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Sustainable Futures 4 (2022) 100091

Contents lists available at ScienceDirect

Sustainable Futures

journal homepage: www.sciencedirect.com/journal/sustainable-futures

An enhanced framework for blood supply chain risk management

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ARTICLE INFO

Keywords:
Risk management
Sustainability
Blood Supply Chain (BSC)
Failure Mode and Effects Criticality Analysis (FMECA)
Fault Tree Analysis (FTA)

ABSTRACT

A blood supply chain (BSC) is a very long and complex sequence of processes heavily sequential. If one of them is executed in an incorrect way and this error is not detected, it leads to an incorrect transfusion outcome, that could seriously affect patients. For this reason, there is a strong need to identify and prevent adverse events along the entire BSC, in order to reduce their probability of occurrence. This also helps improving BSC sustainability from both the environmental and the social perspectives. The paper extends an existing healthcare supply chain risk management framework already applied to the blood transfusion process to address multiple BSC echelons and identify the cause and effect relationships among the adverse events that might occur. To this end, Fault Tree Analysis is added to the risk management tools part of the original framework as well as Key Performance Indicators are applied to detect risky event manifestation.

The first application of the proposed approach to a blood bank and a hospital ward revealed its effectiveness in identifying the BSC activities most subjected to risk. Also, connections between adverse events and causal relationships among their sources were found, leading to understanding whether an adverse event is caused by a risk source in the same echelon where it occurs or by the concurrent manifestation of several adverse events upstream in the BSC. Future research will be devoted to numerically evaluate probability of occurrence and impact of risky events as well as integrating the framework with a classification of criticalities based on their severity.

1. Introduction

A BSC is made up of a number of processes that extend from donors to patients whose purpose is collecting, testing, processing, distributing, and transfusing blood products. The peculiarity of the products and the extension of the processes make BCSs significantly complex. For instance, aspects like blood types, compatibilities, and short shelf lives contribute to increase their complexity level [1]. Therefore, BSCs are highly subjected to risks also because their activities are heavily sequential and even one single error in the operations chain may lead to an incorrect transfusion [2], as exemplified by the Event Tree in Fig. 1 where the most relevant macro-activities performed in blood banks and hospital Ws [3] are represented. Each of them can be executed either in a correct or in an incorrect way and the combination of their outcomes determines the final transfusion result. In principle, if errors are not detected the sequential nature of the process makes transfusions correct only when all the upstream activities are correct and the probability of a correct transfusion equals $(1/2)^n$, being n the number of tasks in a BSC. In fact, for each BSC task, the probability it is correctly performed is equal to 0.5, so the probability of a final correct transfusion is given by multiplying the probability of a correct outcome in each task. Since BSCs are quite long, such a probability would be in general low. Hence the necessity to identify and prevent adverse events taking place in the different SC echelons and to mitigate their effects [4] in order to maximize the probability of a successful transfusion. This reflects on sustainability, in particular on two perspectives of the Triple Bottom Line, namely the environmental and the social ones. The environmental refers to reducing the waste of blood, which is a limited resource, and of the materials involved in the transfusion process, as well as the associated energy consumption (e.g. for refrigerators). The social aspect is here intended as the impact of a positive transfusion outcome on patients' health.

Both researchers and practitioners have recently recognized the relevance of risks given the highly invasive nature of blood transfusion.

Abbreviation: ABS, activity breakdown structure; BB, blood bank; BSC, blood supply chain; FM, failure mode; FMEA, failure mode and effects analysis; FMECA, failure mode and effects criticality analysis; FTA, fault tree analysis; IDEA, "IDentifica Eventi Avversi" (IDentifying Adverse Events); KPI, key performance indicators; RBM, risk breakdown matrix; RBS, risk breakdown structure; SC, supply chain; W, ward.

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https://doi.org/10.1016/j.sftr.2022.100091
Received 11 May 2022; Received in revised form 14 July 2022; Accepted 28 July 2022
Available online 30 July 2022

DONATION: BLOOD DRAWING (@BLOOD BANK)	BLOOD LABELLING AND STORAGE (@BLOOD BANK)	FILLING IN REQUEST FORM AND BLOOD DRAWING FOR TS TEST (@WARDS)	DELIVERING/PICKING UP BLOOD BAGS	BLOOD BAG MANAGEMENT (@WARDS)	TRANSFUSION SET UP (@WARDS)	PERFORMING TRANSFUSION (@WARDS)	TRANSFUSION OUTCOME
CORRECT	**CORRECT**	CORRECT	CORRECT	CORRECT	CORRECT	CORRECT	CORRECT
						NOT CORRECT	NOT CORRECT
					NOT CORRECT	.....	NOT CORRECT
							.....
				NOT CORRECT	.....	.....	NOT CORRECT
			NOT CORRECT	.....			NOT CORRECT
		NOT CORRECT	CORRECT				NOT CORRECT
				.....			.....
			NOT CORRECT	CORRECT			NOT CORRECT
				NOT CORRECT	CORRECT		NOT CORRECT
					NOT CORRECT	**CORRECT**	**NOT CORRECT**
						NOT CORRECT	NOT CORRECT
	NOT CORRECT	CORRECT	.....	.....	.....	.....	NOT CORRECT
							.....
		NOT CORRECT					NOT CORRECT
NOT CORRECT	CORRECT	.....					NOT CORRECT
	NOT CORRECT						NOT CORRECT

Fig. 1. Example of risk propagation in the BSC.

