Original Article

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CONSTRUCTION AND VALIDITY OF CHECKLIST FOR PATIENT SAFETY DURING THE TRANSFUSION PROCESS

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ABSTRACT

Objective: to construct and validate a checklist for patient safety during transfusion.
Method: this is a methodological study whose development took place, between February 2020 and January 2021, at a teaching hospital in Santa Maria, RS, Brazil. The design was based on the survey of items in an integrative literature review, and validity, with 17 health specialists and 8 hemotherapy experts. Pre-test was carried out with 36 professionals from the target population. For data analysis, the Content Validity Index was calculated.
Results: the checklist was composed of 29 items and 90 sub-items, distributed in three domains, corresponding to the transfusion act stages: Pre-transfusion (Medical prescription, Compatibility and Bedside identification); Transfusion (Blood component installation); and Post-transfusion (Monitoring). The items obtained a Content Validity Index predominantly > 0.80 in all stages. After reformulations suggested by participants, a Content Validity Index of 0.98 was obtained in its final version.
Conclusion: the checklist demonstrated evidence of content validity and can be a reliable instrument to promote patient safety during transfusion.

DESCRIPTORS: Blood Component transfusion. Blood safety. Patient safety. Checklist. Biomedical technology. Validation study.

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CONSTRUÇÃO E VALIDAÇÃO DE CHECKLIST PARA SEGURANÇA DO PACIENTE NO ATO TRANSFUSIONAL

RESUMO

Objetivo: construir e validar um *checklist* para segurança do paciente no ato transfusional.
Método: estudo metodológico cujo desenvolvimento ocorreu entre fevereiro de 2020 e janeiro de 2021, em um hospital de ensino de Santa Maria, RS, Brasil. A concepção se deu pelo levantamento dos itens em revisão integrativa da literatura, validação com 17 especialistas da saúde e 8 *experts* em hemoterapia. O pré-teste foi realizado com 36 profissionais da população-alvo. Para análise dos dados, procedeu-se ao cálculo do Índice de Validade de Conteúdo.
Resultados: o *checklist* ficou composto de 29 itens e 90 subitens, distribuídos em três domínios, correspondentes às etapas do ato transfusional: Pré-transfusão (Prescrição médica, Compatibilização e Identificação Beira-leito); Transfusão (Instalação do hemocomponente); e Pós-transfusão (Monitoramento). Os itens obtiveram Índice de Validade de Conteúdo predominantemente >0,80 em todas as etapas. Após realizadas reformulações sugeridas pelos participantes, obteve-se Índice de Validade de Conteúdo de 0,98 na sua versão final.
Conclusão: o *checklist* demonstrou evidências de validade de conteúdo, podendo ser uma ferramenta confiável para promover a segurança do paciente no ato transfusional.

DESCRITORES: Transfusão de componentes sanguíneos. Segurança transfusional. Segurança do paciente. Checklist. Tecnologia em saúde. Estudo de validação.

CONSTRUCCIÓN Y VALIDACIÓN DE UNA LISTA DE VERIFICACIÓN PARA LA SEGURIDAD DEL PACIENTE DURANTE EL PROCESO DE TRANSFUSIÓN

RESUMEN

Objetivo: construir y validar una lista de verificación para la seguridad del paciente durante la transfusión.
Método: estudio metodológico cuyo desarrollo tuvo lugar entre febrero de 2020 y enero de 2021 en un hospital universitario de Santa María, RS, Brasil. El diseño se basó en el levantamiento de ítems en una revisión integrativa de la literatura, validación con 17 especialistas de la salud y 8 expertos en hemoterapia. La preprueba se realizó con 36 profesionales de la población objetivo. Para el análisis de los datos, se calculó el Índice de Validez de Contenido.
Resultados: la lista de verificación estuvo compuesta por 29 ítems y 90 subítems, distribuidos en tres dominios, correspondientes a las etapas del acto transfusional: Pre-transfusión (Prescripción médica, Compatibilidad e Identificación al pie de la cama); Transfusión (Instalación del componente sanguíneo); y Post-transfusión (Monitoreo). Los ítems obtuvieron un Índice de Validez de Contenido predominantemente > 0,80 en todas las etapas. Luego de reformulaciones sugeridas por los participantes, se obtuvo un Índice de Validez de Contenido de 0,98 en su versión final.
Conclusión: la lista de verificación demostró evidencia de validez de contenido y puede ser una herramienta confiable para promover la seguridad del paciente durante la transfusión.

DESCRIPTORES: Transfusión de componentes sanguíneos. Seguridad de la sangre. Seguridad del paciente. Lista de verificación. Tecnología biomédica. Estudio de validación.

INTRODUCTION

Blood component transfusion is one of the most performed care procedures in the world[1]. It is recognized as a strategy for several clinical treatments, in addition to transplants, chemotherapies and surgeries[2]. In this context, actions regarding safety in blood and blood component prescription, use and administration are essential. The transfusion act is a complex procedure that involves a potential risk of human errors, process errors or transfusion reactions related to intrinsic factors of recipients[1,3].

Although some transfusion reactions are inevitable (adverse reaction), the most important cause of serious reactions with risk of death is transfusion with the wrong blood (adverse event) due to failures during the transfusion process[1,4]. The risk of transfusing the wrong blood to the wrong patient is approximately three times greater than the risk of transmitting diseases through blood[4].

Most incidents related to the transfusion process result from human error and errors are often multiple[2]. They correspond to approximately 80% of reported events,[2,5] and the most commonly encountered are incorrect recipient identification and incorrect sample labeling[6]. Among deaths associated with transfusion, at least 45% would be preventable[5,7].

