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Electronic Transfusion Safety System: Characterization of Patient Safety Incidents

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Keywords
Patient safety · Transfusion medicine services · Error · Hemovigilance · e-Health

Abstract

Introduction: The healthcare system is complex and dynamic, and the implementation of information technology is seen as an important aid to patient safety. Data reveal that 1 in every 10 patients in developed countries is affected by a clinical error. The transfusion process involves several stakeholders and multiple stages with various critical points within the hospital. This study aims to understand patient safety incidents caused by failures in the Electronic Transfusion Safety System (ETSS) based on barcode technology in a hospital setting, from storage to the administration of blood components to the patient. ***Methods:*** A retrospective study spanning 3 years (2021–2023) with a mixed-methods approach was chosen. A Focus Group with six experts was conducted, and 136 reports from the anonymized incident reporting database with the typology "Blood and Blood Products" from a hospital in Lisbon were analyzed. ***Results:*** The ETSS diagram using barcodes allowed for the identification and description of all stages and their stakeholders. The critical points identified were patient identification, multiple relabeling, and transportation. A higher incidence rate of near-miss events was observed during sample collection and prescription. ***Discussion:*** This ETSS is hybrid, meaning that it has both human and technological components. Since 96% of the incidents did not cause harm to the patient, error detection and prevention mechanisms are being activated. This study has demonstrated the importance of IT in the transfusion process, as well as the relevance of continuous investment and the involvement of all stakeholders for a better patient safety environment.

Plain Language Summary

The healthcare system is highly complex, and the use of information technology (IT) plays a crucial role in enhancing patient safety. According to the World Health Organization, 1 in 10 patients in developed countries is affected by clinical errors. The transfusion process, which involves numerous stakeholders and multiple stages, has various critical points within hospitals. This study utilized a mixed-methods approach and covered a 3-year period (2021–2023). It involved a Focus Group of 6 experts and analyzed 136 anonymized incident reports related to blood and blood products from a hospital in Lisbon. The study mapped the Electronic

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Transfusion Safety System (ETSS), which uses barcodes, identifying key stakeholders and critical stages in the process. The main critical points identified were patient identification, multiple relabeling, and transportation. The study also found a higher incidence of near-miss events during the sample collection and prescription stages. The ETSS, which integrates both human and technological components, proved effective in detecting and preventing errors, as 96% of the incidents did not result in harm to patients. The study underscores the importance of IT in improving the safety of the transfusion process, highlighting the need for ongoing investment and the active involvement of all stakeholders to ensure a safer healthcare environment.

O Sistema de Segurança Transfusional Eletrónico: caracterização dos incidentes de segurança do doente

Palavras Chave
Segurança do doente · Serviços de medicina transfusional · Erro · Hemovigilância · e-Health

Resumo
Introdução: O sistema de saúde é complexo e dinâmico, e a implementação das tecnologias da informação (TI) é vista como um importante auxílio na segurança do doente. Dados revelam que um em cada dez doentes, nos países desenvolvidos, é afetado por um erro clínico. O circuito transfusional envolve vários intervenientes e etapas com diversos pontos críticos no hospital. Este estudo pretende conhecer os incidentes de segurança do doente, por falhas do Sistema Segurança Transfusional Eletrónico (SSTE) de código de barras desde o armazenamento até à administração dos componentes sanguíneos ao doente. ***Métodos:*** Adotou-se um estudo retrospetivo de três anos (2021–2023) de metodologia mista. Foi realizado um Grupo Focal com seis especialistas e foram analisados 136 relatos da base dados anonimizada de relato de incidentes com a tipologia "Sangue e Hemoderivados" de um hospital em Lisboa. ***Resultados:*** O diagrama SSTE permitiu a identificação e descrição de todas as etapas e seus intervenientes. Os pontos críticos foram: a identificação do doente, as várias reetiquetagens e o transporte. Verificou-se uma maior taxa incidência de quase eventos na colheita da amostra e prescrição. ***Discussão/Conclusão:*** Este SSTE é misto, ou seja, tem uma componente humana e outra tecnológica. Visto que 96% dos incidentes não provocaram danos no doente, estão a ser ativados mecanismos de deteção e prevenção do erro. Este estudo veio demonstrar a importância das TI no circuito transfusional, como também a relevância que existe neste investimento contínuo e o envolvimento de todos os *stakeholders* para um melhor ambiente de segurança do doente.

Introduction

Over the years, we have witnessed a rapid digital transformation in healthcare, and we are facing a technological ecosystem that, inadvertently, leads to new types of errors [1]. Researchers in the field highlight the following three points we must consider: (1) technology is part of the digital healthcare system [2]; (2) new technologies have led to new healthcare practices, and thus, we may encounter technology-induced errors; and (3) technology-induced errors can propagate throughout the healthcare system, meaning that they create an error trajectory [3, 4].

Error Associated with Healthcare

According to the World Health Organization (WHO), the latest global data reveal that 1 in every 10 patients in developed countries is affected by a medical error [5]. In the European Union, the European Observatory on Health Systems and Policies Report estimates that 8–12% of patients admitted to European hospitals experience adverse events, many of which are caused by medical errors [6]. Regarding Portugal, a national study conducted in 2021 revealed that about 10% of hospitalized patients in the country are victims of adverse events, with nearly half of these cases attributed to preventable medical errors [7].

The US Committee for Quality in Healthcare identified in 2000 that 98,000 deaths in hospitals were due to healthcare professional errors [8]. Despite this number being higher than deaths caused by cancer or road accidents, we still fall short in giving it the importance it deserves.

Adverse events that cause unintended harm or injury affect between 3% and 23% of patients, and of these, 3.6% result in preventable hospital deaths [9–11]. These adverse events should be reported by healthcare professionals through appropriate incident reporting systems. In Portugal, they are managed by Patient Safety

Management structures, which, together with professionals, patients, and other entities, promote actions to improve the quality of care and patient safety.

The Institute of Medicine (IOM) report, *To Err Is Human*, determined that "the problem is not bad people in healthcare – it's that good people are working in bad systems that need to be made safer" [3]. This report spurred programs and actions to increase patient safety through health policies, involving decision-makers, professionals, and managers. In this regard, the report recommends transforming paper-based systems, such as medical records and pharmacy orders, into electronic healthcare information systems to make them safer [8].

