A Structured Approach to Analyse Logistics Risks in the Blood Transfusion Process

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Blood transfusion is a critical healthcare process due to the nature of the products handled and the complexity driven by the strong interdependence among the sub-processes involved. Most of the errors causing adverse events originate during the blood logistics activities. Several literature contributions apply risk management to the transfusion process but often in a fragmented and reactive way. Moreover, few of them focus on logistics risks and assess the effectiveness of risk responses through operational key performance indicators (KPIs). The present paper applies a comprehensive and structured approach to proactively identify and analyse logistics risks as well as define responses to improve blood bag traceability, focusing on hospital wards. The implementation of such actions is monitored by specific KPIs whose measurement enables an improved communication flow among actors allowing to uncover residual risks. Future research will extend the application to further blood transfusion settings and supply chain echelons. The outcomes of this work might assist practitioners in improving policy making about blood supply chains. As a matter of fact, they allow a better understanding of the associated material and informational flows and the related risks, which supports setting effective strategies to either prevent adverse events or mitigate their effects.

Keywords: blood transfusion; logistics risk analysis; Failure Mode and Effects Criticality Analysis; key performance indicators

1. Introduction

Healthcare systems are characterized by increasing complexity and consequently they are vulnerable to risks and errors that can easily propagate in an unpredictable way, thus compromising patient safety.[1]

Blood transfusion is an excellent example of complex healthcare process[2,3] being constituted by a set of interdependent sub-processes involving different professionals where any error happening at any stage may cause serious consequences on the downstream phases and ultimately on patients.[4,5] The most common errors encompass patient misidentification, incorrect sample collection and labelling, incomplete or incorrect data entry, prescription and transcription errors, laboratory errors, inappropriate management of storage devices, inappropriate order of blood products, inaccurate handling, delivery, and administration. [6,7] Such errors are caused by a variety of factors, including local environment, policies and guidelines, staffing, poor communication, equipment problems, and human behaviour. [6] The last one, which is a topical issue in the debate about safety, indeed poses the greatest risk in blood transfusion.[8] Blood transfusion errors, and especially those associated with patient identification and administration, in turn bring huge expenses to healthcare systems.[9]

Therefore, the identification and prevention of adverse events are key points to improve blood transfusion safety and in recent years several initiatives (e.g. hemovigilance) have been undertaken[10], many of them concentrating on the quality of blood units. In this context, supply chain efficiency is still a field that deserves further investigation. [7,11] In particular, since transfusion errors are connected not only to blood production but more frequently to blood supply [12], it becomes crucial to deal with the material flows in the transfusion process. As a matter of fact, the high severity errors causing adverse events frequently have their root causes in blood handling and storage

activities. Moreover, logistics is in general recognized to be a central back-end for efficient and effective provision of any healthcare service.[13] Although risk management is regarded as a critical component in the transfusion service [14], a limited number of literature contributions systematically identify and analyse logistics risks. Most of them study errors and apply risk management tools in a reactive way (e.g.[7]), while few works adopt a proactive approach and take a step further by proposing key performance indicators (KPIs) to monitor the effects of risk response strategies overtime. However, proactive risk management, integrated with setting performance standards in the main areas of the transfusion process, is a viable way of tackling the associated problems.[6]

In order to contribute to fill this research gap the present work applies a risk management methodology developed and tested in both the healthcare and the manufacturing sectors[15,16] to provide a structured approach to proactively identify and analyse logistics risks in blood transfusion. Specific KPIs are measured as well as response actions proposed. The focus is on hospital wards because they are highly subjected to adverse events originated by how blood units are managed by both ward themselves and the upstream supply chain echelons. As a matter of fact, most of the errors occur outside the blood bank, in the blood points of use.[17] Additionally, ward activities directly impact on patients, hence the great relevance of reducing the associated risks. This work is part of the IDentifying Adverse Events "IDEA" project sponsored by the Italian Ministry for Education, University, and Research and developed for a couple of years in some Italian hospitals.

The remainder of the paper is organised as follows. Section 2 frames the contribution in the pertinent literature, while Section 3 introduces the reference risk management methodology. Section 4 develops the proposed application to a blood

transfusion process. Finally, in Section 5 benefits, limitations, implications are discussed, and future research directions are proposed as well as conclusions conveyed.

