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The use of indicators in the different stages of the cycle of blood: use of selection tool

O uso de indicadores nas diversas etapas do ciclo do sangue: uso de ferramenta de seleção

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ABSTRACT

Introduction: Hemotherapy is a medical specialty structured with several actions aimed at the quality of the blood component produced and the safety for both the donor and the patient, besides being directly integrated into the health care process. The first indicators for hemotherapy were created to guide the direction of the Blood Quality Program, but, in the hemotherapy scenario, we must consider not only the quality of the blood but also patient and donor safety and hemovigilance actions. **Objective:** Based on the analysis of data available in the various reports and records published by the Brazilian National Health Surveillance Agency [Agência Nacional de Vigilância Sanitária (Anvisa)], the Brazilian Ministry of Health (MH), and the General Coordination of Blood and Blood Products [Coordenação Geral de Sangue e Hemoderivados (CGSH)] in the last five years, we aimed to identify some weaknesses and risks in the transfusion process and propose the use of a tool called the indicators matrix, to prioritize indicators with a focus on transfusion safety. **Methodology:** The selection of indicators was based on the creation of a prioritization matrix, using the strategic axes defined by the WHO, whose objective is to control the entire cycle of blood, including the transfusion process. **Results:** The selection of indicators aims to improve the processes involved throughout the cycle of blood, and the use of the tool aims to facilitate the choice of these indicators according to the scenario of each institution, from a hemotherapy service to a transfusion agency. **Conclusion:** These indicators can improve blood transfusion practices and processes, as well as optimize the manageability of each service, regardless of their complexity. Furthermore, they serve to continuously improve the quality, safety, and efficiency of hemotherapy centers.

Key words: blood; patient safety; indicators.

RESUMO

Introdução: *A hemoterapia é uma especialidade médica estruturada com diversas ações voltadas à qualidade do hemocomponente produzido e à segurança do doador e do paciente, além de estar diretamente integrada ao processo de assistência à saúde. Os primeiros indicadores para hemoterapia foram criados para nortear os rumos do Programa de Qualidade do Sangue, mas, no cenário da hemoterapia, devemos pensar não só na qualidade do sangue, mas também na segurança do paciente e do doador e nas ações de hemovigilância.* ***Objetivo:*** *A partir da análise dos dados disponíveis nos diversos boletins e relatórios publicados pela Agência Nacional de Vigilância Sanitária (Anvisa), Ministério da Saúde (MS) e Coordenação Geral de Sangue e Hemoderivados (CGSH) nos últimos cinco anos, objetivamos identificar algumas fragilidades e os riscos no processo de transfusão e propor a utilização de uma ferramenta denominada matriz de indicadores, para priorizar os indicadores com foco na segurança transfusional.* ***Metodologia:*** *A seleção dos indicadores foi feita a partir da criação de uma matriz de priorização, utilizando os eixos estratégicos definidos pela OMS, cujo objetivo é o controle de todo ciclo do sangue, incluindo o processo transfusional.* ***Resultados:*** *A seleção dos indicadores visa a melhoria dos processos envolvidos em todo o ciclo do sangue, e a utilização da ferramenta tem como objetivo facilitar a escolha desses indicadores de acordo com o cenário de cada instituição, desde um serviço de hemoterapia*

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até uma agência transfusional. ***Conclusão:*** *Esses indicadores podem melhorar as práticas e os processos de transfusão sanguínea, bem como otimizar a capacidade de gerenciamento de cada serviço, independentemente da sua complexidade. Além disso, eles servem para a melhoria contínua da qualidade, da segurança e da eficiência dos centros de hemoterapia.*