To this end, they have undertaken several efforts to address them, such as the establishment of hemovigilance, transfusion reaction reporting, transfusion reaction audits as well as traceability systems based on radio frequency technology. Moreover, specific devices aimed to reduce human errors have been developed [5,6]. However, the influence of BSCs as a whole on transfusion safety has been poorly tackled so far, and in particular the risk associated with the logistics activities supporting blood transfusion has been often neglected although transfusion errors are frequently due to blood supply [7].

Literature about BSC organization is very rich [8–10] but still few contributions identify and analyse risks along the SC flow. Additionally, they usually reactively study adverse events happened in single echelons [11,1112], while overlooking the fact that criticalities are not stand alone but are connected to each other in causal chains spanning over the entire BSC [13]. Finally, single risk management techniques are usually applied while their integrated use would enable to simultaneously look at risks from different perspectives.

In order to contribute to bridge this research gap the present work extends a framework to analyse logistics risks in the BSC [14] by integrating the FTA as well as applying the approach to two interconnected BSC echelons, namely a BB and a hospital W. In such a way, cause and effect relationships among criticalities are identified and analysed to capture how adverse events may spread in the SC. The main aim is finding the root causes for criticalities affecting blood transfusion in order to achieve a more safe and sustainable process. The resulting framework benefits from the combined use of multiple risk management techniques to put forward a systemic risk management framework that investigates different BSC echelons, the associated adverse events, and the connections among them. Not only risks are proactively identified but KPIs to notice their manifestation are also suggested [15].

The remainder of the paper is organized as follows. First the literature background is provided, then the proposed risk management framework and its application are described in detail, and lastly benefits, limitations, implications, and future research directions are discussed.

2. Literature review

Since the present research addresses the field of BSC risk management, the following two literature streams are analysed: BSCs and the associated adverse events and approaches to deal with risks in such SCs.

2.1. BSCs and the associated adverse events

A significant number of literature contributions are available about the material and information flows connecting blood donors, collecting centres, BBs, hospitals, and patients [16,1].

Most of the works focus on single SC echelons. Starting from upstream, authors discussing blood collection are mainly concerned with donor behaviour, policies for blood sourcing [10,17] and capacity planning [18], as well as procurement in case of emergencies [19]. Research on production tackles topics related to the way of breaking down blood into its components, with particular attention to platelets, in both normal and emergency conditions [20,21]. Storing blood products, which is the most debated stage in the BSC because of its many stringent conditions [22], presents studies about inventory policies [8], minimization of total inventory costs [23], and reducing outdated stock [24]. Also in this case, platelets play a key role because of their much reduced shelf life [25].

After understanding BSC stages independently from one another, recently several authors have started exploring multiple echelons and the connections between them [9,26].

Adverse events may affect any of the SC stages mentioned above and seriously harm transfused patients [27]. For this reason, a significant number of contributions discuss such events and the risk they might occur, especially in the very last BSC echelon, namely the points of use, where risks due to human errors in the transfusion step have attracted particular attention in literature [28]. The transfusion errors commonly identified are incorrect data entry, prescription, transcription, inaccurate sample taking and labelling, patient misidentification, blood product ordering not complaint with the needs, inappropriate handling and storage, blood units accepted despite not meeting the quality requirements, and incorrect administration. Among them, inaccurate blood ordering, labelling, and handling are the primary responsible for compromising patient safety [2,6,7]. These findings suggest that errors and risks connected to the logistics process supporting blood transfusion play a significant role. Although the great attention to the downstream part of the transfusion process, some works also regard upstream BSC stages, like blood collection, processing, and distribution, as highly exposed to adverse events [29].

A variety of factors constitute the triggering causes of blood transfusion criticalities, encompassing the healthcare environment, local policies and guidelines, staff training, communication, equipment management, and human behaviour [30].

2.2. Risk management methodologies for BSCs

The serious impacts of adverse events on the outcomes of the blood transfusion process have stimulated the development of a research stream proposing risk management methodologies able to uncover and analyse BSC errors and their effects. Such methodologies rely on risk management techniques commonly implemented in manufacturing industries: Incident Reporting Systems [31], FMEA, FMECA, Decision Tree

Analysis, FTA, Human Reliability Assessment, and Predictive Human Error Analysis [32,33]. Among them, FMEA is by far the most frequently adopted technique since it allows to perform a thorough analysis by defining activities affected by risks, their causes, consequences, and suitable response actions [34].

A lot of authors apply FMEA to the hospital portion of the BSC, and in particular to Ws and indoor transfusion centres, with the aim of uncovering inefficiencies, identifying and classifying failure modes, as well as recommending improvement actions [35,30]. In this context FMEA is sometimes integrated with various techniques like for example Decision Tree Analysis [11]. Additionally, as an output of the FMEA approach, risk KPIs, usually in the form of risk priority indexes, are calculated. To this end, Cagliano et al. [14] propose an approach to study BSC risks based on FMECA that integrates multiple risk management tools in a proactive perspective, but it is limited to a single echelon, namely Ws.

The applications of both FMEA and other risk management techniques to BSC echelons other than points of use are limited. Among the very few contributions available, the one by Han et al. [12] can be mentioned, which deals with process automation in a BB.

