

Validation graphic protocol for assessing safe nursing care in hemodialysis

Protocolo gráfico de validação para avaliação da assistência de enfermagem segura em hemodiálise

Protocolo gráfico de validación para evaluación de asistencia de enfermería segura en hemodiálisis

Renilly de Melo Paiva¹  <https://orcid.org/0000-0001-7902-0378>Flávia Barreto Tavares Chivone¹  <https://orcid.org/0000-0002-7113-2356>Manaces dos Santos Bezerril¹  <https://orcid.org/0000-0002-9003-2334>Marianny Nayara Paiva Dantas¹  <https://orcid.org/0000-0002-8891-0003>Isabelle Campos de Azevedo¹  <https://orcid.org/0000-0001-5322-7987>Adriana Catarina de Souza Oliveira²  <https://orcid.org/0000-0001-8600-4413>Marcos Antonio Ferreira Júnior³  <https://orcid.org/0000-0002-9123-232X>Viviane Euzébia Pereira Santos¹  <https://orcid.org/0000-0001-8140-8320>

How to cite:

Paiva RM, Chivone FB, Bezerril MS, Dantas MN, Azevedo IC, Oliveira AC, et al. Validation graphic protocol for assessing safe nursing care in hemodialysis. Acta Paul Enferm. 2024;37:eAPE00551.

DOI

<http://dx.doi.org/10.37689/acta-ape/2024A000005511>



Keywords

Renal dialysis; Patient safety; Renal insufficiency, chronic; Validation studies

Descritores

Diálise renal; Segurança do paciente; Insuficiência renal crônica; Estudos de validação

Descriptores

Diálisis renal; Seguridad del paciente; Insuficiencia renal crónica; Estudio de validación

Submitted

March 16, 2023

Accepted

October 30, 2023

Corresponding author

Adriana Catarina de Souza Oliveira
E-mail: acatarina@ucam.edu

Associate Editor (Peer review process):

Bartira de Aguiar Roza
(<https://orcid.org/0000-0002-6445-6846>)
Escola Paulista de Enfermagem, Universidade Federal de São Paulo, São Paulo, SP, Brazil

Abstract

Objective: To validate the content and appearance of a graphic protocol for evaluating safe nursing care for hemodialysis patients.

Methods: Methodological study with a quantitative approach, organized into three procedures: theoretical from a Scoping Review; empirical in which the process of constructing the graphic protocol and checklist for the evaluation of safe care took place; finally, the analytics for the validation itself using the Delphi technique and the participation of nine expert judges in two rounds to reach agreement.

Results: The checklist and the graphic protocol were elaborated. As for content validity in Delphi I, three criteria obtained Content Validity Coefficient =0.77 in the checklist. In what corresponds to Delphi II, 80% was achieved in all items regarding the Content Validity Coefficient, all indices were above 0.80. Appearance validation took place using criteria of the Suitability Assessment of Materials in Delphi I, it was possible to achieve a total Content Validity Coefficient greater than 0.80 in all, while in Delphi II the protocols reached agreement greater than 80% and Content Validity Coefficient greater than 0.88, since the checklist showed a higher Content Validity Coefficient with 0.91.

Conclusion: The graphic protocol and checklist for evaluating safe care for hemodialysis patients are presented, valid in their content and appearance.

Resumo

Objetivo: Validar o conteúdo e a aparência de um protocolo gráfico para avaliação do cuidado seguro de enfermagem a pacientes em hemodiálise.

Método: Estudo metodológico com abordagem quantitativa, organizado em três procedimentos: teóricos, a partir de uma *scoping review*; empíricos, na qual ocorreu processo de construção do protocolo gráfico e *checklist* para avaliação do cuidado seguro; por fim, os analíticos, para a validação propriamente dita com uso da técnica Delphi e participação de nove juízes especialistas em duas rodadas para o alcance da concordância.

Resultados: Elaboraram-se o *checklist* e o protocolo gráfico. Quanto à validade de conteúdo, em Delphi I, três critérios obtiveram Coeficiente de Validade de Conteúdo =0,77 no *checklist*. No que corresponde ao Delphi II, foram alcançados 80% em todos os itens referentes ao Coeficiente de Validade de Conteúdo, e todos os índices ficaram acima de 0,80. A validação de aparência ocorreu utilizando critérios de *Suitability Assessment of Materials* no Delphi I. Foi possível atingir um Coeficiente de Validade de Conteúdo total maior que 0,80 em todos, enquanto que, no Delphi II, os protocolos alcançaram concordância maior que 80% e Coeficiente de

¹Universidade Federal do Rio Grande do Norte, Natal, RN, Brazil.

