

## Content validation of an instrument for hemotherapy attention in liver transplants: promoting biomonitoring in health

### Validação do conteúdo de um instrumento para atendimento hemoterápico no transplante hepático: promovendo biovigilância em saúde

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#### ABSTRACT

**Objective:** to develop and validate the content of an instrument to monitor hemotherapy attention in liver transplant patients. **Methods:** methodological study in two stages: 1) Scoping review to identify relevant topics for the elaboration of the instrument; 2) Content validation with five specialists in two rounds, using the Delphi technique. **Results:** the final version of the instrument for hemotherapy care to liver transplant patients had four dimensions: Patient identification; Preoperative; Intraoperative; and Postoperative, to a total of 54 items. After the second round, all items had a content validation index of 0.8 or higher, and the instrument had a final score of 0.97. **Conclusion:** the instrument showed evidence of content validity, meaning it is a useful tool to monitor hemotherapy care for liver transplant patients. **Contributions to practice:** the validation of this instrument will provide teams of transfusion and transplant centers with essential information to guide safe and efficient hemotherapy attention during the entirety of the liver transplant process.

**Descriptors:** Clinical Protocols; Hemotherapy Service; Liver Transplantation; Patient Safety; Nursing.

#### RESUMO

**Objetivo:** desenvolver e validar o conteúdo de um instrumento para acompanhamento do atendimento hemoterápico ao paciente de transplante hepático. **Métodos:** estudo metodológico realizado em duas etapas: 1) Revisão de escopo para identificar tópicos pertinentes à elaboração do instrumento; 2) Validação do conteúdo junto a cinco especialistas em duas rodadas, utilizando a técnica Delphi. **Resultados:** a versão final do instrumento para atendimento hemoterápico ao paciente de transplante hepático consistiu-se em quatro dimensões: Identificação do Paciente; Pré-Operatório; Intraoperatório; e Pós-Operatório, totalizando 54 itens. Após a segunda rodada, todos os itens obtiveram índice de validação de conteúdo de 0,8 ou superior, resultando em um escore final de 0,97 para o instrumento. **Conclusão:** o instrumento demonstrou evidências de validade de conteúdo, tornando-se uma ferramenta útil para o acompanhamento do atendimento hemoterápico a pacientes submetidos a transplante hepático. **Contribuições para a prática:** a validação deste instrumento permitirá às equipes da agência transfusional e de transplantes obterem informações essenciais para orientar um atendimento hemoterápico eficiente e seguro durante todo o processo de transplante hepático.

**Descritores:** Protocolos Clínicos; Serviço de Hemoterapia; Transplante de Fígado; Segurança do Paciente; Enfermagem.

## Introduction

In the last few years, there have been many discussions about biomonitoring in regard to organ and tissue donations. These conflicts showed unique deficiencies in the notification and monitoring of adverse events associated with organ and tissue donation, as well as in the stages of the transplant process. These include adverse reactions to medication, neurotoxicity, prolonged hospitalizations, additional surgical interventions, falls, comas, deaths, and failure or loss of grafts<sup>(1)</sup>.

The National Sanitary Surveillance Agency provides that the main mission of the National Biomonitoring System is to contribute for the patient who receives and donates human cells, tissues, and organs, throughout the entire national territory. Its main goal is to recognize, record, treat, and evaluate data from adverse events associated with the cyclic processes of human cells, tissues, and organs, in a coordinated and immediate way, focused on monitoring and mitigating risks<sup>(2)</sup>, and on establishing requisites and good practices for the hemotherapy service, increasing the safety of the patient<sup>(3)</sup>.

According to data from the National Transplant System, there were 91,266 transplants from July 2015 to December 2018. 29,512 of these were organ transplants. In the same period, there were 145 notifications of adverse events related to organ transplants. 51 of them were associated with liver transplants (TxH)<sup>(1,4)</sup>.

TxH is a complex surgical procedure due to liver function involvement, which means that the patient who undergoes this type of transplant often presents with coagulopathies. Attention and management of blood loss are essential for this procedure, and transfusion therapy is necessary<sup>(5)</sup>. Therefore, the transfusion center team of the hospital must provide a qualified participation to guarantee patient safety.