Unitermos: *sangue; segurança do paciente; indicadores de desempenho.*

RESUMEN

Introducción: *La hemoterapia es una especialidad médica estructurada con diversas acciones orientadas a la calidad del componente sanguíneo producido y la seguridad tanto para el donante como para el paciente, además de integrarse directamente en el proceso asistencial. Los primeros indicadores de hemoterapia se crearon para orientar la dirección del Programa de Calidad de la Sangre de Brasil, pero, en el escenario de la hemoterapia, debemos considerar no solo la calidad de la sangre sino también la seguridad del paciente y el donante y las acciones de hemovigilancia.* ***Objetivo:*** *Basado en el análisis de los datos disponibles en los distintos informes y registros publicados por la Agencia Nacional de Vigilancia Sanitaria de Brasil (Anvisa), el Ministerio de Salud de Brasil (MS) y la Coordinación General de Sangre y componentes Hemoderivados (CGSH) en los últimos cinco años, nos propusimos identificar algunas debilidades y riesgos en el proceso de transfusión y proponer el uso de una herramienta llamada matriz de indicadores, para priorizar indicadores con un enfoque en seguridad de las transfusiones.* ***Metodología:*** *La selección de indicadores se basó en la construcción de una matriz de priorización, utilizando los ejes estratégicos definidos por la OMS, cuyo objetivo es controlar todo el ciclo de la sangre, incluido el proceso de transfusión.* ***Resultados:*** *La selección de indicadores tiene como objetivo mejorar los procesos involucrados a lo largo del ciclo de la sangre, y el uso de la herramienta apunta a facilitar la elección de estos indicadores según el escenario de cada institución, desde un servicio de hemoterapia hasta una agencia de transfusión.* ***Conclusión:*** *Estos indicadores pueden mejorar las prácticas y procesos de la transfusión sanguínea, así como optimizar la capacidad de gestión de cada servicio, independientemente de su complejidad. Además, sirven para mejorar continuamente la calidad, seguridad y eficiencia de los centros de hemoterapia.*

Palabras clave: *sangre; seguridad del paciente; indicadores.*

INTRODUCTION

Blood transfusion is a life-saving intervention. Although there are many investments to find a substitute for blood, there is still no element that can supply it. Therefore, the transfusion of blood and its derivatives is so far extremely necessary.

Transfusion is one of the most used treatments in modern medicine, costing billions of dollars a year; however, despite being a high cost procedure, it is not without risks[1]. A system with active hemovigilance and computerized control before the administration of blood components are some measures adopted in the services of the European Union to increase transfusion safety.

Studies estimate that the occurrence of incidents related to health care, particularly adverse reactions, affect 4% to 16% of hospitalized patients in developed countries. Such data sensitized healthcare systems around the world to improve patient safety[2].

To better identify adverse reactions in transfusion patients, a trained team is required to report all issues pertaining to these events to the hemotherapy service, without compromising the quality of information and data reported. This fact can be evidenced through an analysis of hemovigilance reports from the United Kingdom, in which one of the transfusion safety strategies is based on the training of teams in adverse reactions to transfusion and correlates adverse reactions with the percentage of trained teams[3].

European Union countries, such as Spain, use indicators similar to those used in Brazil; however, the notification of adverse reactions and the control over the disposal of materials used in the procedure show that it requires a whole lot effort in Brazilian centers.

In Brazil, for example, the indicators are: percentage distribution of clinical aptitude and inaptitude of candidates to donation; percentage distribution of donations, according to

frequency; percentage of blood donors in relation to age group; and laboratory unsuitability for markers of communicable diseases by the blood tested. In Spain, some indicators are donation rate per 1000 inhabitants; percentage distribution of donations, according to frequency; percentage of blood donors in relation to age group; laboratory unsuitability for markers of communicable diseases by the blood tested; and blood component transfusion rate per 1000 inhabitants. In the United Kingdom, blood donation and donor experience, as well as maintenance of stocks, transfusion protocols, and adverse reactions to transfusion are some of the indicators. In France, the donation rate per year and the rate of donors between 18 and 19 years old are other examples.

When comparing some indicators, we realize that in Brazil, as well as in Spain, the indicators are related to production; however, the Spanish people perform data analysis per 1000 inhabitants, while Brazilians perform a more regional analysis.

The United Kingdom focuses its actions on hemovigilance, associating it with the experience of the patient and the donor, which is important data for the registration and evaluation of services. France, on the other hand, prioritizes production and manufacturing.