²Universidade Católica de Murcia, Guadalupe de Maciascoque, Murcia, Spain.

³Universidade Federal do Mato Grosso do Sul, Campo Grande, MS, Brazil.

Conflicts to interest: the article "Graphic protocol for evaluating safe nursing care in hemodialysis: validation study" is published in a preprint repository and is published in the Research Square database (<https://www.researchsquare.com/article/rs-1964314/v1>), with DOI <https://doi.org/10.21203/rs.3.rs-1964314/v1>.

Validade de Conteúdo maior que 0,88, já que o *checklist* apresentou maior Coeficiente de Validade de Conteúdo com 0,91.

Conclusão: Apresentam-se o protocolo gráfico e o *checklist* para avaliação do cuidado seguro aos pacientes em hemodiálise válidos em seu conteúdo e aparência.

Resumen

Objetivo: Validar el contenido y la apariencia de un protocolo gráfico para la evaluación del cuidado seguro de enfermería a pacientes en hemodiálisis.

Métodos: Estudio metodológico con enfoque cuantitativo, organizado en tres procedimientos: teórico, a partir de una *scoping review*; empírico, donde se realizó el proceso de elaboración del protocolo gráfico y *checklist* para la evaluación del cuidado seguro; y por último, analítico, para la validación propiamente dicha mediante el uso del método Delphi y la participación de nueve jueces especialistas en dos rondas para alcanzar la concordancia.

Resultados: Se elaboró la *checklist* y el protocolo gráfico. Respecto a la validez del contenido, en Delphi I tres criterios obtuvieron Coeficiente de Validez de Contenido = 0,77 en la *checklist*. En lo referente al Delphi II, se alcanzó el 80 % en todos los ítems relacionados con el Coeficiente de Validez de Contenido, y todos los índices fueron superiores a 0,80. La validación de la apariencia se realizó con los criterios de la *Suitability Assessment of Materials* en Delphi I. Se logró alcanzar un Coeficiente de Validez de Contenido total mayor a 0,80 en todos, mientras que en Delphi II, los protocolos lograron una concordancia mayor a 80 % y Coeficiente de Validez de Contenido mayor a 0,88, ya que la *checklist* presentó mayor Coeficiente de Validez de Contenido con 0,91.

Conclusión: El protocolo gráfico y la *checklist* para la evaluación del cuidado seguro a pacientes en hemodiálisis demostraron ser válidos en su contenido y apariencia.

Introduction

Chronic Kidney Disease (CKD) is characterized by the progressive loss of kidney functions with a consequent reduction in glomerular filtration for a period longer than three months and is commonly associated with chronic diseases such as diabetes and hypertension.⁽¹⁾ According to the International Society of Nephrology (ISN), kidney disease is considered an important public health concern worldwide and is linked to high health costs and low quality of life.⁽²⁾

About 850 million people suffer from CKD worldwide, and 2.4 million of them die annually. In Brazil, it is estimated that more than 10 million people have the disease, with an evolving morbidity and mortality rate.^(3,4)

CKD has the capacity to affect different systems of the organism, thus generating other damages to health. As a result, treatment consists mainly of Renal Replacement Therapy (RRT), through invasive techniques such as dialysis, which aims to take over the main function of the kidneys. Among its types, there are peritoneal dialysis (PD) and hemodialysis (HD).^(2,5)

Accordingly, HD stands out, since it is the predominant renal clearance technique, currently adopted for 92% of patients with end-stage renal disease (ESRD).⁽⁶⁾ This procedure is performed by means of equipment with the purpose of remov-

ing toxic substances and liquid concentrated in the blood due to kidney failure.⁽⁷⁾

Due to its complexity, HD can confer risks inherent to the care of patients undergoing this condition, provided by factors of the environment itself and the work process, such as: constant infusion of high-alert medications; handling of patients by different professionals; problems related to vascular access; and poor communication in urgent decisions related to treatment, aspects that can favor the occurrence of adverse events (AE).⁽⁸⁾

Studies^(9,10) reveal high rates of occurrence of AE inpatients under HD, and indicate infections, hemorrhages in vascular access, extracorporeal system coagulation, hypo/hypertension, dizziness and nausea as main damages.