2. Risk Management in Blood Supply Chains

Blood supply chains can be defined as the flows of materials and information involving donors, collecting centres, blood banks, hospitals, and patients. They are composed of a number of echelons, namely blood procurement, processing, storage, distribution, and management by hospital wards.[18] Since this work concentrates on the last stage, where transfusions to patients are carried out, Table 1 summarises the main phases of the portion of the blood supply chain taking place within wards [6], together with the relevant errors and adverse events debated by literature and the contributions discussing ways to address risks.

Table 1. Studies about errors and risks within wards in the blood supply chain

There are a number of contributions that list and describe the main errors in blood transfusion, usually starting from the analysis of case studies about transfusion centres and hospitals. Furthermore, several risk management techniques widely used in manufacturing industries, such as Failure Mode and Effects Analysis (FMEA), Failure Mode and Effects Criticality Analysis (FMECA), Decision Tree Analysis, Human Reliability Assessment, and Predictive Human Error Analysis[19], have started being applied to the blood supply chain. FMEA is one of the most implemented tools in this arena because it provides a more detailed analysis than other risk management techniques[6], since it looks at the entire risk escalation process, from causes of risks as far as their effects and possible response actions. Some authors[6] encourage the use of FMEA not only to study risks and define countermeasures but also after their implementation

with the aim of checking the achieved improvements. Among the available contributions, Borelli and others[20] analyse by means of the FMECA approach the inefficiencies of a hospital blood transfusion centre and how RFID-based process reengineering might overcome them. Key risk performance indicators, such as the average, the peak, and the maximum value of risk priority indexes (RPIs), are calculated for each failure mode. Corrective actions, including a labelling system, are then proposed. Finally, Lu and others[6] adopt FMEA and classify blood supply chain risks in hospital wards according to their type and RPI value. After preventive measures are defined and put in action, FMEA is again used to evaluate the consequent RPI reductions.

Among recent contributions, Boonyanusith and Jittamai[21] propose a risk management framework addressing the entire blood supply chain from collection to transfusion. In particular, they develop and test with a case study a proactive risk management framework articulated in two steps. The first one is aimed to assign priorities to risk agents by paying particular attention to those characterised by high probability of occurrence and able to cause high severity events. The second step is instead devoted to analyse risk management actions for each agent. Other authors include risk management analyses in studies about the blood supply chain structure. For instance, Hosseini-Motlagh and others[22], in their model focused on inventory allocation and supply chain cost reduction, look at the risk associated with blood type substitution during the transfusion phase.

The performed literature analysis reveals a certain interest in studying errors and adverse events happening in the ward blood supply chain up to bedside transfusion, together with the factors determining their manifestation, and relevance is given to sample collection and blood bag handling and storage. However, safety in the transfusion supply chain is scarcely considered.[23] In particular risk management frameworks are still few,

they often do not consider all the ward blood supply chain phases, especially those related to blood bag storage and picking, and a system-based perspective is needed.[7] Very often a single risk management technique is applied to blood transfusion, namely FMEA, without integrating it with other techniques according to the undertaken phase of the risk management process. Furthermore, a reactive attitude to risk is quite diffused when tackling blood transfusion. As a matter of fact, most of the studies about errors and adverse events in Table 1 are based on past occurrences and just some of the discussed risk management contributions take a proactive perspective.[6,21] The reviewed works often limit the risk management process to the response identification and implementation phases, without assessing the performance of such actions and the new risks that might arise as a consequence of them. However, as highlighted by some authors, there is a growing need for addressing the performances related to safety and quality in the blood supply chain.[24] Contributions proposing indicators do exist but the KPIs they suggest are purely risk-oriented, typically computed based on risk priority numbers, and do not address the basic operational constraints on blood transfusion material flows, such as temperature and time.[25]

The present paper applies a risk management methodology already implemented in heterogeneous logistics environments to a new context, namely the blood transfusion process. The purpose is twofold. On the one hand, the proposed approach proactively identifies and analyses possible sources of logistics risks, together with their potential effects, as well as formulates risk responses. On the other hand, it suggests operational KPIs to monitor improvement actions and to prevent the emergence of new risks. A structured and systemic view is ensured by addressing the whole risk escalation process, from risk sources as far as the effects of risk response initiatives. Also, FMEA is

combined with a number of different techniques based on the process phase that is addressed.

