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CONSTRUCTION AND VALIDATION OF AN INSTRUMENT FOR SAFE TRANSFUSION PRACTICE

Construção e validação de instrumento para a prática transfusional segura

Construcción y validación de un instrumento para la práctica transfusional segura

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RESUMO

Objetivo: construção de um instrumento, do tipo *checklist*, como subsídio para segurança transfusional beira-leito. **Método:** foi empregada a Técnica Delphi, contando com a participação de 18 especialistas em hemoterapia na primeira etapa e 11 na segunda. Para a validação de conteúdo, foi utilizado o cálculo do índice de validade de conteúdo, com concordância ≥ 80% na primeira e ≥ 90% na segunda rodada de julgamento. **Resultados:** na primeira fase, dos 67 itens iniciais, 15 foram retirados por contabilizar índice de validade de conteúdo < 80%. O instrumento foi reformulado para nova avaliação dos especialistas, contando com 53 itens e 11 observações e intervenções. Destes, 8 itens foram retirados por contabilizarem índice de validade de conteúdo < 90%. O coeficiente alfa de Cronbach calculado para o *checklist* foi de 0,8940. **Conclusão:** o *checklist* poderá auxiliar na segurança da assistência hemoterápica em enfermagem, visto que apresenta boa confiabilidade.

DESCRITORES: Estudo de validação; Transfusão de sangue; Medicina transfusional; Pesquisa metodológica em enfermagem.

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ABSTRACT

Objective: to develop a checklist to support transfusion safety at the point-of-care. **Method:** the Delphi technique was used with the participation of 18 hemotherapy specialists in the first phase and 11 in the second one. The content validity index was calculated for content validation, with agreement ≥ 80% in the first phase and ≥ 90% in the second phase. **Results:** in the first phase, 15 of the 67 initial items were removed for having a content validity index < 80%. The instrument was reformulated for a new expert evaluation with 53 items and 11 observations and interventions. Of these, 8 items were removed due to content validity index < 90%. The Cronbach's alpha coefficient calculated for the checklist was 0.8940. **Conclusion:** the checklist could help to ensure the safety of hemotherapy care, as it has a good reliability.

DESCRIPTORS: Validation Study; Blood transfusion; Transfusion medicine; Nursing methodology research.

RESUMEN

Objetivo: elaborar una herramienta de tipo *checklist* para apoyar la seguridad transfusional a pie de cama. **Método:** se utilizó la técnica Delphi, con la participación de 18 especialistas en hemoterapia en la primera etapa y 11 en la segunda. Para la validación del contenido se calculó el índice de validez de contenido, con un acuerdo ≥ 80% en la primera y ≥ 90% en la segunda ronda de valoración. **Resultados:** en la primera fase, de los 67 ítems iniciales, se eliminaron 15 por tener un índice de validez de contenido < 80%. Se reformuló el instrumento para una nueva evaluación por expertos, con 53 ítems y 11 observaciones e intervenciones. De éstos, se eliminaron 8 ítems por tener un índice de validez de contenido < 90%. El coeficiente alfa de Cronbach calculado para lo *checklist* fue de 0,8940. **Conclusión:** Lo *checklist* podría contribuir a garantizar la seguridad de los cuidados de enfermería en hemoterapia, ya que presenta una buena fiabilidad.

DESCRIPTORES: Estudio de validación; Transfusión sanguínea; Medicina transfusional; Investigación metodológica en enfermería.

INTRODUCTION

Although the blood cycle involves several professionals and techniques so that the product generated is safe, the point-of-care transfusion is a crucial step in maintaining this safety and the professional responsible for the procedure must take a series of actions to ensure a transfusion with minimal risk.