In 2011, the IOM report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, highlighted the problem that the introduction of information technologies in healthcare is introducing new errors into an already complex system when they are not well designed. This report also identified poor interaction between professionals and technologies, which can affect diagnosis, lead to failures in diagnostic tests, and impact patient treatment. The implementation of information technologies in the healthcare system, which is already complex and dynamic, carries added responsibility, making it essential for there to be cooperation and synergy between technology companies and healthcare organizations [12].

According to the WHO, the "Conceptual Framework for the International Classification for Patient Safety" has three definitions:

1. Near miss: an incident that was detected in time and did not reach the patient.
2. No harm incident: an event that reached the patient but caused no perceptible harm.
3. Harmful incident: an incident that results in direct harm to the patient. An adverse event results in preventable harm to the patient, while an adverse reaction refers to unavoidable harm resulting from a justified action or a correct procedure [13].

Transfusion System and Technology

Transfusions of blood and blood components are essential for the continuation of certain medical therapies, such as surgeries due to trauma or diseases like cancer or anemia. The objectives of blood transfusions are to restore or maintain oxygen transport, promote hemostasis, and restore blood volume [14].

According to the WHO, the transfusion process is considered complex as it involves multiple stakeholders and includes a circuit with critical points where errors can occur. This process entails high financial costs due to the need for highly specialized human resources, specialized authorities, and advanced technology [15].

Patient safety in blood transfusion depends on the safety of the derived components and the safety of the process, which involves a series of interconnected steps: ordering and prescribing blood components; patient identification; collecting and labeling patient blood samples; pretransfusion compatibility procedures and blood issuance; collection and transportation of blood units within the hospital; handling blood units in the clinical area; blood administration; patient monitoring; and managing adverse transfusion events [15].

Although the primary goal of the blood transfusion process is to improve patient health and survival, it carries risks of adverse events: errors, transfusion reactions, and transmission of infections. These adverse events have been documented since 1990 in the Hemovigilance Systems of each country.

Legislation on Hemovigilance Systems

The European Quality Management System, based on hemovigilance studies from member states, acknowledges significant risks to patients resulting from failures in the transfusion process. It highlights the need to comply with European directives in this area [3].

As per Ordinance No. 3387/2018, published in the Portuguese Official Gazette, 2nd series, No. 67, on April 5, 2018, the implementation of a Patient Blood Management (PBM) Program in 9 hospital establishments of the National Health Service (NHS) was mandated during the year 2018. To operationalize this program, Clinical Guideline No. 011/2018, dated June 11, was published by the Directorate-General for Health (DGH), jointly proposed by the Portuguese Institute of Blood and Transplantation (PIBT) and the Department of Health Quality of the DGH, with the aim of proposing new policies for the dissemination and implementation of PBM as a healthcare standard [16].

Under the provisions of paragraph g of No. 3 of Ordinance No. 11199/2020, published in the Portuguese Official Gazette, 2nd series, No. 222, on November 13, 2020, amended by Ordinance No. 1752/2021, published in the Portuguese Official Gazette, 2nd series, No. 32, on February 16, 2021, it was determined: the implementation of the PBM program in hospital establishments of the National Health Service, and the creation of the National Commission for the Monitoring and Operationalization of the PBM [17].

In the UK, the risk of death from transfusion is approximately 1 in 117,000 transfusions, and the risk of serious harm is 1 in 21,000 issued components [18]. More

than 85% of incidents reported by the Serious Hazards of Transfusion (SHOT) are still caused by errors. These include near-misses (about 40% of all reports) as well as actual events [18].

The entire blood transfusion process used to be manually verified by a professional, resulting in lower work efficiency and a higher potential for error. Several studies have demonstrated that closed-loop electronic prescription and distribution with patient identification via radio frequency identification (RFID) reduce errors in the transfusion circuit [18–20]. A 10-year retrospective analysis in England and Wales concluded that three-quarters of the incidents reported due to technological failures could have been preventable [21].

Hemovigilance Model and Integration with Electronic System

The blood hemovigilance circuit involves several processes within a hospital, as show in Figure 1. It begins with the doctor who prescribes and orders the blood components for the patient. The nurse then collects the patient's blood sample. Next, the Healthcare Assistant (HA) transports it to the laboratory of the Immunohematology Service, where the Clinical Laboratory Technician receives the sample and performs the necessary pretransfusion tests. The technician also records the release of the blood components that will be administered by the nurse. The nurse is also responsible for monitoring the patient's vital signs and symptoms during the transfusion and notifying the Immunohematology Service laboratory if any adverse reaction occurs. In the case of an adverse reaction, the nurse must alert the doctor to decide whether to continue or stop the process, as well as to notify the Clinical Laboratory Technician, who is responsible for reporting the incident to the PIBT [22].

The set of these processes, as outlined in the previous blood circuit diagram, is covered by the integration of software that connects the hospital to a closed network with digital technology. This system involves scanning barcodes from a patient's wristband using a Personal Digital Assistant (PDA) and scanning the labels of blood units. However, this process is not fully digital yet, as it still includes a manual written component by healthcare professionals. This technology sends a series of alerts to the PDA screen for systematic confirmation by the healthcare professional, thereby reducing the probability of incidents and increasing the efficiency and effectiveness of this electronic system.

In conclusion, reducing human intervention in some stages of the transfusion process lowers the probability of errors, and IT solutions play a significant role in ensuring patient safety. Nevertheless, even with the use of technology in this area, incidents continue to be reported. According to some professionals, there are limitations in this electronic system related to the paper-based component of certain records, such as medical prescriptions and vital signs, which can lead to illegibility and data inconsistencies, and, consequently, the reporting of incidents [22].

The general objective of this study is to understand patient safety incidents caused by failures in the Electronic Transfusion Safety System (ETSS) based on barcode technology in a hospital setting, from storage to the administration of blood components to the patient. The specific objectives are: (1) to map the transfusion circuit, identifying human and technological intervention; (2) to characterize patient safety incidents related to Blood and Blood Products, documented in the years 2021, 2022, and 2023; and (3) to identify the critical points in the transfusion circuit with a view to improving the technological system.

Materials and Methods

Study Design

To achieve the proposed objectives, it is intended to conduct a retrospective observational study over 3 years (2021, 2022, and 2023) at a hospital center in the Lisbon area. To address the proposed objectives, a mixed methodology was chosen: a qualitative methodology and a quantitative methodology, as show in Figure 2. This study received approval from the Board of Directors and the Ethics Committee of this hospital center. Throughout the study, all confidentiality and data protection procedures were observed.

