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Infographic on quality deviation: educational tool on technical complaints about blood bags to guide health services

Infográfico sobre desvio de qualidade: ferramenta educacional sobre queixas técnicas de bolsas de sangue para orientação de serviços de saúde

Joellyngton da Silva Pimentel*

Maria da Penha Rodrigues dos Santos

Michele Feitoza-Silva

[I] Instituto Aggeu Magalhães (IAM), Fiocruz Pernambuco, Recife, PE, Brail

* **E-mail:** joellyngtonp@gmail.com

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ABSTRACT

Introduction: The Blood Bag consists of sterile plastic bags that store fractions of blood, classified as risk III by the Ministry of Health (MS), and subjected to various compliance tests, which are crucial for transfusion procedures and disease treatment. Post-market monitoring of this input is carried out by the Technovigilance System in Brazil through the Notification System in Sanitary Surveillance (Notivisa), which is mandatory for companies holding registration and optionally for healthcare professionals. **Objective:** To propose an educational infographic based on the main technical complaints reported for Blood Bags in Notivisa from 2013 to 2016, according to a reference study. Method: This is a descriptive methodological study, involving documentary analysis and the construction of an educational technological product based on the production of an infographic from a reference study (Cruz et al., 2018). **Results:** The infographic is based on the main technical complaints reported for Blood Bags in Notivisa between 2013 and 2016, according to a reference study. During this period, 458 notifications of technical complaints were received, reporting 520 problems. The most frequently reported reasons were: bent or broken needle (15.6%), seal defects (10.2%), and leakage of the anticoagulant and/or preservative solution (9.6%), all representing risks of adverse events due to potential compromise of the input quality. **Conclusions:** The infographic could be a simplified information and education tool for healthcare professionals, strengthening the implementation of patient safety culture and contributing to care qualification. Additionally, it brings scientific and technical information closer in a more accessible and playful way, reducing the complexity of scientific results.

KEYWORDS: Health Surveillance; Patient Safety; Medical Device Legislation; Education, Continuing

RESUMO

Introdução: A bolsa de sangue consiste em bolsas plásticas estéreis, que armazenam frações do sangue, sendo classificada como risco III pelo Ministério da Saúde (MS). Ela é submetida a diversos ensaios de conformidade, fundamentais para procedimentos de transfusão e tratamento de doenças. O monitoramento pós-comercialização desse insumo é realizado pelo Sistema de Tecnovigilância no Brasil, por meio do Sistema de Notificações em Vigilância Sanitária (Notivisa), com notificações realizadas obrigatoriamente pelas empresas detentoras de registro e, facultativamente, pelos profissionais de saúde. **Objetivo:** Propor um infográfico educacional com base nas principais queixas técnicas (QT) notificadas para bolsas de sangue no Notivisa, no período de 2013 a 2016, conforme estudo de referência. Método: Trata-se de um estudo metodológico, de caráter descritivo, baseado em análise documental, para a construção de um produto tecnológico educativo fundamentado na produção de um infográfico a

partir da análise de um artigo publicado por Cruz et al. (2018). **Resultados:** O infográfico baseia-se nas principais QT notificadas para as bolsas de sangue no Notivisa, entre 2013 e 2016, conforme um estudo de referência. Durante esse período, houve 458 notificações de QT, relatando 520 problemas. Os motivos mais notificados foram: agulha torta ou quebrada (15,6%), defeito no lacre (10,2%), e extravasamento da solução anticoagulante e/ou preservadora (9,6%), todos representando riscos de eventos adversos devido à possível comprometimento da qualidade do insumo. **Conclusões:** O infográfico poderá ser uma ferramenta de informação e educação simplificada para o profissional da saúde, fortalecendo a implementação da cultura de segurança do paciente contribuindo para a qualificação do cuidado, além disso, aproxima a informação científica e técnica de forma mais acessível e lúdica, diminuindo a complexidade dos resultados científicos.