It should be noted that liver transplant surgeries are classified as major surgeries due to both their size, complexity, length, to the existence of an anhe-

patic stage, and to factors associated with the graft. Furthermore, there is a great likelihood that this surgery leads to loss of fluids and blood, since the liver is the vital organ responsible for blood coagulation and albumin secretion. During the surgery, which may last from six to ten hours, harmful events may take place, such as ischemia, hypoxia, infections, hypotension, and hemorrhages. Also, at the time of implanting the healthy organ, there may be hydroelectric dysfunctions and disturbances in the acid-basic balance, making these patients more susceptible to complications<sup>(5)</sup>.

Considering this setting, the nurse, as a manager of the transplant process, has the role and responsibility of guaranteeing that assistance is safe, effective, and high-quality, through a direct overview of each stage of the process<sup>(6-7)</sup>. In the context of logistics and organization of organ and tissue donations, this professional is responsible, especially, for monitoring and tracking failures and/or problems in any stage of the transplant, especially in liver transplants, due to the complexity of the procedure<sup>(8)</sup>.

The nurse can be the technical responsible for hemotherapy services, as long as they have the adequate education<sup>(8)</sup>. This professional has a commitment in regard to scenarios of TxH and blood transfusion, due to their legal and ethical responsibility of working both in the coordination of transplants and in the management of hemotherapy drugs, frequently used in these surgeries<sup>(5,8)</sup>.

It is widely recognized that nurses are essential both for the management of processes and in direct assistance to patients and their families, as well as in the elaboration of instruments, manuals, regulations, protocols, and standard operational procedures - especially in the construction and implementation of institutional protocols for a rational use of blood, a safe transfusion management, and blood monitoring<sup>(8)</sup>.

The intraoperative period of this surgery requires nursing attention and management. Thus, there must be instruments that can give support to these

professionals during their activities in regard to this surgery. It should be noted that there are validated instruments to provide support to the nurse, considering patient safety management in the surgical center. A previous study adapted the safe surgery checklist for liver transplants<sup>(9)</sup>. This instrument allows the nurse to manage each step of surgical time during the surgery. However, a previous literature review could not yield instruments to manage blood transfusion in this type of surgery.

The transfusion of blood components is a procedure that, despite being beneficial to the health of those who need it, significantly increases the risks of complications, morbidity, and mortality through liver transplant patients; it may also lead to potentially major adverse effects, such as hemolytic reactions, non-hemolytic fever reactions, anaphylactic events, circulatory overload, infectious disease transmissions, and citrate intoxication<sup>(4,10)</sup>. Therefore, the nurse in the frontlines of care must control and manage this process; the same is valid for the entire surgical center team.

Thus, since there are no specific instruments to give support to the management of blood components in this surgery, the elaboration of this instrument is essential to support the nurse in the control, safety, effectiveness, and organization of these components. Administrative instruments to implement good practices of health care and service management have an essential role in the direct promotion of patient safety, focusing on the standardization of conducts<sup>(5,11)</sup>.

As a result, it is extremely important to create validated instruments to improve the quality of the health care provided to patients, since, if adequately validated, these instruments organize communication in the health team, directly interfering in the definition of priorities and the logistics of care, as well as in the organization of time<sup>(12)</sup>. Consequently, this would generate the ability to coherently provide information on the probable health state of the patient, or in specific situations, facilitating a faster and more efficient intervention.

Considering the complexity of TxH and that bleeding is the most concerning early complication in this procedure, as well as the fact there is no tool to provide hemotherapy care to the patient who is undergoing this surgery, the guiding question of this study was: What is the information needed to create an instrument for hemotherapy care to liver transplant patients? The goal of this study is to develop and validate the content of an instrument to monitor hemotherapy attention in liver transplant patients.

## Methods

This is a methodological study, with a quantitative approach, carried out in two distinct stages: 1) development of an instrument; 2) content validation and layout through evaluation of specialist judges.

To construct the instrument, we carried out a scoping review<sup>(13)</sup> in 14 databases, aimed to map the main health care strategies and the potential predictors to follow up the hemotherapy care of liver transplant patients. Our findings allowed identifying preoperative characteristics of receptors that affect the need for blood transfusions in patients who are candidate for liver transplants, together with strategies implemented to minimize blood loss during the procedure. This information, coupled with a framework of adverse events and biomonitoring, gave support to the elaboration of the tool, which was validated by experts in the field. The first version of the instrument had four dimensions: identifying the patient, preoperative, intraoperative, and postoperative, with a total of 47 items.