Qualitative Methodology

To address the first and third specific objectives: Mapping the transfusion circuit by identifying human and technological interventions and identifying critical points in the transfusion circuit with a view to improving the technological system, a Focus Group was chosen that corresponds to a qualitative research methodology aimed at generating discussion and ideas, which may not be consensual, to meet the objectives [23].

Sample

For this purpose, the participation of six specialists was enlisted, selected through convenience sampling, with multidisciplinary knowledge in this study area. The participants included a doctor specialized in Immunohematology

(D), an intensive care nurse (NU), a member of the Patient Safety Office in the field of Blood and Blood Products (PSD), a Diagnostic and Therapeutic Technician (DTT), a hospital administrator (HA) responsible for Immunohematology, and a Computer Science Engineer (ENG) that works as a programmer.

Description of Procedures

All panel members were sent, via email, a support document prior to the session, which included an introduction to the topic and the issues to be discussed, as well as an informed consent form for participation. The meeting took place in person in a conference room at a hospital in the healthcare center on June 3, 2024, lasting approximately 1 h.

After receiving informed consent from all participants for data collection and audio recording of the meeting, the discussion began. Information collection during the meeting was conducted in two ways: audio recording, which was transcribed and then deleted to ensure participant anonymity, and by a note-taker who recorded key ideas from the meeting.

In the initial phase of the meeting, with the support of the moderator and a chart, a walkthrough of the Transfusion Circuit and the professionals involved at each stage was conducted, aiming to produce a diagram detailing all manual and technological stages.

In the subsequent phase, a series of ideas were generated by the experts based on two questions:

1. Where are the flaws in the transfusion circuit?
2. How can technology in the transfusion circuit be improved?

After the session was concluded, the author subsequently applied the qualitative technique, Thematic Analysis, to create the diagram of the ETSS, as well as to identify the main failures according to the experts, the critical points of the circuit, and the possible improvements to be adopted.

Quantitative Methodology

To address the second specific objective: Characterize patient safety incidents related to Blood and Blood Products, documented in 2021, 2022, and 2023. These years were chosen because they are the most recent 3 years at the time of the study and provide sufficient data for this research due to having a significant sample size.

Data Source

Data were collected from an anonymized Incident Reporting database related to the category "Blood and Blood Products." This database was provided to the author in an Excel file with no references or identification of the involved professionals or incident reporters, as well as no identification of the patients and members of the patient safety office – risk managers.

Sample

The database contains approximately 145 reports of incidents related to blood over the 3 years under study; however, only 136 reports were considered. The 9 excluded reports pertain to industrially prepared blood products, which are considered medications. These blood products include plasma, plasma proteins, human albumin, and coagulation factors. These do not fall under the ETSS, and their transfusion circuit is different, as these blood products are requested from the hospital pharmacy.

Variables under Study

- Dependent variable:
  - Reports of incidents related to blood: records made by professionals on the incident reporting platform of the hospital center – discrete quantitative variable.
- Independent variable:
  - Calendar year: For this study, incident reports from the three consecutive years 2021, 2022, and 2023 were selected – ordinal qualitative variable.
  - Professional area: All professionals involved in the transfusion circuit within the hospital were included: doctor, nurse, DTT – clinical analyst, and healthcare assistant (HA) – nominal qualitative variable.
  - Process phase: The phase of the transfusion circuit where the incident occurred – prescription, sample collection, supply/request, pretransfusion testing, storage, delivery, presentation/packaging, monitoring, and administration – ordinal qualitative variable.
  - Type of problem: The issue that resulted in the incident – electronic validation failure, delay in administration, wrong patient, label/administration instruction, incorrect storage, dose/blood product omitted, wrong blood product, presentation/packaging, extravasation/infiltration, puncture/rupture of the unit, incorrect quantity, and adverse reaction – nominal qualitative variable.
  - Type of damage to the patient: The classification of the incident report is performed by the patient safety office – risk manager, using 5 levels: reportable occurrence, no damage, minor damage, moderate

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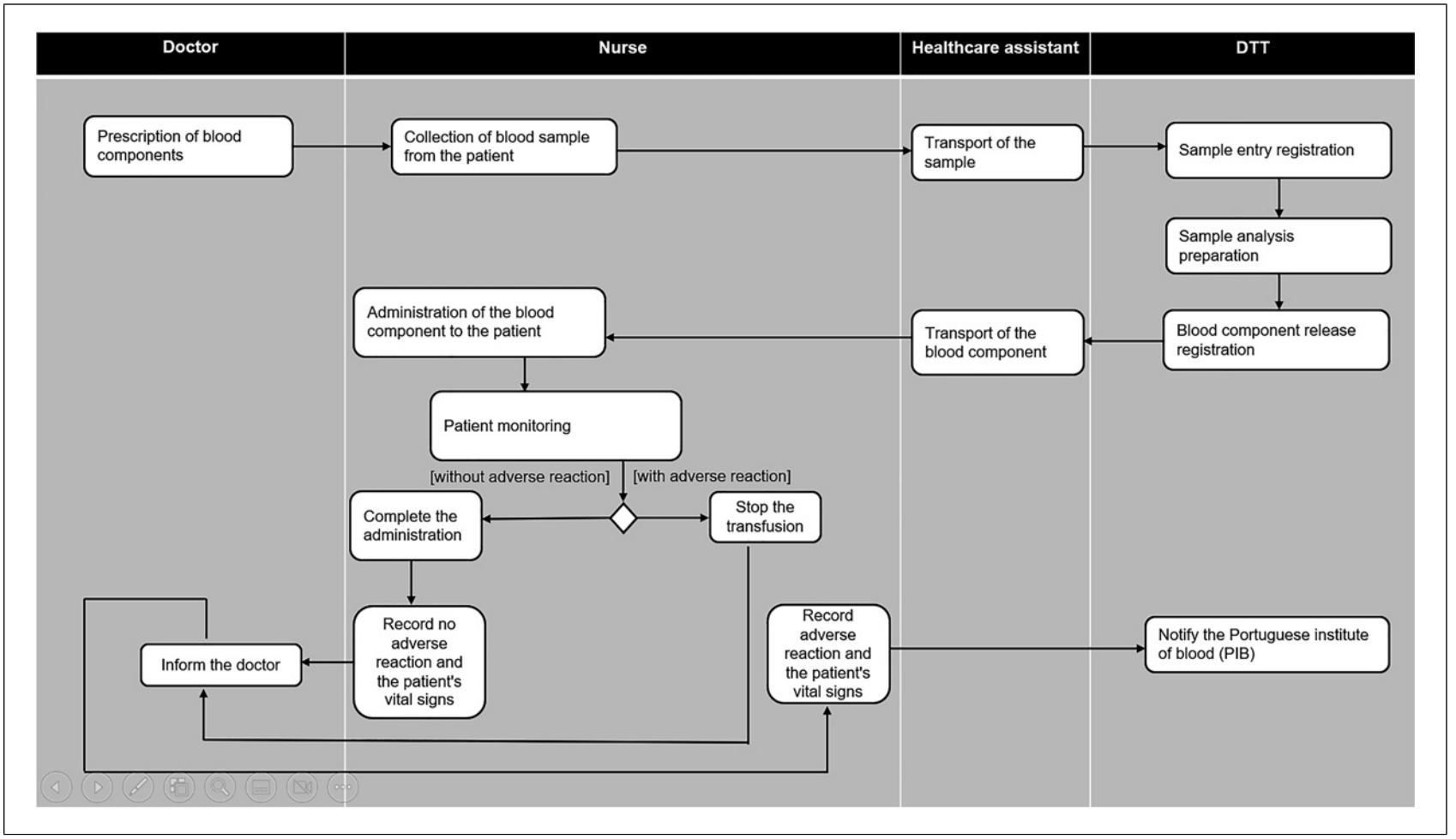