3. Basics of the Risk Management Methodology

This work relies on a risk management methodology developed by Cagliano, Grimaldi, and Rafele[16] and Cagliano, De Marco, Grimaldi, and Rafele[15] as a systematic way of analysing and managing logistics and supply chain risks in both healthcare and manufacturing environments. In particular, Cagliano, Grimaldi, and Rafele [16] identify four stages to deal with logistics risks in healthcare supply chains, namely Context Analysis, Process Mapping, Risk Identification and Assessment, and Failure Modes and Waste Analysis. Such a method has been considered by other authors in later healthcare studies about for instance managing waste[26] and proactively identifying and assessing risks in national health systems.[27] This framework is able to foster effective decision making about reducing failure and waste but only through a qualitative analysis limited to a single process echelon. Thus, in order to overcome these limitations, the approach has been extended by Cagliano, De Marco, Grimaldi, and Rafele[15] by adopting a quantitative perspective supported by the use of KPIs. In fact, the risk analysis phase of their approach, consequent to risk identification, integrates performance indicators able to quantitatively capture any variation in process efficiency and effectiveness. KPIs assess the effects of risk occurrence on activities and are defined based on the nature of the risky events at issue. They are then measured and compared against their target values. Moreover, the investigation of the cause and effect relationships among KPIs allows understanding how the risk occurrence impacts spread throughout an entire supply chain. This enhanced risk management methodology, which has been leveraged in several authors' works (e.g.[28,29]), will be here applied to the logistics process underpinning blood

transfusion in a hospital ward. In particular, the phases of the method previously mentioned will be implemented according to the following three steps:

(1) Analysis of the transfusion process.
(2) Analysis of the criticalities of the transfusion process and definition of risk responses.
(3) Identification of KPIs to monitor the efficiency and effectiveness of the process.

Some of them are furtherly deployed into a number of sub-steps as detailed in Section 4.

4. Application of the Risk Management Methodology

The risk management methodology introduced in Section 3 has been applied to a three-stage blood supply chain operating in Northern Italy. A blood bank collects blood and the associated components from donors, then processes, stocks, and distributes them in order to satisfy the demand of a number of customers, being them the wards of the parent hospital, other hospitals or transfusion centres. On average 60,000 red blood cell bags, 7,000 platelet bags, and 4,000 litres of plasma are produced every year. Out of them, about 37,000 red blood cell bags, 6,500 platelet bags, and 3,000 litres of plasma are transfused in the same time span. Such volumes make the blood supply chain at issue a meaningful context for the application of a risk management methodology.

Being the transfusion activities quite similar in any ward, a representative department in the same hospital where the blood bank is located has been selected based on the availability of information on criticalities. This is the Department of Oncological Surgery.

4.1. Analysis of the transfusion process

The approach starts with analysing the current logistics flows supporting the transfusion process and identifying the risks that might occur.

4.1.1 Context Analysis and Process Mapping

As the first phase of context analysis, a project team is formed including the authors, the head physician and the head nurse of the ward under investigation, the head of the blood bank, and other blood transfusion actors. The team reviews blood procurement, handling, and administration activities by the ward with the aim of identifying where risks might manifest themselves and their past occurrences. This job is complemented by reviewing working procedure documents, performing field observations as well as analysing the findings of semi-structured interviews involving the main process actors. In such a way a knowledge basis is formed allowing to develop process mapping.

Due to the field analysis carried out during the project, the case transfusion process is decomposed into seven phases. In order to deeply analyse these phases, each of them is in turn broken down into a number of elementary activities that are organized in an Activity Breakdown Structure (ABS) (Appendix A). The detailed tasks are about both the operations involving material flows and the related information exchange. This is extremely important because many risky events in the blood transfusion process are due to scarce information and communication, often caused by the limited integration among the information systems used by different supply chain echelons.

Process sheets are developed in order to track additional information for each ABS lowest level activity, such as inputs and outputs, supporting hardware and software resources, necessary controls, and processed information. A careful analysis of such process sheets supports the identification of the main criticalities affecting each activity.

A modified version of the process sheets suggested by Cagliano, Grimaldi, and Rafele [16] is used according to the available information.