It has been observed that, within the scope of the Consolidation Ordinance No. 5, which consolidates the norms on health actions and services of the Unified Health System (SUS), there is no definition of which professional is responsible for performing the transfusion act.[1] However, in the routine of health institutions, it is observed that the nursing team are the professionals who mainly work in the performance of blood transfusions. This observation is corroborated by the fact that the Federal Council of Nurses (COFEN) has been issuing resolutions since 1997 that deal with hemotherapy in nursing, with COFEN Resolution No. 709/2022 being the current regulation.[2]

Despite the outstanding performance of the nursing team in the transfusion act and its fundamental importance in maintaining a safe blood cycle, an integrative review pointed out that the level of knowledge of nursing professionals in transfusion is below the desirable, implying risks for the recipient.[3] In this context, the use of checklist instruments is presented as an alternative to improve transfusion safety, since it is a structured work tool that contains a series of behaviors, items or tasks to be considered and/or followed, with the aim of performing a systematic observation of the procedure.[4]

In view of the above, the objective of this study was to construct a checklist instrument as an aid to transfusion safety at the point-of-care.

METHOD

This is a methodological development study carried out between November 2018 and May 2019. Methodological studies focus on the development, validation and evaluation of methodological tools or strategies.[5]

The theoretical basis of the items listed for the tool was based on the Consolidation Ordinance No. 5 and the British Society of Hematology Guideline for the Administration of Blood Components.[1,6]

The aspects of transfusion safety described in these publications were listed, resulting in 67 items grouped into sections according to the chronological sequence of the Transfusion Act.

To form the jury, 30 experts were selected through the Lattes platform on the website of the National Council for Scientific and Technological Development (CNPq), by searching for "hemotherapy" and "blood transfusion". The snowball method was then used to reach professionals who are not in the academic environment but who have extensive experience in hemotherapy. Thus, the participants of the panel were divided into two groups:

group 1 was made up of the experts selected through the Lattes platform and group 2 was made up of the experts selected through the snowball technique. The inclusion criteria for group 1 were: to be a nurse, physician, biomedical or pharmacist, master or physician, Brazilian, with publications, projects or researches in the field of hemotherapy; and for group 2: to be a Brazilian nurse, physician, biomedical or pharmacist, with professional experience of more than or equal to three years in a hemotherapy service. Exclusion criteria were: not having performed the evaluation of the instrument within the prescribed period of 30 days in the first phase and 20 days in the second phase.

It was decided to use the Delphi technique, a comprehensive approach based on a series of "phases" in which a group of experts give their opinion on a specific topic.[7] Two cycles of judgment were adopted, succeeding the following steps: construction of the instrument to be validated; selection of experts; sending the instrument; first evaluation of the instrument by the expert panel; receipt of the evaluations; statistical analysis; reformulation of the instrument; second evaluation of the reformulated instrument by the expert panel; receipt of the second evaluation; statistical analysis; reformulation of the instrument; final version of the instrument; submission of the final version to the experts.

The data were collected using the Google Forms® tool, and a link to access the form with all the items included in the checklist, the level of agreement to be marked, and a space below each of the sentences was sent by email to the experts for comments of any kind related to the items. The degree of agreement was assessed using a Likert scale with the following values: 1 - strongly disagree, 2 - disagree, 3 - agree, and 4 - strongly agree. All participants also completed a characterization form.

For each of the sentences, a content validity index (CVI) was obtained by the quotient of the number of 3 or 4 responses and the total number of responses.[8] Judgments with a CVI < 0.8 in the first phase of testing and < 0.9 in the second phase of testing were excluded from the checklist. The total CVI of the instrument was calculated as the sum of all separately calculated CVI divided by the number of items considered in the evaluation.[8] The analysis of the internal consistency of the instrument was performed by calculating the Cronbach's alpha coefficient.

Fisher's exact test was used to check whether there was a difference in the experts' responses item by item according to the characteristics of interest, assuming a p-value < 0.05. The categories of the characteristics of interest were grouped so there were only two categories in each characteristic. All calculations were performed using R software.

The present study complied with national and international ethical requirements. The experts were informed of the objective of the research and the ways to achieve it, confirming their consent to participate by registering their agreement in the informed consent form, which was applied electronically through the Google Forms® tool.

The research is in accordance with the principles of Resolution No. 510/2016 of the National Health Council (CNS) and was approved by the Research Ethics Committee (CEP) of the Federal University of Juiz de Fora, filed under CAAE No. 89113618.6.0000.5147, Opinion Number: 2.870.119, on September 3, 2018.