To validate the content of the instrument, we used the Delphi technique, a systematic tool to evaluate information via expert judgment (specialists and evaluator judges), by reaching consensus between them in the validation of a certain topic<sup>(14)</sup>. This makes it possible to identify items that should be added or removed from the instrument to improve measurement<sup>(15)</sup>. This stage was carried out from January to December 2022.

At first, we invited six nurses with experience in liver transplant and/or who worked in transfusion agencies of Santa Catarina and São Paulo, since these are reference centers for this type of transplant. Inclusion criteria were: minimum experience of two years in the field of hemotherapy and clinical work in the liver transplant team. We excluded those who did not respond within ten days after the email invite was sent. In this stage, two participants answered our invitation. They were classified as our “seed” participants.

Each seed received the informed consent via email, and the first version of the instrument on hemotherapy care for liver transplant patients. The instrument was sent in a *Microsoft Word*® format and included guidance on how to analyze it. The seeds should analyze all items presented, choosing between the options: «Keep item», «Keep item with changes», or «Exclude item». When the seeds chose «Keep item with changes» or «Exclude item», they were asked to provide suggestions and explanation, or justify the exclusion of the item. Furthermore, there were four extra items for evaluation regarding the structure/layout of the instrument. In it, the seeds should evaluate the sentences presented and choose between the options «Adequate», «Partially adequate», or «Inadequate». When they selected the options «Partially adequate» or «Inadequate», they were supposed to present suggestions for changes and a justification. Therefore, the instrument was adjusted according with the evaluations received, originating the second version of the instrument. It is worth noting that a first stage was carried out with the group of seeds, in order to send a better elaborate proposal of the instrument for validation by the expert judges.

To invite judges, we got the email of those responsible for the transfusion center of institutions that carry out liver transplants in Santa Catarina. At first, we invited four judges, one from each institution. Then, using the snowball technique, we invited five others, to a total of nine evaluators.

The first contact with the judges was carried

out through a letter-invite sent via email, containing explanations about the procedure of content validation, and indicating a 15-day deadline. For those who accepted collaboration, the informed consent was sent together with the second version of the instrument of hemotherapy care and the link to access the evaluation instrument.

The specialist judge had to conform to at least two of the following requisites: having five-year or longer experience in the transfusion center; be a specialist, MS, or PhD; having monitored liver transplants in the institution. We excluded those who did not answer the questionnaire within the deadline in the invite. The validation included five specialist judges.

For data collection, we elaborated a *Google Form*® with two parts: the first regarding the characterization of the specialists; the second presenting four sections of the instrument and their items, in addition to a section about the structure of the instrument. These added up to 48 items in the first round.

Item validation included questions about the content (hemotherapy content to the liver transplant patient); language (linguistic characteristics, terms, concepts, understandability, and writing style); layout/presentation (refers to the format in which the instrument is presented, and whether it is clear and raises one’s interest of filling it in). In this stage, judges scored the items of the instrument in a Likert scale, where 4 - totally adequate (TA): the item was kept in its entirety; 3 - Adequate (A): the item was kept in its entirety; 2 - partially adequate (PA): the item was kept with alterations; or 1 - inadequate (I) : the item was excluded. When the options “Partially adequate” or “Inadequate” were selected, judges were supposed to present suggestions of change or justifications.

Data analysis was carried out in absolute frequency (n) and percentages (%) of responses of specialist judges, with confidence intervals (CI) of 0.12-0.24. Also, we used the content validation index (CVI) as a criteria. This calculation was carried out by dividing the total number of judges who gave a score

of 3 (adequate) and 4 (totally adequate) by the total number of experts who participated in the validation round<sup>(16)</sup>. It is also of note that the number of judges was within the recommended 5 to 10 in the validation process<sup>(16)</sup>.

The project was approved by the Research Ethics Committee at the Universidade Federal de Santa Catarina, under opinion 3,369,093/2019 and Certificate of Submission for Ethical Appreciation 08656819.3.0000.0121. The instrument has been copyrighted in the Copyright Registry of the Brazilian Book Chamber.

## Results

Through the scoping review, we found that the main possible predictors for the need of blood transfusions are: the results of lab exams, such as hemoglobin, platelets, hematocrits, and fibrinogen, in addition to the model for end stage liver disease (MELD, in the English acronym), time of surgery, and time of cold ischemia to which the graft was submitted. Based on these factors we developed the first version of the instrument, which was sent to the participants.

