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Development and Content Validation of a Transfusion Safety Checklist

Construção e Validação de conteúdo de *Checklist* para Segurança Transfusional

Construcción y Validación de Contenido de una *Checklist* para la Seguridad Transfusional

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ABSTRACT

Objective: To develop and validate the content of a transfusion safety checklist for the Santa Catarina blood network. **Methodology:** A methodological study conducted in three stages: Exploratory phase (integrative literature review and situational diagnosis); Instrument development phase; and Content validation phase by experts. **Results:** Twelve health professionals working in Transfusion Agencies within the Santa Catarina blood network took part in the Content validation phase. Comprised by 18 items, the validation instrument obtained an overall Content Validity Index (CVI) of 0.98, with all items above 0.80. The final instrument, the Transfusion Safety Checklist, consists of 26 verification items distributed across the Pre-analytical, Analytical and Post-analytical stages. Its application may contribute to the safety of patients undergoing hemotherapy, serving as a managerial care tool aimed at improving care quality, reducing adverse events and strengthening the safety culture. **Conclusion:** The instrument encompasses all stages of the transfusion process and can be applied by different professionals, from medical prescription to post-transfusion monitoring. As a limitation, after incorporating the experts' suggestions, the final version was not subjected to a new evaluation round, reinforcing the need for further usability and clinical validation studies.

DESCRIPTORS:

Blood Safety; Health Personnel; Patient Safety; Nursing Care; Blood Transfusion.

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RESUMO

Objetivo: Construir e validar um *checklist* de segurança transfusional para a hemorrede de Santa Catarina. **Metodologia:** Pesquisa metodológica, que compreendeu três etapas: fase exploratória (revisão integrativa de literatura e diagnóstico situacional), fase de construção do instrumento e fase de validação de conteúdo por especialistas. **Resultados:** Participaram da validação de conteúdo 12 profissionais de saúde que atuam em Agências Transfusionais na hemorrede de Santa Catarina. O instrumento de validação, composto por 18 itens, obteve Índice de Validade de Conteúdo (IVC) total de 0,98, com todos os itens superiores a 0,80. O instrumento final, denominado *Checklist de Segurança Transfusional*, é composto por 26 itens de verificação distribuídos nas etapas pré-analítica, analítica e pós-analítica. Sua aplicação poderá contribuir para a segurança do paciente hemoterápico, constituindo ferramenta gerencial de cuidado voltada à melhoria da qualidade assistencial, à redução de eventos adversos e ao fortalecimento da cultura de segurança. **Conclusão**: O instrumento construído contempla todas as etapas do ato transfusional e pode ser aplicado por diferentes profissionais, desde a prescrição médica até o acompanhamento pós-transfusional. Como limitação, ressalta-se que a versão final, após incorporação das sugestões dos especialistas, não foi submetida a nova rodada de avaliação, o que reforça a necessidade de estudos complementares de usabilidade e validação clínica.

DESCRITORES:

Segurança do Sangue; Pessoal de Saúde; Segurança do Paciente; Cuidados de Enfermagem; Transfusão de Sangue.

RESUMEN

Objetivo: Construir y validar el contenido de una *checklist* de seguridad transfusional para la red de sangre de Santa Catarina. **Metodología:** Estudio metodológico desarrollado en tres etapas: etapa exploratoria (revisión integradora de literatura y diagnóstico situacional), etapa de construcción del instrumento y etapa de validación de contenido por especialistas. **Resultados:** En la etapa de validación de contenido participaron 12 profesionales de la salud que trabajan en Agencias Transfusionales de la red de sangre de Santa Catarina. El instrumento de validación, compuesto por 18 ítems, obtuvo un Índice de Validez de Contenido (IVC) total de 0,98, con todos los ítems superiores a 0,80. El instrumento final, denominado *Checklist de Seguridad Transfusional*, está compuesto por 26 ítems de verificación distribuidos en las etapas preanalítica, analítica y posanalítica. Su aplicación puede contribuir a la seguridad del paciente hemoterápico, constituyendo una herramienta gerencial de cuidado orientada a la mejora de la calidad asistencial, la reducción de eventos adversos y el fortalecimiento de la cultura de seguridad. **Conclusión:** El instrumento abarca todas las etapas del proceso transfusional y puede ser aplicado por diferentes profesionales, desde la prescripción médica hasta el monitoreo postransfusional. Como limitación, se destaca que la versión final, tras la incorporación de las sugerencias de los especialistas, no fue sometida a una nueva ronda de evaluación, lo que refuerza la necesidad de estudios complementarios de usabilidad y validación clínica.