The reviewed literature shows that BSCs have been extensively studied as far as the aspects characterising their single echelons are concerned. However, the majority of the available contributions neglect the relationships between different stages [1], which are the building blocks on which any kind of SC is founded. Additionally, the existence of adverse events affecting BSC operations is widely recognized but the methodologies for dealing with the risk these events might occurs are still few. Again, they are limited in scope to one echelon, usually the points of use. Thus, consistently with the general BSC literature, there is a lack of works that identify the cause and effect links between criticalities taking place in different BSC echelons which ultimately produce adverse events at the patient level. A holistic approach is highly recommended in complex healthcare environments because it leads to a better understanding of risk [36]. Such a comprehensive analysis is facilitated by the combined use of multiple methodologies helping address different facets of BSC risks [37]. On the contrary, current literature largely relies on the application of single risk management techniques. Moreover, many frameworks proposed in the blood transfusion arena react to already occurred adverse events, while a proactive risk attitude is desirable in the healthcare field to improve patient safety [31].

The present work builds on the methodology by Cagliano et al. [14] by integrating it with a risk management tool, namely FTA, in order to comprehensively analyse the adverse events happening in multiple BSC echelons and establish causal connections among them. This, together with the introduction of operational KPIs able to detect risk manifestations, allows a proactive approach that enables blocking adverse event chains before they impact on patients, thus contributing to increase the probability of a correct transfusion. The proposed framework also aims to contribute to satisfy the need for healthcare SC practices that promote sustainability not only from an environmental but also from a social point of view [38].

3. Extended BSC risk management framework

Since the ultimate goal of this work is helping identify and prevent adverse events in blood transfusion having their root causes in logistics activities, just the negative meaning of the risk notion will be addressed, neglected those situations where risks constitute positive opportunities for processes.

3.1. Framework steps

The proposed BSC risk management framework is based on the approach by Cagliano et al. [14] to analyse logistics risks in a single BSC echelon, namely an hospital W. This in turn constitutes an application to the blood management and transfusion process of a framework to study risks in the healthcare sector previously developed by the same authors [39], which integrates different process and risk management tools, such as ABS, RBS, RBM, and FMECA.

The reference methodology can be subsumed under the following steps:

(1) Process mapping.
(2) Risk identification.
(3) Adverse event analysis.
(4) Studying causal relationships among adverse events.

These steps define a procedure to assess risk and the associated possible adverse events but do not include the successive steps of risk response planning.

The present work extends the Cagliano et al. [14] approach in three different ways. First of all, by adopting a SC perspective, and no more a single echelon one, multiple BSC tiers are addressed. Then, in order to understand how risks spread along them, the adverse event analysis phase is integrated with a FTA, which establishes causes and effect relationships among adverse events happening in different SC stages. FTA has been already used to study risk in several healthcare contexts, such as Intensity-Modulated Radiation Therapy [40] or cybersecurity related to telemedicine [41]. Finally, adverse events are associated with operational KPIs able to detect their occurrence. Thus, KPIs are not just used to monitor the effectiveness of risk responses, as in Cagliano et al. [14], but they are applied earlier in the risk management process to capture adverse event manifestation.

3.2. Framework application

The present section illustrates the application of the extended framework to two representative BSC echelons, namely a BB and a hospital W receiving blood products fromit. The activities, risk sources, adverse events, and KPIs that are here considered are typical of BBs and Ws taking part in blood transfusion and are derived from the 'IDEA' Project, sponsored by the Italian Ministry for Education, University, and Research (DM 49046 as of October, 15th 2008), in which the authors were involved. Such project aimed at studying models to cope with adverse events in the blood transfusion process assisted by information and communication technology and focused on a BSC located in Northern Italy. However, the authors' scope is not assessing a specific BSC or process but rather presenting a methodological approach to risk management in BSC processes.

3.2.1. Process mapping

Before defining risk sources, the portions of the overall blood transfusion process performed at the two selected SC echelons need to be understood. The BB at issue is part of a large public hospital and collects blood and blood components both at its premises and in the external centres run in collaboration with donor associations. It processes blood products, stores, and delivers them to both the Ws of the parent hospital and to a number of other public hospitals, local healthcare agencies, and private clinics. The studied W is a surgery department that orders blood bags to the BB according to the needs of patients undergoing operations. It receives, checks, and stores them in a dedicated refrigerator from where blood units are picked to be delivered to operating rooms where transfusions are carried out.

Sub-processes taking place at both the BB and the W are investigated through interviews with personnel, review of the existing working procedures, and direct observation of operations. Then they are decomposed into process phases, macro-activities, and elementary activities until an appropriate level of detail is reached. Such a task is facilitated by an ABS as suggested by the Cagliano et al. [14] approach.

In total, 7 process phases (i.e. macro-activities) and 99 elementary activities are identified for the BB and 7 process phases and 78

Table 1
Excerpt from the RBM for blood transfusion process at the blood bank.

