

## Risk Management in Hospital Wards: The Case of Blood Procurement and Handling

Anna C. Cagliano\* Sabrina Grimaldi \*\*  
Giulio Mangano \*\*\* Carlo Rafele\*\*\*\*

*Department of Management and Production Engineering, Politecnico di Torino, Torino, Italy*

\* [anna.cagliano@polito.it](mailto:anna.cagliano@polito.it) \*\* [sabrina.grimaldi@polito.it](mailto:sabrina.grimaldi@polito.it) \*\*\* [giulio.mangano@polito.it](mailto:giulio.mangano@polito.it) \*\*\*\* [carlo.rafele@polito.it](mailto:carlo.rafele@polito.it)

**Abstract:** Blood transfusion is among the most complex healthcare processes including a variety of interrelated sub-processes of different nature. Therefore, it is highly exposed to risks and such a fact is witnessed by the several errors and adverse events occurring every year. Although there is quite a significant body of literature about risk management in transfusion, risks connected with blood product procurement and handling have been scarcely investigated. The present work integrates three risk management tools developed in the project management and manufacturing areas to put forward a structured approach to identify and analyze causes of risks, their manifestations and effects. Its first application to a hospital ward revealed its potential to generate knowledge about blood transfusion uncertainty and the associated criticalities, thus increasing the level of maturity towards risks of healthcare organizations. Future research will refine and extend the approach by applying it to various healthcare settings.

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### 1. INTRODUCTION

Blood transfusion is a complex healthcare (HC) process constituted by multiple, different, and interdependent sub-processes where errors associated with traceability, blood prescription as well as order and delivery management propagate and ultimately impact on patients (Crookston et al., 2015; Maskens et al., 2014; Stainsby et al., 2005). Many heterogeneous factors are responsible for them, such as local environment, policies and guidelines, staffing, poor communication, equipment problems, and human behaviour (Lu et al., 2013).

The identification and prevention of adverse events caused by such errors play a crucial role to guarantee blood transfusion safety but they are not enough investigated by current literature (Maskens et al., 2014). To be more precise, the processes connected with blood product procurement and handling are responsible for a relevant portion of adverse events (Ibojie and Urbaniak, 2000) but studies on this topic are limited. As a matter of fact, despite several works on the structure and behaviour of the blood supply chain (BSC) echelons (Katsaliaki et al., 2014; Mobasher et al., 2015), still few pieces of literature analyse risks in a BSC. Also, they typically address risks in a reactive way (Borelli et al., 2015; Erminio and Pilloni, 2015; Maskens et al., 2014), while a proactive perspective is usually neglected. Thus, the purpose of this work is developing a structured approach to identify and analyse risks before they occur in the portion of the BSC located at hospital wards. To this end, tools commonly applied in the project management and industrial sectors, such as the Risk Breakdown Structure (RBS), the Risk Breakdown Matrix (RBM), and Failure Mode and Effects Criticality Analysis (FMECA) are integrated. Each risk

source is associated with the pertinent process activities and its potential effects are assessed through FMECA. The approach is illustrated by means of a case study. Reducing risks in hospital wards is of paramount importance since their activities directly impact on patients. Additionally, decreasing risks in blood procurement and handling activities brings as a consequence a risk reduction in the whole transfusion process since the high severity errors causing adverse events often originate in the BSC.

The reminder of the paper is organised as follows. Section 2 provides a review of the pertinent literature and Section 3 presents the risk management tools used in the work. Section 4 details how the proposed approach applies them to a case hospital ward. Finally, Section 5 discusses benefits, limitations, implications, and future research directions as well as conveys conclusions.

### 2. RISK ANALYSIS IN BLOOD TRANSFUSION

A number of literature contributions focus on the different types of errors and adverse events in blood transfusion as well as on the implementation of risk management methodologies to identify and analyse them.