In the 1980s and 1990s, a confluence of factors sparked interest in reducing transfusion risks. The discovery of bloodborne hepatitis C and human immunodeficiency virus (HIV) raised questions about the safety of transfusions. During this period, the World Health Organization (WHO) was already concerned with the quality of health services.

With the emergence of the acquired immunodeficiency syndrome (Aids) in 1980, there was a need for an effective participation of the Brazilian Ministry of Health (MH) in the formulation of the national hemotherapy policy and management, which provided an incentive to the development and improvements in the sector and in the health surveillance agencies[4]. Thus, we observe in the various works that cite the history and evolution of hemotherapy in Brazil, that the changes in the Brazilian hemotherapy system did not occur through the intervention of specialists, nor by direct government influence, but rather for random causes, such as the advent of Aids and economic reasons[5].

Based on this scenario and WHO guidelines, Brazil, in 1990, started the Brazilian Quality and Productivity Program [Programa Brasileiro de Qualidade e Produtividade (PBQP)], created to support the modernization of Brazilian companies and spread the concept of quality in health services[6]. In 1998, the MH introduced this process in hemotherapy with the launch of the "Blood with Quality Assurance throughout its Process until 2003" program. From that date onwards, the first hemotherapy indicators emerged in the Brazilian scenario[7], parameters used to evaluate and monitor data on hemotherapy production; however, they did not reflect risk tracking and transfusion safety monitoring throughout the cycle of blood[8].

The indicators, according to the Intergenerational Health Information Network [Rede Intergeracional de Informações para a Saúde (RIPSA)], contain relevant information about the sanitary condition, and should reflect the health situation and serve to monitor health conditions[9]. Therefore, the indicator development is a process whose complexity can vary from the simple direct counting to the calculation of more sophisticated rates or indexes. However, it must reflect the objective to be measured, which, in this work, is transfusion safety.

As it is not an easy task to choose an indicator in transfusion safety, since the objective of the selected indicator may not be estimated, we used a tool that allowed the establishment of a point scoring system, which facilitated the selection of indicators and contributed to an analysis of the others evaluated, allowing the development of a set of useful indicators in monitoring transfusion safety.

OBJECTIVE

Based on WHO guidelines[10] on safety when donating blood, several actions were defined within four strategic axes for transfusion safety: legislation, donation, tests, and transfusion. The aim of this study was to select a group of indicators from the organization of actions in a tool called a prioritization matrix. At the end of the method application, a set of indicators was chosen in a more informed manner and in accordance with the intended objectives.

METHODOLOGY

An observational study was performed, in which secondary source data through bibliographic research were used. To select and, later, score the indicators, a tool called a prioritization matrix was used. For its creation, we selected and organized several actions according to the WHO guidelines[10]; in addition, we researched, in the various national bulletins, concepts that point out, as closely as possible, the objective of the indicator, which is transfusion safety.

In the stage of selecting actions that could be used as indicators, the WHO guidelines that divide the actions for transfusion safety

into four major areas were followed: regulatory mechanisms; blood donation; tests performed on blood; and clinical use of blood[10]. In the creation of this matrix, the actions were systematized in an Excel spreadsheet; then, we performed a trade-off analysis on the quantitative stage[11]. This expression denotes a choice conflict between several options, making a quantitative choice, followed by a qualitative one.

The first analysis (quantitative) was based on objective criteria; the second analysis (qualitative), to choose among the candidate indicators we used the ranking established by the prioritization matrix, as a starting point. After applying the methodology and creating the matrix in an Excel spreadsheet, actions were selected to be used as indicators, according to eliminatory and classification criteria.

In the first stage of the quantitative analysis, it was defined which eliminatory criteria would serve as a basis for selecting indicators; later, they were arranged in the prioritization matrix through the following elements: E0 or E1, where 0 – do not meet, and 1 – meet.

In this stage, the selection of the indicator had to meet objective criteria, such as: be relevant, add value to the process or service, be from a reliable source, and be simple. As the elimination criteria were necessarily met by the candidate indicator, all indicators were scored.

The classification criteria served to establish a ranking of candidate indicators, enabling a weighting qualitative analysis, which contributed to a less intuitive selection of performance measures.