PALAVRAS-CHAVE: Vigilância Sanitária; Segurança do Paciente; Legislação de Dispositivos Médicos; Educação Continuada

INTRODUCTION

The blood bag, regulated by Collegiate Board Resolution (RDC) No. 544, of August 30, 2021, and RCD No. 751, of September 15, 2022, consists of sterile plastic bags that store blood fractions and may contain anticoagulants and/or preservation solutions, tubes, needles, and associated containers, depending on their purpose. It is a strategic input of the Ministry of Health (MS), classified as risk III (high risk), which is subjected to various physical, chemical, physicochemical and biological tests to prove its compliance, mostly validated by the National Institute for Quality Control in Health (INCQS)[1,2].

This input is used for the storage, transport, separation, and administration of whole blood and its fractions, and its production is centralized and highly complex. It is widely used in blood transfusions as an adjunct treatment for various diseases, and its use is monitored by Transfusion Committees, which create general quality principles that seek to identify and investigate quality deviations[3].

In Brazil, the Technovigilance System is responsible for the post-market surveillance of medical devices (MD), which can be carried out through the notification of technical complaints (TC) and related adverse events (AE). TCs consist of suspected alterations/irregularities in a product that could compromise patient safety[4]. The monitoring process became more strategic when the Brazilian National Health Surveillance Agency (Anvisa) made available in 2006 the Notification System in Sanitary Surveillance (Notivisa) web system, implemented as the official post-marketing surveillance system[5].

Among the efforts to ensure patient safety, the Ministry of Health published Ordinance No. 529, of April 1, 2013, which established the National Patient Safety Program (PNSP) with the aim of contributing to the qualification of care in healthcare facilities, through the implementation of Risk Management and Patient Safety Centers (NSP), promoting a culture of safety in which professionals and managers take responsibility for the patient's well-being, prioritizing safety above financial and operational goals, promoting organizational learning in an educational manner[6].

The NSPs, also provided for in RDC No. 36 of July 25, 2013, are responsible for drawing up the Patient Safety Plan for health services. This document establishes strategies and actions for managing patient risks, from the first care to discharge, implementing protocols established by the Ministry of Health, such as the safety protocol for the prescription, use, and administration of blood and blood components[7,8]. This health education strategy is essential for health services. The incorporation of activities that stimulate the production of technical skills, debate and promote interaction between education, health, and the work process is of paramount importance. The National Policy for Permanent Education in Health (PNEPS), established by Ministerial Order GM/MS No. 198 of February 13, 2004, aims to qualify the training of workers in the Unified Health System (SUS), guided by Ministerial Order GM/MS No. 1996 of August 20, 2007[9].

In this context, the educational infographic is a valuable tool for health education, as it facilitates access to scientific information in an efficient and clear way, as it uses visual resources (eidetic, chromatic, topological). It also has a demonstrative and argumentative function, especially when it presents scientific evidence, disseminates facts and phenomena to the public, and contributes to formal and informal scientific learning[10].

The central hypothesis of this study was the possibility of building an infographic that would simplify complex data obtained from specific scientific research into blood bags, based on Notivisa's TC notifications.

To test this hypothesis, previous approaches and experiences proposed in the production of infographics on other medical products were used[11,12].

It's worth noting that simplifying information brings professionals closer together for more qualified and rational actions. Thus, the construction of playful infographics with direct language, based on scientific studies, can represent a simplified educational tool for healthcare professionals with a direct impact on patient safety.

This study was driven by a question that addresses the complexity of scientific research findings, with a focus on technovigilance. The main question asks whether it is possible to use playful methods to facilitate understanding of the TCs that can be perceived during the use of MD and which are mentioned in the referenced study.

Therefore, the aim of this study was to propose an educational infographic based on the main TCs notified for blood bags on Notivisa between 2013 and 2016, according to the reference study.