4.1.2 Risk Identification

After getting a deep understanding of the activities underlying logistics flows, the next step is identifying the related risk sources. Based on the previous context analysis and process mapping phases the project team, together with a panel of personnel carrying out operational activities, defines specific risk sources as well as classifies them in a Risk Breakdown Structure (RBS).[31] The RBS provides a hierarchic and systemic representation of the causes of criticalities according to different levels. The RBS template proposed by Cagliano, Grimaldi, and Rafele [16] is partially modified to take into consideration the peculiarities of the process at issue. Risk sources are first divided into internal and external ones depending on whether the ward is able to control them or not. Internal sources are furtherly decomposed into Organization, Structure, Technology, Communication, and Blood Supply categories. This last risk type is classified as external by Cagliano, Grimaldi, and Rafele[16] but it is here considered as internal because the activities connected with the supply and processing of blood components are directly managed by the hospital wards and the blood bank and not by external entities. The internal risk classes are in turn decomposed according to the above mentioned RBS template although same minor adjustments are made. In the Blood Supply category particular relevance is given to product quality being it sensitive to time and temperature variations during supply. Quality is here considered as an internal risk source because it can be monitored by the case ward being blood components processed in the same hospital.

The external risk sources deal with regulatory and environmental issues. The first sub-class is added to the reference RBS to stress the role played by regulation as a constraint contributing to determine the degree of uncertainty in the blood transfusion process.

Appendix B shows an excerpt from the RBS for the blood transfusion process at issue: a total of 48 risk sources are defined.

The defined risk sources are associated with those activities they might affect through the Risk Breakdown Matrix (RBM).[32] Table 2 provides an excerpt from the developed RBM. As an example, the rows report some activities belonging to the phases "1. Completing the Request for Blood Bags and Pre-Transfusion Tests" and "4. Transfusion Setup", while the columns display the risk sources included in the "Human Resources" sub-class.

The complete RBM, which is available from the authors, shows that the risk sources impacting on the largest number of activities are those about human resources (e.g. RBS 1.10 Controls, RBS 1.12 Personal Characteristics) and communication (e.g. RBS 4.2 Traceability). Conversely, the activities mostly affected by risk are part of the process phases named "1. Completing the Request for Blood Bags and Pre-Transfusion Tests", "2. Collecting Blood Bags from the Blood Bank", and "3. Managing Blood Bags by the Ward".

These outcomes witness the high influence of human factors and communication reliability on the performance not only of the clinical part of blood transfusion but also of its supporting processes. Moreover, they confirm literature findings[7] that uncertainty often manifests itself in blood handling activities.

Table 2. Excerpt from the RBM for the blood transfusion process

4.2. Analysis of the Criticalities of the Transfusion Process and Definition of Risk Responses

Each RBM cell is completed with the criticalities that might occur as a consequence of the associated risk source impacting on the corresponding activity. Such criticalities contribute to originate risky events along the entire risk escalation process. Thus, based on interviews as well as the developed process sheets and RBM, the criticalities for the process at issue are defined and classified into Failure Modes (FMs), which are directly experienced by transfused patients, and types of Waste (Ws), which are non-value added time periods and unnecessary resources that however do not affect patients (Table 2). In total eight FMs and five Ws are found. The complete list of FMs and Ws is available from the authors. A single FM or W may appear in multiple RBM cells because it may be generated by more than one risk source and may affect different activities.

With the aim of analysing causes, effects, probability of occurrence, and impacts of each criticality, FMECA is applied. Following the pieces of information provided by the FMECA table for each criticality[6]: the process phase, the activity code, the risk source, the criticality, the probability of occurrence, the impact, the detectability, the effects, and the risk responses. In particular,

- *Probability of occurrence*: the probability levels are defined based on the experience of the blood transfusion process actors involved as:
  - Low: probability of occurrence < 0.5%
  - Medium: 0.5% ≤ probability of occurrence ≤ 5%
  - High: probability of occurrence > 5%
- *Impact*: the organizational impacts address the waste of time and resources while executing activities. The clinical impacts measure how risky events affect

patients. Both the organizational and the clinical impacts are assessed by means of a three-item qualitative scale (low, medium, high) defined together with process actors.