DESCRIPTORES:

Seguridad de la Sangre; Personal de Salud; Seguridad del Paciente; Atención de Enfermería; Transfusión Sanguínea.

INTRODUCTION

Blood transfusions are clinical procedures widely performed at the global level. Although 112 million whole blood samples are collected per year at the global level, approximately 14 million units of whole blood bags and red blood cell concentrate are in fact transfused. This difference reflects losses due to clinical, serological and technical inadequacy throughout the hemotherapy process. Transfusions are life-saving procedures and take place every day in hospitals and outpatient services[1].

When properly performed, they are safe and effective. The entire team involved in blood component transfusions should be aware of such components, their use indications, alternative options available, risks and benefits, as well as of the possible reactions and how to implement additional treatments if necessary. Transfusions lacking proper indication should be avoided, and patients and family members alike should be advised about the risks, benefits and alternatives regarding these procedures[2].

The undesirable adverse events that may result from blood component transfusions are mostly due to human errors. Therefore, due knowledge about hemotherapy products, the necessary care measures and hemosurveillance is essential for such adverse events to be prevented[3].

Transfusion safety is a critical health care aspect and requires a systematic approach to minimize risks and optimize outcomes in patients. In this sense, it is essential to offer transfusion training based on encompassing and updated knowledge to the entire health team. The importance is also noted for teams to understand how these cognitive biases and assumptions contribute for adverse events to take place, in order to enable adopting mitigation strategies[2].

Checklist use to improve patient safety has been increasingly adopted both at the global level and in the national scope, proving to be effective as a tool that is easy to use and implement, aiming to ensure that all stages are duly performed and recorded[4-5].

National studies show the validity of instruments of this nature in different hemotherapy contexts: Rambo and Magnago[5] validated a checklist for transfusions in hospitalization units; Bezerra, Cardoso, Silva and Rodrigues[6] developed a specific instrument for blood transfusions in children; and Alves and Campos[7] created a checklist for secondary- and tertiary-level care units.

Although these instruments represent significant progress, none of them was developed for the specific context of the Transfusion Agencies (TAs) from a structured blood network, which is characterized by multiprofessional assistance, by complexity of flows across services and by the need to comply with the current legislation[8,9]. This scenario evidences a gap that justifies developing an instrument duly contextualized for the Santa Catarina blood network, capable of integratedly encompassing the Pre-analytical, Analytical and Post-analytical stages inherent to the transfusion process, contemplating the different professional profiles involved in the HEMOSC TAs. Considering this need, the current study

proposes developing and validating the content of a transfusion safety checklist for the Santa Catarina blood network.

OBJECTIVE

To develop and validate the content of a transfusion safety checklist for the Santa Catarina blood network.

METHODOLOGY

Type of study

A methodological research study focused on developing and validating the structure of a managerial care technology on transfusion safety. The study consisted of three stages: 1) Exploratory phase: literature review and situational diagnosis regarding the reality of the service; 2) Technology development phase, giving rise to Version 1; and 3) Technology validation phase, resulting in the final version (Version 2). The study followed the recommendations set forth in the *COnsensus-based Standards for the selection of health Measurement Instruments* (COSMIN) guideline for validation studies targeted at measurement instruments in the health area[10].

Study protocol

The Exploratory phase consisted in the integrative literature review and in a situational diagnosis regarding the reality of the service. The integrative review was conducted during the second half of 2024 in the SCOPUS (Elsevier), Web of Science, Science Direct, PubMed and Cochrane Library databases (among others), using the following controlled descriptors: *"Transfusão de Sangue" OR "Blood Transfusion" OR "Transfusión Sanguínea" AND "Pessoal da Saúde" OR "Health Personnel" OR "Personal de Salud"*. Studies published from 2020 to 2024 and written in English, Portuguese and Spanish were included. The materials excluded were reviews without methodological syntheses, experience reports lacking empirical data and publications not specifically dealing with the transfusion process. Once the search, screening and eligibility analysis stages were over, 13 studies comprised the final sample of the review[11].