National Health Surveillance System

Since the Federal Constitution (FC) of 1988, following the health reform proposals of the 1980s, especially the health reform, health surveillance (Visa) actions have legally become the responsibility of the Unified Health System (SUS), especially Visa and the National Health Surveillance System (SNVS), however, the implementation of Visa in Brazil has proved challenging due to its intrusive nature and its ability to intervene in sensitive sectors of society, presenting significant difficulties[13].

This field of action is often driven by specific health crises, highlighting the need for both national and international cooperation for an effective approach. This is evidenced by the fundamental role played by the SNVS in the joint management of health risks, characterizing it as a state action with the capacity to intervene in crucial activities such as production, trade and the provision of health services[13].

The structuring of the Visa is fundamental for the advancement of the SUS, as its essentially preventive nature makes it an important space for citizenship and social participation, constituting a privileged space for health promotion, due to the need for interaction with society, and the possibility of health education, that is, the actions of the Visa seek to realize the right to health, seeking to eliminate or reduce health risks[14].

This action, strongly based on social participation, is a reflection of participatory democracy and the joint creation of public health policies. Organic Health Laws No. 8.080, of September 19, 1990, and No. 8.142, of December 28, 1990, legitimize social participation as a fundamental principle of the SUS, which also applies to Visa. The contribution of Health Councils, Health Conferences, and other social control bodies is vital, as it allows the population to participate directly in the preparation, execution and evaluation of health surveillance actions[15,16].

The Brazilian Health Surveillance System was formalized with a broad area of action, similar to the United States, The regulation of food and medicines was organized separately from epidemiological surveillance, making the Brazilian model peculiar in comparison to other countries, the Brazilian federative system is characterized by the unequal participation of the federated entities in the construction of the SUS[17].

This inequality in the construction of the SUS between different regions of Brazil is related to the disparity in the capacity to create wealth and well-being for their populations. The Brazilian Institute of Geography and Statistics (IBGE) states that around 25% of Brazilian municipalities have up to 5,000 inhabitants, and 90% have up to 50,000. These smaller municipalities generally face management difficulties, and their Visa activities are often precarious. Furthermore, it was only in 2004 that the municipalities began to take part in the negotiations on the decentralization of health surveillance, which initially privileged the state level[17].

The SNVS and Anvisa were established by Law No. 9,782 of January 26, 1999. The SNVS is responsible for regulation, monitoring, control, and inspection, as well as defining Visa policy and intervening in health risks related to the production and circulation of goods and services of interest to health[18].

Since the SNVS is the body responsible for all health regulation in Brazil and is part of the SUS, it follows the principle of decentralization. SNVS actions are coordinated between the three federal entities, involving multiple organizational levels. However, the SNVS faces structural limitations and different interpretations of the role of Visa, which assumes various responsibilities in risk management, including authorizing pre-market and post-market aspects[12].

In Brazil, Visa is a structural executive part of the operationalization of the SUS, and the use and exploitation of the system's attributes is a challenge for the system's managers. Due to its size and specification, it is necessary to develop and qualify its actions, articulating them in the three spheres of government, since its full structuring is essential for the advancement of the SUS[14].

Technovigilance

Anvisa is responsible for sanitary control at all stages of the manufacture, marketing, and post-marketing of medical products so that adequate standards of safety and quality can be maintained. The system responsible for post-marketing surveillance is the Health Surveillance Notification and Investigation System (Vigipós), and the surveillance of MDs, which is the subject of this study, is technovigilance, defined as "The surveillance system for AE and TC of health products in the phase, with a view to recommending the adoption of measures to ensure the protection of the population's health"[19,20].

Technovigilance is crucial for the safety of MDs and must operate in conjunction with risk management. Anvisa's area dedicated to product monitoring performs a complex task, using TC notifications from registration holders and healthcare professionals to identify quality deviations and AEs related to MDs, making a significant contribution to minimizing risks[11].

This post-market monitoring process became more strategic when, at the end of 2006, Anvisa made Notivisa available, a single channel for receiving notifications of AEs and TCs related to health. It is an online information system that was designed as a tool for effective communication between SNVS entities, facilitating access to information on medical products[19].