- *Detectability*: a three-item qualitative scale is again used. The associated numerical thresholds are defined by the actors involved in the analysed transfusion process:
  - Low: detection probability < 95%
  - Medium: 95% ≤ detection probability ≤ 99%
  - High: detection probability > 99%
- *Effects*: they are associated with FMs. A X sign means that a FM brings effects limited to one activity, while the logical operator AND states that a FM, together with other FMs, might ultimately have a clinical effect on patients.
- *Risk Responses:* interventions can be of different nature, such as technological, like the automation of key processes, or related to staff, like the feedback on performance or the use of standardized practices.[33]

Table 3 shows an excerpt from the FMECA table developed for the studied blood transfusion process together with examples of the key risk responses defined.

As already mentioned, two main parameters need to be controlled in order to deal with material flow risks, namely the time and the temperature at which blood bags are kept during the entire process. Time is a critical issue because transfusion operations have to be performed within a specific time frame since some blood components are subjected to quarantine periods to ensure they are not affected by viruses and deteriorate very quickly. The latter issue also requires an appropriate blood bag temperature.[34,35] For such reasons, risk responses are often aimed at introducing technologies, such as RFID, enabling to track blood units and quickly and easily monitor time and temperature during

their transportation and storage.[36] Moreover, in order to improve information flows, these solutions may be coupled with a shared information management system enabling real time communication between blood banks and wards.

The proposed risk responses have been assessed by the ward and blood bank personnel. It has been estimated that the RFID tracking system, together with a standard information management system, would allow saving a significant amount of time in transfusion activities because they could be managed in a more correct and efficient way. Additionally, the shared information management system has been considered as a fundamental step towards an effective implementation of the RFID technology supporting the blood supply chain. In such a context, particular attention should be given to a reliable patient identification and data acquisition about the blood unit status.

Table 3. Excerpt from the FMECA table for the blood transfusion process – part 1

Table 3. Excerpt from the FMECA table for the blood transfusion process – part 2

4.3. Monitoring Process Key Performance Indicators

In the present step of the application a set of KPIs is proposed to detect the risky events that might take place after the implementation of risk responses (Table 4). However, such KPIs can support the identification of risky event occurrence also before the application of intervention actions.[37] This is possible because risk manifestation changes the process performance and so the values of the associated indicators. In such a way the ability of risk responses to reduce the existing risks and the possible new risks that might originate from such responses can also be assessed.

4.3.1 Defining Key Performance Indicators

The metrics defined in Table 4 are based on literature and the experience of the actors involved; particular importance is given to time and temperature indicators. It is worth mentioning that I_{11}, I_{12}, I_{14}, and I_{15} are the only KPIs already monitored in the AS IS process, since data availability in the analysed ward is very limited, being information mainly exchanged either just verbally or via many different paper forms.

Table 4. Suggested KPIs for the transfusion process

With the aim of linking performance measurement with risk analysis, each KPI is then related in the RBM to the FMs and Ws it is able to monitor[15]. This allows a clear and quick understanding on risk manifestation and on how effective the undertaken improvement measures are to either reduce or avoid the risky events associated with RBM cells. KPI association is performed firstly according to the nature of the process activity at issue and secondly based on the risk sources that might impact on that activity.

4.3.2 Preliminary Results of Key Performance Indicators Assessment

The risk responses introduced in the second step of the application of the risk management methodology underwent a six-month preliminary implementation test in the reference hospital ward, which gave the opportunity to understand the benefits from monitoring KPIs. Measuring KPIs made possible to generate information about the residual criticalities after risk response application. To be more precise, it allowed to uncover the main logistics threats by identifying the specific activities where they take place. In particular, the indicators that proved to be most useful were I_2, I_5, I_{13}, and I_{15}. For confidentiality reasons their numerical values cannot be disclosed.

The assessment of KPI I_{13} showed that problems with patient identification were experienced because of misunderstandings about codes, which were manually entered in the information system. In fact, at the beginning of the test period the staff offered a certain resistance to the new information management system, leading to errors and partial use of it. For instance, several times blood bag requests were still issued by means of paper forms, with potential mistakes in the downstream process phases. As a consequence, incomplete information about the events affecting blood bags during their lifecycle was produced, preventing from correctly calculating some KPIs.

Nevertheless, the indicators measured during the test demonstrated a good effectiveness of risk responses. The RFID technology enabled a reliable control on the blood bag integrity. In fact, KPIs I_2 and I_5 proved that the temperature of incoming blood bags was usually within the clinically acceptable range of values, regardless transportation duration.