Fig. 1. Diagram of hemovigilance processes.

Fig. 2. Scheme of the methodology applied to the study.

damage, and near miss. This classification aligns with the International Classification for Patient Safety by WHO(25) – ordinal qualitative variable.

Data Analysis

A descriptive analysis was conducted to characterize the variables using Excel software version 2407. The variables are described with absolute frequencies and their respective percentages.

Results

During the Focus Group meeting, with the help of all participants, it was possible to construct a diagram of the ETSS with barcode technology, including all the steps involving the four direct participants: the doctor, the nurse, the healthcare assistant, and the diagnostic and therapeutic technician, as shown in Figure 3. It can be observed that this is a mixed system, as it features both human and technological components.

The ETSS begins with the "Prescription" of blood or blood products, which is written by the responsible doctor on paper and handed over to the nurse. The nurse, at the patient's bedside, confirms the patient's identity, manually inputs the patient's data into the PDA, and manually registers the ETSS bracelet to identify the patient. The nurse then performs the "Collection of the patient's sample for typing" and affixes the barcode labels. The HA is responsible for the "Transport of the sample and requisition" to the laboratory. Next, the DTT performs the "Validation of the patient's identity: between the sample and the requisition," then performs the "Control of the extraction and scanning of the sample and requisition" through barcode reading, carries out the "Pretransfusion tests," and finally makes a "Manual record in various computer systems of the release of the blood component" and affixes the ETSS barcode label and performs another scan. The transportation of the blood components unit to the service where the patient is located is done by the HA. The nurse then follows these steps for ETSS validation: (1) manual validation of labels, (2) scanning the blood component's tag, (3) scanning the patient's bracelet, (4) scanning the 1st blood unit identification code, and (5) scanning the 2nd blood unit identification code. After "Entering vital signs" into the ETSS PDA, the nurse can begin the "Administration of the blood component to the patient." During the transfusion process, the nurse must "Monitor the patient" by assessing the patient's vital signs every 10 or 15 min. If the patient experiences an adverse reaction, the nurse must "Stop the administration" and "Inform the doctor," who will decide, as a team, whether to continue or terminate the transfusion. If they decide on the "Termination of administration," the nurse must "Record the vital signs and adverse reactions in the ETSS" and "Complete the patient safety incident report." The HA then "Sends the report and the blood unit" to the laboratory. The DTT "Receives and evaluates the need for notification to the Portuguese Institute of Blood." If the patient does not experience any adverse reactions, the nurse completes the "Termination of administration" and "Records the vital signs in the ETSS."

Experts emphasized that all stages of the transfusion circuit are critical for the occurrence of errors. However, they identified three critical points where errors are likely to occur:

1. Patient identification: Errors can occur during the prescription stage by the doctor, where the patient's name is written manually on paper, or during the blood sample collection by the nurse. Problems may arise if the nurse misreads the patient's name or incorrectly identifies the sample, as they must manually write the name on the wristband and requisition form and then apply the barcode label.
2. Relabeling of samples and blood units: According to laboratory technicians, multiple labels are applied to samples as per protocol. Since the ETSS code is valid for only 3 days, labels are sometimes reused to avoid confusion, especially if the patient is hospitalized for an extended period and requires more than one blood unit.
3. In the blood unit transportation: experts reported that the ETSS barcode on each unit only corresponds to the transfusion request without additional information. This limitation sometimes results in blood components being delivered to incorrect departments. Such errors can lead to delays in patient transfusions or, alternatively, exceed the optimal storage time for the blood unit. This situation may cause the blood to become unusable, resulting in waste.

Consequently, the following question was posed to the experts: How can technology in the transfusion circuit be improved? They specified seven key points to enhance patient safety:

1. Electronic prescription
2. Unique patient wristband
3. Interoperability between hospital information systems
4. Connectivity between vital signs monitoring systems and hospital information systems
5. Timely administration alarms for each blood unit
6. Printing of barcode labels from wristband scanning
7. Electronic prescription from wristband scanning