The situational diagnosis was made in July 2025 by means of an electronic instrument developed in the *Google Forms*® platform, with the participation of 11 professionals from the HEMOSC Hemotherapy service working in TAs. The diagnosis instrument consisted of two blocks: the first one was devoted to the participants' sociodemographic profile and professional experience; in turn, the second was targeted at transfusion safety in the Santa Catarina blood network, addressing perceptions about critical aspects inherent to the transfusion process, incidence of adverse events and gaps in the current protocols.

Along with the integrative literature review, performing the situational diagnosis assisted in developing the minimum structure for the transfusion safety checklist. In order to confer validity to the instrument, a content validation process in charge of experts was carried out in August 2025, with 12 professionals from the Santa Catarina Hemotherapy service working in the HEMOSC TAs.

The content validation experts (nurses, biologists, biophysicians and biochemists) were selected by means of non-probability sampling based on the following inclusion criteria: at least one year working in Hemotherapy; minimum specialization degree in the area; and proven clinical and/or academic experience. The number of experts was established according to the parameters recommended by Pasquali[12]. The following exclusion criteria were considered: technical-level professionals working in the transfusion agencies and those on holidays or away from work for any reason during the data collection period.

Each expert was sent an invitation letter via the institutional email service to take part as content validator, along with Version 1 of the instrument in PDF format and the assessment questionnaire. The answers were collected via electronic means in *Google Forms®*. The assessment questionnaire was structured in two blocks: the first one was devoted to characterizing the participants and the second to validating the content of the technology proposed.

The researchers analyzed the suggestions made according to two criteria: clinical pertinence for the TA context; and coherence with the fundamentals of hemosurveillance and with the current legislation. Any and all items with suggestions by at least two experts and backed by the literature were incorporated as a priority; the others were discussed in a consensus meeting among the researchers. The final version (Version 2) was the result of incorporating the suggestions that were accepted. It is noted that this version was not subjected to a new evaluation round by the experts.

Data analysis

The instrument proposed by Leite et al.[13] for Health Educational Content Validation (*Instrumento para Validação de Conteúdo Educativo em Saúde*, IVCES) was used, adapted to the specific requirements of this research. Differently from the 26 verification items that comprise the checklist prepared in this study, the instrument has 18 assessment items and is divided into three domains: 1) Objectives: comprised by six criteria related to purposes, goals or aims; 2) Structure/Presentation: comprised by nine items related to organization, structure, strategy, coherence and sufficiency; and 3) Relevance: comprised by three criteria related to significance, impact, motivation and interest.

The items were assessed using a four-point scale, as follows: 1) Inadequate; 2) Partially adequate; 3) Adequate; and 4) Fully adequate. The Content Validity Index (CVI) was used for content validation, calculated by dividing the number of “3” and “4” answers by the total number of answers. The

result should be higher than 0.80 to determine agreement on a given aspect[14]. The data were computed in a *Microsoft Office Excel*® spreadsheet and analyzed descriptively by calculating absolute frequencies.

Ethical aspects

The project was approved by the institutional Research Ethics Committee under Opinion No. 7,612,377 and Ethical Appraisal Submission Certificate (*Certificado de Apresentação para Apresentação Ética*, CAAE) No. 86750225.4.0000.0118, in consonance with resolutions No. 466/2012, No. 510/2016 and other regulations set forth by the National Health Council (*Conselho Nacional de Saúde*, CNS)[15-16].

RESULTS

The process to develop the instrument was grounded on a triangulation among the findings from the integrative literature review, the diagnosis regarding the reality of the service made along with the professionals working in the HEMOSC Hemotherapy service and the current legal devices. Version 1 (resulting from this phase) consisted in 26 verification items organized in three stages: Pre-analytical (eight items), Analytical (eight items) and Post-analytical (ten items), with “Yes”, “No” and “Not applicable” as answer options and a field for comments.

