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Operational Risk in Storage and Land Transport of Blood Products

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Abstract. Blood transfusions contribute to saving and improving the quality of life of thousands of people in the world every day. There is no alternative to satisfy the demand for blood in medical procedures and there is no substitute for human blood (blood is supplied voluntarily by donors). Therefore, blood should be seen as a scarce resource in the world. Currently, the donation rate in Colombia is considered low. However, the donor deficit is not the only problem for this type of institution, other factors within the biological and logistical control of the chain directly affect the safety and availability of blood, making the functioning of the blood supply chain an interesting study problem to treat. This supply is exposed to the possibility of unexpected events affecting the normal functioning of its activities, this is called operational risk. These risks affect the performance of organizations and it is therefore important to work on their identification and prioritization so that organizations can guide their efforts to mitigate or eliminate them. Due to the social and economic importance of improving blood supply systems, the present work identifies, Prioritizes and provides mitigation actions for the impact of operational risks associated with the storage and land transport of blood products in Colombia.

Keywords: supply chain risk management, operational risk, fuzzy-QFD methodology, blood banks, probability-impact matrix.

1 Introduction

According to the World Health Organization (WHO), blood donations help save lives and improve people's health [1]. Hence, the different authorities on the issue see the need to launch awareness campaigns on the importance of blood donation.

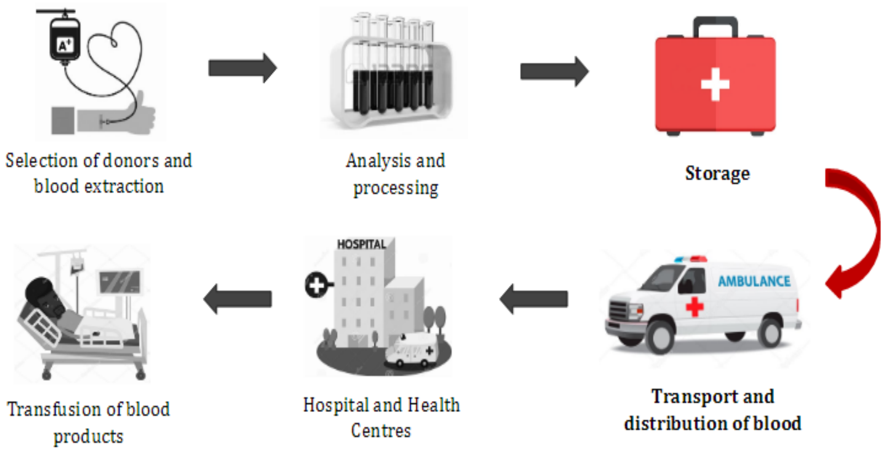

Fig. 1. Blood supply chain.

A sample of the work carried out by these entities is that, globally, approximately 112,5 million units of blood are donated per year, according to data collected and published by WHO as of June 2017. Moreover, in Colombia, only between 2014 and 2015, according to figures revealed by the National Institute of Health, around 792.000 units of blood were collected per year [2].

However, the blood that is donated is not sufficient to meet the demand for this supply. In Colombia, the rate of donations is 15,4 per thousand inhabitants when ideally there would be between 30 and 40 donors for every thousand people in the country, according to Gabriel Cubillos, member of the board of directors of the Colombian Association of Blood Banks and Transfusion Medicine ACOBASMET (2016). In the annual report of the Blood Bank Network for 2017, it is stated that:

> *"Considering on average in Colombia a unit of red blood cells has an economic value for the system of $291.733 [3] and more than 30,000 units of red blood cells were discarded from blood banks for controllable causes, it is estimated that the Health System lost in processing costs about 8,700 million pesos ($8'751.900.000), which can result in a detriment for blood banks, and failures related to demand satisfaction, which for this component was 88,8% and 90% for platelets".*

Incorrect risk management in this process not only entails a huge loss of economic resources for the country and the health sector, but directly affects the patient's health and quality of life [4], the latter being the most important impact. This is why risk management takes on prominence, seeking to reduce, eliminate or avoid disturbances of the physical and information flows that affect the interaction of the different links in the supply chain [5]. The chain can be presented graphically in Figure 1.

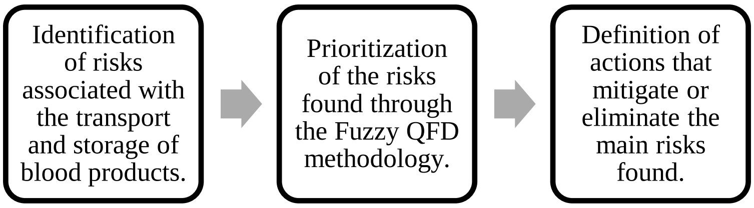

Fig. 2. Methodological design.