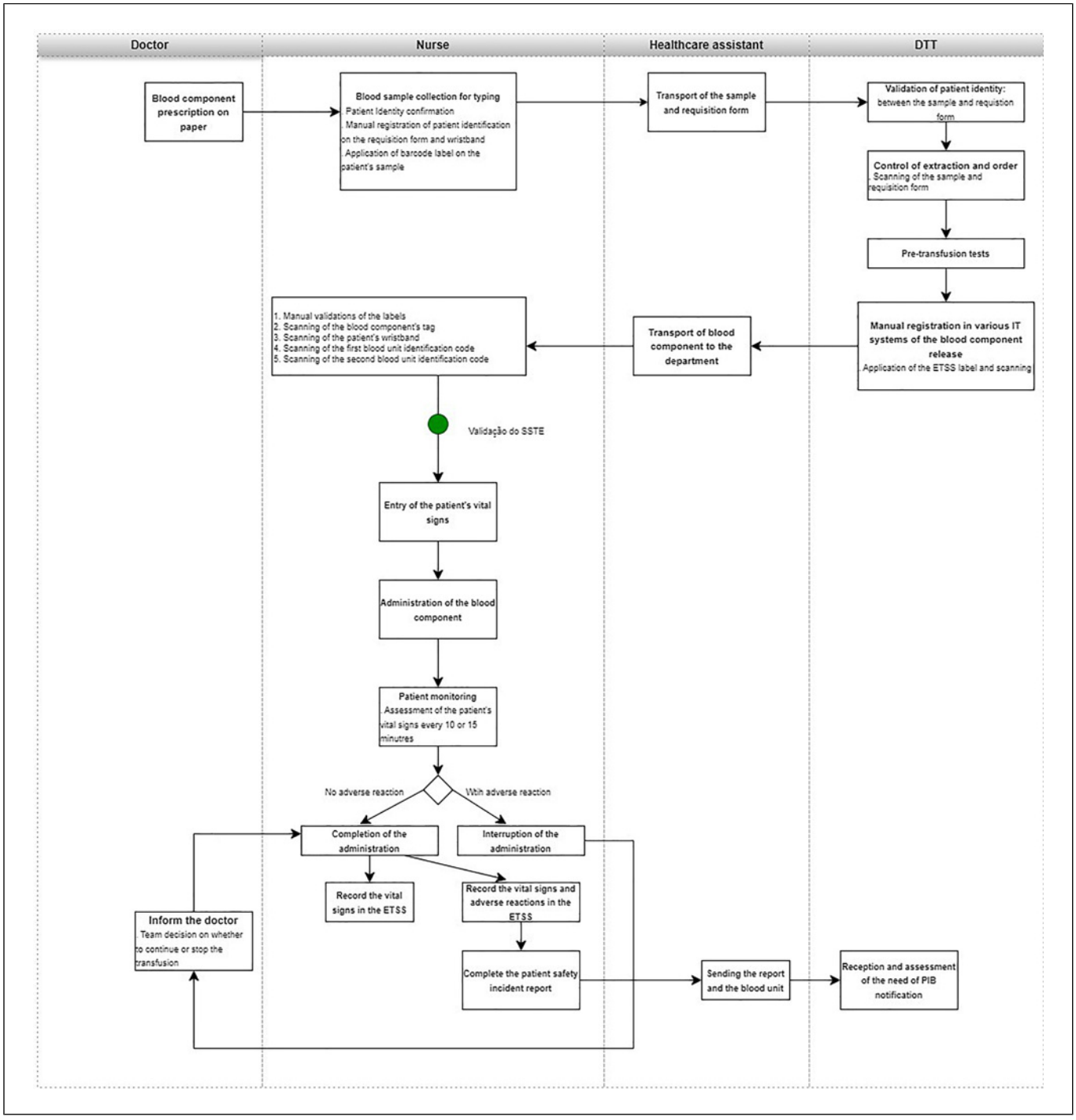

Fig. 3. Diagram of the Electronic Transfusion Safety System circuit.

To characterize the patient safety incidents related to blood and blood derivatives, a detailed analysis of the anonymized Incident Reports database is provided.

According to Table 1, there is a progressive increase in the number of reported incidents year by year: in 2021 with $n = 38$ (27.9%), in 2022 with $n = 40$ (29.4%), and in 2023 with $n = 58$ (42.6%). The largest increase was

Table 1. Distribution of total patient safety incidents by year and type of patient harm

	2021	2022	2023	Total
Type of damage, n (%)				
Reportable occurrence	2 (1.5)	2 (1.5)	6 (4.4)	10 (7.4)
Near miss	20 (14.7)	25 (18.5)	25 (18.4)	70 (51.5)
No harm	13 (9.6)	11 (8.1)	26 (19.1)	50 (36.8)
Minor harm	3 (2.2)	0 (0.0)	1 (0.7)	4 (2.9)
Moderate harm	0 (0.0)	2 (1.5)	0 (0.0)	2 (1.5)
Total	38 (27.9)	40 (29.4)	58 (42.6)	136 (100.0)

Table 2. Distribution by professional area reporting incidents in the "Blood/ Derivatives" category for the year 2021 and the type of patient harm

	2021				
	doctor	nurse	DTT	HA	total
Type of damage, n (%)					
Reportable occurrence	0 (0.0)	0 (0.0)	1 (2.6)	1 (2.6)	2 (5.3)
Near miss	1 (2.6)	1 (2.6)	18 (47.4)	0 (0.0)	20 (52.6)
No harm	4 (10.5)	6 (15.8)	3 (7.9)	0 (0.0)	13 (34.2)
Minor harm	0 (0.0)	3 (7.9)	0 (0.0)	0 (0.0)	3 (7.9)
Moderate harm	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	5 (13.2)	10 (26.3)	22 (57.9)	1 (2.6)	38 (100.0)

observed between 2022 and 2023, with an increase of about 13%.

Over these 3 years, the type of damage classified as "near miss" by the patient safety department (PSD) represents more than half of the incident reports, with $n = 70$ incidents (51.5%), followed by "no harm" to the patient, $n = 50$ (36.8%), then "communicable occurrence," $n = 10$ (7.4%), followed by "minor harm," $n = 4$ (2.9%), and finally "moderate harm," $n = 2$ (1.5%). No incidents were classified as "severe harm" by the PSD.

Regarding the incident reports made by the professional classes involved in the ETSS between doctors, nurses, DTT, and HA, there is an increase in reports from all classes except for nurses between 2021 and 2022. As shown in Tables 2–4, DTTs are the professionals who report the most incidents in all 3 years: 22 reports (57.9%) in 2021, 26 reports (65%) in 2022, and 32 reports (55.2%) in 2023, totaling 80 reports (58.8%) out of 136 incidents. However, in 2023, the percentage of reports by DTTs is lower compared to the total incidents of that year, despite the absolute frequency being higher.