In this way, improving transfusion safety involves taking precautions regarding avoidable risks in order to reduce opportunities for human errors to occur. In this regard, using technologies for this purpose can be an efficient measure. This is one of the strategies proposed by the Global Action Plan for Patient Safety 2021-2030 and includes the implementation of new technologies to improve health care safety[8].

Among the technologies that assist in safe care, the checklist has been highly recommended. The efficiency of this instrument can be demonstrated by the successful use of the safe surgery checklist[9] and can serve as a stimulus for other areas of care, such as hemotherapy. Considering that, in care practice, elements considered simple and obvious are often left unchecked for reasons such as interruptions, urgent clinical situations, stressful working conditions, inattention, among others,[3] the checklist can be used to ensure that a process or task is performed as planned. With it, it can be checked that all important stages have been completed.

Although in the Brazilian context there are checklists designed for the transfusion procedure, these specifically encompass nursing care[10]. In view of this, the construction of the checklist proposed here is justified due to the lack of instruments, in checklist format, of a multidisciplinary nature, which allow the checking and inspection of the execution of all procedures necessary in transfusion practice, from medical prescription, sample collection, pre-transfusion tests, blood component implantation in patients and reaction monitoring. Therefore, the checklist created represents an instrument with the potential to improve the safety of blood component recipients. Furthermore, its implementation can also positively influence health professionals' work routine, reducing the occurrence of errors during transfusion. Considering the above, the objective was to construct and validate a checklist for patient safety during transfusion.

METHOD

This is a methodological study,[11] developed between February 2020 and January 2021. The construction and validity process consisted of four stages: literature review; committee of specialists (care professionals); committee of experts (researchers); and pre-testing with the target population.

In the first stage, a search was carried out in the scientific literature, through an integrative review and analysis of recommendations of hemotherapeutic standards and guidelines,[12–13] to survey the care considered essential in hemotherapeutic practice. The second stage consisted of assessing the checklist items by a committee of specialists composed of health professionals who carry out their activities in processes involving blood component prescription, preparation and administration at a teaching hospital in Rio Grande do Sul. Based on participants' practical knowledge, the distribution of items in the checklist was defined, and a first round of validity was carried out. The third stage included checklist validity by a committee of experts with a high level of specialization and scientific knowledge in hemotherapy working at health institutions located in several states in Brazil. In the fourth stage, called pre-test, semantic analysis was carried out in order to assess item clarity, verifying the ease of reading and adequate understanding for members of the target population.

Participant selection for the committee of specialists occurred through non-probabilistic and intentional sampling. Doctors, nurses, pharmacists, laboratory technicians or nursing technicians, with technical experience in processes involving blood component prescription, preparation and administration, were included. The sample consisted of 17 health professionals, considering recommendations on the ideal number of specialists in validity studies from 6 to 20 participants[14].

Participants were approached during the work shift. The data collection instrument was delivered in a brown envelope, and each participant was free to fill out the instrument and, according to their preferences, agree with the researcher the best time to collect the envelope. The instrument consisted of a sociodemographic characterization questionnaire and a preliminary list of items (48 items and 80 sub-items) with the respective assessment criteria regarding Domain, Clarity and Relevance[14]. Domain corresponded to the moment of execution of care in the transfusion process: pre-transfusion (1); during transfusion (2); and post-transfusion (3). Domain assessment was intended to define the distribution of items according to transfusion stages in the checklist.

Regarding Clarity, it was assessed whether items/sub-items were written in an comprehensible way. Regarding Relevance, it was judged whether items reflected the concepts involved and whether they were relevant and appropriate to achieve the proposed objectives. For these two criteria, a 4-point Likert scale was established for measurement, ranging from 1 "Incomprehensible" to 4 "Totally comprehensible" for Clarity and from 1 "Irrelevant" to 4 "Totally relevant" for Relevance.

For the committee of experts, the selection of eligible participants was carried out through an active search on the *Platforma Lattes* of the Brazilian National Council for Scientific and Technological Development (CNPq – *Conselho Nacional de Desenvolvimento Científico e Tecnológico*). For inclusion, a scoring system was adapted[15], considering the degree (specialization, master's, doctoral and post-doctoral degrees), scientific production, knowledge and care practice on the subject. The sum of scores could vary from 1 to 14 points, selecting those who totaled at least five points.

As in the previous stage, recommendations from scientific literature were followed to define the number of participants[14]. Professionals were invited via email, and it was observed that the participants' institutions were not repeated in order to obtain the greatest diversity of health services and, therefore, guarantee a construct that meets regional variations.

The data collection instrument had two sections: one with sociodemographic data to characterize participants and another for content validity, containing the domains and items/sub-items updated after the first round of validity. Experts gave their opinion on the Clarity and Relevance of the checklist items using the same four-point Likert scale as in the previous stage.

In pre-test, health professionals (doctors, nurses, pharmacists, nursing technicians and laboratory technicians) working in any of the stages of transfusion, i.e., professionals from the public-target who will use the checklist in clinical practice, were included. Of a total of 414 eligible workers, 36 agreed to participate in the research, upon returning the forms.

The data collection form, sent via electronic mail, due to the restrictions imposed by the pandemic context, was composed of questions on respondent sociodemographic and work characterization and checklist items/sub-items, resulting from modifications suggested in the previous stage. Participants assessed the level of difficulty in understanding each checklist item. For this, a four-point Likert scale was used.

In the validity (specialists and experts) and pre-test stages, participants were asked to write suggestions for improvement or new writing in items or sub-items in which assessment criteria were classified with a score of 1 or 2. It was also possible to suggest item/sub-item deletion or addition. Thus, at the end of each stage, the modifications resulting from participants' assessment were made and a new version of the checklist was obtained that would be submitted to the subsequent stage.