Process phase	ElementaryACTIVITY CODE	Internal risk sources 1. Organization Human resources RBS 1.7	RBS 1.10	RBS 1.12	RBS 1.13	4. Communication Information exchanges RBS 4.2
4. Blood processing and storage	ABS 4.3		FM 2; FM3 I_2; I_3; I_5; I_9		FM 2; FM 3 I_2; I_3; I_5; I_9	
5. Blood distribution	ABS 5.1.1.1	FM 2; FM3; FM 5; FM 6 I_3		FM 2; FM 3; FM 5; FM 6 I_3	FM 2; FM 3; FM 5; FM 6 I_3	FM 2; FM 3; FM 5; FM 6 I_3
	ABS 5.1.1.3	FM 18; FM19; FM 22 I_4; I_{10}	FM 18; FM 19; FM 22 I_4; I_{10}	FM 18; FM 19; FM 22 I_4; I_{10}		FM 18; FM 19; FM 21; FM 22 I_4; I_{10}
	ABS 5.1.3.11		FM 22 I_{10}	FM 22 I_{10}	FM 22 I_{10}	FM 22 I_{10}
7. Request and tube check-in	ABS 7.2	FM 9; FM 13 I_6; I_8	FM 9; FM 13 I_6; I_8		FM 9; FM 13 I_6; I_8	

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

Process phase	Elementary activity code	Internal risk sources 1. Organization Human resources RBS 1.7	RBS 1.10	2. Structure Layout RBS 2.6	3. Technology Information system RBS 3.8	RBS 3.9	4. Communication Information exchanges RBS 4.3
1. Completing the request for blood bags and pre-transfusion tests	ABS 1.3	FM 15; FM 16 I_6; I8	FM 15; FM 16 I_6; I8				
	ABS 1.6	FM 16; FM 17 I_6; I8	FM 16; FM 17 I_6; I8				
2. Collecting blood bags from the blood bank	ABS 2.6	FM 18 I_{10}; I_{11}; I_{15}	FM 18 I_{10}; I_{11}; I_{15}		FM 18 I_{10}; I_{11}; I_{15}	FM 18 I_{10}; I_{11}; I_{15}	FM 18 I_{10}; I_{11}; I_{15}
4. Transfusion setup	ABS 4.3	FM 10; FM 23 I_{12}; I_{14}	FM 10; FM 23 I_{12}; I_{14}				
5. Performing transfusion	ABS 5.2	FM 11 I_7		FM 11 I_7	FM 11 I_7		

elementary activities for the W. An excerpt from the ABSs of both the BB and the representative W is provided in the Appendix (Tables A1 and A2). Due to the very large numbers of elementary activities, the complete ABSs are available from the authors upon request.

3.2.2. Risk identification

The knowledge of the blood transfusion process developed in the first step of the framework, together with interviews with managers and personnel, allow to identify the sources of risks that might affect elementary activities. They are organised in a RBS, which enables a classification of risks according to their type. Being based on a taxonomy system, the RBS serves the purpose of tracking adverse events by their nature and of disclosing their latent causal factors, thus making it possible to monitor the level of patient safety. Moreover, the RBS can be considered as a reporting tool that contributes to increase risk awareness and culture [31].

Since the representative BB and W are part of the same SC, they share analogous risks for the transfusion process, therefore only one RBS is created (Table A3 in the Appendix). It is developed by adapting the template put forward by Cagliano et al. [39,14] and categorizes risk sources into those that are under the control of either the BB or the W (internal) and those that are outside their control (external). Seven detailed risk classes are taken into account: Organization, Structure, Technology, Communication, Blood supply, Regulation, and Environment which reflect the organizational, operational, and environmental factors that are recognised to prevent the implementation of sound SC management practices in healthcare [42].

Risk sources are then associated with the ABS activities to create the RBMs for the BB and the W, excerpts from which are presented in Tables 1 and 2. The filled cells highlight the elementary activities where risk sources might manifest themselves. ABSx and RBSx show the codes of elementary activities and risk sources respectively. Moreover, FMx are the codes of the Failure Modes identified for the processes under study and Ix the codes of the KPIs adopted to detect adverse events (Section 3.2.3). The purpose of the current step is just identifying such cells and not performing any quantitative assessment. Their content shown in Tables 1 and 2 will be discussed in the 'Adverse event analysis' step.

The complete BB and W RBMs, which are available from the authors, reveal that the risk sources impacting on a large number of activities belong to the categories 'Human resources' (e.g. RBS 1.7 Working procedures knowledge and compliance, RBS 1.10 Controls, RBS 1.12 Personal characteristics) and 'Communication' (e.g. RBS 4.2 Traceability, RBS 4.3 Feedbacks). On the one hand, the BB activities affected by a large number of risk sources are part of the process phases 'Blood processing and storage', 'Blood distribution', and 'Request and tube check-in'. The W activities mostly subjected to risk are included in the process phases 'Completing the Request for Blood Bags and Pre-Transfusion Tests', 'Collecting Blood Bags from the Blood Bank', and 'Managing Blood Bags by the W'. First, such outcomes highlight that the behaviour of human resources and a reliable communication among them are key determinants of the blood transfusion process performance. Second, they provide further evidence that logistics activities are subjected to uncertainty and errors.

Table 3
Failure Modes associated with logistics activities.