In the quality standards for the circulation of MDs, conformity is understood as the product's compliance with established technical specifications and standards, in order to correctly perform its intended functions[21].

Technovigilance actions therefore aim to adopt measures to prevent, reduce damage, eliminate or reduce risks, and products must perform their functions in such a way as not to compromise professional and patient safety. To this end, Anvisa acts to regulate, monitor and inspect MD registration holders[22].

Regulation and quality of the blood bag product in Brazil

Blood, produced in the bone marrow, is made up of red blood cells, leukocytes, and platelets and performs vital functions such as transporting oxygen, defending against infections, and controlling bleeding. Blood transfusion involves the transfer of blood from a donor to a recipient, and is essential in the treatment of severe anemia, blood volume replacement, recovery of oxygen transport capacity, among other blood problems[23].

The first attempt at transfusion, which took place in the 15th century, resulted in the death of both the donor and the recipient. However, William Harvey's subsequent studies into blood circulation paved the way for the development of transfusion practice. In the 19th century, concern about postpartum hemorrhages led to new studies on transfusions. In the 20th century, technological advances enabled the creation of blood banks, and transfusion techniques were improved during wars. In the 1980s, the introduction of plastic bags allowed for more efficient blood fractionation[23].

The blood bag is regulated by RDC No. 544/2021, which re-establishes the specific and general quality parameters for plastic bags used in the collection, storage, and transfer of human blood. They can contain anticoagulant and/or preservative solutions depending on their purpose, are sterile and apyrogenic, and contain a needle and output and collection tubes[2].

The manufacture and quality control of blood bags are regulated by technical standards established to guarantee the quality of blood and its components, given that products and services can present "intrinsic" risks inherent to their use, as well as manufacturing defects, diagnostic errors, and the precautions required in production, distribution, use, and waste disposal. With mass production and the global circulation of products, the risks of defects can transcend national borders, accompanying the growth of import processes[24].

Currently, the central reference laboratory in the country responsible for blood bag compliance is INCQS, which is technically linked to Anvisa and administratively to the Oswaldo Cruz Foundation (Fiocruz). Blood bags are analyzed using various chemical, physical-chemical, and biological tests. The high demand for this product demonstrates the need for quality parameters to ensure product safety[24,25].

Quality analyses are procedures carried out to verify product conformity through prior, control, fiscal, and comparative analyses. A quality management system is applied by Anvisa's official laboratories, based on international standards, with professional qualifications, control of environmental conditions, traceability, and availability. The laboratories also take part in external accreditation assessments[23].

The blood bag testing process is a documented practice that certifies the effectiveness of procedures and systems. This process includes laboratory studies and confirmation of suitability for specific purposes, guaranteeing reliable results. Validation is aligned with international and national standards. Validation definitions range from analytical performance parameters to method consistency verification. The regulations seek to ensure the quality and reliability of analytical methods in the production of blood bags[24].

Anvisa, through the Health Surveillance System, seeks to ensure the availability of health supplies and products that meet quality assurance requirements. Quality monitoring is carried out by Official Laboratories, such as INCQS and the Central Public Health Laboratories of the States (LACENS). Due to the high demand for blood bags, it is crucial to study the quality parameters to guarantee the safety, efficacy and credibility of these products[25].

The infographic

During the 19th century, publications in Brazil were dominated by written texts, a consequence of the technological restrictions of the time. However, in the 20th century, a series of scientific and technological advances had a profound impact on magazines. The evolution of printing and photography, with the emergence of photojournalism, were important milestones. With technological progress and innovations in printing, journalistic language in print media, particularly magazines, became increasingly visual. Infographics, together with photographs and illustrations, have gained prominence as an effective and attractive way of representing technical information[26].