RESULTS

Of the 30 experts invited to participate in the expert panel, 18 evaluated the instrument in the first phase and 11 in the second phase. Of the 18 first-phase judges, the majority are nurses (50%), followed by physicians (33.3%), with a Ph.D. as the highest degree (50%). Of the 11 judges who responded in the second phase, 45.5% are nurses and 54.5% are physicians.

The initial checklist was a comprehensive tool covering transfusion safety procedures in pre-, intra- and post-transfusion care, divided into nine sections, namely Section A - Assessment of the blood component request/order; Section B - Supplementary data; Section C - Recipient's blood sample for pre-transfusion testing (if collected by the nursing team); Section D - Transport of the collected material to the hemotherapy service; Section E – Pre-transfusion assessment of the recipient; Section F - Transport of the blood component bag; Section G - Identification of the bag to be transfused; Section H - Verification of the blood component bag; Section I - Transfusion act. The first version consisted of 67 questions.

Of the original 67 items, 15 were removed due to CVI < 0.8. There were two mergers of items. The first merged three sentences related to visual analysis of the bag into a single item, and the second merged two items related to transfusion records into a single sentence. Twenty-four items remained unchanged, nineteen items had slightly changed, and eight items were added. It was decided to remove four questions that received a CVI > 0.8. Two of them were related to venous access care because, according to the experts, although it was a relevant topic, they were related to general care and not specific to hemotherapy. The other two questions had answer options that were not limited to "yes and no", which raised doubts among the specialists on the use of the Likert technique and did not meet the objectivity expected of the instrument, especially for its use in clinical practice.

In some items, the judges emphasized the need to signal some observation. In order to meet this suggestion, a new column was added to the instrument with observations and interventions that should be performed/indicated by professionals in clinical practice. In the second phase of the study, such observations

were subjected to expert evaluation. The overall CVI for the checklist after the first stage of rating was 0.89.

In the second stage, 53 items and 11 observations and interventions were scored. Seven items and one observation had a CVI < 0.9 and were removed. Regarding modifications, only one observation was changed and one item was added. The total CVI of the checklist was 0.95.

Cronbach's alpha coefficient was calculated for each section of the checklist and for the instrument as a whole. Table 1 shows the results.

Table 1 - Cronbach's Alpha Coefficient Calculation. Juiz de Fora, MG, Brazil, 2019

Section	Alpha	Standard Deviation	N	Mean (correlation)	Median (Correlation)
Total	0,8939	0,9003	56	0,1804	0,1398
A	0,6269	0,6599	14	0,2170	0,1936
B	0,8059	0,8065	3	0,5816	0,5163
C	0,5866	0,7453	5	0,4225	0,3730
D	0,25	0,2594	4	0,1490	0,1490
E*			1		
F	0,8144	0,8792	10	0,4212	0,1490
G	0,64	0,6810	2	0,5163	0,5163
H	0,8416	0,8267	17	0,2845	0,1304

Source: The Authors.

The judges' resposes did not present significant statistics (p> 0.05) when stratified by the characteristics of physician, non-physician, time since graduation, with or without a doctorate. Therefore, it was possible to conclude that there is no disagreement between the experts' responses according to any characteristic of interest, demonstrating that, even with different academic backgrounds and degrees of specialization, the judges denoted a similar degree of agreement with the items on the checklist.

The final version of the checklist, after the two phases of evaluation by the expert panel, was composed of 47 items, in addition to 10 observations and interventions, divided among eight domains, namely: assessment of the blood component request, supplementary data, identification of the recipient's blood sample for pre-transfusion tests (when collected by the nursing team), pre-transfusion evaluation of the recipient, transport of the blood component bag, identification of the bag to be transfused, verification of the blood component bag, transfusion act. The instrument is presented in Attachment 1.