FM 1	Possible errors in the pronunciation of personal data by the donor
FM 2	Labels positioning on the wrong blood bag
FM 3	Incorrect detection of the temperature of blood bags and of the time they have been kept at a temperature different from the recommended one
FM 4	Applying the label is difficult due to the frozen surface
FM 5	Errors caused by donors and patients with similar names
FM 6	Errors due to manually recording blood bag requests in the information system
FM 7	The number of feedback modules that are returned is less than the number of bags that have been delivered
FM 8	Possible errors in writing new donor data on blank labels
FM 9	Difficulty in identifying the correct blood bag request priority
FM 10	Mismatch between blood bag requests and the associated patients
FM 11	Adverse transfusion reaction
FM 12	Tube exchange
FM 13	Incorrect or incomplete blood bag requests and blood samples
FM 14	Error in formulating the question to ask for the patient's name
FM 15	Errors while transcribing information from medical records, examination reports, and other documents
FM 16	Errors in the tax code transcription
FM 17	Errors while transcribing information on tubes
FM 18	Errors during blood bag delivery or pick up
FM 19	Delivery of a number of blood bags different from the ordered one
FM 20	Problems with closing the refrigerator door
FM 21	Blood bag – patient incompatibility due to information system errors
FM 22	Assigning blood bags not meeting clinical specifications
FM 23	Blood products of not compliant

It is worth mentioning that the RBM filling degree depends not only on the existence of risks but also on their detectability according to the information collected through interviews and past data analysis. Thus, a blank matrix cell might mean that either no risks exist or information about possible risks is not available.

3.2.3. *Adverse event analysis*

The RBM analysis further evolves into the definition of the adverse events that might originate as a result of the occurrence of risk sources while performing the associated activities. To this end the outputs of the two previous phases are used, together with additional interviews and direct investigation of activities, should they be necessary. FMs associated with logistics activities negatively affecting the transfusion process are here defined. They might happen both in the physical and the information flow of a BSC. In total twenty-three FMs emerged in the previously mentioned 'IDEA' Project, involving both the BB and the W at issue. The meaning of the ones reported in Tables 1 and 2 is in Table 3.

It is interesting to point out that many of the identified FMs may arise in the BB because of its high degree of complexity. Hence the necessity to study risk propagation from upstream BSC echelons as far as points of use.

A deep knowledge of each adverse event is then acquired through a FMECA. Table 4 shows an example of the outcomes of FMECA applied to the BB. It points out the main aspects recognized as important in the analysis of healthcare incidents by Itoh et al. [31]; risk reduction measures are not specified since out of the scope of the present work. A five-item qualitative scale (Very Low, Low, Medium; High, and Very High) is adopted for both occurrence probability and detectability. Regarding the impact, the organizational one assesses the influence of adverse events on the use of time and resources, while the clinical one addresses the influence on patients. In Table 4 they are both measured through a three-item qualitative scale (Low, Medium, and High). In the present application, the assessment scales are defined based on the experience of the actors of the studied blood transfusion process and the number of scale levels is directly proportional to the amount of the obtained information: the more the pieces of information the more accurate the scale. However, quantitative evaluations are recommended whenever numerical data are available. Finally, an adverse event might have effects that either are limited to one single activity or propagate to multiple activities, also combining with the effects of other adverse events happening in the downstream BSC phases. In such a way, the adverse event effects can then affect the patients undergoing transfusion. These two situations are represented in Table 4 by an X sign (effects limited to one single activity) and the logical operator AND (effects spreading in the BSC) respectively.

Table 5
Operational KPIs used to detect adverse events.

I_1	Number of blood bags returned (booked and not transfused) / total Number of blood bags requested
I_2	Number of blood bags to be discarded/ Number of validated blood bags
I_3	Number of discarded blood bags due to quality issues / Number of inspected blood bags
I_4	Number of blood bags with a delivery time longer than two hours/Number of delivered blood bags
I_5	Number of discarded blood bags due to incorrect storage temperature/Number of stored blood bags
I_6	Number of incorrect transfusion requests/Number of transfusion requests
I_7	Number of adverse transfusion reactions/ Number of transfused blood bags
I_8	Number of not compliant tubes sent by the W/Number of sent tubes
I_9	Number of not correctly labelled blood bags/Number of labelled blood bags
I_{10}	Number of distributed blood bags not meeting clinical specifications/ Number of delivered blood bags
I_{11}	Number of blood bags to be discarded (not meeting the required temperature and delivery time)/ Number of received blood bags
I_{12}	Number of blood bags not correctly associated with patients/ Number of transfused blood bags
I_{13}	Average time for handling requests
I_{14}	Average time between blood bag picking from fridge and transfusion
I_{15}	Number of blood bags with expired TS/ Number of received blood bags

Table 4
Sample FMECA for the Blood Bank.