Data from all validity and pre-test stages were compiled and analyzed using the Statistical Package for the Social Sciences (SPSS®) version 18.0. Comments and suggestions for the items were typed into a Microsoft Word® file, being considered when changing the items and preparing each version of the checklist.

Content validity in relation to item agreement was measured by the Content Validity Index (CVI) in the committee of specialists, committee of experts and pre-test stages. In all assessments, scores 3 and 4 expressed a higher level of agreement among participants. To calculate the CVI for each item/subitem, the sum of responses 3 and 4 was considered and divided by the total number of responses[14]. To assess the instrument as a whole, the mean CVI of the items/sub-items calculated separately was used.

As an acceptance criterion, an ideal agreement ≥ 0.80[14] was established both for the CVI of each item and for the instrument's general assessment. Those that did not reach this percentage would be reformulated or discarded from the instrument.

In pre-test, it was established that, if there were many doubts on the part of the respondents (CVI < 0.80), the items that were difficult to understand would be readjusted and returned to participants for a new round of pre-test. This procedure would continue until no further changes were necessary.

The research project followed the recommendations of Resolution 466/2012 of the Brazilian National Health Council and complementary resolutions, and was approved by the Research Ethics Committee. At all stages, participants were informed and consented to the research by signing the Informed Consent Form (ICF).

RESULTS

Committee of specialists

A total of 17 health professionals from the researched institution participated in this stage. There was a predominance of female participants (N=15; 88.2%), with a mean age of 42.3 years (±9.1), nurses (N=7; 41.2%), with a mean training time of 18.6 years (±8.8) and with specialization/residency (N=7; 41.2%). All participants had undergone training/qualification in hemotherapy (N=17; 100%) and used to participate in transfusion procedures five or more times a week (N=11; 64.7%).

As for the form items and sub-items, all had CVI above 0.80, both for Clarity and Relevance, with a minimum of 0.82 and a maximum of 1.0. The mean for Clarity was 0.98, and for Relevance was 0.99. The overall CVI was 0.98. However, even with satisfactory results among the evaluators, there were suggestions for review and comments regarding the layout, correction of some terms and better wording of an item.

Comments and suggestions were analyzed and, for the most part, accepted to adapt the checklist. For this, the evidence found in the literature was also taken into account. Based on specialists' suggestions, five items ("Does the patient have an identification wristband?"; "Were the patient and/or companion instructed about the transfusion (risks, benefits, signs and symptoms of reaction)?"; "Was the recipient's religion verified?"; "Was the informed consent requested?"; "Was the FNIIT (Transfusion Incident Notification and Investigation Form) completed?" and two sub-items ("Age" of "Does the blood component request form contain information for correct patient identification?" item; and "Were they punctured?" of the "Does the patient have patent venous access?" item) were excluded. Two sub-items were added (Date of release of bag/proof of compatibility in "Was the blood component label checked?" item and "If NO: Was the hemotherapy service notified?" of "Was the blood component infused within a maximum of 4 hours?" item), some items/sub-items, compiled, and others underwent a change in the order of presentation and had their wording changed.

The result of such modifications gave rise to the first version of the checklist, which was composed of 31 items and 92 sub-items, totaling 123 items/sub-items. Based on the distribution of items by specialists, they were arranged into 3 domains: Pre-transfusion, Transfusion and Post-transfusion. The Pre-transfusion domain was composed of 21 items, and the Transfusion and Post-transfusion domains were composed of 5 items each.

Committee of experts

At this stage, eight health professionals participated. The committee of experts was composed of women (100%), with a mean age of 44.6 years (±12.2). They came from the Southeast (N=4; 50%), South (N=3; 37.5%) and Northeast (N=1; 12.5%). The predominant professional category was nursing (N=6, 75%), with a mean training time of 19.8 years (±9.2). Most had a master's degree (N=5; 62.5%), having developed a dissertation or thesis in the area of hemotherapy (N=7; 87.5%).

Experts carried out their activities in hemotherapy (N=7; 87.5%), whether in a hospital environment (N=4; 50%) or blood centers (N=3; 37.5%), participating in five or more transfusion procedures times a week (N=4; 50%). All participants had scientific production on hemotherapy (N=8; 100%). Regarding the score established as an inclusion criterion, the mean was 10.2 points (±2.5), with a minimum of 8 and a maximum of 14 points.

After returning the forms, an item-by-item analysis of both the CVI values and experts' comments and suggestions was carried out. Suggestions were weighted even on items with high agreement. In the Pre-transfusion domain, three sub-items (Weight (pediatric patients); Pre-transfusion tests; and Ratio of blood components transfused) had CVI lower than 0.80 in the Clarity category. Also, one item (Need to collect a blood sample for cross-matching?) and one sub-item (List of blood components transfused) presented a CVI lower than 0.80 in the Relevance item, and the CVI ranged from 0.63 to 0.75. The other items and sub-items had values above 0.80.

In the Transfusion domain, one item (Was recipients' clinical status followed up during transfusion?) presented a CVI lower than 0.80 in the Clarity item; one item (Has the professional who monitors the transfusion been trained and is able to identify signs and symptoms of a transfusion

reaction?) and one sub-item (In slow infusion?) had CVI lower than 0.80 in the Relevance item, and the CVI scored 0.75. The other items and sub-items had values above 0.80. In the Post-transfusion domain, all items and sub-items presented a CVI greater than 0.80.

Thus, in the three domains, the CVI ranged from 0.63 to 1.0. The mean for the Clarity and Relevance items was 0.97. Of the items with CVI below 0.80, the "Ratio of blood components transfused" subitem from the Pre-transfusion domain and the "Has the professional monitoring the transfusion had training and is able to identify signs and symptoms of a transfusion reaction?" item from the Transfusion domain were excluded. In addition to the deletions, other small adjustments, such as changes to the wording and compilation of items/sub-items, were made.