That said, it is understood the need to implement patient safety (PS) in HD services, which involves a multidisciplinary team performing correct and essential care actions such as the use of aseptic techniques, infection prevention and assessment of individual parameters.^(11,12)

Such practices encourage safe and qualified care exercised with protagonism by nursing, which has a key role in also acting in the resolution of intercurrents and monitoring of HD, in addition to being responsible for performing the technique, preparing patients, implementing dialysis equipment, in addition to providing guidance on the procedure and health education, practices that demand qual-

ification, training and tools that enhance suitable and safe HD.^(7,12,13)

In this regard, it is considered important to build instruments that aim to promote PS in the scope of identifying the level of safety in the processes related to the care provided in the scenario of dialysis units, as well as pointing out weaknesses/gaps, in order to take measures be taken for safer HD care.⁽⁸⁾

The use of protocols stands out among them, which allow systematizing and organizing services, in addition to assessing safe HD care by standardizing techniques based on scientific evidence, thus assisting professionals' work by guiding procedures and conducts inherent to the care provided and offering better assistance.⁽¹⁴⁾

The protocol in an instrument that directs the health care of users indicated for care and preventive actions through the use of knowledge and technologies supported scientific evidence.⁽¹⁴⁾

Therefore, it is essential to assess nursing care in dialysis units through specific instruments, such as graphic protocols, duly prepared and validated, which enable implementing interventions in order to minimize occurrence of AE, promoting PS and providing better care to patients with CKD.

Thus, the following guiding question was outlined: what contents and appearance need to have a protocol to assess safe care for patients under HD? The aim of this study is to validate a graphic protocol content and appearance for assessing safe nursing care for patients under hemodialysis.

Methods

This is a methodological study with a quantitative approach, conducted according to Pasquali's psychometric framework.⁽¹⁵⁾ This study design is characterized by promoting data investigation, organization, and analysis, as well as instrument and technique production and validation within the scope of research, in order to generate suitable and reliable materials that can be used by other researchers.⁽¹⁶⁾

The study population consisted of expert judges in the area. They had the role of assessing whether

the material content and appearance was suitable and consistent with what is proposed.⁽¹⁷⁻¹⁹⁾

Experts were after an analysis of their resumes submitted to the *Plataforma Lattes* through the following search strategy: Search mode [subject (title or production keyword)] – Hemodialysis; in the databases – doctors and other researchers; Professional practice: Major Area – Health Sciences/Area – Nursing, in order to identify health professionals in Brazil able to act as instrument evaluators.

To select the judges, the criteria adapted from Fehring⁽²⁰⁾ were used, consisting of a minimum score of five points, namely: Master's degree in nursing, with dissertation on HD and/or PS (1 point); Research published in the HD area (3 points); Article published in the nursing field in a reference journal (3 points); Experience as a professor in the PS area in nursing for at least 6 months (2 points); Specialization certificate in the PS area (1 point) with a maximum score of 14 points.

An initial number of 40 judges was selected. It is known that, for the validation process, a minimum number of six experts is needed according to the framework;⁽¹⁵⁾ however, considering possible losses that are recurrent in this approach, this number was chosen.⁽²¹⁾ After selection, an invitation letter was sent by email, which contained clarifications about the research content and objectives and the importance of their participation.

For validation, the Delphi technique was used, which is characterized by the organized and progressive use of a questionnaire, used to structure the communication process and enable experts to provide a collective and qualified opinion on existing problems. It is noteworthy that the Delphi technique can have as many rounds of analysis as necessary until reaching the recommended level of agreement.⁽¹⁷⁾

The scientific evidence identified in the scoping review supported the process of building a graphic protocol and a checklist to assess safe care for patients with CKD under HD. Still in the empirical procedures, it is worth highlighting the validation carried out through analysis and judgment by expert judges in the area.

The research validation process took place between 2019 and 2020, according to theoretical, empirical and analytical procedures. For theorists, a scoping review was built in order to identify and map the contents related to safe care in HD.

Considering the positive responses, the Informed Consent Form (ICF) was sent via e-mail for participants to sign. After receiving the document, the form was provided to experts, in order to start the graphic protocol content and appearance validation, which were granted in full for assessment via Google Forms.