The use of infographics in print media dates back to the early 18th century, with notable examples in London's The Daily Courant and The Times. Magazines such as Time had been using infographics since the 1930s. From the 1970s onwards, newspapers began to hire professionals specializing in graphics. USA Today, in the 1980s, and Macintosh, in 1985, revolutionized journalistic design and the production of infographics, respectively. In Brazil, newspapers such as Época, O Globo, and Folha de São Paulo, as well as publications from Editora Abril, such as Superinteressante and Mundo Estranho, stand out for their frequent and well-received use of infographics[26].

An infographic is a form of communication that combines text and image to convey a visually attractive and informative message, as defined by Módolo[26]. De Pablos highlights two meanings for the term: one related to computer graphics software and the other associated with the historical human desire for communication, involving both information technology and analog media[42]. Infographics can exist in analog and digital formats, both of which have the potential to facilitate communication[27]. Fust characterizes it as a text that presents information eloquently, combining words and images[24]. Schmitt understands it as a hybrid communication system, integrating images, words and numbers into verbal and visual systems[42].

Despite some ambiguity in the concept, all the authors agree that the essential characteristic of infographics is the visual representation of information, using resources such as images, icons, and computer media, providing a multimedia approach[27].

The evolution of information on digital platforms, which surpasses traditional reading methods in printed media, enhances the user experience through the interactivity provided by visual information, allowing for a variety of approaches. Emphasis is placed on the use of animated infographics in the educational context. In the school setting, images are valuable teaching resources that facilitate the presentation and debate of information, encouraging creativity and supporting the development of scientific concepts. Authors such as Pessoa and Maia see infographics as dynamic and interactive learning tools that modernize scientific texts and make them more appropriate for the educational environment[28].

Patient safety

Patient safety is defined by the World Health Organization (WHO) as: reducing the risk of unnecessary harm associated with health care to an acceptable minimum. The Institute of Medicine (IOM) report To Err is Human revealed high incidences of AEs in US hospitals. Around 100,000 AEs occurred annually in the United States, with an estimated annual financial impact of between 17 and 29 billion dollars. Other international studies have confirmed the high incidence of AE in health services, indicating that it occurs in an average of 10% of hospitalized patients, 50% of which are preventable[29].

In 2004, the WHO expressed concern about patient safety and created the World Alliance for Patient Safety in response. This global alliance, later transformed into the Patient Safety Program, aimed to organize concepts and definitions of patient safety and propose measures to reduce risks and mitigate AEs[29].

In Brazil, services that deal with blood transfusions, the control and prevention of healthcare-related infections, and anesthesia services are considered pioneers in actions aimed at patient safety, especially because of the associated risk. These services have been implementing strategies to ensure safety in care processes for a long time, achieving positive results. However, many of these strategies are still not properly recognized by administrators and healthcare professionals, or are not effective in communicating what is intended[29].

Among the reinforcements to promote patient safety, Ordinance No. 529 of 2013, published by the Ministry of Health, establishes the PNSP with the aim of contributing to the qualification of care in healthcare establishments, through the implementation of Risk Management and NSP, promoting a culture of safety in which professionals and managers take responsibility for the patient's well-being, prioritizing safety above financial and operational goals, promoting organizational learning[30].

Large-scale use of a MD, even if it meets quality standards, can present risks and challenges that are not identified in smaller samples. Strict post-market monitoring is essential to prevent risks to consumer health and safety, ensuring a balanced market with products that meet legal standards. However, when a product or service performs poorly, it can pose dangers to the consumer or the environment, causing harm to society[21].

In this context, quality deviations can compromise patient safety, causing incidents and AEs that can cause avoidable harm to the patient. NSPs are responsible for drawing up the Patient Safety Plan in Health Services, which includes risk management actions: identification, analysis, evaluation, monitoring, and communication of risks in health services. The structuring of the center is mandatory and applies to public, private, philanthropic, civilian, or military institutions, including those that carry out teaching and research activities[31].