In general, the checklist items were considered valid, obtaining an overall CVI of 0.97. In relation to the first version, after the deletions, joints and additions, the second version of the checklist was created, consisting of 29 items and 90 sub-items, totaling 119 items and sub-items to be checked.

The final structure of the checklist took into account the transfusion processes (prescription, compatibility, bedside identification, installation and monitoring) and the health professional who performs it. In this context, it was divided into five moments, according to the executor of each process. They were determined and constituted as follows: the Pre-transfusion domain was divided into three moments: moment 1 was called *Medical prescription*, consisting of one item (number 1) and 14 sub-items. Moment 2 was called *Compatibility* and consisted of 12 items (numbers 2 to 13) and 24 sub-items. Moment 3 was called *Bedside identification*, consisting of 7 items (No. 14 to 20) and 19 sub-items. The Transfusion domain originated moment 4 – *Installation*. This was composed of 4 items (numbers 21 to 24) and 15 sub-items. The Post-transfusion domain originated moment 5, called *Monitoring* and consisting of 5 items (numbers 25 to 29) and 18 sub-items.

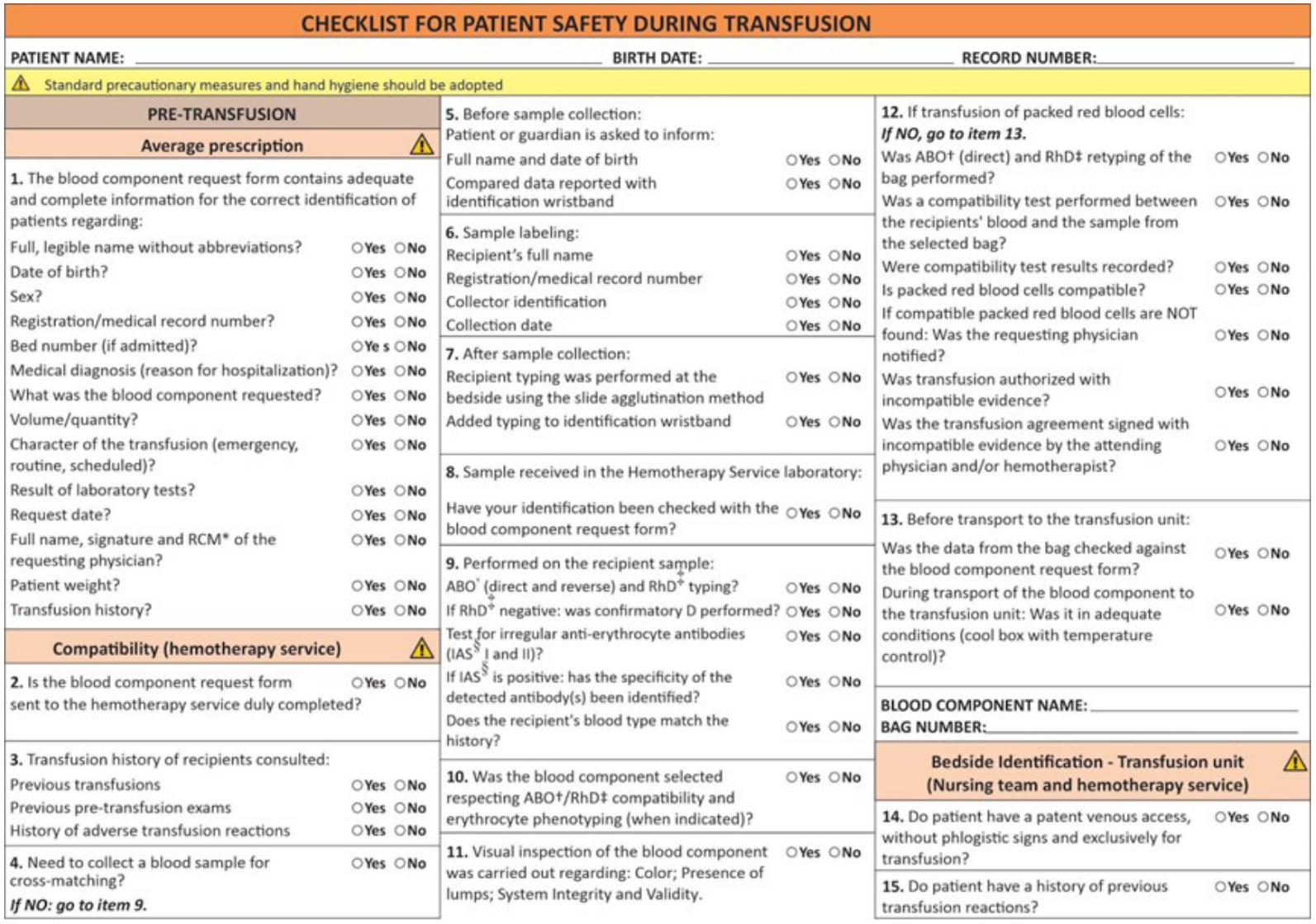
In items relating to patient identification and other checks at the bedside, before installing the blood component, the possibility of double checking was added, following the guidance of experts.

Pre-test

This stage of assessing the Clarity/understanding of the items that made up the second version of the checklist was carried out in two rounds and included the participation of 36 health professionals.

Female participants predominated (N=28; 77.8%), with a mean age of 43.8 years (±9.0). Regarding training, nursing technicians predominated (N=14; 38.9%), with a mean training time of 15.7 years (±8.3), and those who had specialization/residency (N=18; 50%). Most performed transfusion procedures five or more times a week (N=13, 36.1%).