DISCUSSION

Blood transfusion, although it is a therapeutic procedure with a wide normative control in Brazil and which beneficial effects are already proven when correctly indicated, still carries several risks. Incompatible transfusions are the main cause of severe transfusion reactions and death, mainly caused due to errors during the transfusion process, such as incorrect identification of the patient, samples or blood bags, labeling errors, omission of the final point-of-care check before administration and lack of patient monitoring during the procedure.[10]

Although the checklist developed in this study is aimed at nurses who administer transfusions, it is important to emphasize that transfusion is a multiprofessional practice. And, considering the objective of constituting a complete tool capable of maximizing transfusion safety, we sought to establish a panel with professionals from different backgrounds so that the discussion could be broadened.

In the first phase of evaluation, the study had 4 different categories of higher education professionals (nurse, physician, pharmacist and biomedical). In the second phase, 3 different categories participated (nurse, physician, and pharmacist). Multidisciplinarity in content validation evaluations is the occasion when it can really be said that the work is done as a team, valuing different opinions and approaches to the same subject.[11]

There is no defined standard number of participants that make up the panel, ranging from 10 to 1000 in published studies. A study to develop and validate a nursing instrument for patients in intensive care units had a panel of 11 experts. A study validating a competency matrix for primary care nurses had 80 reviewers.[12-14] Thus, the final number of experts for this study was consistent with what has been observed in the literature.

The judges had an average of more than 20 years of experience. In terms of titles, physicians prevailed. They are therefore professionals with quality, professional sophistication and technical-scientific preparation, which lends greater legitimacy to their opinions and, consequently, to the instrument evaluated.[13]

The CVI measures the proportion of experts who agree on certain aspects of an instrument and its items. The acceptable level of agreement among the members of the panel should be at least 0.80 and preferably greater than 0.90.[8,15] The overall value of the CVI for the checklist was 0.89 in the first evaluation by the experts, an index that would already be sufficient for the end of the trial phases. Nevertheless, in order to improve the instrument, it was reformulated and a new phase of evaluation was carried out, which resulted in an overall CVI of 0.95 and an efficient level of agreement.

In terms of homogeneity, the Cronbach's alpha coefficient calculated for the instrument was 0.89. Considering the reliability values for the coefficient as: >0.90 - excellent; >0.80 - good; >0.70 - acceptable; >0.60 - questionable; >0.50 - poor and <0.50 - unacceptable, it is considered reliable and has internal consistency. It is worth noting that for reliability to be considered excellent, an alpha value of 0.90 is required, which is very close to the value achieved by the instrument.[16]

The potential of this study lies in the development of a checklist that includes all the items to be observed before, during and after transfusion for the safety of the procedure, in addition to the possibility of using this instrument as a roadmap for future observational research. Regarding the limitations of the study, it is important to mention the reduction of the panel of experts from the first to the second phase, even with the periodic reminders sent; the application of the Delphi technique, which, despite its numerous advantages, reduces the possibility of discussion between the judges and the researcher; and the difficulty of developing a small instrument that objectively encompasses all the stages of the transfusion process.

CONCLUSION

Despite the limitations raised, the overall CVI value and Cronbach's alpha indicate that the checklist is a valid instrument with the potential to increase patient safety in the transfusion process culminating in the transfusion act, which is predominantly performed by nursing professionals.

It is believed that the instrument built and validated can represent an important tool to help nurses and nursing technicians responsible for transfusions.

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ATTACHMENT 1

Point-of-Care Transfusion Safety Checklist

Items to consider	Check			Observations and interventions
Section A - Assessment of the blood component request/order	Yes	No	Not Applicable	
1- Recipient's full name without abbreviations?				Accurate identification of the patient to be transfused and the blood component is essential. Any doubts should be clarified with the prescriber and/or the hemotherapy service.
2- Date of birth?				
3- Sex?				
4- Medical record number or patient number?				
5- Bed number (for inpatients)?				
6- Indication for transfusion?				
7- Transfusion, gestational and transfusion reactions history?				
8- Weight?				
9- Blood component requested with volume or quantity?				
10- Registration of transfusion modality (planned, routine, urgent or emergency)?				
11- Laboratory results justifying the blood component indication?				
12- Date of request?				
13- Requesting physician information (full name, signature, and CRM number)?				
SECTION B - Supplementary data				
14- Does the medical record verify consent for transfusion of blood and blood components?				Important for professional support in case of ethical implications. If not available, arrange for the appropriate department in the institution.
15- Is transfusion clearly prescribed?				
SECTION C- Recipient's blood sample for pre-transfusion testing (if collected by the nursing team)				
16- Full name of the recipient without abbreviations on the collection tube?				
17- Identification number (medical record or registration number) on the collection tube?				
18- Date of collection?				
19- Legible identification of the collector?				
20- Identification made at the time of collection?				