The content validation participants were 12 health professionals working in the HEMOSC TAs, namely: five biophysicians (41.6%), four nurses (33.3%) and three biochemists (25%); 11 (91.7%) of them belonged to the female gender and one (8.3%) to the male one. As for their degrees, three (25%) had completed undergraduate courses, four (33.3%) had some *stricto sensu* graduate degree and five (41.7%) had completed *lato sensu* graduate training. Their time working in the institution varied between one and 33 years (mean of 11), six (50%) worked in the assistance area, five (41.7%) did so in management and one (8.3%) developed laboratory and teaching activities. This heterogeneity in terms of training and performance areas conferred amplitude and representativeness to the process to evaluate the instrument.

As shown in Table 1, all 18 items in the validation instrument (adapted IVCES) reached an overall CVI of 0.98, with none of them below 0.80.

The suggestions made by the experts mainly pointed to structural adjustments and to including items related to assistance aspects identified as critical in the local practice. Chart 1 presents the suggestions made and the result obtained in the analysis performed by the researchers.

Table 1. Content Validity Index corresponding to all 18 items in the validation instrument (adapted IVCES) applied to the Transfusion Safety Checklist. n=12, Chapecó, SC, 2025.

Items	Item CVI
Objectives: purposes, goals or aims	
1. It addresses the topic proposed: Transfusion Safety	1
2. It assists in the professionals' routine/It is useful	1
3. It clears doubts about the topic addressed	0.92
4. It provides a reflection on the topic	1
5. It urges behavioral changes	1
6. It guides, informs and sensitizes on the topic	1
Structure/Presentation: organization and strategies	
7. Adequate language for the target audience: health professionals	1
8. Appropriate language for the educational material	1
9. Interactive language, allowing for active involvement in the process	1
10. Correct information	1
11. Objective information	0.92
12. Necessary information	1
13. Logical sequence of ideas	1
14. Current topic	1
15. Adequate text size	0.92
Relevance: significance, impact, motivation and interest	
16. It stimulates learning	0.92
17. It contributes to knowledge in the area	1
18. It arouses interest in the topic	1

Chart 1. Experts' suggestions to modify the Transfusion Safety Checklist. Chapecó, SC, Brazil, 2025.

Expert	Suggestions	Result after the Analysis performed by the authors
E1	Incorporate an assessment of the pre-transfusion history.	Recommendation accepted.
E7	Adjust font size.	Recommendation accepted.
E9	Render questions more objective.	Recommendation accepted.
E11	Include an item to verify that the patients are duly identified with a bracelet and headboard chart in the case of recipients with impaired sensory levels.	Recommendation accepted.
E12	Include a field about the need for a special procedure/blood component change.	Recommendation accepted.
E12	Include a field on transfusion guidelines for the patients.	Recommendation accepted.
E12	Include a field to double-check the blood component with the patient.	Recommendation accepted.
E12	Remove the "Not applicable" option from some items.	Recommendation accepted.

The final version was created after incorporating the suggestions that were accepted, as presented in charts 2 and 3.

Chart 2. Transfusion Safety Checklist – Version 2, front. Chapecó, SC, 2025.