According to changes suggested by judges, the protocol was adjusted and sent back for analysis with indicated modifications. It should be noted that two Delphi rounds were needed to reach a significant level of agreement among judges.^(15,17)

Regarding the criteria used to validate the protocol content, judges assessed the protocol according to suitability requirements as follows: behavior, objectivity, simplicity, clarity, relevance, accuracy, variety, modality, typicality, credibility, range, and balance.⁽¹⁵⁾

For the appearance validation procedures, the adapted categories proposed by the Suitability Assessment of Materials (SAM) were defined as criteria, namely: content, language, illustrations, layout, motivation and culture, which are scored using a scale, where two means adequate and zero, not adequate.⁽²²⁾ Based on the content provided by the SR, a checklist and a graphic protocol were elaborated, which were formulated in line with the Donabedian framework.⁽²³⁾

In the analytical procedures, judge validation data were tabulated in Microsoft Excel 2010 and, later, analyzed using simple descriptive statistics with regard to judge characteristics. The Content Validity Coefficient (CVC) was also calculated according to the formula inferred by the methodological framework,⁽¹⁵⁾ in addition to the level of agreement.⁽¹⁸⁾ CVC > 0.8 and agreement parameters equal to or greater than 80% as to its suitability were considered relevant for the study.^(15,17)

The research followed the ethical precepts contained in Resolution 466, of December 12, 2012, of the Brazilian National Health Council, approved

by a Research Ethics Committee 3.915.158, with CAAE (*Certificado de Apresentação para Apreciação Ética* - Certificate of Presentation for Ethical Consideration) 29259020.7.0000.5537.

Results

Initially, a scoping review (SR) was developed to identify contents related to safe health care for patients with CKD under HD, the search for studies resulted, after eligibility criteria, in eight studies that comprised the final sample. The main findings regarding safe HD care are in figure 1, grouped into structure, process and result items.

Safe hemodialysis care	
Structure	<ul style="list-style-type: none"> • Check that needle size meets the prescription, that dialyzer type meets the prescription, that all dialysis parameters have been entered as prescribed. • Identify the dialyzer and lines with patient name, serology, and date of first use. • Perform machine pre- and post-test before each session to certify system sterilization. • Ensure exclusivity of nursing technicians for patients recently admitted to the institution with unknown serology.
Process	<ul style="list-style-type: none"> • Sanitize hands. • Properly handle and monitor vascular access. • Check safety in pre-session. • Use checklists for infection control on the HD unit. • Arrange an action plan in advance in case of adverse effects. • Confirm patients' identity and review of reported problems and medications to be performed. • Assess signs of infection in case of catheter absence of residual disinfection agent. • Check dialysate prescription, confirm with patients for the beginning of the procedure and confirm vascular access.
Result	<ul style="list-style-type: none"> • Reduce permanent catheter insertion by adopting the Fistula first program.

Figure 1. Synthesis of contents related to safe care for patients with CKD under HD organized in structure, process and result

Its organization took place through the presentation of three aspects of protocols regarding safe HD care in dialysis sectors, which have the purpose of assessing specific elements. Such protocols are divided into: structure (infrastructure, materials, equipment and human resources); process (patient identification, effective communication, healthcare-associated infection prevention, safety in the use of medications, care with the session); and result (PS indicators). Along with these protocols, a checklist was created, consisting of the same elements and dimensions already mentioned, as the

protocol is assessed based on checklist responses to consider safe, partially safe or unsafe care. The graphic protocol content and appearance validation was carried out in two Delphi rounds; in Delphi I, nine judges participated, and in Delphi II, six. Its sociodemographic characteristics are described in table 1.

Table 1. Sociodemographic characteristics of the judges participating in the study in Delphi I and II rounds

Sociodemographic characteristics	Delphi I (n=9) n(%)	Delphi II (n=6) n(%)
Sex		
Female	8(88.9)	5(83.3)
Male	1(11.1)	1(16.7)
Field of action		
Teaching	3(33.3)	3(50.0)
Care	1(11.1)	1(16.7)
Teaching and care	5(55.6)	2(33.3)
Professional patient safety practice		
5 to 9 years	2(22.2)	2(33.3)
Over 10 years	7(77.8)	4(67.7)

Regarding content validity verification, it was found that, in the first Delphi round, checklist clarity, accuracy and modality (CVC =0.77) did not reach levels of suitability. As for the protocol items, all of them presented CVC greater than or equal to 0.80. Regarding appearance validity through SAM, in the first round, it was possible to achieve a total CVC greater than 0.80 in all materials, although the culture component referring to the process protocol did not reach a minimum CVC of 0.80 (CVC=0.06). After Delphi I, judges' considerations about the protocol and the checklist were received and assessed whether they would be included or not. Suggestions considered relevant were accepted and inserted into the material for later reassessment by re-sending with the modifications, and those discarded were forwarded to judges with a justification for their non-use. The synthesis of these suggestions is described in figure 2.