Correct understanding of the risks associated with the use of non-compliant healthcare products can be improved through strategies that improve existing teaching and learning practices. In this scenario, it is important to develop techniques and behaviors in healthcare professionals that can provide adequate guidance on the possibility of failures and their impacts. It is essential that these professionals consider patient safety and integrate its concepts and principles into their daily practices to ensure the successful provision of health services, always valuing patient-centered care[11].

METHOD

This article is a descriptive methodological study, based on documentary analysis, for the construction of an educational technological product based on the production of an infographic.

Based on an analysis of an article published on blood bag TC, the most prevalent quality deviations that could be assessed by visual inspection were chosen. Based on the segregation of the deviations, an educational infographic was created, associating the chosen deviations with actions related to patient safety.

Publication analysis

To build the infographic, it was essential to analyze and systematize the data available in the article entitled "*Perfil das notificações de queixas técnicas de bolsas de sangue comercializadas no Brasil após a publicação do novo regulamento técnico*" (Profile of notifications of technical complaints of blood bags marketed in Brazil after the publication of the new technical regulation), produced by Cruz et al. (2018) and published by the journal Temas e Saúde, volume 18, number 3, ISSN 2447-2131, in the public domain[32].

The study by Cruz et al. (2018) analyzes the profile of TC notifications of blood bags in Brazil, before and after the implementation of the new technical regulation. The research was carried out between 2012 and 2016, using the Notivisa System with filters for period, product name and type of TC. The study emphasizes that the prior analysis carried out by INCQS is an important tool for the SNVS, but does not guarantee

health quality. It highlights the importance of health monitoring to acquire products of acceptable quality and avoid TCs that lead to notifications[32].

This article was the basis for the infographic. The study only used TC data, which made it possible to associate the reason for notification (functionality, appearance and labeling) with the number of notifications per year. The primary data is available from Anvisa, the SNVS coordinator.

The search carried out in the indexed databases - PubMed, Scientific Electronic Library Online (SciELO), Coordination for the Improvement of Higher Education Personnel (CAPES), Virtual Health Library (VHL), and Latin American and Caribbean Health Sciences Literature (LILACS), as well as Google and Google Scholar, used the Health Science Descriptors (DeCS) and words related to the subject of this study. During the period in question, no other work was found relating to TC notifications of blood bags.

Choosing the items to be covered

The article was understood methodologically and it was observed that it was from individual evaluations of the notifications submitted to Notivisa that the authors constructed the table shown in the Figure, which served as the basis for choosing the deviations that would be present in the construction of the infographic.

The inclusion criteria for the technological product were the most prevalent non-conformities, i.e. those that were most reported during the study period.

A restriction when selecting the non-conformities was to ensure that the most common ones could be identified through a simple visual inspection. This approach was adopted to avoid including non-conformities that require complex assessments in the infographics due to the heterogeneous level of experience of care professionals.

The infographic

A playful character was developed to represent the blood bag product. In addition, color patterns were added to the infographic, ensuring that when it is published or available for download on digital platforms, the color contrast is maintained, as well as the creation of a Quick Response Code (QR Code) to facilitate access to the original scientific study.

Ethical considerations

The study complies with the criteria and recommendations established by National Health Council (CNS) Resolutions No. 466 of December 12, 2012 and No. 510 of April 7, 2016. Only secondary data was used, with no patient data, and for this reason it is free from assessment by the Research Ethics Council (CEP) system and the National Research Ethics Commission (CONEP), in accordance with Article 1, item II - research that uses publicly accessible information, under the terms of Law No. 12,527, of November 18, 2011, - and item III - research that uses information in the public domain[33,34].

RESULTS AND DISCUSSION

Publication analysis

During the period when the article was being analyzed, according to the authors, 458 TC notifications were submitted, and 520 problems were identified. This difference occurred because, in some notifications, there was more than one type of non-compliance[32]. The most reported reasons were: bent or broken needle (15.6%), seal defect (10.2%), and anticoagulant and/or preservative solution leakage (9.6%), deviations that expose the population to the risk of AE, since they can compromise the functionality of the strategic input and also the quality of the blood or fraction stored or conveyed[1,2,32].