Participants were divided into two groups: seeds and judges, to a total of seven participants. The seeds were female nurses, one of which was a specialist, while the other was a PhD. Both workers had substantial experience in regard to hemotherapy care and liver transplants, respectively.

The judge group included five women, from 35 to 57 years old. Their time in this line of work varied from 10 to 30. Regarding their titles, two were specialists, one was an MS, and two were PhDs. All were health workers, with four nurses and one physician. Three of them work exclusively in hospitals, one in direct care and research, and another in direct care and teaching.

The early version of the instrument, elaborated after a scoping review, consisted in four sections:

Patient identification, Preoperative, Intraoperative, and Postoperative, with 47 items. After the seeds provided their evaluation, 80% of items were kept with no change; 11% were kept but altered; and 9% were excluded.

After incorporating the changes suggested, we created the second version of the instrument, which included the same four sections, with a total of 44 items. We also added a fifth section to evaluate the structure of the instrument, which meant there was a total of 48 questions for analysis.

After the first round of judge content validation, 72% agreed that the items should be kept. 18 items got a maximum score, 18 had a CVI of 0.8, and 12 items did not reach the minimum CVI. These were reformulated for the second round. The item related to the ABO system, associated with blood type classification (A, B, O, and AB) had a score of 0.4, the lowest. The total CVI of the instrument in the first round was 0.82.

After making the adjustments proposed by the judges, we elaborated the third version of the instrument, formed by 50 items regarding the content and 4 regarding the layout of the tool, to a total of 50 items. In this new version, in addition to the preexisting sections, we added a specific part to identify the ABO system of the receptor, and another for pertinent donor information; we also separated the postoperative from the immediate postoperative period. Furthermore, we changed the structure, title, and layout of the instrument, in addition to relocating some items from other sessions.

In the second round, items that had not reached  $CVI \geq 0.8$  in the first were sent for validation and analysis; others, despite a favorable score, were edited. Table 1 shows the items in their final form and the CVI found, with CVI 1 indicating the first round, and CVI 2 indicating the second. Items added after first round suggestions have no score for CVI 1.

**Table 1** – Results of scores by specialist judges. Florianópolis, SC, Brazil, 2023

Topic evaluated	CVI*	
	1	2
1. Patient identification		
1.1 Full name	1	1
1.2 Hospitalization Unit	0.8	0.8
1.3 Bed	1	1
1.4 National Health Card Number	1	1
1.5 General register in the Transplant Center	0.8	1
1.6 Date of birth and age	1	1
1.7 Date of the procedure	1	1
1.8 Surgery proposed	1	1
1.9 Surgery carried out	1	1
1.10 ABO System <sup>†</sup> and <sup>‡</sup> RhD; Direct <i>Coombs</i> ; Irregular Antibody Screening (DAS); Need for phenotyped blood bag and special blood products for the transplanted patient	0.4	0.8
1.11 Previous diseases: ( ) Yes ( ) No. Which:	1	1
1.12 Repeated transplant: ( ) ( ) No. Double transplant: ( ) Yes ( ) No. Transplanted organs and date of the last transplant	0.8	1
Phone for contact	1	1
1.14 Ethnicity; Weight; Height; Mother's full name	-	0.8
1.1.1 Donor		
1.1.2 ABO and RhD system	-	0.8
1.1.3 Irregular Antibody Screening	-	1
1.1.4 Cold and hot ischemia times of the graft	1	1
2. Preoperative		
2.1 Base disease that led to an indication of the liver transplant	1	1
2.2 MELD value	1	1
2.3 Hemoglobin	0.8	1
2.4 Hematocrit	0.8	1
2.5 Platelet	0.8	1
2.6 Total bilirubin, direct bilirubin, and indirect bilirubin	0.6	0.8
2.7 Fibrinogen	0.6	1
2.8 Serum albumin	0.8	1
2.9 Serum creatine	0.8	1
2.10 Urea	0.8	1
2.11 Serum sodium	0.8	1
2.12 International Normalized Ratio	0.8	1
2.13 Prothrombin time	0.8	1
2.14 Previous blood transfusions; Date of last transfusion; Amount of blood products transfused; Red blood cells; Plasma; Platelets; Cryoprecipitate	0.6	1
2.15 Was there a transfusion reaction: ( ) Yes ( ) No. Which?	1	1
2.16 Prophylaxis indication for future transfusions in case of previous transfusion reactions: ( ) Yes ( ) No. Which:	-	1
2.17 Blood bank required: ( ) Yes ( ) No. Blood products requested from the bank and amount of these products	1	1
2.18 Autologous transfusion	0.6	1
2.19 Programmed recovery of intraoperative blood and recovered volume	0.6	0.8
2.20 Coombs test	-	1
2.21 Observations, professional signature, and date	1	1
3. Intraoperative period		
3.1 Thromboelastography was carried out	0.6	1
3.2 Thromboelastometry was carried out - ROTEM®	0.6	1
3.3 Estimated time of the surgical procedure	0.8	1
3.4 Administration of antifibrinolytics and recombinant coagulation factor VIIa: ( ) Yes ( ) No. Which: Dosage:	0.6	1
3.5 Was a transfusion necessary: ( ) Yes ( ) No. Blood products: Volume:	0.8	1
3.6 Observations, professional signature, and date	1	1
4. Postoperative		
4.1 Surgical adverse events: ( ) Yes ( ) No. Which: and Reaction/transfusion adverse events: ( ) Yes ( ) No. Which:	0.8	1
4.2 Total length of surgery	1	1
4.3 Surgical technique used	0.8	0.8
4.4 Type of anesthetic	0.8	0.8
4.5 Blood products transfused in the first 24 postoperative hours and volume/amount:	-	0.8
4.8 Risk of large-scale transfusion	-	0.8
4.9 Observations, professional signature, and date	1	1
5. Instrument structure		
5.1 Title of the Instrument	0.6	1
5.2 Size of the Instrument	0.8	1
5.3 Layout/ Design / Color	0.4	1
5.4 Font size and disposition of the text throughout the instrument	0.6	1