Corresponding to the Delphi technique's second round, the level of agreement reached at this stage was greater than 80% in all items assessed by experts, thus confirming the suitability of these aspects when integrating the instrument. As for CVC, all contents reached validation indexes above 0.80, with a total CVC of 0.88. Regarding the appear-

Elements	Comments and suggestions
Structure	<p>Infrastructure dimension: (infrastructure) there is an error in the writing of the word birth, it was written in the plural (births). In this same item, wouldn't it be interesting to include the mother's full name as patient identification? Add the reprocessing date to the item; adapt the correct verb form.</p> <p>Material and equipment dimension: Materials and equipment: I suggest including a sub-item to ensure the single use and non-reprocessing of the entire system used by the newly admitted patient with unknown serology. Has it been verified that needle size, dialyzer type and dialysis parameters have been entered as prescribed? I suggest the following complement: "Check whether the needle size for arteriovenous fistula (AVF) is as prescribed."</p>
Process	<p>Patient identification dimension: In items, even if inserting the ID card number, I find it interesting to include the mother's full name. Have patients' identity, review of reported problems and medications to be taken been confirmed?</p> <p>Effective communication between professionals, patient and family dimension: Has patient and family education, focusing on hand hygiene awareness and early recognition of signs and symptoms by catheter, been conducted?</p> <p>Healthcare-associated infection prevention dimension: In the infection prevention item, it is important to include AVF as well, as we know that the infection does not only present itself in the CVC. Remove the word "maintenance" because it was decontextualized. Complete sentence: Prepare materials for placement and maintenance of venous catheter centers</p> <p>Dialysis care dimension: Include on the importance of checking patients' axillary temperature to ensure the dialysis machine temperature control and possible symptoms of hypothermia. Complete sentence: Professionals sanitize their hands before and after using gloves; In items that present repeated information- Review possible complications about access. Replace the excerpt "vascular access washed properly" with arteriovenous fistula (AVF) member washed properly.</p>
Result	<p>Safe arteriovenous fistula insertion dimension: Review the excerpt "Reduced permanent catheter insertion...", I suggest removing the word "permanent."</p>

Figure 2. Synthesis of judges' suggestions for the protocol and the checklist

ance validation process using the SAM criteria, in the second round, the protocol reached agreement greater than 80% and CVC greater than 0.88. The checklist presented a higher CVC with 0.91, according to tables 2 and 3, with Pasquali's adapted criteria and SAM.

Discussion

Regarding the main findings of this SR, they were organized according to structure, process and result (Donabedian's triad).⁽²⁴⁾ Items classified into structure are highlighted as infrastructure, inputs and human resources.

The indicators found in the studies highlighted the dialyzer processing, dialysis machine type, exclusively for nursing professionals for patients with unknown serology.^(8,25)

Table 2. CVC values after Delphi I and II in Pasquali's criteria

Pasquali's adapted criteria	CVC content validity agreement							
	Checklist		Protocol structure		Protocol process		Protocol result	
	Delphi I	Delphi II	Delphi I	Delphi II	Delphi I	Delphi II	Delphi I	Delphi II
Behavior	0.85	0.88	0.88	0.88	0.88	0.88	0.85	0.88
Objectivity	0.92	0.88	0.92	0.88	0.88	0.88	0.88	0.88
Simplicity	0.88	0.88	0.92	0.88	0.92	0.88	0.92	0.88
Clarity	0.77	0.88	0.88	0.88	0.85	0.88	0.88	0.88
Relevance	0.96	0.94	0.92	0.88	0.92	0.88	0.92	0.88
Accuracy	0.77	0.83	0.92	0.88	0.88	0.88	0.88	0.88
Variety	0.81	0.83	0.88	0.88	0.88	0.88	0.88	0.88
Modality	0.77	0.83	0.92	0.88	0.92	0.88	0.88	0.88
Typicality	0.92	0.99	0.92	0.88	0.92	0.88	0.92	0.88
Credibility	0.85	0.94	0.92	0.88	0.92	0.88	0.92	0.88
Range	0.88	0.94	0.92	0.88	0.92	0.88	0.92	0.88
Balance	0.88	0.94	0.92	0.88	0.88	0.88	0.88	0.88
Total CVC	0.87	0.88	0.92	0.88	0.90	0.88	0.88	0.88