The "near miss" is the most reported incident in 2021 and 2022, as shown in Table 1, whereas in 2023, "no harm" becomes the most reported incident. Tables 2–4 reveal a growing trend for "near miss" incidents, with an increase of approximately 10% from 2021 (20 incidents, 52.6%) to 2022 (25 incidents, 62.5%). However, between 2022 and 2023, there is no change in the number of "near miss" incidents (25 incidents), but their representation decreases to 43.1%, representing a 19.4% reduction in these incidents. On the other hand, "no harm" incidents increased by 17.3% between the last 2 years, from 11 incidents (27.5%) in 2022 to 26 incidents (44.8%) in 2023.

Analyzing Tables 2–4, it is observed that nurses are the second highest reporters of incidents, with 10 reports (7.4%) in 2021, 6 reports (4.4%) in 2022, and 12 reports (8.8%) in 2023, with "no harm" being the most reported event in all 3 years. Doctors are the third highest class of professionals reporting incidents, with 5 reports (3.7%) in 2021, 7 reports (5.1%) in 2022, and 13 reports (9.6%) in 2023. They also report more "no harm" incidents.

HA reported only 3 incidents over the 3 years, with 1 incident (0.7%) per year.

Table 3. Distribution by professional area reporting incidents in the "Blood/ Derivatives" category for the year 2022 and the type of patient harm

	2022				
	doctor	nurse	DTT	HA	total
Type of damage, n (%)					
Reportable occurrence	0 (0.0)	2 (5.0)	0 (0.0)	0 (0.0)	2 (5.0)
Near miss	2 (5.0)	1 (2.5)	21 (52.5)	1 (2.5)	25 (62.5)
No harm	4 (10.0)	2 (5.0)	5 (12.5)	0 (0.0)	11 (27.5)
Minor harm	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Moderate harm	1 (2.5)	1 (2.5)	0 (0.0)	0 (0.0)	2 (5.0)
Total	7 (17.5)	6 (15.0)	26 (65.0)	1 (2.5)	40 (100.0)

Table 4. Distribution by professional area reporting incidents in the "Blood/ Derivatives" category for the year 2023 and the type of patient harm

	2023				
	doctor	nurse	DTT	HA	total
Type of damage, n (%)					
Reportable occurrence	2 (3.4)	0 (0.0)	3 (5.2)	1 (1.7)	6 (10.3)
Near miss	0 (0.0)	2 (3.4)	23 (39.7)	0 (0.0)	25 (43.1)
No harm	11 (19.0)	9 (15.5)	6 (10.3)	0 (0.0)	26 (44.8)
Minor harm	0 (0.0)	1 (1.7)	0 (0.0)	0 (0.0)	1 (1.7)
Moderate harm	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	13 (22.4)	12 (20.7)	32 (55.2)	1 (1.7)	58 (100.0)

In Table 5, we can see that four phases of the ETSS with the highest number of incident reports are "Sample Collection" with $n = 42$ (30.9%), "Prescription" with $n = 21$ (18.4%), "Administration" with $n = 21$ (15.4%), and "Delivery" with $n = 20$ (14.8%). In both "Sample Collection" and "Prescription," the most reported problem is "Wrong Patient" with $n = 40$ and $n = 23$, respectively. Consequently, this is also the problem with the highest frequency, $n = 68$ (50%). "Delay in Administration" is the second most reported issue with $n = 21$ (15.4%), followed by "Incorrect Storage" with $n = 10$ (9.6%).

Regarding the patient harm caused during the 3 years in each phase of the process (Table 6), $n = 130$ (95.7%) of incidents did not result in any harm, $n = 4$ (2.9%) involved minor harm, and $n = 2$ (1.7%) involved moderate harm, with no records of severe harm. In cases of minor and moderate harm, patients require medical observation, minor treatment, follow-up, and guidance. The phases "Prescription" and "Sample Collection" had the most "near miss" incidents, but no recorded harm to patients in these two phases. In the "Delivery" and "Administration" phases, more incidents with no harm to the patient were observed, with $n = 14$ (10.3%) and $n = 17$ (12.5%), respectively. The "moderate harm" incidents occurred during the "Preparation/Dispensing" and "Administration" phases.

In Table 7, we can see that "Wrong Patient" accounts for $n = 68$, half of the reported incidents, but did not cause any harm to the patient. The second most recurrent issue is "Delay in Administration," with $n = 21$ (15.4%) of reports, which caused more harm to patients, including 2 cases of minor harm and 1 case of moderate harm. "Wrong Patient" and "Delay in Administration" were the most reported problems, with the latter being the cause of only moderate harm to the patient.

Discussion

Today, information technology in healthcare is an essential element in patient-centered care and patient safety. In this study, the transfusion safety technology consisted of barcode reading software, which has been in operation at this hospital center since 2018, across all hospitals.

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Table 5. Relative distribution of problem types at each phase of the transfusion circuit process

Type of problem	Process phase										Total, *n* (%)
	prescription	sample collection	supply/ request	pretransfusion tests	preparation/ dispensing	storage	delivery	presentation/ packaging	monitoring	administration	
Inability to perform electronic validation	1	1	0	1	0	0	0	0	1	2	6 (4.4)
Delay in administration	1	0	4	1	2	0	10	1	0	2	21 (15.4)
Wrong patient	23	40	1	2	1	0	0	0	0	1	68 (50.0)
Label/administration instruction	0	1	0	0	0	0	0	0	0	0	1 (0.7)
Improper storage	0	0	1	0	0	4	2	0	0	3	10 (7.4)
Not performed	0	0	3	1	0	1	7	0	0	1	13 (9.6)
Omitted dose/ blood product	0	0	0	0	1	0	1	0	0	0	2 (1.5)
Incorrect blood/ blood product	0	0	0	0	2	0	0	0	0	0	2 (21.5)
Presentation/ packaging	0	0	0	0	0	0	0	0	0	0	0 (0.0)
Extravasation/ infiltration	0	0	0	0	0	0	0	0	0	1	1 (0.7)
Unit puncture/ breakage	0	0	0	0	0	0	0	0	0	6	6 (4.4)
Incorrect quantity	0	0	0	0	1	0	0	0	0	1	2 (1.5)
Adverse reaction	0	0	0	0	0	0	0	0	0	4	4 (2.9)
Total, *n* (%)	25 (18.38)	42 (30.9)	9 (6.6)	5 (3.7)	7 (5.1)	5 (3.7)	20 (14.7)	1 (0.7)	1 (0.7)	21 (15.4)	136 (100)