\*CVI: Content Validity Index; <sup>†</sup>ABO: blood type classification group: A,B,O, and AB; <sup>‡</sup>RhD: antigen D\*

After the second validation round, 83% of judges found our items to be totally adequate, 11% found them to be adequate, and 6% found them partially adequate. In this stage, no exclusions were suggested - only adjustments. At the end, all items had a CVI ≥ 0.8.

For the content validation stage, we carried out

two rounds of analysis and validation, to guarantee all items reached a CVI ≥ 0.8. The final instrument had a CVI of 0.97. No specialist judge abandoned the research. Figure 1 shows the final version of the instrument, after the content validation and further adjustments were finished.

INSTRUMENT FOR HEMOTHERAPY CARE IN LIVER TRANSPLANTS	
Full Name: _____ N° National Register: _____	
Unit: _____ Bed: _____ *RGCT: _____ Contact phone: _____	
Date of birth: ___/___/___ Age: ___ Ethnicity: ___ Weight: ___ Height: ___ Mother's name: _____	
Procedure Date: ___/___/___ Surgery Proposed: _____ Surgery Conducted: _____	
Previous diseases: ( ) Yes ( ) No. Which: _____	
Double transplant: ( ) Yes ( ) No. Transplanted organ(s): _____	
ABO receptor system	Donor
ABO System: _____ Rh: ( ) positive ( ) negative. Direct Coombs: _____	ABO System: _____ Rh: ( ) positive ( ) negative.
Irregular Antibody Screening: ( ) Yes ( ) No. Which: _____	Irregular Antibody Screening: ( ) Yes ( ) No. Which: _____
Need for phenotyped blood bag? ( ) Yes ( ) No. Which: _____	Time of graft cold ischemia: _____
Special blood products for the transplanted patient? ( ) Yes ( ) No. Which: _____	Time of graft hot ischemia: _____
Preoperative period	
Base disease that led to an indication of the liver transplant: _____ MELD: _____	
Hemoglobin: _____ Hematocrit: _____ Platelets: _____ Total bilirubin: _____ Direct bilirubin: _____ Indirect bilirubin: _____ Fibrinogen: _____ Serum albumin: _____ Serum creatine: _____ Urea: _____ Serum sodium: _____ International normalized ratio: _____ Prothrombin time: _____	
Previous blood transfusion: ( ) Yes ( ) No. Date of last transfusion: ___/___/___ Amount (in units)/Volume(ml) of transplanted blood products: Red blood cells: _____ Plasma: _____ Platelet: _____ Cryoprecipitate: _____	
Was there a transfusion reaction: ( ) Yes ( ) No. Which: _____	
Prophylaxis indication for future transfusions in case of previous transfusion reactions: ( ) Yes ( ) No. Which: _____	
Blood bank required: ( ) Yes ( ) No. Blood products requested from the bank: _____ Amount: _____	
Notes: _____ Signature from the professional: _____ Date: ___/___/___	
Intraoperative period	
Thromboelastography was carried out: ( ) Yes ( ) No. Thromboelastometry was carried out: ( ) Yes ( ) No. Total length of surgery: _____	
Administration of antifibrinolytics and recombinant coagulation factor VIIa: ( ) Yes ( ) No. Which: _____ Dosage: _____	
Programmed intraoperative blood recovery: ( ) Yes ( ) No. Volume recovered: _____	
Was a transfusion necessary: ( ) Yes ( ) No. Blood products: _____ Amount (Unit)/Volume(ml): _____	
Notes: _____ Signature from the professional: _____ Date: ___/___/___	
Postoperative	
Surgical adverse events: ( ) Yes ( ) No Which: _____	
Reactions/transfusion adverse events: ( ) Yes ( ) No. Which: _____	
Total length of surgery: _____ Surgical technique used: _____ Anesthetic applied: _____	
Notes: _____ Signature from the professional: _____ Date: ___/___/___	
Immediate postoperative	