PRE-ANALYTICAL STAGE		ANALYTICAL STAGE	
CONFIRM	**CHECK**	**CONFIRM**	**CHECK**
1. Are all the HSR* fields properly filled-in and signed by the requesting physician?	( ) Yes ( ) No	9. Do the pre-transfusion sample data coincide with the HSR data?	( ) Yes ( ) No
2. Are the blood component requested, the amount and the special procedures in line with the patient's diagnosis?	( ) Yes ( ) No	10. Is the blood component requested in the HSR available?	( ) Yes ( ) No
3. Is the blood component requested prescribed in the patient's medical chart? In case of surgical reserve, select “Not applicable”.	( ) Yes ( ) No ( ) Not applicable	11. Does the blood component present the necessary phenotyping, volume and special procedure/change?	( ) Yes ( ) No ( ) Not applicable
4. Has the patient and/or family member signed the FICF?	( ) Yes ( ) No ( ) Not applicable	12. Do the results obtained in the tests performed coincide with those found in the pre-transfusion history?	( ) Yes ( ) No ( ) Not applicable
5. Does the patient have a pre-transfusion history?	( ) Yes ( ) No	13. After detecting positive IAS*, are the sector where the patient is and the requesting physician informed about the laboratory findings and course of action to follow?	( ) Yes ( ) No ( ) Not applicable
6. Has a pre-transfusion sample been collected? In case of a 72-hour valid sample, select “Not applicable”	( ) Yes ( ) No ( ) Not applicable	14. In the case of incompatible blood components, has the requesting physician authorized the transfusion and signed the corresponding form to assume responsibility for such incompatibility?	( ) Yes ( ) No ( ) Not applicable
7. If Yes, are all the ID label data duly filled-in, with no abbreviations?	( ) Yes ( ) No	15. Were the results obtained in immuno-hematological tests double-checked in the records book?	( ) Yes ( ) No
8. If requesting an emergency transfusion, has the transfusion authorization form been filled-in and signed by the physician, and is it available along with the other documents?	( ) Yes ( ) No ( ) Not applicable	16. Has the blood component x HSR cross-test label been double-checked with another professional before the blood component left the TA?	( ) Yes ( ) No

*HSR: Hemotherapy Service Request
*IAS: Irregular Antibody Screening

Chart 3. Transfusion Safety Checklist – Version 2, back. Chapecó, SC, 2025.

POST-ANALYTICAL STAGE		COMMENTS
CONFIRM	**CHECK**	
17. Does the blood component visual inspection meet the standards?	( ) Yes ( ) No	
18. Have the recipient's vital signs been measured before the transfusion?	( ) Yes ( ) No ( ) Not applicable	
19. Does the recipient have a viable venous access?	( ) Yes ( ) No	
20. Has all the information about the blood component transfusion been communicated to the patient and/or their family members?	( ) Yes ( ) No	
21. Has the blood component been double-checked with the patient at the bedside?	( ) Yes ( ) No	
22. In case of recipients with impaired sensory levels, has all the information been double-checked with a health professional or against the patient's ID bracelet/chart?	( ) Yes ( ) No ( ) Not applicable	
23. Were vital signs measured during the first 10-15 minutes and at the end of the transfusion?	( ) Yes ( ) No ( ) Not applicable	
24. Did the recipient present any transfusion reaction sign?	( ) Yes ( ) No	
25. Has any additional care action been taken in relation to the adverse event/transfusion reaction?	( ) Yes ( ) No ( ) Not applicable	
26. Have all the transfusion records been properly made in the recipient's medical chart?	( ) Yes ( ) No	

DISCUSSION

The instrument achieved content validity with an overall CVI of 0.98 and all its 18 items were assessed as above the minimum 0.80 threshold[14]. This result is similar to the one obtained by Rambo and Magnago[5], who found a high CVI in a checklist for transfusions in hospital units, as well as to the findings in Bezerra et al.[6], whose instrument for blood transfusions in children reached an agreement level above 0.80 in all domains. The consistency of these findings reinforces that organizing the transfusion process into systematized stages favors devising instruments with high agreement levels among experts.

The aspect differentiating the instrument that was validated is its specificity for the context of the TAs from a statewide blood network. As opposed to previously published checklists developed for

hospitalization units[5,7] or for specific population groups[6], this instrument gathers in a single document all three stages of the transfusion process (Pre-analytical, Analytical and Post-analytical), considers the characteristic multiprofessional performance inherent to TAs and is in line with the requirements set forth in the current legislation. This normative alignment is especially relevant because it confers the character of a regulatory compliance device to the instrument, going beyond the function of a simple checklist.

The fact that the instrument is divided into the three stages of transfusion care (in terms of the pre-analytical, analytical and post-analytical components) is in line with other studies[5,6,7] previously conducted in different regions of the country and proves to be effective to improve transfusion safety, in addition to providing aids for the everyday professional practice as a reference both for professionals recently incorporated to Hemotherapy services and for those who have worked in them for longer periods of time, as guidance to be followed.