Activity code	Risk source	Adverse event code	Occurrence probability	Impact		Detectability	Effects
	RBS Code			Organizational	Clinical		
ABS 4.3	RBS 1.7; RBS 1.10; RBS 1.12; RBS 1.13	FM 2	Very Low	Low (more time and resources needed)	High (serious consequences on transfused patients)	High	X; AND
ABS 5.1.1.3	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 18	Low	High (in the case of wrong transfusion); Low (if the FM is promptly detected	High (serious consequences on transfused patients)	High	X; AND
ABS 7.2	RBS 1.7, RBS 1.10, RBS 1.12, RBS 1.13	FM 13	Medium	Low (asking the W for a new blood sample)	-	High	X; AND

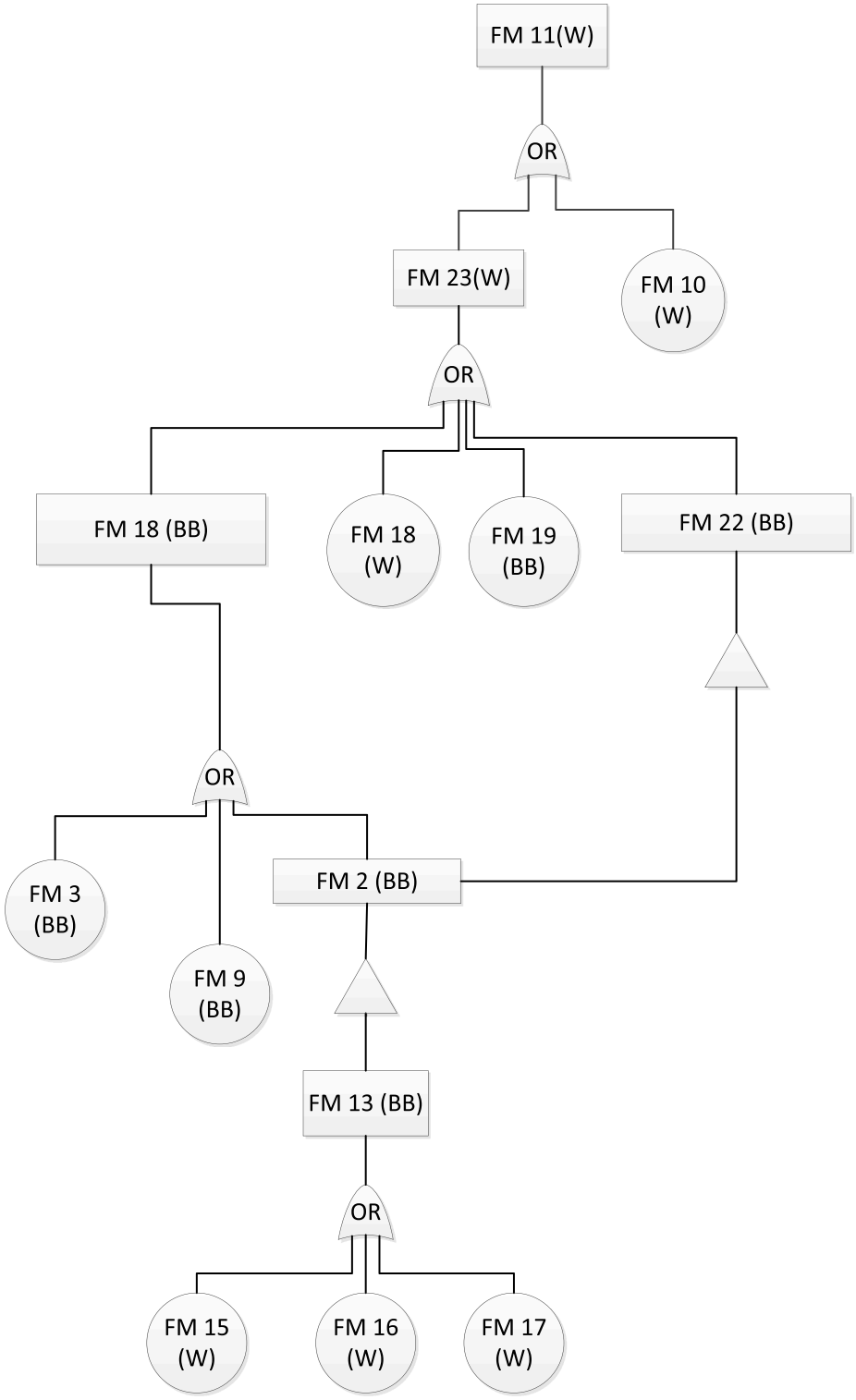

Fig. 2. Example of FTA application.

3.2.4. Operational KPIs

In order to detect the adverse event occurrence and quantitatively assess its effects, operational KPIs are used. Such metrics evaluate the performance of activities when the associated risk sources manifest themselves [43], thus they can be inserted in the RBMs (Tables 1 and 2). In such a way, KPIs are also able to provide information about the extent to which adverse events are intercepted and blocked by the implemented risk control measures. They may be selected based on literature reviews [44] as well as the experience of the process actors involved in the application of the proposed framework. The information provided by KPIs complements FMECA because it helps establishing the degree of criticality of adverse events, prioritizing them, finding appropriate risk reduction measures, and monitoring the results of their implementation. The KPIs mentioned in Tables 1 and 2 are defined in Table 5.

As suggested by their definitions, these KPIs allows to detect adverse events associated with poor performance of logistics activities such as blood bag ordering, labelling, delivery, storage, as well as handling by the W. The information to measure them can be collected either by

means of an information management system or through paper records. Of course, the use of an information management system makes KPI monitoring quicker and more reliable.