It is worth noting that, after the analysis, all the most prevalent non-conformities were identifiable and could therefore be included in the infographic.

It is important to note that the study did not consider TC that cannot be observed through simple visual inspection, since the professional could not reliably decide, segregate or report quality deviations.

Choosing the items to be covered

The inclusion of knowledge about products used in patient care is a strategy and a stimulus for continuing education, for professional training that is more focused on patient and procedural safety[11].

Thus, the infographic aims to educate the professional to understand the causes, consequences and contributing factors to AE, facilitating decision-making, eliminating or reducing risk circumstances for the patient, making their work more critical and reflective, in this sense, for the preparation of the infographic, the main TC were identified according to the Table, built from Figure[35].

The infographic

The infographic aims to encourage the segregation of blood bags that show deviations, identifying alterations before the procedure begins. To do this, the deviation must be visually inspectable by the healthcare professional.

A successful experience with visual inspection is that carried out in the processing of medical products in sterilization centers, where visual inspection is a mandatory and indispensable item for effective processing. This service is close to hemotherapy services, as both are considered high risk[36].

The development of infographics based on deviations observed in MD is part of this collaborative research between Fiocruz Pernambuco, INCQS and the Espírito Santo State Health Department. The blood bag product is among the first five sub-projects

Records of technical complaints related to blood bags from 2012 to 2016							
Description of Technical Complaints	Number of notifications						
	2012	2013	2014	2015	2016	Total	%
Functionality							
Needle disconnected	5	7	12	6	6	36	6.9
Bent and/or broken needle	2	11	13	28	27	81	15.6
Bag connector defective	3	0	6	8	6	23	4.4
Defective seal	6	2	0	34	11	53	10.2
Needle obstruction	4	3	0	7	2	16	3.1
Vacuum system compromised	1	1	0	6	1	9	1.7
Defective retractable system (needle)	0	0	6	1	0	7	1.3
Labeling and Packaging							
Primary packaging broken	2	0	10	4	13	29	5.6
Batch or product data missing	1	1	1	2	5	10	1.9
Aspect							
Disassembled bag	1	1	2	3	1	8	1.5
ExtraVisation of blood	1	5	12	14	12	44	8.5
Leakage of anticoagulant and/or preservation solution	8	8	13	9	12	50	9.6
Presence of a clot	1	1	1	0	0	3	0.6
Altered color of anticoagulant and/or preservative solution and/or preservative	0	0	0	8	9	17	3.3
altered pH and absence of anticoagulant solution and/or preservative solution	0	1	2	0	3	6	1.2
Presence of holes and micro-holes in the bag	5	0	2	1	4	12	2.3
Presence of holes and micro-holes in the collection tube	1	0	1	3	2	7	1.3
Presence of dirt, stains or foreign bodies inside the product	3	1	3	8	11	26	5.0
Others	6	9	17	23	28	83	16.0
Total	**50**	**51**	**101**	**165**	**153**	**520***	**100**

*Sometimes there was more than one type of non-conformity in the same notification, which is why the total number of technical complaints (520) was higher than the total number of notifications registered in Notivisa (458).
Source: Cruz et al.[32].

Figure 1. Selection of the guiding framework translated into Portuguese from the reference article.

Table. Description of technical complaints subject to visual inspection from 2012 to 2016, before, during and after use.

Description of technical complaints	No.	%
Functionality		
Bent, broken, and/or disconnected needle	117	33.82
Defective seal	53	15.35
Labeling and packaging		
Primary packaging broken	29	8.38
Batch or product data missing	10	2.89
Aspect		
Leakage of blood and/or solution	94	27.17
Presence of dirt, stains or foreign bodies inside the product	26	7.51
Altered color of the solution	17	4.91
Total	**346**	**100**

Source: Research data, 2024.
n: Number of notifications subject to inspection.

prioritized, because it is a Risk III product, according to current legislation, and because it represents the most important strategic input in Brazilian hemotherapy, coordinated by the MS.