The selected classification criteria are listed in **Table 1**.

The data were arranged in two columns that represent the degree of requirement fulfillment of the candidate indicator to the established criterion called QR and classified as: none (0), little (1), or much (2), in addition to the degree of importance of the criterion (weight), called QI, classified as: low (3), medium (5), high (7), and very high (9).

The same criteria were used and scored according to the degree of care QR and the degree of importance QI.

In **Table 2**, we have the actions selected and distributed in the four major areas.

After selection, these indicators were distributed in the prioritization matrix (**Table 3**), in which it is possible to observe that the lines represent the indicators that are candidates, and the columns present information on the nature of the indicator, according to the eliminatory and qualifying criteria. Finally, the total that represents the score of the points acquired by the indicator was obtained, based on whether the established criteria were met.

After applying the tool to the selected indicators, a total number of points was generated, resulting from the multiplication of the

TABLE 1 – Eliminatory and qualifying criteria

Eliminatory	Qualifying
	Q1. Representativeness
E1. Relevance	Q2. Measurability
E2. Add value	Q3. Source reliability
E3. Be reliable	Q4. High availability
E4. Simple	Q5. Simplicity of construction and interpretation

TABLE 2 – Selection of indicators

Regulatory mechanisms	Blood donation
Health risk record with more than 70% of compliant items	Percentage of donations in relation to the general population
Quality Management System implemented	Number of bags collected/produced/1000 inhabitants/year
Internal and external audit program	Number of bags collected/produced/beds served/year
Certification Program	Percentage of one-time donors greater than 20%
Disposal index – percentage represented by expired and discarded units over the total produced units	Donor adverse reaction
	Bacterial contamination
Types of blood tests	**The clinical use of blood**
Proficiency testing/participation in external quality assessment	Hemotherapy coverage – daily maintenance of the strategic stock needed to meet the 3-day demand
Assurance of blood component quality control	Number of days without strategic stock/days/month
Percentage of general unsuitability of serology	Distribution and therapeutic use of these products or blood components
Percentage of unsuitability by types of serology tests	pRBC/bed served rate
	Requests fulfilled in compliance with transfusion protocols
	Adverse reactions to transfusion – transfusion-related reactions
	Surgical reservation in compliance with transfusion protocols
	RTP
	Compatible/transfused index
	Operating transfusion committee

pRBC: packed red blood cells; RTP: rate of transfused patient.