KPI I_{15} reported a number of blood bags returned to the blood bank greater than the actual one. This was due to an incomplete integration of the information management system in the process. Units whose temperature does not meet requirements but still falls within a tolerance range are not returned but transfused. However, the associated information was not recorded by the new information system, thus compromising the ability to correctly calculate KPI I_{15} and ultimately traceability.

Overall, the developed risk responses enabled to make emerge and systematically collect a variety of information on logistics flows so that a significant larger number of KPIs could be measured than in the AS IS situation.

5. Discussion and Conclusions

Literature and practical evidence show that the root causes of most of the high severity errors producing adverse events in blood transfusion are grounded in logistics flows but scarce attention is given to this area and structured approaches are still scarce. The present work applies a formalized methodology for risk analysis to the blood transfusion process, in order to provide an organized way to identify and investigate logistics risks before they occur. A first key benefit is given by the proactive perspective the approach takes, which is advocated by literature as a means to optimize blood transfusion but it is still adopted by few authors.[6] Second, by relying on a comprehensive risk management methodology, the proposed approach allows to carry out a systemic study[7] that, thanks to the FMECA scheme, takes into account all the main risk sources together with the relationships among the related criticalities. A further advantage of the proposed approach is that it allows not only to identify risk responses but also to define KPIs to measure the actual operational improvements they bring, thus enabling to fully manage the changes introduced in the transfusion process. This characteristic contributes to fill the current gap about the assessment of risk response performance by taking into account the relevant parameters that should be controlled in blood management, namely time and temperature.[34,38] KPIs support decision-making in order to reduce waste, correctly manage blood bags, and ultimately better shape a healthcare process. Finally, being the steps of the approach quite general in scope, they enable its application to a variety of blood transfusion systems and to different blood supply chain echelons.

Both academic and practical implications can be identified for this work. From an academic point of view, it can foster proactive risk management in blood transfusion by addressing the ancillary processes underpinning the clinical one. In particular, it can help researchers to pay the required attention to blood product flows. In such a context, the

proposed approach may constitute a guideline to develop specific methodologies to prevent future adverse events based on the analysis of past errors. Furthermore, it stimulates research on the use of performance measurement in the transfusion process with the purpose of constantly monitoring risks and the effectiveness of responses to them. Finally, the application to blood transfusion constitutes a further validation and an extension of Cagliano, Grimaldi, and Rafele's[16] and Cagliano, De Marco, Grimaldi, and Rafele's[15] contributions.

The present work might be a reference for practitioners to better understand the material and informational flows involved in their blood transfusion processes and to cope with the related adverse events in a more efficient way. In particular, the steps of the risk management methodology enable its application at different levels of detail, from process analysis to the identification of risk sources and the investigation of the associated criticalities, depending on the risk maturity degree of a healthcare organization. Also, both qualitative and quantitative assessments of probability of occurrence, impact, and detectability of criticalities are possible. Moreover, being constituted by relatively simple process analysis and risk management techniques, the proposed approach helps healthcare institutions to become confident with risk management issues thus increasing their risk maturity. The proposal of specific KPIs assists in identifying the parameters needing attention and provides organizations with practical tools to monitor the effectiveness of actions to either prevent risks or mitigate their effects.

However, this work suffers from some limitations. First of all, the successful application of the risk management methodology requires a strong and constant support and a proactive vision by healthcare institutions. During the implementation discussed in the paper involving managers and staff right from the beginning was crucial in order to make them understand the benefits that can be achieved and thus gain their commitment

and collaboration. However, this situation might not exist especially when organizations are mostly focused on managing day-by-day operations. Second, the lack of past data, due to the scarce risk maturity of the reference blood transfusion context, did not allow to develop quantitative FMECA evaluations. Third, the application of risk response actions and the consequent KPI measurement were performed at a pilot level and as such they need a more extensive implementation. Finally, the methodology requires an extended validation in order to evaluate its effectiveness. Therefore, future research efforts will be directed towards deepening the evaluation of the performance of risk responses in the reference case, together with applying the risk management methodology to multiple and heterogeneous blood transfusion supply chains by also performing a risk quantification. In this way it will be possible to provide a complete assessment of the application of the proposed approach.