After analyzing item understanding, it was found that only the "Modality of transfusion" subitem of the medical prescription moment presented CVI=0.16. The others were >0.80. Based on participants' suggestions, the wording of a subitem considered inappropriate was adjusted. "Modality of transfusion" was changed to "Character of transfusion (emergency, routine or scheduled)" and subjected to a new round of assessment by the same participants from the first round. The analysis of the second round showed a 100% agreement level. At the end of the pre-tests, the final version of the checklist was obtained (Figures 1 and 2) with an overall CVI of 0.98.



CHECKLIST FOR PATIENT SAFETY DURING TRANSFUSION

PATIENT NAME: _____ **BIRTH DATE:** _____ **RECORD NUMBER:** _____

⚠ Standard precautionary measures and hand hygiene should be adopted

PRE-TRANSFUSION

Average prescription ⚠

1. The blood component request form contains adequate and complete information for the correct identification of patients regarding:

- Full, legible name without abbreviations? ○Yes ○No
- Date of birth? ○Yes ○No
- Sex? ○Yes ○No
- Registration/medical record number? ○Yes ○No
- Bed number (if admitted)? ○Yes ○No
- Medical diagnosis (reason for hospitalization)? ○Yes ○No
- What was the blood component requested? ○Yes ○No
- Volume/quantity? ○Yes ○No
- Character of the transfusion (emergency, routine, scheduled)? ○Yes ○No
- Result of laboratory tests? ○Yes ○No
- Request date? ○Yes ○No
- Full name, signature and RCM* of the requesting physician? ○Yes ○No
- Patient weight? ○Yes ○No
- Transfusion history? ○Yes ○No

Compatibility (hemotherapy service) ⚠

2. Is the blood component request form sent to the hemotherapy service duly completed? ○Yes ○No

3. Transfusion history of recipients consulted:

- Previous transfusions ○Yes ○No
- Previous pre-transfusion exams ○Yes ○No
- History of adverse transfusion reactions ○Yes ○No

4. Need to collect a blood sample for cross-matching? ○Yes ○No

If NO: go to item 9.

5. Before sample collection: Patient or guardian is asked to inform:

- Full name and date of birth ○Yes ○No
- Compared data reported with identification wristband ○Yes ○No

6. Sample labeling:

- Recipient's full name ○Yes ○No
- Registration/medical record number ○Yes ○No
- Collector identification ○Yes ○No
- Collection date ○Yes ○No

7. After sample collection:

- Recipient typing was performed at the bedside using the slide agglutination method ○Yes ○No
- Added typing to identification wristband ○Yes ○No

8. Sample received in the Hemotherapy Service laboratory:

- Have your identification been checked with the blood component request form? ○Yes ○No

9. Performed on the recipient sample:

- ABO† (direct and reverse) and RhD‡ typing? ○Yes ○No
- If RhD‡ negative: was confirmatory D performed? ○Yes ○No
- Test for irregular anti-erythrocyte antibodies (IAS§ I and II)? ○Yes ○No
- If IAS§ is positive: has the specificity of the detected antibody(s) been identified? ○Yes ○No
- Does the recipient's blood type match the history? ○Yes ○No

10. Was the blood component selected respecting ABO†/RhD‡ compatibility and erythrocyte phenotyping (when indicated)? ○Yes ○No

11. Visual inspection of the blood component was carried out regarding: Color; Presence of lumps; System Integrity and Validity. ○Yes ○No

12. If transfusion of packed red blood cells:
If NO, go to item 13.

- Was ABO† (direct) and RhD‡ retyping of the bag performed? ○Yes ○No
- Was a compatibility test performed between the recipients' blood and the sample from the selected bag? ○Yes ○No
- Were compatibility test results recorded? ○Yes ○No
- Is packed red blood cells compatible? ○Yes ○No
- If compatible packed red blood cells are NOT found: Was the requesting physician notified? ○Yes ○No
- Was transfusion authorized with incompatible evidence? ○Yes ○No
- Was the transfusion agreement signed with incompatible evidence by the attending physician and/or hemotherapist? ○Yes ○No

13. Before transport to the transfusion unit:

- Was the data from the bag checked against the blood component request form? ○Yes ○No
- During transport of the blood component to the transfusion unit: Was it in adequate conditions (cool box with temperature control)? ○Yes ○No