Table 6. Relative distribution of types of harm to the patient at each phase of the transfusion circuit process

Process phase	Type of harm to the patient						Total, *n* (%)
	reportable occurrence, *n* (%)	near miss, *n* (%)	no harm, *n* (%)	minor harm, *n* (%)	moderate harm, *n* (%)	severe harm, *n* (%)	
Prescription	0 (0.0)	25 (18.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0)	25 (18.4)
Sample collection	0 (0.0)	41 (30.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0)	42 (30.9)
Supply/request	3 (2.2)	1 (0.7)	5 (3.7)	0 (0.0)	0 (0.0)	0 (0)	9 (6.6)
Pretransfusion tests	0 (0.0)	2 (1.5)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0)	5 (3.7)
Preparation/dispensing	0 (0.0)	1 (0.7)	5 (3.7)	0 (0.0)	1 (0.7)	0 (0)	7 (5.1)
Storage	1 (0.7)	0 (0.0)	4 (2.9)	0 (0.0)	0 (0.0)	0 (0)	5 (3.7)
Delivery	5 (3.7)	0 (0.0)	14 (10.3)	1 (0.7)	0 (0.0)	0 (0)	20 (14.7)
Presentation/packaging	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0)	1 (0.7)
Monitoring	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0)	1 (0.7)
Administration	1 (0.7)	0 (0.0)	17 (12.5)	2 (1.5)	1 (0.7)	0 (0)	21 (15.4)
Total	10 (7.4)	70 (51.5)	50 (36.8)	4 (2.9)	2 (1.5)	0 (0)	136 (100.0)

For the first objective of the study, mapping the transfusion circuit as detailed in the diagram clarifies both the human and technological components involved. The human component still plays a role in several phases, such as prescribing components, confirming patient identity, manually recording patient identity on the bracelet and requisition, manually entering vital signs, validating between the sample and requisition, and manually entering various information systems. Therefore, it can be said that it is a mixed system with a high tendency for human error.

Studies identify four main causes of medical error: inadequate communication – failures in communication between healthcare professionals or between professionals and patients; medication errors – incorrect prescriptions, wrong dosages, or failures in medication administration; incorrect diagnoses – delays or errors in diagnosing medical conditions; and fatigue and work overload – long working hours and inadequate rest for healthcare professionals [8, 24, 25].

These studies support the current analysis of incident reports, which shows that the "Prescription" phase is the second most reported incident, accounting for about 18% of incidents. Additionally, the "Administration" of blood components accounts for 15% of incidents, and delays or issues in "Delivery" also represent 15% of incidents. The "Administration" and "Delivery" phases have the highest number of incidents with "no harm" to the patient. However, it was in the "Administration" phase that 2 cases of "moderate harm" to patients were reported.

In analyzing the incident reporting database related to "Blood and Blood Derivatives" provided to the authors, it was found that each incident report is classified for the type of harm caused to the patient twice: first by the healthcare professional and then by the risk manager of the patient safety office. The risk manager classifies the incident based on a comprehensive assessment according to WHO guidelines [8]. This study relies solely on the risk manager's classification. Over these 3 years, the risk manager identified 6 incidents with harm (4.4%), including 4 minor and 2 moderates.

In the analysis of the sample from the incident reporting platform, it is observed that the "near miss" is the type with the most representation in the years 2021 and 2022, with a 10% increase between them. This may indicate that errors were being prevented from passing through safety barriers to avoid failure. However, between 2022 and 2023, there is a decrease of approximately 19.4% in "near miss" notifications, although the absolute number of reported "near miss" incidents in 2023 is higher than in the previous year (increase from $n = 26$ to $n = 32$). This translates to about 96% of incidents not causing harm to patients. This means that errors are being detected before reaching the patient, indicating that risk prevention and detection mechanisms are being activated

Table 7. Relative distribution of types of patient harm at each phase of the transfusion circuit process

Type of problem	Type of harm to the patient						Total, *n* (%)
	reportable occurrence, *n* (%)	near miss, *n* (%)	no harm, *n* (%)	minor harm, *n* (%)	moderate harm, *n* (%)	severe harm, *n* (%)	
Inability to perform electronic validation	1 (0.7)	2 (1.5)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0)	6 (4.4)
Delay in administration	1 (0.7)	1 (0.7)	16 (11.8)	2 (1.5)	1 (0.7)	0 (0)	21 (15.4)
Wrong patient	0 (0.0)	66 (48.5)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0)	68 (50.0)
Label/administration instruction	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0)	1 (0.7)
Improper storage	3 (2.2)	0 (0.0)	7 (5.1)	0 (0.0)	0 (0.0)	0 (0)	10 (7.4)
Not performed	5 (3.7)	0 (0.0)	8 (5.9)	0 (0.0)	0 (0.0)	0 (0)	13 (9.6)
Omitted dose/blood product	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0)	2 (1.5)
Incorrect blood/blood product	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0)	2 (1.5)
Presentation/packaging	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0)	0 (0.0)
Extravasation/infiltration	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0)	1 (0.7)
Unit puncture/breakage	0 (0.0)	0 (0.0)	6 (4.4)	0 (0.0)	0 (0.0)	0 (0)	6 (4.4)
Incorrect quantity	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.7)	0 (0.0)	0 (0)	2 (1.5)
Adverse reaction	0 (0.0)	0 (0.0)	2 (1.5)	1 (0.7)	1 (0.7)	0 (0)	4 (2.9)
Total	10 (7.4)	70 (51.5)	50 (36.8)	4 (2.9)	2 (1.5)	0 (0)	136 (100)

in a timely manner, suggesting that the use of this ETSS yields positive results. This aligns with the WHO's 2030 goal to "Improve Patient Identification and Communication" and suggests the adoption of new digital technologies [9].

To address the 3rd objective of the study, in the Focus Group meeting, experts identified one of the critical points of this system as patient identification at two moments: during prescription and sample collection. This finding is consistent with the database analysis, as the "Wrong Patient" incident is the most prevalent, accounting for about 50% ($n = 68$) of the 136 incidents, with higher values at the prescription and sample collection stages. Both stages involve paper and manual writing; thus, the experts emphasize the importance of electronic prescribing to reduce errors.