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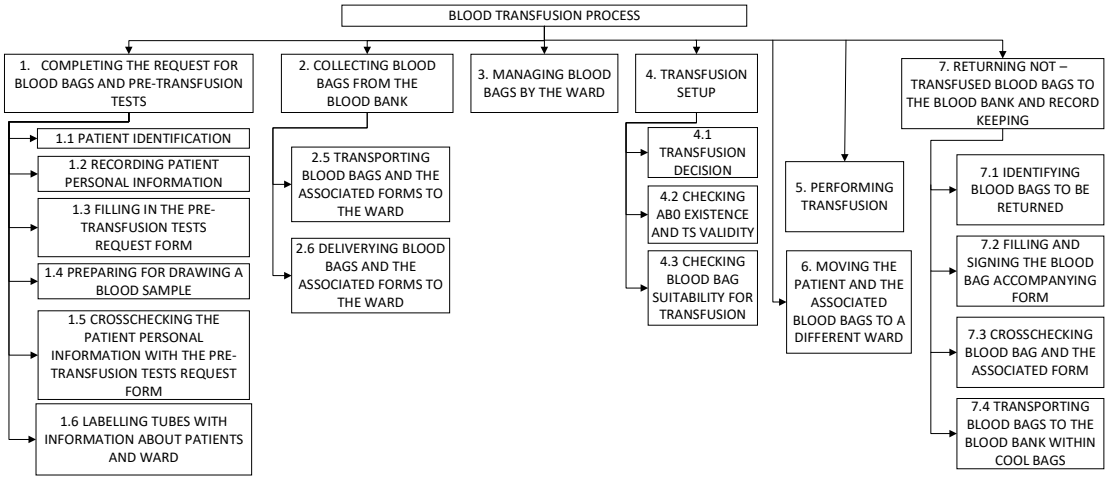
Appendix A – Excerpt from the Activity Breakdown Structure of the Transfusion Process



Appendix B – Excerpt from the Risk Breakdown Structure of the Transfusion Process

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	RBS CODE
RBS for the Blood Transfusion Process	Internal Risk Sources	1. Organization	Human Resources	Working Procedures Knowledge and Compliance	1.7
				Professional Training	1.8
				Availability of Personnel in Charge of Supervising Activities	1.9
				Controls	1.10
				Interpersonal and Group Dynamics and Consequent Level of Cooperation	1.11
				Personal Characteristics	1.12
				Know How	1.13
		2. Structure			
		3. Technology			
		4. Communication	Information Exchanges	Information Exchanges According to Procedures	4.1
				Traceability	4.2
				Feedbacks	4.3
			Communicating Variations and Decisions	Operational Decisions	4.4
				Changes in the Demand for Blood Components	4.5
		5. Blood Supply			
		6. Regulation	Compliance with Regional		6.1

	External Risk Sources		and National Laws		
		7. Environment	Social Issues		7.1
			Natural Events		7.2
			Epidemiological Events		7.3

Ward blood supply chain phases	**Errors and adverse events**	**Risk management literature contributions**
Sample collection and blood products orders	Wrong sample collection and tube labelling[7,38,39] Incorrect data entry[6,40] Blood ordering not compliant with requirements[7]	Boonyanusith and Jittamai [21] Lu and others[6]
Receiving and checking blood products	Blood products delivered to the wrong ward[6] Blood bags accepted despite not meeting the required quality criteria[7] Checks not performed on incoming blood products[6]	Boonyanusith and Jittamai [21] Lu and others[6]
Storing blood products	Inaccurate handling[7] Inappropriate management of storage devices[6]	Boonyanusith and Jittamai[21]
Picking blood products and checking their suitability for transfusion	Inaccurate handling[7]	

Performing blood transfusion	Patient misidentification [36,38] Wrong transfusion/adverse transfusion reactions[5,10]	Boonyanusith and Jittamai [21] Borelli and others[20] Hosseini-Motlagh and others[22] Lu and others[6]

Table 1. Studies about errors and risks within the wards in the blood supply chain

RBM for the Blood Transfusion Process								
Process Phase	**Activity Code**	**Internal Risk Sources**						
		1. Organization						
		Human Resources						
		RBS 1.7	RBS 1.8	RBS 1.9	RBS 1.10	RBS 1.11	RBS 1.12	RBS 1.13
1. Completing the Request for Blood Bags and Pre-Transfusion Tests	ABS 1.1	FM 2			FM 2		FM 2	FM 2
	ABS 1.2	FM 3, FM 4			FM 3, FM 4		FM 3, FM 4	FM 3, FM 4
	ABS 1.3	FM 3, FM 4			FM 3, FM 4		FM 3, FM 4	FM 3, FM 4
	ABS 1.4							
	ABS 1.5							
	ABS 1.6	FM 4, FM 5			FM 4, FM 5		FM 4, FM 5	FM 4, FM 5
4. Transfusion Setup	ABS 4.2	W 4			W 4		W 4	W 4