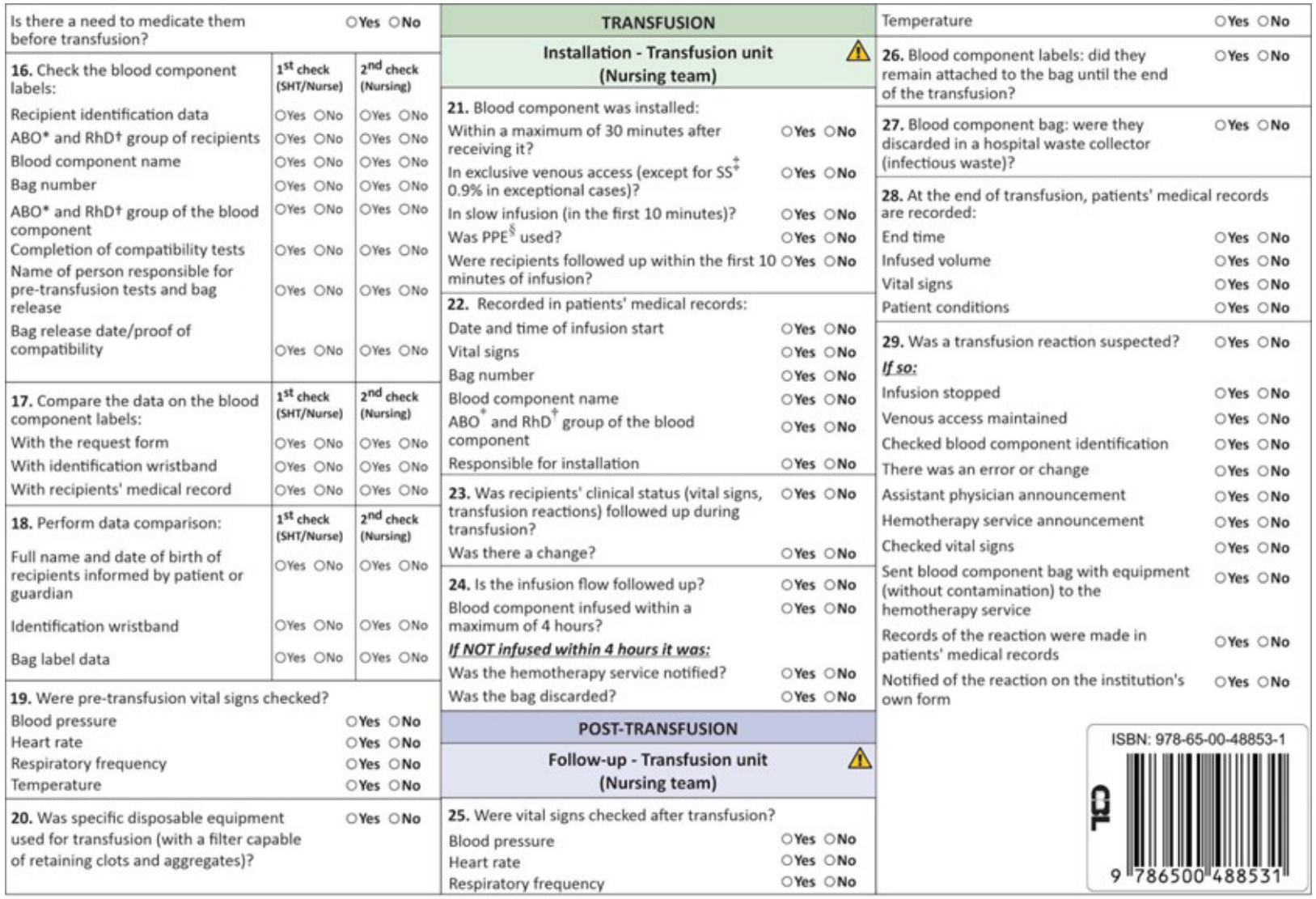
BLOOD COMPONENT NAME: _____
BAG NUMBER: _____

Bedside Identification - Transfusion unit (Nursing team and hemotherapy service) ⚠

14. Do patient have a patent venous access, without phlogistic signs and exclusively for transfusion? ○Yes ○No

15. Do patient have a history of previous transfusion reactions? ○Yes ○No

Figure 1 – Checklist for patient safety during the transfusion process – final version, front. Santa Maria, RS, Brazil, 2021.
Caption: *RCM = Regional Council of Medicine; †ABO = human blood group system; ‡RhD = D antigen of the Rh blood group system (Rhesus factor); §IAS = irregular antibody screening



Is there a need to medicate them before transfusion? ○Yes ○No

16. Check the blood component labels:	1st check (SHT/Nurse)	2nd check (Nursing)
Recipient identification data	○Yes ○No	○Yes ○No
ABO* and RhD† group of recipients	○Yes ○No	○Yes ○No
Blood component name	○Yes ○No	○Yes ○No
Bag number	○Yes ○No	○Yes ○No
ABO* and RhD† group of the blood component	○Yes ○No	○Yes ○No
Completion of compatibility tests	○Yes ○No	○Yes ○No
Name of person responsible for pre-transfusion tests and bag release	○Yes ○No	○Yes ○No
Bag release date/proof of compatibility	○Yes ○No	○Yes ○No

17. Compare the data on the blood component labels:	1st check (SHT/Nurse)	2nd check (Nursing)
With the request form	○Yes ○No	○Yes ○No
With identification wristband	○Yes ○No	○Yes ○No
With recipients' medical record	○Yes ○No	○Yes ○No

18. Perform data comparison:	1st check (SHT/Nurse)	2nd check (Nursing)
Full name and date of birth of recipients informed by patient or guardian	○Yes ○No	○Yes ○No
Identification wristband	○Yes ○No	○Yes ○No
Bag label data	○Yes ○No	○Yes ○No

19. Were pre-transfusion vital signs checked?
- Blood pressure ○Yes ○No
- Heart rate ○Yes ○No
- Respiratory frequency ○Yes ○No
- Temperature ○Yes ○No

20. Was specific disposable equipment used for transfusion (with a filter capable of retaining clots and aggregates)? ○Yes ○No

TRANSFUSION

Installation - Transfusion unit (Nursing team)

21. Blood component was installed:
- Within a maximum of 30 minutes after receiving it? ○Yes ○No
- In exclusive venous access (except for SS‡ 0.9% in exceptional cases)? ○Yes ○No
- In slow infusion (in the first 10 minutes)? ○Yes ○No
- Was PPE§ used? ○Yes ○No
- Were recipients followed up within the first 10 minutes of infusion? ○Yes ○No

22. Recorded in patients' medical records:
- Date and time of infusion start ○Yes ○No
- Vital signs ○Yes ○No
- Bag number ○Yes ○No
- Blood component name ○Yes ○No
- ABO* and RhD† group of the blood component ○Yes ○No
- Responsible for installation ○Yes ○No

23. Was recipients' clinical status (vital signs, transfusion reactions) followed up during transfusion? ○Yes ○No
- Was there a change? ○Yes ○No

24. Is the infusion flow followed up? ○Yes ○No
- Blood component infused within a maximum of 4 hours? ○Yes ○No

If NOT infused within 4 hours it was:
- Was the hemotherapy service notified? ○Yes ○No
- Was the bag discarded? ○Yes ○No