Items to consider	Check	Observations and interventions
Section D- Pre-transfusion assessment of the recipient		
21- Were vital signs checked immediately prior to the start of the transfusion?		
22- Was the presence of alteration(s) in vital signs communicated to the attending physician to determine a course of action?		Determine whether the transfusion should be continued or temporarily suspended. It is important to note that the communication was made and the action taken.
23- If pre-transfusion medication was prescribed, was it administered and controlled?		
Section E - Transportation of the Blood Component Bag		
24- Was an appropriate container used to transport the blood component from the transfusion center or blood bank to the site of transfusion?		
Section F - Check of the transfusion card of the bag to be transfused		
25- Does the transfusion card (the label attached to the bag) contain the full name of the recipient?		Discrepancies in the transfusion card data are an impediment to proceeding with the transfusion. The hemotherapy service must be activated and the transfusion can only occur after the issue is resolved.
26- Does the transfusion card contain the recipient's ward and bed?		
27- Does the transfusion card contain the recipient's ABO and RhD typing?		
28- Does the transfusion card contain the identification number of the bag of blood components to be transfused?		
29- Does the transfusion card contain the ABO and RhD typing of the bag to be transfused, similar to the label of the blood component?		
30- If a bag of blood components with special procedures (deleukocitation and/or irradiation) is prescribed, is this information included on the transfusion card?		
31- Does the transfusion card contain the date of shipment of the blood component for transfusion?		
32- Does the transfusion card contain the name of the person responsible for performing the pre-transfusion tests?		
33- Does the transfusion card contain the name of the person responsible for releasing the blood component?		
SECTION G - Blood Component Bag Inspection		
34- Inspection of the bag for integrity, appearance and color?		Any anomaly in the appearance or color of the bag, as well as its integrity, should be reported to the hemotherapy service and the bag should be returned.

Items to consider	Check	Observations and interventions
SECTION H - Transfusion Act		
35- Has the presence of a physician on site been verified to supervise the transfusion and attend to possible transfusion reaction?		At least one physician must be present at the healthcare facility at the time of transfusion.
36- Has the recipient or his representative been informed of the procedure, if possible?		
37- Has the recipient or his/her representative been instructed to report to the healthcare professional any signs and symptoms that occur during and after the transfusion?		
38- Has it been verified that the transfusion equipment is appropriate for the blood component to be transfused?		
39- Is the person responsible for infusing and monitoring the patient a nurse or a nursing technician under the supervision of a nurse?		
40- If the recipient is conscious, has the patient been identified immediately prior to the transfusion by providing his or her full name and checked against the medical prescription, identification bracelet, and transfusion card?		
41- Is the venous line used exclusively for transfusion?		Only 0.9% sodium chloride can be infused in Y with transfusion.
42- Did the professional responsible for monitoring the patient remain with the patient during the first ten minutes of the transfusion?		
43- Was the date and time of the beginning and end of the transfusion recorded?		Packed red blood cells may be held at room temperature for no more than 30 minutes before starting the infusion.
44- Were vital signs checked and recorded immediately after the end of the transfusion?		
45- Did the nursing professional responsible for the transfusion document the procedure in the patient's medical record?		The record must include the identification number of the bag transfused, the start and end times of the infusion, and a description of the transfusion reaction, if any.
46- In case of signs and/or symptoms, did the nursing team act according to the SOP?		
47- If there was a transfusion reaction, was the notification properly completed?		Outpatients and/or patients transfused at home should be advised to contact the service in the event of complications, especially in the 24 hours following transfusion.