Table 3. CVC values after Delphi I and II in the SAM criteria

SAM criteria	CVC content validity agreement							
	Checklist		Protocol structure		Protocol process		Protocol result	
	Delphi I	Delphi II	Delphi I	Delphi II	Delphi I	Delphi II	Delphi I	Delphi II
Content	0.96	0.94	0.96	0.94	0.92	0.88	0.92	0.88
Language	0.88	0.88	0.96	0.94	0.92	0.88	0.92	0.88
Illustration	0.96	0.88	0.92	0.94	0.88	0.88	0.88	0.88
Layout	0.96	0.94	0.96	0.88	0.92	0.88	0.92	0.88
Motivation	0.96	0.88	0.96	0.88	0.92	0.88	0.92	0.88
Culture	0.99	0.94	0.99	0.88	0.06	0.88	0.92	0.88
Total CVC	0.96	0.91	0.96	0.91	0.92	0.88	0.92	0.88

From this perspective, studies emphasize that water quality control was essential in preventing risks to patients, indicating that this should be organized before the HD procedure.^(8,25)

As for the items classified as process, hand hygiene, use of checklists to avoid infection, relationship between professional and patient and patient data collection in printed form for each session were pointed out.⁽²⁶⁻²⁸⁾

It is emphasized that patient protection and safety activities must be performed by a multidisciplinary team, with aseptic techniques for infection prevention and assessment of individual patient results.^(11,29)

Furthermore, the items highlighted as a result are related to care products, changes in health status related to this care. Studies have highlighted catheter insertion reduction by using the Fistula First program to maintain arteriovenous fistula (AVF).

The use of AVF can present complications, such as stenosis and infection, although, when compared to the central venous catheter, which has a lower mortality rate, it is therefore recommended as the

first choice access in patients under HD in the Fistula First Catheter Last guideline.^(27,30)

The graphic protocol construction aimed to contribute to the development of new interventions to promote safe HD care through identification of strengths and weaknesses in services, which occurred through the checklist production as the main part. The aforementioned made it possible to organize and structure the instrument by making it possible to visually verify the proposed tasks and consult to assist in assessing and analyzing the various graphic protocol items.⁽¹⁸⁾

For a safe use of the instrument in health services, the item validation process becomes necessary to reach reliability. This procedure was carried out by judges' assessment.

It is noted that most experts in the study have more than 10 years of professional experience in the PS area.

With regard to sex, women prevailed among judges who were part of the study. The fact is consistent with the historical context of nursing and its first schools in which there was a predominance of

women in the profession, although over the years men have been increasingly inserted.⁽³¹⁻³³⁾

Regarding the field of action, it was identified that the majority works with care and teaching linked to PS and HD. A study says that the combination of these areas of activity makes professionals develop approximation and better associations between patient care and scientific research.^(34,35)

In the content and appearance validation process, in the first Delphi round, three criteria did not have suitability values greater than or equal to 0.80. We sought to reassess the items, in order to make them understandable, as clarity was not validated in the checklist, which could cause inconsistency in understanding and consequent inappropriate use of the instrument. This criterion has higher levels of difficulty to be valid, as it varies according to the interpretation capacity of both the builder and the user.⁽³⁶⁾

The second criterion not validated was accuracy, which indicates that an item may not be suitable and cause confusion, since accuracy means that each item must have a distinct and defined position.⁽¹⁵⁾ Modality, third criterion, refers to the formulation of sentences with expression of modal reaction.⁽¹⁵⁾

For appearance validation, using the SAM criteria, in the Delphi I round, only the process protocol culture item was below 0.80. This criterion is characterized by the observation of the instrument content regarding its logic, language and experience, in order to verify if it is culturally suitable for the target audience.

Thus, it is observed that the graphic protocol obtained CVC values above 0.80, which highlights the significant agreement among judges and that the use of the instrument helps assessing safe care in HD.

Regarding the level of agreement of the instruments after completion of two Delphi rounds, it is clear that the material has valid content to assess safe care for patients under HD through agreement among judges.

As limitations of this validation study, the number of judges who made up this stage stands out, as in the first Delphi round it consisted of nine, and in the second round, six. Loss of judges can represent

losses. Despite the limitations, this study contributes to PS and quality management of HD services.

Conclusion

The graphic protocol for assessing safe nursing care in HD was validated through assessment by expert judges and reached agreement on all instrument items after the Delphi rounds. Thus, the instrument use and adoption in health institutions that have HD service can contribute to PS and quality management, as it aims to assist in safe care for patients with CKD under HD and, with that, the possibility of minimizing AE through improvement cycles. It is considered that further research on this topic is essential to optimize knowledge on PS and HD, in order to ensure quality care for patients with CKD.