Table 1. Linguistic scale.

Linguistic Scale	**Very low (VL) Insignificant (I)**	**Low (L) Minor (Mi)**	**Medium (M) Moderate**	**High (H) Critical (C)**	**Very high (VH) Severe (S)**
Numerical equivalence	1	2	3	4	5

2 Methodology

The methodological design for the development of the project is presented below in Figure 2. The methodology will have three phases.

2.1 Identification of Operational Risks Associated with the Transport and Storage of Blood Products

From the literature and through the application of questionnaires to experts, the main risks associated with the transport and storage of blood products are identified. The application of the questionnaire was carried out individually and allowed the experts to rate the risk, both in probability and impact, using the linguistic scale illustrated in Table 1.

After the application of the questionnaire, responses are consolidated and processed according to the scale. The data obtained apply Equation 1 and Equation 2 to obtain the percentages of risk application and weighted averages of probability of occurrence and magnitude of impact:

Equation 1: Weighted average of the magnitude of risk i:

$$\bar{X}_i = \frac{\sum_{j=1}^{n}(B_{i,j} \times M_{i,j})}{n} \quad ; \quad \forall\, i. \tag{1}$$

Equation 2: Weighted average probability of risk i:

$$\bar{Y}_i = \frac{\sum_{j=1}^{n}(B_{i,j} \times P_{i,j})}{n} \quad ; \quad \forall\, i. \tag{2}$$

$\bar{X}_i$ =Weighted average of the magnitude of risk i,

$\overline{Y}_i$ = Weighted average probability of risk i,
$B_{i,j}$ = Expert's criterion j if i applicable as risk (1,0),
$M_{i,j}$ = Expert's qualification j on the impact of risk i,
$P_{i,j}$ = Expert's qualification j on the probability of risk i.

Once these data are obtained, the Impact Matrix is established. Risks in the green section are negligible risks, risks in the yellow section are risks with a moderate probability of occurrence, while the risks of the orange and red sections are critical risks and it is those that are selected for the next phase.

2.2 Prioritization of Operational Risks Through Fuzzy-QFD

The following methodology is based on the article by [6], and also the specific methodological proposal for prioritization described in [7] in which the following phases are determined:

- Identify the internal variables "What's",
- Determine the relative importance of "What's",
- Identify strategic objectives or "How's",
- Determine the correlation between "What's and How's",
- Determine the weight of the "How's",
- Determine the impact of risk on strategic objectives "How's",
- Prioritize the risks involved.

2.3 Operational Risk Mitigation Strategies or Actions

On the basis of the above qualifications, strategies must be defined in order to mitigate or eliminate the risks present in the process and thereby improve the process. As a final step it is important to emphasize in the implementation of actions aimed at transferring, eliminating and/or reducing the risks of the process and to apply focused strategies on the individual or associated machinery [8].

3 Results

The results are then presented using the methodology set out in the previous chapter for the identification and prioritization of operational risks associated with the transport and storage of blood products in Colombia, with the aim of developing actions aimed at mitigation and risk reduction.

Table 2. Validation and weighted averages of operational risks.

Risk Description	Id	Probability of Occurrence	Impact
Equipments that make up the cold chain without meeting minimum specifications and international standards (WHO).	R_1	2,74	4,05
Equipment used in unstandardized transport and storage.	R_2	2,84	3,95
Lack of availability of technical support, spare parts and maintenance services for cold chain equipment.	R_3	2,53	3,79
Cuts in the power supply that prevent the continuous operation of cooling equipment.	R_4	2,05	4,11
Use of picnic fridges due to the shortage of portable refrigerators suitable for blood conservation.	R_5	2,63	2,63
Equipment without sufficient technology for temperature control (Devices with built in temperature control failures and maintenance threshold overruns alarms).	R_6	2,95	4,05
Equipment's inability to maintain a stable temperature under extreme ambient temperature and humidity conditions (from +2 °C to +6 °C, the operating temperature of the equipment being +4°C).	R_7	2,53	3,95
Lack of or inadequate advice from the operator/transporter to the sender on the technical specifications for the transport of the total blood, hemocomponents and samples.	R_8	2,47	4,00
Lack of professionals specialized in Transfusion Medicine.	R_9	2,79	3,37
Absence/Error in the labelling of transport units.	R_{10}	2,26	4,05
Use of FIFO policies (First components processed, first to be sent for use).	R_{11}	0,89	1,42
Failure in the absorbent material between the primary container (total blood unit or hemocomponent) and the secondary container (hermetically sealed plastic bag) in order to prevent leakage affecting the outer container (refrigerator where blood is transported).	R_{12}	1,74	2,89
Documentation relating to the dispatch and transport of incomplete or poorly registered total blood.	R_{13}	2,00	2,89
No standardised or digital recording system.	R_{14}	2,32	2,68
It's a traffic accident.	R_{15}	2,26	3,68
Inefficient route for the transport of total blood, blood cells and samples.	R_{16}	1,79	2,53
Technical failures in the vehicle.	R_{17}	1,84	3,00