Blood products transfused in the first 24 postoperative hours: _____ Amount (Unit)/Volume(ml): _____	
Risk of large-scale transfusion: ( ) Yes ( ) No.	
Notes: _____ Signature from the professional: _____ Date: ___/___/___	

RGCT: General register in the Transplant Center; IAS: Irregular Antibody Screening; MELD: Model for End-stage Liver Disease

**Figure 1** – Final version of the Instrument for Hemotherapy Care in Liver Transplants. Florianópolis, SC, Brazil, 2023

## Discussion

The use of instruments in the practice of health aims to optimize and qualify health processes, promoting stability in conduct and attention, and increasing patient safety<sup>(17)</sup>. In the field of nursing, validating instruments that guide practice is a synonym of advancing health technologies for the profession, promoting the development of the work process in a standardized, simplified, and objective manner, and contributing for the continuity of care and the safety of the patient and the team itself<sup>(18-19)</sup>.

The validity of the content includes abstract concepts and measurable indicators, meaning that it exposes how much each item in the instrument is relevant for the subject and how adequate it is for the practice<sup>(17)</sup>. In this context, the instrument proposed aids in hemotherapy care to TxH patients, to organize their practice, basing it on better evidence and biomonitoring, since these are procedures that involve multiprofessional teams from multiple sectors.

This instrument includes items related to the identification of the liver transplant patient, including results from the immune-hematologic exams, organ donor information, and pre-, intra-, and postoperative periods. Regarding patient identification, the judges did not reach a consensus in the first round, suggesting that information related to immune-hematologic exams should be added, such as blood type, direct *Coombs*, irregular antibody screening, and observations about the need for phenotyped blood bags and special blood components for the liver transplant patient. They also suggested adding information on the organ donor, such as: blood type, irregular antibody screening, as well as graft cold and hot ischemia times.

These suggestions were accepted and added to the instrument due to their importance in the procedure. Immune-hematologic exams include an identification of the ABO system, which is the most significant one among blood groups for transfusion therapy. Blood groups can be determined according with the presence or absence of antigens A and/or B in the membrane of erythrocytes, and by the presence of

antibodies anti-A and/or anti-B in the blood plasma. This system is extremely importance, as it is directly related with the compatibility of blood transfusions and is essential for the safety and success of the procedure<sup>(20)</sup>.

The RhD system is the second most complex blood group and, together with the ABO system, is widely used as a reference for transfusion<sup>(21)</sup>. In blood classification tests, the RhD factor is tested simultaneously with the ABO group, since these are the most common antigen groups in the laboratory environment. It is determined by verifying whether the antigen D is present in the membrane of the red blood cell<sup>(22)</sup>. The discovery of this blood group was essential to develop and improve blood transfusion techniques, since, earlier, this process was only based on the ABO system, presenting several failures and risks to the patient.