Acknowledgements

Coordenação de Aperfeiçoamento de Pessoal de Nível Superior/ CAPES-DS Social Demand Doctoral Scholarship. Coordenação de Aperfeiçoamento de Pessoal de Nível Superior/ CAPES-DS Social Demand Master's Scholarship. PQ1D Conselho Nacional de Desenvolvimento Científico e Tecnológico/ CNPQ research productivity grant (2019-2023).

Collaborations

Paiva RM, Federal FBTC, Bezerril MS, Dantas MNP, Azevedo IC, Oliveira ACS, Ferreira Júnior MA and Santos VEP contributed to the design of the study, analysis and interpretation of data, writing of the article, relevant critical review of the intellectual content and approval of the final version to be published.

References

1. Aguiar LK, Prado RR, Gazzinelli A, Malta DC. Fatores associados à doença renal crônica: inquérito epidemiológico da Pesquisa Nacional de Saúde. *Rev Bras Epidemiol.* 2020;23(1):e200044.

2. International Society of Nephrology (ISN). Chronic Kidney Disease. Belgium: ISN; 2019 [cited 2021 May 19]. Available from: www.theisn.org/global-atlas
3. Sociedade Brasileira de Nefrologia (SBN). Dia Mundial do rim - 2020. Publicação oficial da Sociedade Brasileira de Nefrologia. São Paulo: SBN; 2020 [citado 2021 Maio 19]. Disponível em: <https://www.sbn.org.br/noticias/single/news/dia-mundial-do-rim/>
4. Souza AC, Alencar KC, Landim NL, Oliveira PM, Leite CM. Perfil epidemiológico da morbimortalidade e gastos públicos por Insuficiência Renal no Brasil. *Research. Soc Dev.* 2020;9(9):e510997399.
5. Sutrisno S, Fawzi A, Dwianggamawati MS. The Different of Quality of Life Between Patient with Kidney Failure Undergoing Hemodialysis and Continuous Ambulatory Peritoneal Dialysis (CAPD). *J Ilmiah Kesehatan.* 2019;8(1):28-33.
6. Neves PD, Sesso RC, Thomé FS, Lugon JR, Nascimento MM. Censo Brasileiro de Diálise: análise de dados da década 2009-2018. *Braz J Nephrol.* 2020;42(2):191-200.
7. Santos AF, Fernandes AM, Sena DC, Carvalho GA, Júnior LS, Pellense MC. Atuação do enfermeiro frente às principais complicações em pacientes durante o procedimento de hemodiálise. *Rev Humano Ser.* 2018;1(1):114-27.
8. Aguiar LL, Guedes MV, Galindo NN, Melo GA, Almeida PC, Oliveira RM, et al. Validação de instrumento de avaliação da segurança de pacientes renais em hemodiálise. *Acta Paul Enferm.* 2018;31(6):609-15.
9. Hull KL, March DS, Churchward DR, Graham-Brown MP, Burton JO. The effect of extended-hours hemodialysis on outcomes: a systematic review and meta-analysis. *Hemodial Int.* 2020;24(2):133-47.
10. Sousa MR, Silva AE, Bezerra AL, Freitas JS, Neves GE, Paranaguá TF. Prevalência de eventos adversos em uma unidade de diálise. *Rev Enfermagem UERJ.* 2016;24(6):e18237.
11. Aguiar LL, Guedes MV, Oliveira RM, Leitão IM, Pennafort VP, Barros AA. Enfermagem e metas internacionais de segurança: avaliação em hemodiálise. *Cogitare Enfermagem.* 2017;22(3):e45609.
12. Lima AF. Custo direto do acompanhamento da hemodiálise convencional realizada por profissionais de enfermagem. *Rev Bras Enferm.* 2017;70(2):357-63.
13. Wang J, Yue P, Huang J, Xie X, Ling Y, Jia L, et al. Nursing intervention on the compliance of hemodialysis patients with end-stage renal disease: a meta-analysis. *Blood Purif.* 2018;45(1):102-9.
14. Vieira TW, Sakamoto VT, Moraes LC, Blatt CR, Caregnato RC. Métodos de validação de protocolos assistenciais de enfermagem: revisão integrativa. *Rev Bras Enferm.* 2020;73(5):e20200050.
15. Pasquali L. Instrumentação psicológica: fundamentos e práticas. Porto Alegre: Artmed; 2010. 560 p.
16. Polit DF, Beck CT. Fundamentos de pesquisa em enfermagem: avaliação de evidências para a prática de enfermagem. 7th ed. Porto Alegre: Artmed; 2011. 456 p.