#### 2.1 Errors and Adverse Events Analysis

Ex-post analysis of transfusion errors in hospitals is a topic debated by several authors in recent literature. Maskens et al. (2014) identify the most frequent high severity errors such as wrong sample labelling, inappropriate ordering of blood, lack of accurate handling, and samples accepted despite not meeting the required criteria. They find that inappropriate ordering and inaccurate blood sample labelling and handling

pose the greatest threats to patient safety. However, they advocate paying attention to the entire transfusion process through the development of systemic approaches to decrease errors and inefficiencies. Karim et al. (2014) analyse adverse reactions, especially those due to accidental ABO incompatible transfusions. In this context patient and tube identification are recognized to be critical activities. Crookston et al. (2015) discuss causes and response actions for bedside transfusion complications. Finally, Stainsby et al. (2005) identify the steps that are more prone to errors: transfuse decision, blood sampling for pre-transfusion tests, blood processing in laboratories, blood collection and administration. They claim that tracking patients and blood units plays a crucial role to enhance safety.

## 2.2 Application of Risk Management Methodologies

Risk management approaches well known in several manufacturing sectors have been implemented to assist reducing BSC criticalities. Among them, Failure Mode and Effects Analysis (FMEA), FMECA, Decision Tree Analysis, Human Reliability Assessment, and Predictive Human Error Analysis can be mentioned (Cagliano et al., 2015). In particular, FMEA appears to be one of the most applied tools in the HC arena because it provides a more detailed analysis than other risk management techniques and allows to identify the specific process activities subjected to risks (Han et al., 2013; Lu et al., 2013). As a matter of fact, most of the contributions about risk management in blood transfusion propose such a methodology. Several authors adopt FMEA to analyse the transfusion process in hospital settings. Borelli et al. (2015) use FMECA to detect the inefficiencies of a hospital blood transfusion centre and the possibility of overcoming them with RFID-based process reengineering. Dehnavieh et al. (2015) combine the Health Care Failure Mode and Effects Analysis (HFMEA) with decision-making trees to investigate the blood transfusion process in a paediatric emergency department. Through qualitative and quantitative assessments they find failure modes and classify them in non-acceptable, acceptable, controllable, and eliminable risks. Stanton et al. (2007) propose FMEA to reduce the risk of clerical errors in blood ordering and administration. Finally, Han et al. (2013) use FMEA to assess the level of automation in a blood bank. The performed literature review reveals there is an extensive discussion about the types of blood transfusion errors. Many of them are connected to blood product procurement and handling, as it can be seen from the examples reported in Section 2.1. However, previous contributions are usually limited to identifying and classifying errors and do not provide practical approaches to address them. Additionally, available risk management methodologies are very often intended to analyse the effects of errors and adverse events after they occur rather than to perform ex-ante analyses of their triggering causes and of the operational conditions where they might manifest themselves.

The present paper builds upon the existing contributions on blood transfusion risk management and offers a structured approach to systematically and preliminarily identify potential risk sources together with the activities that might be affected by them. Moreover, relationships between risk sources and the effects of their possible occurrence are established.

## 3. RISK MANAGEMENT TOOLS

The goal of this section is briefly presenting the three risk management tools that are used in the research, namely RBS, RBM, and FMECA.

### 3.1 Risk Breakdown Structure

First introduced in the project management field, the RBS can be generally defined as a source-oriented grouping of risks that organizes and defines the total risk exposure. Each descending level represents an increasingly detailed definition of sources of risk (Hillson, 2002; Project Management Institute, 2013). Thus, the RBS provides a hierarchic and systemic representation of the causes of criticalities according to different levels: the lower the RBS level, the more detailed the risk definition. The total number of levels should be set so that the RBS is both comprehensive, that is it includes all possible risk sources, and easy to understand and use to monitor risks. Risk sources are usually divided into internal and external ones depending on whether the organization undertaking risk analysis is able to control them or not. The RBS has been already adopted in the HC sector. For instance, in Cagliano et al. (2011) it is part of a methodology to analyse risks which is applied to a hospital pharmacy. The RBS template proposed by such authors will be here partially modified to take into account the peculiar characteristics of the blood transfusion process.

### 3.2 Risk Breakdown Matrix

Also the RBM comes from the project management arena (Hillson, 2003; Hillson et al., 2006). It provides a very straightforward way to associate the risk sources defined by the RBS with the activities where they might manifest themselves by organizing them in the rows and in the columns of a table. Then, risk identification can be carried out by simply putting crosses into the table cells corresponding to couples risk source – activity. Every cross means that the associated risk source impact on the corresponding activity. The RBM, already applied to HC for example by Cagliano et al. (2011), offers a comprehensive perspective on the criticalities of structured and complex processes.

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