TABLE 3 – Matrix of indicators

Nº	Name	Nature																
		Eliminatory					Qualifying											Total
							Requirement fulfillment					Degree of importance						
		E1	E2	E3	E4	Subtotal 1	QR1	QR2	QR3	QR4	QR5	QI1	QI2	QI3	QI4	QI5	Subtotal 2	
1	Health risk bulletin with more than 70% of compliant items	1	1	1	1	1	2	2	2	2	2	9	9	9	9	9	90	90
2	Quality Management System implemented	1	1	1	1	1	2	1	1	1	1	9	5	5	5	5	38	38
3	Internal and external audit program	1	1	1	1	1	2	1	1	2	1	9	9	7	9	9	61	61
4	Certification Program	1	1	1	1	1	2	2	2	1	1	9	9	9	5	5	64	64
5	Disposal index – percentage represented by expired and discarded units over the total produced units	1	1	1	1	1	2	2	2	2	2	9	9	7	7	9	82	82
6	Percentage of donations in relation to the general population	1	1	1	1	1	1	2	2	2	1	7	7	9	9	9	66	66
7	Number of bags collected/produced/1000 inhabitants/year	1	1	1	1	1	1	2	2	2	1	7	7	9	9	9	66	66
8	Number of bags collected/produced/beds served/year	1	1	1	1	1	2	2	2	2	2	9	9	9	9	7	86	86
9	Percentage of one-time donors greater than 20%	1	1	1	1	1	2	2	2	2	2	7	9	9	9	9	86	86
10	Donor adverse reaction	1	1	1	1	1	2	2	2	2	2	9	9	9	9	9	90	90
11	Platelet transfusion-related bacterial contamination	1	1	1	1	1	2	1	1	1	2	9	9	9	9	9	63	63
12	Proficiency testing/participation in external quality assessment	1	1	1	1	1	2	2	2	1	2	9	9	9	7	9	79	79
13	Assurance of blood component quality control	1	1	1	1	1	2	2	2	1	1	9	9	9	7	5	66	66
14	Percentage of general unsuitability of serology	1	1	1	1	1	2	2	2	2	2	9	9	7	9	9	86	86
15	Percentage of unsuitability by types of serology tests	1	1	1	1	1	2	2	2	2	2	9	9	7	9	9	86	86
16	Hemotherapy coverage - daily maintenance of the strategic stock needed to meet the 3-day demand	1	1	1	1	1	2	2	1	1	2	9	9	7	7	7	64	64
17	Number of days without strategic stock/days/month	1	1	1	1	1	2	2	1	1	2	9	9	7	7	9	68	68
18	Distribution and therapeutic use of these products or blood components	1	1	1	1	1	2	1	1	1	1	9	5	5	7	7	42	42
19	pRBC/bed served rate	1	1	1	1	1	2	2	2	2	2	9	9	7	7	9	82	82
20	Requests fulfilled in compliance with transfusion protocols	1	1	1	1	1	2	2	2	2	2	9	9	7	7	9	82	82
21	Transfusion-related reactions (adverse reactions to transfusion)	1	1	1	1	1	2	2	1	1	2	9	9	7	7	9	68	68
22	Surgical reservation in compliance with transfusion protocols	1	1	1	1	1	2	2	1	1	2	7	7	5	7	7	54	54
23	RTP	1	1	1	1	1	2	2	1	1	2	9	7	7	7	9	64	64
24	Compatible/transfused rate	1	1	1	1	1	2	2	2	2	2	7	7	7	9	9	78	78
25	Operating transfusion committee	1	1	1	1	1	2	2	2	2	2	9	9	9	9	9	90	90

pRBC: packed red blood cells; RTP: rate of transfused patient.

eliminatory criteria – assigned weight 1 – and the classification criteria, to which the following formula was applied: (QR1*QI1) + (QR2* QI2) + (QR3* QI3) + (QR5* QI4) + (QR5*QI5), generating, by the end, a score of points that corresponds to the degree of requirement fulfillment of the indicator with the established criteria.

Therefore, through this tool, it was possible to rank candidate indicators in descending order of points obtained, according to the fulfillment of the chosen criteria.

After this phase, in cases where the indicators had the same score, the selection criterion used was simplicity and ease of measuring the indicator by the hemotherapy service.

RESULTS

From the total of 25 indicators initially selected, as shown in Table 2, we applied the prioritization matrix, scoring them according to the eliminatory and classification criteria. In **Table 4**, we obtained the score of all selected indicators after performing the qualitative analysis. From then on, it was possible to apply quantitative analysis, selecting the two indicators that achieved the highest scores per area. The eight indicators selected are shown in **Table 5**.

When analyzing the eight final indicators, we observed that, in legislation and regulatory processes, the monitoring of health risk

TABLE 4 – Indicator points score by area

Order	Processes	Name	Total
1º	Regulatory mechanisms	Health risk bulletin with more than 70% of compliant items	90
2º		Quality Management System implemented	38
3º		Internal and external audit program	61
4º		Certification Program	64
5º		Disposal index – percentage represented by expired and discarded units over the total produced units	82
1º	Blood donation	Percentage of donations in relation to the general population	66
2º		Number of bags collected/produced/1000 inhabitants/year	66
3º		Number of bags collected/produced/beds served/year	86
4º		Percentage of one-time donors greater than 20%	86
5º		Donor adverse reaction	90
6º		Platelet transfusion-related bacterial contamination	63
1º	Types of blood tests	Proficiency testing/participation in external quality assessment	79
2º		Assurance of blood component quality control	66
3º		Percentage of general unsuitability of serology	86
4º		Percentage of unsuitability by types of serology tests	86
1º	The clinical use of blood	Hemotherapy coverage – daily maintenance of the strategic stock needed to meet the 3-day demand	64
2º		Number of days without strategic stock/days/month	68
3º		Distribution and therapeutic use of these products or blood components	42
4º		pRBC/bed served rate	82
5º		Requests fulfilled in compliance with transfusion protocols	82
6º		Transfusion-related reactions (adverse reactions to transfusion)	68
7º		Surgical reservation in compliance with transfusion protocols	54
8º		RTP	64
9º		Compatible/transfused rate	78
10º		Operating transfusion committee	90

pRBC: packed red blood cells; RTP: rate of transfused patient.