17. Marques JB, Freitas D. Método DELPHI: caracterização e potencialidades na pesquisa em Educação. *Pro-Posições.* 2018;29(2):389-415.
18. Hernández-Nieto RA. Contributions to statistical analysis. Mérida: Universidad de Los Andes; 2002. 228 p.
19. Medeiros RK, Júnior MA, Pinto DP, Vitor AF, Santos VE, Barichello E. Modelo de validação de conteúdo de Pasquali nas pesquisas em Enfermagem. *Rev Enfermagem Refer.* 2015;4(4):127-35.
20. Fehring RJ. The Fehring model. In: Carrol-Johnson RM, Paquete M. Classification of nursing diagnoses: proceeding of the tenth conference. Philadelphia, EUA: Lippincott Company, 1994. pp. 55-62.
21. Góes FS, Fonseca LM, Camargo RA, Oliveira GF, Felipe HR. Educational technology "Anatomy and Vital Signs": evaluation study of content, appearance and usability. *Int J Med Inform.* 2015;84(11):982-7.
22. Sousa CS, Turrini LR, Poveda FB. Tradução e adaptação do instrumento "Suitability Assessment of Materials" (SAM) para o português. *Rev Enferm UFPE Online.* 2015;9(5):7854-61.
23. Donabedian A. Evaluating the quality of medical care. 1966. *Milbank Q.* 2005;83(4):691-729.
24. Gomes AT, Ferreira MA Jr, Salvador PT, Bezerril MS, Chivone FB, Santos VE. Segurança do paciente em situação de emergência: percepção da equipe de enfermagem. *Rev Bras Enfermagem.* 2019;72(3):789-95.
25. Marcelli D, Matos A, Sousa F, Peralta R, Fazendeiro J, Porra A, et al. Implementation of a quality and safety checklist for haemodialysis sessions. *Clin Kidney J.* 2015;8(1):265-70.
26. Rocha RP, Pinho DL. Segurança do paciente em hemodiálise. *Rev Enferm UFPE Online.* 2018;12(12):3360-7.
27. Hamid HÁ, Bouanane H, Ibrahim A, Ismail S, El sayed A, Mahmoud KM, et al. Effective prevention bundle to eliminate catheter-related bloodstream infections in ambulatory hemodialysis patients. *Canadian J Infection Control.* 2019;34(1):54-7.
28. Fadili W, Adnoui A, Laouad I. Hemodialysis safety: Evaluation of clinical practice. *Saudi J Kidney Dis Transpl.* 2016;27(3):553-6.
29. Silva DM, Marques BM, Galhardi NM, Orlandi FS, Figueiredo RM. Hands hygiene and the use of gloves by nursing team in hemodialysis service. *Rev Bras Enferm.* 2018;71(4):1963-9.
30. Murea M, Geary RL, Edwards MS, Moossavi S, Davis RP, Goldman MP, et al. A randomized pilot study comparing graft-first to fistula-first strategies in older patients with incident end-stage kidney disease: Clinical rationale and study design. *Contemp Clin Trials Commun.* 2019;14:100357.
31. Dornelles AE, Reis CN, Panozzo VM. Juventude latino-americana e mercado de trabalho: programas de capacitação e inserção. *Rev Katálisis.* 2016;19(1):81-90.
32. Santos SA, Santos RM, Barros LM, Santos WB, Costa LM. Inserção masculina no primeiro curso de graduação em enfermagem de Alagoas - 1974/1984. *Hist Enfermagem Rev Eletr.* 2016;7(1):336-45.
33. Gleriano JS, Marca NC, Justi J. Perfil e significados para a formação em enfermagem. *Rev Saúde Desenvol.* 2017;11(6):85-101.
34. Fernandes CN, Souza MC. Docência no ensino superior em enfermagem e constituição identitária: ingresso, trajetória e permanência. *Rev Gaúcha Enferm.* 2017;38(1):e64495.
35. Silva IR, Leite JL, Trevizan MA, Mendes IA, Silva TP, Lins SM. Aprender pela pesquisa: do Ensino da ciência ao campo assistencial da enfermagem. *Escola Anna Nery.* 2017;21(4):e20160329.
36. Leite SS, Áfio AC, Carvalho LV, Silva JM, Almeida PC, Pagliuca LM. Construction and validation of an Educational Content Validation Instrument in Health. *Rev Bras Enferm.* 2018;71(4 suppl 4):1635-41.