POST-TRANSFUSION

Follow-up - Transfusion unit (Nursing team)

25. Were vital signs checked after transfusion?
- Blood pressure ○Yes ○No
- Heart rate ○Yes ○No
- Respiratory frequency ○Yes ○No
- Temperature ○Yes ○No

26. Blood component labels: did they remain attached to the bag until the end of the transfusion? ○Yes ○No

27. Blood component bag: were they discarded in a hospital waste collector (infectious waste)? ○Yes ○No

28. At the end of transfusion, patients' medical records are recorded:
- End time ○Yes ○No
- Infused volume ○Yes ○No
- Vital signs ○Yes ○No
- Patient conditions ○Yes ○No

29. Was a transfusion reaction suspected? ○Yes ○No

If so:
- Infusion stopped ○Yes ○No
- Venous access maintained ○Yes ○No
- Checked blood component identification ○Yes ○No
- There was an error or change ○Yes ○No
- Assistant physician announcement ○Yes ○No
- Hemotherapy service announcement ○Yes ○No
- Checked vital signs ○Yes ○No
- Sent blood component bag with equipment (without contamination) to the hemotherapy service ○Yes ○No
- Records of the reaction were made in patients' medical records ○Yes ○No
- Notified of the reaction on the institution's own form ○Yes ○No

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Figure 2 – Checklist for patient safety during the transfusion process – final version, back. Santa Maria, RS, Brazil, 2021.
Caption: *ABO = human blood group system; †RhD = D antigen of the Rh Blood Group System (Rhesus factor); ‡ SS = saline solution; §PPE = Personal Protective Equipment

DISCUSSION

The checklist, after small adjustments, showed evidence of content validity as a health technology for patient safety during transfusion, reaching an overall CVI above 0.80. In relation to the initial format, categorization occurred into domains and, later, into moments, in addition to reformulations in wording, arrangement of items/sub-items and few exclusions that contributed to improving the checklist.

Regarding content, the Pre-transfusion domain was composed of items referring to the processes carried out before installing the blood component in recipients' venous access. This domain encompassed three moments: Medical prescription, Compatibility and Bedside identification. The Pre-transfusion stage is the one that involves more care and professionals from different backgrounds, such as doctors, laboratory technicians, nursing technicians and nurses, and is essential to guarantee safety in the remainder of the transfusion act.

Medical prescription initializes the transfusion act and is the first part of the checklist. It is a legal document that justifies the need for the procedure and must be completed correctly in accordance with current regulations[1,16–18]. A filling failure can compromise the safety of the entire process. Prescription errors can lead to unnecessary blood component administration, errors in identifying patients in the request and incorrectly identified samples. These deviations can result in serious morbidity and mortality[19]. Given this, the most notable adjustment in terms of improving understanding occurred in the modality of transfusion subitem, which presented a CVI below 0.80 in pre-test. Classifying the modality of transfusion is a way of signaling to the hemotherapy service patients' severity and the time they are able to wait for transfusion without compromising their clinical status. In hemotherapeutic legislation, this term is used[13]. However, due to its low understanding, it was replaced by Character of transfusion, and its possibilities were described (Emergency, Scheduled or Routine).

Compatibility included the sample collection and pre-transfusion testing phases. Scientific evidence indicates that the most frequent near misses during transfusions occur due to errors in identifying the sample tubes[3]. They can occur as a consequence of incorrect patient identification, leading to the collection of a sample from the wrong patient or incorrect patient identification, therefore, leading to wrong blood component administration. It is estimated that one in every six incompatibility reactions is due to error in sample identification[5].

Analysis of errors that resulted in wrong blood transfusion or administration to wrong recipients determined that 57.5% of them were due to failures in patient identification.[5] Therefore, the use of an identification wristband is an internationally recommended practice and corresponds to the first international goal for patient safety[20]. The patient identification process is fundamental to ensuring safety and quality in health institutions. However, there are gaps in relation to the institution of protocols[21]. Checking patient identification is essential to guarantee the safety of a procedure. Failures in this process can result in incompatible transfusions[2,5]. An item that addressed confirmation of the presence of a wristband was removed from the checklist content, as it is a common requirement for all care procedures; however, the need for verification remained before blood component sample collection and installation.

Any blood transfusion, except in cases of emergency, must only be carried out after carrying out tests. This is due to the occurrence of possible transfusion reactions linked to failures in pre-transfusion tests, such as the existence of antibodies not detected in the irregular antibody screening (IAS)[17,22]. However, with regard to immunohematological tests, in another checklist prepared for transfusion practice, there is a gap regarding this check[10]. The presence of items related to this in the checklist is extremely important for preventing errors in transfusion, as it is in the laboratory, during the execution

of tests, that most near misses are intercepted[19]. For instance, errors attributed to sample collection can be detected and intercepted in the laboratory based on recipients' transfusion history[19].

The item that addresses recipients' blood typing at the bedside raised several opposing comments in the committee of experts, however it was maintained. This is a practice not used in most Brazilian institutions and not foreseen in current blood therapy legislation. However, it was already a requirement in previous regulations and continues to be practiced at the institution of this study as it is considered a barrier to avoid errors arising from sample collection and a means of ensuring patient safety. This technique is also used in other countries[5]. It allows confirming recipients' ABO group and identifying possible discrepancies between the result obtained in the bedside test and that in the laboratory. This measure prevents the transfusion of an incompatible blood component.

In bedside identification, the processes to be carried out after blood component release upon its arrival at the transfusion unit are compiled. The main focus at this point is the checking and comparison of patient identification data, bag information, medical prescription data and medical records. A study identified that health professionals only checked medical prescription and recipients' full name. Checking patient identification data against bag data and double-checking were ignored[23]. Most errors occur at patients' bedside, of which incorrect identification is the most common[5]. Therefore, confirming data at the bedside, before transfusion, is the most critical stage in preventing transfusion errors, as it is the last opportunity to detect any error made in previous stages[16,22,24]. This failure in transfusion involves risks that can culminate in incidents that lead to temporary incapacity, the need for medical intervention, increased length of hospital admission and death[23].