TABLE 5 – Final indicators

Indicators	Points
Health risk bulletin with more than 70% of compliant items	90
Disposal index – percentage represented by expired and discarded units over the total produced units	82
Donor adverse reaction	90
Percentage of one-time donors greater than 20%	86
Proficiency testing/participation in external quality assessment	79
Percentage of general unsuitability of serology	86
Surgical reservation in compliance with transfusion protocols	82
Operating transfusion committee	90

and the disposal rate were the most scored criteria, representing the need to monitor health risks as a practice of ensuring transfusion safety by the hemotherapy services.

Analysis of the disposal of blood components by validity or for other reasons may indicate a need for readjustment of stock or process realignment and would serve as a strategic action on stock management.

In the axis that reports donor search and blood donation, adverse reactions with the donor and the percentage of one-time donors represented the most scored actions, which demonstrates the impact of this indicator on the safety of care and maintenance of blood stocks.

As for blood tests, actions such as external quality control and monitoring of serological incapacity were the most scored. Such actions reflect the guidelines of the United Kingdom hemovigilance service[12] on proficiency tests as a strategy for transfusion safety.

In the scenario of clinical use of blood, the score showed that the existence and adequacy of medical orders to transfusion protocols, as well as the existence of an active transfusion committee were the best scored, simple measures that manage to ensure better transfusion care and safety, especially after analyzing the work by Nature, which describes the indiscriminate use of transfusion[1]. A committee for the analysis of transfusion practices and the development of clinical protocols are among the practices mentioned in the SHOT (Serious Hazards of Transfusions) hemovigilance report as actions to guarantee transfusion safety[3].

Therefore, the eight best scored indicators, when analyzed and compared with hemovigilance practices and reports in countries

such as the United Kingdom, France, and Spain[3], obtained correspondence with what is described in terms of transfusion safety and, in fact, reflect the objective to be measured, a critical factor for an indicator.

DISCUSSION

In this work, the objective was transfusion safety and, after completing the indicator selection stage, we organized a table with 25 indicators distributed among the four processes selected based on the WHO guidelines and the national data, as shown in Table 4. Therefore, after building the prioritization matrix and mapping the indicators, each service or manager will be able to analyze the scored data and choose, preferably, among the best-scored options, those that best express their objectives.

In scoring these indicators, besides the data published in hemotherapy bulletins in Brazil[8], data from countries such as Spain[12] and the United Kingdom[3] were used. We also present the experience of a master's student specialist in Quality Management and Hemotherapy Services[13].

It is important to report that the prioritization matrix has a dual purpose: to facilitate the selection of indicators, according to the established weighted criteria, and to explain why some indicators already used and apparently established did not score well in the analysis of transfusion safety. When comparing the adverse reactions of donors and patients, we noticed that the score of events associated with donors scored more than that of patients. This happened because in donors these episodes are noticed, most of the time, already in the hemotherapy service, which are then the source of much more reliable data. It is noteworthy that, in applying the methodology, one of the classification criteria for scoring was the data reliability; therefore, we understand that information traceability is a strategy to obtain reliable indicators.

CONCLUSION

After using the prioritization matrix, we conclude that it can be used to select a group of indicators based on a certain purpose, if the manager defines the objective to be achieved, the demands that should be mapped and the information that will be needed for monitoring and evaluating results.

In this context, we understand that the use of the tool was useful in building a group of indicators with the highest score to be used and allowed, through the ranking obtained, a reflection on the other 17 selected indicators. It is noteworthy that for a better use of the tool it is necessary to define the criteria that will serve as a basis for selection, and those that should serve for classification and scoring.

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