3.2.5. Studying causal relationships among adverse events

After getting a deep knowledge of single adverse events, the investigation of risk propagation along a BSC is achieved by studying causal relationships among them through FTA [27]. This method is used in many fields related to healthcare, such as Radiation Oncology [45] and outpatient settings [46]. FTA is a technique that deals with failures in a comprehensive way since it supports building models of how they take place in all the components of a system. It is based on fault tree diagrams, which display the logical relations between the failure of entire systems and the failures of their components [47,48]. In the present work the system failures are represented by the adverse events affecting transfused patients (e.g. adverse transfusion reactions and other less severe events) while the component failures are constituted by the adverse events occurring in the different BSC echelons. FTA enables to understand whether an adverse event is caused by the manifestation of another single adverse event or by the concurrent occurring of a number of adverse events. Therefore, an adverse event may be caused by either the associated risk source shown in the RBM or by other adverse events upstream in the BSC, which are in turn due to other risk sources defined in a different RBM. In this way, the RBMs of multiple BSC echelons and their risk sources are related to each other through the identified connections among their adverse events. This is of particular relevance in the healthcare sector given the need for an integrated approach to SC management in order to successfully operate in a highly complex environment [42].

To carry out FTA the outputs of FMECA are used, in particular those about the impacts and the effects of adverse events. Through this approach several chains of adverse events can be recognized in the same BSC. Fig. 2 shows one possible causal chain between some of the FMs introduced in Tables 1 and 2. The symbols BB and W within brackets show whether a FM takes place in the BB or in the W.

At the W, errors while either completing a request for blood bags or transcribing patient information on the tubes containing blood samples for pre-transfusion tests (FM 15, FM 16, FM 17) cause the BB to receive incorrect or incomplete requests (FM 13), which in turn may cause BB operators not correctly label blood bags before their delivery (FM 2). At the BB either this last event or the incorrect tracking of blood bag temperature (FM 3) or the inability of giving the correct priority to blood bag requests (FM 9) may lead to errors while delivering or collecting blood bags for points of use (FM 18). This last adverse event can be due not only to the BB but also to the W and is one possible cause for receiving blood products of not compliant quality (FM 23) together with the delivery of blood bags not meeting quantity and clinical requirements (FM 19; FM 22). The availability of blood units not of the expected quality or mismatches between blood bag requests and patients at the W (FM 10) can finally lead to incorrect transfusions and consequent adverse reactions (FM 11).

It is worth mentioning that no AND operators are shown in Fig. 2 because the BSC at issue lacks control points and so even one single adverse event can negatively impact the next SC steps.

The analysis of the connections among FMs highlights a strong relationship between the sequence of both FMs and the associated process activities. This stresses the importance of prevent risky events upstream in the SC to either avoid or reduce their propagation chain in order to limit the probability that patients are affected by adverse events.

4. Discussion and conclusion

Although the great attention received by blood transfusion risks especially in recent years, a systemic vision of how they originate and spread along BSC echelons as far as patients is still lacking [7]. This is a crucial issue because several adverse events affecting patients are produced not by merely clinical activities but rather by the way blood products are managed [49].

The key value of the BSC risk management framework proposed in this work is that it offers a structured method based on FTA to connect adverse events in multiple SC stages according to cause and effect chains. Such relationships can be proactively examined before criticalities take place. On the contrary, the main stream research about the topic is usually limited to the identification of single adverse events and the measurement of their effects in only one setting, mostly the blood points of use, and preferably after they occurred [11,30]. Moreover, the integration of techniques operating at different detail levels allows applying the framework regardless the organisational maturity towards risks and even in those healthcare contexts with scarce information availability. Also, the framework steps can be implemented both before and after carrying out risk responses. Furthermore, the developed methodology supports a detailed analysis of activities, risk sources, adverse events together with the study of specific links among the latter. This permits a deep understanding of the numerous ramifications of adverse event propagation along BSCs. The operational KPIs underpinning the framework overcome the traditional use of risk priority numbers and prove that indicators adopted by organizations to assess their daily tasks can serve the purpose of monitoring risks. Such characteristics make the methodology suitable to find out the most critical BSC stages where risk control systems should be provided to increase the probability of correct transfusion.

Finally, the presented framework fosters environmental and social sustainability in the transfusion process. Proactively addressing the logistics aspects that might compromise transfusion helps preventing several kinds of waste impacting on the environment. For example, a better management of stocks avoids having to discard expired packs, which would lead to a waste of blood and possible shortages in critical situations. Blood bags that cannot be transfused also bring a waste of the associated materials, such as the package, and the energy needed to keep the quality required for the blood components, like the one consumed to make refrigerators work. Also, avoiding adverse events seriously affecting patients allows to achieve social sustainability in terms of ensuring transfusion safety and improving people health.

The work brings both academic and practical implications. First, this contribution stimulates the development of research that improves the understanding of the root origins of BSC risks by taking a systemic and proactive perspective on not only clinical processes but also logistics ones. Also, it can be a starting point to include operational KPIs in risk management methods. From a methodological point of view, the proposed framework advances the approaches by Cagliano et al. [39,14] by adding FTA as a means of developing the potential of FMECA to support building relationships among adverse events happening in multiple BSC echelons, as well as by suggesting KPIs to measure risk manifestation. Healthcare institutions might adopt the framework to closely control blood transfusion hazards and enhance their awareness toward risks. In particular, the possibility of applying it at different levels of detail and its ability to provide meaningful results even with qualitative data might result very interesting. Also, by offering examples of risk sources, activities, failure modes, and KPIs, the present work reveals to organizations the aspects that deserve attention in a BSC.