The direct *Coombs* test, or direct human anti-globulin test, is a laboratory method that evaluates how antibodies react to red blood cells, to determine whether the blood tissue will be rejected by the immune system of the organism tested. Normally, this test is carried out to diagnose autoimmune hemolytic anemia, acute or delayed immunological hemolytic reactions, and to avoid transmitting antibodies through blood transfusion<sup>(23)</sup>.

The irregular antibody screening is the search for free antibodies in the blood serum or plasma of donors and/or receptors. Positive test results suggest the presence of irregular antibodies in the blood plasma of the donor and/or receptor, requiring another test, the irregular antibody identification, to determine the specific antibodies, that is, to determine against which specific agglutinogen this antibody is reacting. This test is paramount, since it aims to reduce the risk of transfusion-related hemolytic reactions, thus increasing the safety of the patient who is undergoing a transfusion<sup>(24)</sup>.

Data related to the donor, and information related to ABO and RhD systems, as well as irregular antibody research, are extremely important to avoid and/or identify the passenger lymphocyte syndrome, whe-

re there is an immune-mediated hemolysis after the transplant of solid organs from the same ABO group. This syndrome is caused by donor lymphocytes that produce antibodies against the receptors red blood cells, causing hemolysis<sup>(25)</sup>. This can take place in up to 40% of liver transplants, requiring interventions such as blood transfusions, medication, or therapeutic apheresis<sup>(26)</sup>.

Cold and hot ischemia times are important predictors for the evolution of the liver transplant and the survival of the graft. There are studies in literature according to which donor age and steatosis, cold and hot ischemia times (surgery) are the risk factors most commonly associated with primary graft dysfunction<sup>(27-28)</sup>.

In the preoperative, the items about bilirubin, fibrinogen, and previous blood transfusions did not reach the minimum CVI of 0.8. After judge evaluation, the items about bilirubin and fibrinogen had their presentation modified. The item about previous blood transfusions, in turn, was completely reformulated, in order to be more complete, addressing questions such as previous blood transfusions, date of previous transfusion; amount of blood components transfused: red blood cell, plasma, platelets, and cryoprecipitate. Later, the items were sent for a new evaluation, where all achieved a CVI of 0.8 or higher, being thus considered to be validated.

Regarding the intraoperative period, items about thromboelastography, thromboelastometry, previous use of antifibrinolytics, and recombinant coagulation factor VIIa did not reach the minimum CVI, being modified. In the second round, all items received the maximum CVI, 1.

The thromboelastography and the thromboelastometry are tests that allow real-time functional evaluation of blood coagulation. These exams aim to measure viscoelastic blood properties in such a way as to choose, as well as possible, the blood components necessary for the case. Therefore, when applied to the liver transplant, thromboelastometry and thromboelastography provide important, real-time information about perioperative coagulopathy, helping to conduct

hemotherapy adequately and providing faster results than when traditional exams<sup>(13)</sup>.

Blood transfusion is a situation where the individual is in contact with hitherto unknown antigens. Therefore, it is extremely important to know the blood groups of those involved, because, if the patient does not have a certain antigen of a blood group, they may produce antibodies against this antigen<sup>(29)</sup>.

## Study limitations

Study limitations include the low number of judges who accepted participation. Nine judges were invited to participate, five of whom accepted.

## Contributions to practice

In the future, we plan to make available the instrument produced for transfusion centers of institutions that carry out liver transplants, allowing its practical application and, consequently, contributing to improve the attention to these patients in order to increase their safety and better manage their care.

## Conclusion

This study reached its goals, validating the content of and the structure of an instrument created to help hemotherapy care to liver transplant patients, aided by judges who are specialists in the subject. The final version of the instrument counted on 54 items, reaching the Content Validation Index of 0.97, a result good enough to be used by institutions that carry out liver transplants.

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## Authors' contribution

Concept and project or analysis and interpretation of data; writing of the manuscript or relevant critical revision of the intellectual content; final approval of the version to be published; agreement to be responsible for all aspects of the manuscript and guarantee the precision and integrity of any of its parts: Magalhães ALP, Goetze BS.

Analysis and interpretation of data and relevant critical review of the intellectual content; Approval of the final version to be published; agreement to be responsible for all aspects of the manuscript and guarantee the precision and integrity of any of its parts: Knihs NS, Mattia D, Silva EL.

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