Concentrating the most professionals involved and the highest risk of failures, the Pre-analytical stage encompasses from filling-in the HSR (legal document that warrants transfusion procedures) to collecting and identifying pre-transfusion samples. Some studies indicate that failures in this stage are among the main causes of inadequate transfusions and preventable adverse events[9-17]. Having included items about pre-transfusion history and the need for special procedures or to change blood components in the final version (both suggestions made by the experts) strengthens the instrument's capacity to detect specific risks in the TA context.

Effective communication among professionals emerges as a critical factor in the Analytical stage. Communication failures can result in not selecting the correct blood component, in delayed release of results and in recording errors[2]. Having included double-checks of immuno-hematological results as a mandatory item in the instrument formalizes an internationally recognized safety barrier, most frequently neglected in high-demand environments[8,18].

As for the Post-analytical stage (when the blood component transfusion is made), it encompasses from visually inspecting the product to post-transfusion recording. Rigorous monitoring of vital signs and early identification of transfusion reactions are pointed out as fundamental for recipients' safety[19,20,21]. Having included the item on guidelines for patients and family members (missing in previously published instruments) and the one on bedside double-checks along with the patients reflects a recipient-centered care model, in consonance with the international patient safety targets[5,22-23].

From the care management point of view, the instrument can be incorporated to institutional protocols, acting as a compliance monitoring device that can also identify bottlenecks in the transfusion process. For permanent health education, it represents a systematized framework for baseline treatments and periodic recycling processes, bridging the gap identified in the literature regarding scarcity of

structured instruments to support training of Hemotherapy teams[24-25,26]. The diversity of professionals that took part in the validation process (biophysicians, nurses and biochemists) reinforces its multiprofessional applicability, an essential aspect in services where different categories share the responsibility for transfusion procedures.

As for the validation process, it is important to acknowledge that the changes incorporated to the final version (such as adding new items) were not subjected to a second evaluation round by the experts. As described in Zarli et al.[27], studies employing the Delphi technique demonstrate that content validity is consolidated by means of successive rounds until reaching consensus. Not having implemented a second round constitutes a methodological limitation that does not invalidate the data obtained, as all items were above the minimum CVI and the changes were based on previously defined criteria; however, it is recommended that future studies incorporate multiple evaluation rounds to strengthen validity of the instrument.

Study limitations

This study has limitations that must be considered when interpreting its results. In the first place, the final version of the instrument (resulting from incorporating the experts' suggestions such as adding new items and making structural adaptations) was not subjected to a second evaluation round. Although the methodological criteria adopted to analyze the suggestions minimized this risk, it is recommended for future studies to implement multiple validation rounds.

Secondly, the study was conducted in a single statewide blood network and with a small sample of experts, which limits generalizability of the findings to other hemotherapy contexts. In addition, the instrument has not yet undergone clinical validation or a pilot test in real-life environments, mandatory stages to assess its usability, application time, adequacy to care flows and impact on the incidence of adverse events. These gaps reinforce the need for complementary construct validity, reliability and clinical impact evaluation studies before adopting it at a large scale.

Contributions for the Nursing, Health or Public Policy areas

The study offers relevant contributions for Nursing and Public Health, as it has developed and validated a managerial care instrument duly contextualized for the reality of the TAs from a statewide blood network. It offers insights for professionals and managers to identify risk factors in the transfusion process, thus preventing adverse events. In the case of Nursing, it strengthens the production of care technologies targeted at qualifying the assistance provided in the Public Health system and at enhancing the patient safety culture in Hemotherapy services.

CONCLUSION

The process followed to develop and validate the content of the Transfusion Safety Checklist showed that this instrument meets the validity criteria, with CVI values above 0.80 in all 18 items assessed and an overall CVI of 0.98. The tool has 26 verification items distributed into the Pre-analytical, Analytical and Post-analytical stages, with accessible language and applicability to the different professional profiles in Hemotherapy services.

As a managerial care tool, it has potential to qualify the professional practice, assist in permanent education processes and promote the patient safety culture in Hemotherapy environments. The following is recommended for its impact to be duly measured and its validity enhanced: conducting a pilot test that assesses its usability in a real-life setting; implementing a new evaluation round by experts on the final version; and developing construct validity and reliability studies, aiming to consolidate it as a reference instrument for the Brazilian blood network.

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