The playful character representing the "blood bag" was created using the artificial intelligence (AI) Bing Creator. After a few prototypes, the character was chosen by the creators of this research.

The strategy of using the playful character is related to studies that indicate that playfulness can be a resource that facilitates the entire learning and teaching process[37].

A QR Code was created on the canva.com website, using the free functions provided. It was then downloaded in Portable Network Graphic (PNG) format and used later in the infographic to direct and facilitate access to the original study and the infographic.

The QR Code is an up-to-date, easy-to-read, and accessible technology that only requires a smartphone to use. It is commonly used as a teaching resource by educators. Although not everyone has access to the technological resources to read the QR Code, it is an indispensable tool nowadays, as it is part of many people's daily lives[38].

Blood centers are health units within the SUS and are distributed throughout Brazil. They are responsible for collecting, processing, storing and distributing blood and its fractions, and are essential for the entire blood flow, indispensable for meeting all transfusion demands, guaranteeing a continuous supply of blood, used as an adjunct treatment for various diseases[39].

Source: Bing Creator, 2023.

Figure 2. Playful character to represent the blood bag.

Source: Canva, 2023.

Figure 3. QR Code linking to published data.

Source: Canva, 2024.

Figure 4. Infographic on quality deviation in blood bags.

The healthcare landscape is transforming, with new treatments and technologies bringing both therapeutic potential and threats to patient safety. Despite global efforts, patient harm remains substantial and patient safety is a fundamental principle that requires an organized structure to minimize risk and harm, as each stage of the care process has insecurity. Clear policies, effective leadership, data for improvement and qualified professionals are essential for safe healthcare[40].

Safe, incident-free care is a central theme on the world stage. The WHO has launched several guidelines aimed at strengthening discussions in healthcare institutions, with the creation of Patient Safety Plans, promoting a culture of safety in which patients, workers, managers and families are involved. Although there are major challenges, there are several effective strategies being used, such as professional training and research[41].

In the context of patient safety and safe care education, infographics are seen as effective strategies for encouraging healthcare professionals to access information about the AE and TC reporting process. The combination of elements such as text, image, sound, and video in digital environments makes it easier to understand the content. In addition, infographics are a dynamic and attractive way of quickly conveying concepts and examples from professional practice[28].

In this context, the infographic represents a tool for professional improvement, promoting education based on scientific knowledge, with a direct impact on care practices and patient safety. The initiative seeks to positively influence health services, encouraging professionals to adhere to preventive measures. To this end, the infographic took into account the results of the main non-conformities most frequently reported and subject to visual inspection, a playful character, a QR Code and the logos of the partner institutions in this study[12].

The final version of the infographic, the result of this study, will be made available as a technological product. The intention is to share it through partnerships, including Fiocruz, INCQS, LACENS, and health services, especially blood centers. The focus is to provide an accessible and beneficial resource for the health community, promoting the dissemination of critical information, bringing scientific information closer to the daily lives of professionals.

CONCLUSIONS

The infographic was successfully created, fulfilling the objective of this work. This instrument could be a simplified educational tool for healthcare professionals, strengthening the implementation of a patient safety culture and contributing to the qualification of care in all healthcare establishments, as well as bringing scientific and technical information closer together in a more accessible and entertaining way, by reducing the complexity of scientific results.

It is hoped that the application of this educational tool in care practice will contribute to a better understanding of its effectiveness in patient safety and that further studies can address these developments.

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Authors' Contributions

Pimentel JS - Conception and planning (study design), acquisition, data analysis and interpretation, and writing of the paper. Feitoza-Silva M - Planning (study design), data analysis and interpretation, and writing of the paper. Santos MPR - Data analysis and interpretation, writing of the paper. All the authors approved the final version of the paper.

Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.