was the application of the Hemophilia Functional Independence Score (FISH), which should be filled out every six months, and the evaluation of coagulation factor self-infusion, which should be performed annually.

DISCUSSION

The use of measuring instruments in healthcare practices is progressively increasing. In the nursing field, validating instruments that guide practice is synonymous with the development of health technologies for the profession since it becomes possible to direct nursing care and improve the quality of care[20].

Advantages have been pointed out for the use of care instruments, such as greater safety for users and professionals, reduced variability of care actions, improved qualification of professionals for care decision making, ease of incorporating new technologies, care innovation, more rational use of available resources, and greater transparency and cost control. Also, as advantages, protocols facilitate the development of process and outcome indicators, knowledge dissemination, professional communication, and care coordination[11,19].

According to recommendations from specialists in hereditary coagulopathies from Northeastern Brazil on the role of the nurse in the care of people with hemophilia, it describes the importance of using validated instruments: "The nursing consultation to the person with hemophilia should be performed in all hemophilia treatment centers, using a standardized and validated instrument applied by a nurse with experience in hereditary coagulopathies"[21: e121].

The recommendations aim to unify nursing in care practice, ensuring its leadership, its role in the consultation, with autonomy to select patients who are candidates for prophylaxis treatment, request laboratory tests according to internal protocols, and participate in the therapeutic decision [21].

Several studies [22-25] demonstrate that content-valid instruments subsidize the development of nursing care practice, and by using the Delphi technique to reach consensus among experts, it minimizes direct influence, allows access to distant participants, and favors personal and clinical reasoning.

Nursing consultation to PwH is recommended in the The Brazilian Hemophilia Manual[26] and the World Federation of Hemophilia Guidelines for the Treatment of Hemophilia [1] as a fundamental part of patient care and is considered an important technological strategy for health care, supported by law, exclusive to nurses, and that offers numerous advantages in the care provided.

In this context, it is often suggested that the role of nurses will become increasingly important in the future provision of care for PwH [5-10,21]. According to the European Haemophilia Consortium:

> Nurses are an extremely valuable resource in the care of patients with hemophilia and are taking on increasing responsibilities, including treating acute bleeding, organizing outpatient clinics, training parents and children in venipuncture and prophylaxis, and prescribing clotting factor concentrates and other medications [27:14].

The profile of the judges who validated the instrument showed a high number of monthly attendances to patients with coagulopathies, demonstrating experience in hematology care. The instrument was built in a reference blood center for PHC care in Northeastern Brazil and validated by nine specialists from blood centers in the country, providing greater reliability and legitimacy to the instrument.

The judges' analysis of the instrument showed the need to add data and refine categories to improve its content, and the following were inserted: number of cigarettes/day; presence of inhibitor, date of last training, first, historical peak, general title; coagulation factor infusion/auto-infusion training; immunization; number of children, sexual activity, family planning, and sports activities.

The application of NC requires continuous training of nurses for clinical reasoning, using clinical examination tools [4-6] as well as for nursing diagnosis, so nursing diagnoses and referrals made by nurses were added to the instrument in order to ensure autonomy.

The final version of the instrument was applied to a sample of 30 PcH, through a pilot test, and there was no difficulty in application by the outpatient clinic nurses.

According to the Ministry of Health, nurses need to perform three consultations per hour, with no distinction between new and follow-up consultations [28]. Therefore, the nurse has an average of 20 minutes to perform the nursing consultation. It was observed that the duration of the consultations for application of the research instrument was reduced with the practice of applying the instrument, reaching the recommended average.

Similarly, an international study [29] found an average duration of NC of 10 minutes, with a minimum of four minutes and a maximum of 35 minutes. The authors stated that the duration of the consultation is associated with the characteristics of the client, presence of comorbidities and the level of practice of the professional. In this research, PwH had several comorbidities such as hemarthrosis, arthropathies, inhibitors against coagulation factors, which may have contributed to a longer time in the application of the instrument in the first consultations.

It was verified that most of the judges had no difficulty in understanding the instrument, a positive fact in the evaluation, demonstrating that there were no significant differences in the use of the instrument between the groups. The instrument was implemented in the service in electronic format, and nurses from other blood centers in the Northeast of the country are being trained to use it.

The limitation of the study was the absence of studies on nursing consultation instruments and/or protocols for people with hemophilia or hereditary coagulopathies that could serve as models or compare results.

CONCLUSION

Elaborating and validating an NC tool for hemophilia is important for clinical and scientific nursing practice, since it represents an innovation in decision making, in the application of standardized terminologies, providing autonomy, technical support and ethical support to nurses. However, further studies are suggested: there is a lack of literature on NC tools for hemophilia, both nationally and internationally.

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