Another important issue, suggested by participants and which was not initially foreseen, was double-checking. Double-checking is a method that consists of checking blood component and patient data by two professionals[25]. It is a proactive strategy to reduce the risk of errors and strengthen patient safety, favoring the detection and prevention of up to 95% of errors in the transfusion process[3].

After content validity, the presence of some items in the checklist was reconsidered, such as patient and/or companion guidance, verification of recipients' religion and request for informed consent. Informed consent represents the act of patients or their legal representative deciding, agreeing and approving diagnostic or therapeutic procedures indicated for them, after information and explanations, under medical responsibility[26]. Therefore, requesting recipients' consent includes prior guidance and verification of religion, taking into account cases of refusal of the procedure for religious reasons (Jehovah's Witnesses), and, therefore, must be considered before filling out the form transfusion request[1]. The same occurred in the construction of the checklist for blood transfusions in children, in which the presence of the item was considered unnecessary[10].

In the Transfusion domain, items and sub-items related to care were included from blood component installation until the end of infusion. The processes at this stage of the transfusion act are the responsibility of the nursing team (nurses and nursing technicians), who follow up patients to the place where they will receive the transfusion. This phase underwent few changes, including adjustments that improved item clarity, such as patient monitoring. It was necessary to clarify what should be observed in relation to recipients' clinical status. Strict observation of vital signs and other clinical parameters during transfusion is essential to identify possible transfusion reactions[1,16,18,22,24]. A study showed that errors may have occurred when patients' condition was no longer monitored during transfusion, causing harm to patients.[3] Therefore, it was specified that clinical status referred to vital signs and signs and symptoms of transfusion reactions. Early detection of these events represents a way to minimize damage resulting from possible reactions.

A controversial item in this domain was in relation to professionals' knowledge of transfusion procedures. Blood component administration requires knowledge and skills to avoid the occurrence of complications and irreversible damage to patients[3,5,17–18,24]. However, a study has proven that errors cannot be eradicated simply by requiring training[2]. Therefore, the item was excluded from the checklist, which does not refute its importance for the transfusion act, on the contrary, it is essential in health care as a whole. The purpose of exclusion was to provide greater objectivity to the instrument with items specific to the transfusion process.

As for the Post-transfusion domain, it consisted of items and sub-items, which covered the processes after the end of infusion, i.e., monitoring. At this stage, the main focus is monitoring the patient in relation to possible transfusion reactions and adopting appropriate therapeutic management. In this case, monitoring is assigned to the nursing team of the unit where the recipient is located.

This monitoring must be 24 hours, considering the possibility of immediate transfusion reactions occurring during this period[18,27]. All items and sub-items were considered valid.

The alert symbol and a header were also added to the checklist, warning of the need to follow standard precautionary measures throughout the transfusion process, especially hand hygiene. This is an item not included in the surgical safety checklist[20]. It was also excluded in the construction of the checklist for blood transfusion in children because it was considered, in that study, a widespread universal practice.[10] However, low adherence to handwashing during transfusion assistance has been observed, indicating that only 68% of professionals they executed it[23]. Therefore, hand hygiene in the daily routine is still deficient and needs to be encouraged to raise awareness of the importance of this habit,[28] especially in preventing transfusion reactions due to bacterial contamination.

The checklist constructed involves all stages of the transfusion act, being, therefore, a multidisciplinary instrument that can be used in its entirety, starting with the medical prescription and monitoring all the processes of the transfusion act, or even be used at separate moments, according to each one of the professional categories involved.

As limitations of this study, the difficulty of selecting the participants of the committee of experts stands out, which required an extensive search on the *Plataforma Lattes* and subsequent location of the emails. There is also the difficulty of obtaining answers from both the committee of experts and the pre-test, considering the research was carried out using an online form, due to the restrictive measures related to the pandemic context.

CONCLUSION

After a thorough process of construction and content validity by specialists, experts and target audience, the checklist for patient safety during transfusion presented evidence of validity, obtaining CVI > 0.80 in all stages and 0.98 in its final version. It is composed of 29 items and 90 sub-items, distributed in three domains, corresponding to the transfusion act stages: Pre-transfusion, formed by three moments (Medical prescription, Compatibility and Bedside identification); Transfusion, consisting of a moment (Installation); and Post-transfusion, with a moment (Monitoring).

As a contribution to care, the checklist can be used as a instrument for changing daily practice and promoting a patient safety culture. This will be a theoretical-practical instrument based on scientific evidence and current legislation, and will be able to provide the multidisciplinary team with adequate and consistent instructions on the steps to be followed during transfusion, enabling standardization in care practice and safety in the transfusion process. Future studies are suggested to evaluate the effectiveness of the checklist for transfusion safety.

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NOTES

ORIGIN OF THE ARTICLE

This study is part of a dissertation entitled "*Construção e validação de checklist para a segurança do paciente no ato transfusional*", presented to the Graduate Program in Nursing, *Universidade Federal de Santa Maria*, in 2021.

CONTRIBUTION OF AUTHORITY

Study design: Rambo CAM, Magnago TSBS.
Data collection: Rambo CAM.
Data analysis and interpretation: Rambo CAM, Magnago TSBS.
Discussion of results: Rambo CAM, Magnago TSBS.
Writing and/or critical review of content: Rambo CAM, Magnago TSBS.
Review and final approval of the final version: Magnago TSBS.

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CONFLICT OF INTEREST

There is no conflict of interest.

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