Table 2. Excerpt from the RBM for the blood transfusion process

PROCESS PHASE	ACTIVITY CODE	RISK SOURCE		CRITICALITY		PROBABILITY OF OCCURRENCE
		Category	RBS Code	Code	Description	
2. Collecting blood bags from the blood bank	ABS 2.5, ABS 2.6	Human Resources, Communication	RBS 1.7, RBS 1.10, RBS 1.11, RBS 1.12, RBS 1.13, RBS 4.1, RBS 4.2, RBS 4.5	FM 6	Errors in Blood Bags Pickup or Delivery	Low
7. Returning not – transfused blood bags to the blood bank and record keeping	ABS 7.4	Human Resources	RBS 1.7, RBS 1.10, RBS 1.12, RBS 1.13, RBS 4.2	W 5	Not Transfused Bags not Promptly Returned to the Blood Bank	High

Table 3. Excerpt from the FMECA table for the blood transfusion process – part 1

PROCESS PHASE	IMPACT		DETECTABILITY	EFFECTS		RISK RESPONSES
	Organizational	**Clinical**		**Limited to the activity**	**Impacting on patients**	
2. Collecting blood bags from the blood bank	High (if a wrong transfusion occurs as a consequence of the criticality and thus a compensation for the mistake is required) Low (if the criticality is promptly detected)	High (if the criticality is not detected it might cause serious consequences for transfused patients)	High	X	AND	Introducing controls in pickup and delivery activities by means of RFID tags placed on both blood bags and the cool bags carrying them during transportation. The information about blood bags is crosschecked with the associated requests.
7. Returning not – transfused blood bags to the blood	Medium (when the blood bag cannot be used anymore)		Low	X	-	Computerizing the blood transfusion process and having the blood bank and the hospital wards adopt the same information management system, so that they can share the information about how many and which blood bags have been used. Tracing blood

bank and record keeping						bags within the hospital by means of RFID tags

Table 3. Excerpt from the FMECA table for the blood transfusion process – part 2

PROCESS PHASE	KPI CODE	KPI DEFINITION	REFERENCES
1. Completing the request for blood bags and pre-transfusion tests	I_1	Number of incomplete requests/Total number of requests sent to the blood bank	Project team
2. Collecting blood bags from the blood bank	I_2	Number of discarded incoming blood bags/ Total number of incoming blood bags	Project team
	I_3	Number of incoming blood bags with temperature above range/ Total number of incoming blood bags	Davis, Geiger, Gutierrez, Heaser, and Veeramani [38]
	I_4	Number of incoming blood bags with temperature below range/ Total number of incoming blood bags	
	I_5	Number of incoming blood bags with high temperature profile/Total number of incoming blood bags	
	I_6	Number of blood bags with no temperature recorded/ Total number of incoming blood bags	Chiang and Huang [34]
3. Managing blood bags by the ward	I_7	Average blood bag storage time	Davis, Geiger, Gutierrez, Heaser, and Veeramani [38]
	I_8	Average time between blood bag picking and transfusion	

	I_9	Number of blood bags with outdated TS/ Total number of stocked blood bags	Project team
	I_{10}	Number of blood bags discarded because of inappropriate storage temperature/Total number of stocked blood bags	Davis, Geiger, Gutierrez, Heaser, and Veeramani [38]
4. Transfusion Setup 5. Performing transfusion	I_{11}	Number of transfused blood bags/Total number of requested blood bags	Project team
	I_{12}	Number of adverse reactions/Total number of transfused blood bags	Project team
	I_{13}	Number of blood bags not correctly associated with a patient/Total number of transfused blood bags	Project team
	I_{14}	Total number of transfusion feedbacks sent to the BB/ Total number of transfused blood bags	Project team
7. Returning not – transfused blood bags to the blood bank and record keeping	I_{15}	Number of returned blood bags/ Total number of delivered blood bags	Project team
	I_{16}	Average time from blood bag picking and return	Project team

Table 4. Suggested KPIs for the transfusion process