Some studies reveal that involving patients in their own identification during blood transfusions, when possible, is a fundamental practice to enhance patient safety, prevent errors, and strengthen the patient-clinician relationship. Additionally, it empowers patients, making them active participants in their care, which can lead to better clinical outcomes and greater patient satisfaction [26, 27].

A study published in the Journal of the American Medical Informatics Association showed that electronic prescribing reduces the relative risk of medication errors by 55% [28]. Another systematic review from the same journal emphasizes that the combination of electronic prescribing and Clinical Decision Support Systems has a significant impact on reducing error rates, particularly in hospital settings, also related to medication [29]. This is like the case of blood component prescribing. As noted in the Focus Group, experts considered electronic prescribing an improvement in the ETSS, as it is an important tool for reducing errors in patient identification, since "Prescribing" is one of the processes with the most reported incidents in the hospital center's platform.

Data from SHOT in the UK, between 1996 and 2008, revealed that about 40% of incident cases were related to transfusions of incorrect blood components [30].

Conversely, in this study, the problem type "Incorrect Blood/Blood Derivative" accounts for only 3% of reported incidents, suggesting a positive impact of new technologies in the healthcare field. However, it is important to note that this study from the UK is several years old, and the information might be different now, reflecting improvements in results due to advancements in IT.

Another critical point identified by experts in the ETSS was relabeling, which requires multiple labels for unit and patient identification. In this regard, the use of RFID systems could address this issue. RFID tags placed on blood bags and associated with patient data enable real-time traceability and automatic compatibility checks before transfusion. These devices help reduce identification errors and improve blood traceability, ensuring that each unit can be tracked. RFID systems also integrate with hospital information systems and lead to greater operational efficiency in hospitals [31].

The WHO advocates for a clear policy and a positive organizational culture of incident reporting without blame or retaliation. It is essential to create an atmosphere that encourages values, and praises professionals for reporting their errors [13]. Only by understanding system failures and the harm caused to patients can improvements in service quality be made. This may be reflected in the hospital center, where there has been a noticeable increase in notifications, especially in the last 2 years, 2022 and 2023.

In this study, a significant discrepancy in notifications was observed between professional classes. The DTTs were the most frequent reporters, yet it was during the "Prescription" and "Sample Collection" stages, functions performed by doctors and nurses, respectively, that the highest number of incident reports was recorded. The ETSS diagram also shows that nurses interact most with patients, thus having more stages of patient identity confirmation, which corresponds to the incidents classified as "wrong patient." This suggests that there may be an issue with underreporting incidents, as some studies indicate that only 7–15% of adverse events are reported [32].

As described by experts, DTTs are involved in the transfusion circuit work in the Laboratory Department, where they must make several manual entries into various information systems. Therefore, it would be beneficial to have Integrated Laboratory Information Systems, allowing for more automated management of compatibility tests, reservations, and unit tracking, ensuring better communication between different hospital services and real-time data sharing.

Some authors argue that technological innovation should not be limited to "closing the loop" [33], as connectivity among various information systems in departments should ensure the quality of medical care. Access to updated and comprehensive information translates into more effective clinical decision-making. As specialists mentioned in the Focus Group meeting, interoperability between systems and connectivity between information systems and vital signs monitoring systems are crucial.

The Focus Group experts listed several improvements for the ETSS that could be addressed with today's cutting-edge technology. They suggested the following solutions:

- Electronic Patient Identity Verification – Utilizing biometric technology (fingerprint, facial recognition) to ensure accurate patient identification [34].
- Real-time alert and monitoring protocols – Systems that monitor patients' vital signs in real-time and generate automatic alerts in case of anomalies or adverse reactions, allowing for immediate clinical response [35].
- Mobile applications for transfusion safety – Mobile apps designed for clinicians to verify blood compatibility and monitor transfusions, facilitating quicker access to information [36].
- Artificial intelligence and data analysis: The use of AI algorithms to analyze a compilation of data, enabling predictive risk analysis and personalizing clinical decisions based on the patient's medical history [37].

These advanced systems are progressively being integrated into hospital settings, reducing the need for human intervention and making the transfusion circuit safer, more efficient, and less susceptible to human error. Proactive risk management involves understanding errors and controlling risk by establishing priorities and focusing on innovation. It anticipates potential issues conceptually, identifying the causes of risk. This contrasts with reactive models where responses occur after problems arise, compromising outcomes [38].

Regarding the health technology industry, it is responsible for advancing implementation and optimization. However, the involvement of healthcare providers in innovation and sharing success is crucial to facilitate peer-to-peer learning among hospitals [33]. For this ETSS, it is important to transition some manual steps to fully technological ones, as highlighted by professionals in the Focus Group. Continuous training and training for the professionals involved are also needed.

There were limitations to the study, such as information bias and retrospective bias commonly found in such research. The registration form does not have a

parameter distinguishing whether the incident was caused by human or technological failure. Another limitation is related to the qualitative methodology used, specifically the Focus Group technique, which provides an exploratory and in-depth view of the topic but may introduce moderation bias and social desirability bias, meaning that results cannot be generalized [23].

The use of a transfusion safety system is undoubtedly valuable in preventing incidents involving patients. In this hospital, over 3 years, there were only 6 incidents with patient harm and no recorded deaths. In the last year, 2023, there was a decrease in the proportion of "near misses" and an increase in "no harm" incidents.

It would be interesting to analyze the transfusion safety system diagram and address the critical points identified by Focus Group experts, such as patient identification, relabeling of barcodes, and blood unit transportation. Additionally, implementing new measures suggested by experts, such as electronic prescriptions, could help create new strategies for patient safety barriers. In the future, the introduction of various technologies will likely reduce error rates in the transfusion circuit and promote a safer and more efficient environment for patient care.

This study highlights the importance of continuous improvement in these systems through software upgrades and the involvement of all stakeholders. Continuous investment in technological innovations and ongoing training for medical teams can significantly transform blood transfusion practices and, consequently, the quality and efficiency of patient care. As technologies evolve, it is crucial for institutions to integrate innovations into their clinical protocols, thereby enhancing patient safety and trust in healthcare services.

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Statement of Ethics

This study was approved by the Ethics Committee of a Hospital Center in the Greater Lisbon area with No. 570.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Author Contributions

M.H., T.M., and S.R.: conception of the idea and methodology; M.H.: formal analysis, investigation, writing and preparation of the manuscript, and editing. T.M. and S.R.: manuscript review. All authors read and approved the final version of the manuscript.

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