Some limitations can also be mentioned. The framework requires a strong and lasting commitment by managers and personnel involved in the transfusion process, which might not be available when operators do not completely understand the importance of risk and of an effective method to deal with it. The paper presents some illustrative application examples, but the framework still needs a validation campaign in real environments. Finally, risk occurrence probability and impact are estimated only in a qualitative way.

Future research will be focused on applying the proposed framework to multiple BSCs and developing numerical assessments of probabilities of occurrence, impacts, and KPIs with the aim of refining its steps. Quantitatively measuring the probability of occurrence of each single FM allows, based on the relationships defined through FTA, the calculation of occurrence probabilities downstream in the BSC [50].

Moreover, numerically evaluating the risk impacts would complete the framework in order to fully estimate each FM. To this end, the introduced KPIs can help measuring both the probability of occurrence and the impact of risk. In particular, the deviation of the KPI values from their acceptable thresholds requires the attention of decision-makers. In such a situation they should define appropriate risk reduction measures.

Finally, the values of probability of occurrence and impact could also be useful to develop an approach to rank the risky events affecting the different BSC echelons.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

A dutiful thanks goes to the personnel of the Hospital W and the BB where the study was conducted for their active participation in the research.

No competing interests are reported for this paper.

This research was funded within the 'IDEA' project sponsored by the Italian Ministry for Education, University and Research (DM 49046 as of October, 15th 2008).

Appendix

Tables A1–A3

Table A1
ABS of the Blood Bank.

ABS Blood Bank	Process phases	Elementary activities
	1. Managing donations at Blood Bank	…..
	2. Managing donations at external collection centres	…..
	3. Blood analysis	…..
	4. Blood processing and storage	…..
		4.3 General validation, labelling, and storage
		4.4 Red blood cell validation, labelling, and storage
		4.5 Buffy coat validation, labelling, and storage
		4.6 Validation, labelling, and storage of plasma for clinical use
		4.7 Validation, labelling, and storage of plasma for blood component production
		4.8 Validation, labelling, and storage of plasma for Plasmasafe production
		4.9 Production and storage of platelet pools
		…..
		4.12 Blood component processing
	5. Blood distribution	5.1.1.1 Managing red blood cell requests
		…..
		5.1.1.3 Picking red blood cell bags up
		5.1.2.9 Pre-delivery check (on request distribution of platelet pools)
		…..
		5.1.2.11 Delivery (on request distribution of platelet pools)
		5.1.3.11 Pre-delivery check (on request distribution of plasma)
		5.1.3.13 Delivery (on request distribution of plasma)
		…..
	6. Returning blood components	…..
	7. Request and tube check-in	…..
		7.2 Receiving and accepting requests and tubes
		…..

Table A2
ABS of the Ward.

ABS Ward	Process phases	Elementary activities
	1. Completing the request for blood bags and pre-transfusion tests	…..
		1.2 Recording patient personal information
		1.3 Filling in the pre-transfusion tests request form
		…..
		1.6 Labelling tubes with information about patients and ward
		…..
		1.10 Filling in blood component prescription
		…..
	2. Collecting blood bags from the Blood Bank	…..
		2.5 Transporting blood bags and the associated forms to the Ward
		2.6 Delivering blood bags and the associated forms to the Ward
	3. Managing blood bags by the Ward	…..
		3.4 Storing blood bags in the refrigerator
		3.5 Daily monitoring of stored blood bags
		…..
	4. Transfusion setup	…..
		4.3 Checking blood bag suitability for transfusion
		…..
	5. Performing transfusion	…..
		5.2 Regulating and monitoring transfusion
		…..
	6. Moving the patient and the associated blood bags to a different Ward	…..
	7. Returning not – transfused blood bags to the Blood Bank and record keeping	…..

Table A3
RBS for the blood transfusion process.

Level 0	Level 1	Level2	Level3	Level 4	RBS Code
RBS for the blood transfusion process	Internal risk sources	1. Organization	Organizational structure	Activity planning	1.1
				Roles	1.2
				Responsibility levels	1.3
				Stakeholder involvement	1.4
				Human resources policies and management	1.5
				Workloads	1.6
			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
			Patient safety promotion policies	Guidelines and diagnostic-therapeutic pathways	1.14
				Error reporting systems	1.15
		2. Structure	Facilities and equipment	Design	2.1
				Material handling equipment	2.2
			Layout	Workspaces	2.3
				Ordinary maintenance plans	2.4
				Extraordinary maintenance plans	2.5
				Workplace safety	2.6
				Workplace logistics	2.7
			Networks	Infrastructure, networks, digitalization, and automation	2.8
				Service interruptions	2.9
		3. Technology	Equipment	Computerized workstations	3.1
				Blood refrigerators	3.2
				Operations and upgrade	3.3
			Information system	Internet network	3.4
				Intranet network	3.5
				Data transfer	3.6
				Information security	3.7
				Continuity of service	3.8
				Data backup	3.9
		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	Provision of blood components by external collection points	Quality of delivered products	5.1
				Delivered documentation	5.2
			Internal blood component management	Quality of products taken from blood refrigerators	5.3
				Documentation management	5.4
	External risk sources	6. Regulation	Compliance with regional and national laws		6.1
		7. Environment	Social issues		7.1
			Natural events		7.2
			Epidemiological events		7.3

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