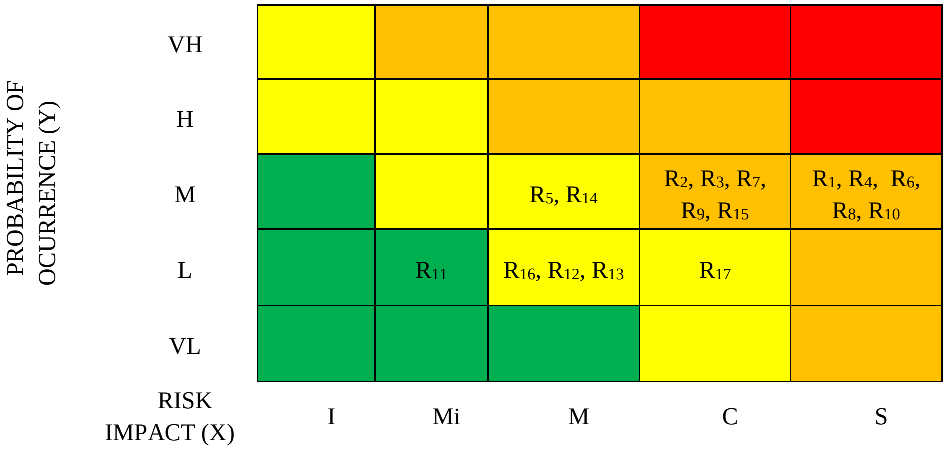

Fig. 3. Risk probability-impact matrix.

3.1 Identification of Operational Risks

Table 2 presents the identified risks and the results of the application of the questionnaire.

Once the risks are identified with their probability of occurrence and the impact they generate, these results are placed in a probability-impact matrix, taking into account the rating each expert considers for each risk. This is shown in figure 3.

3.2 Prioritization of Operational Risks

Thereafter, operational risks will be prioritized in the processes of transport and storage of blood products, with the FQFD methodology as mentioned above based on Chapter 5 of [9], and the risks to be taken into account for this prioritization will be the risks located in the red and orange areas of the probability matrix – impact of Figure 3. These are the risks of greater inference in the aforementioned processes.

The result of applying the aforementioned methodology is presented in Table 3, which shows that the critical risks are R6, R2, R10 and R7, which also have been classified as equipment and human hazards.

In accordance with this prioritization, action plans are established to help reduce or mitigate the impact of these plans in relation to the strategic objectives of the process, for this purpose the eight defined risks will be classified into two categories, taking into account that they are risks arising as a result of people and equipment.

3.3 Actions Aimed at Mitigation

Once the risk prioritization stage was completed, the choice was made to group the risks according to their origin, resulting in two groups: risks associated with equipment and risks associated with staff. For each grouping, the Cause-Effect tool is used to investigate the causes related to each type of risk. Subsequent to the identification of cases, interviews with experts are conducted to identify actions to mitigate or eliminate prioritized risks.

After proper validation with the expert panel, the following actions were identified:

Actions Aimed at Risk Mitigation for Equipment:

- Appropriate packs must be available to maintain temperature over long distances. These packages are: Cardboard box, isothermal box and isothermal fridge. Additionally, for the protection of hemocomponents inside the refrigerator can be used damping materials such as absorbent paper or bubble paper among others [10].
- A preventive review program is recommended for all the teams that make up the chain, taking into account the specialty of each equipment and the times required in case of full or partial replacement and the availability of their spare parts.
- A program of revision and calibration must be in accordance with international standards and minimum specifications for the use of cold chain equipment for the process.

Actions Aimed at Risk Mitigation for Staff:

- Human resource needs should be identified and ensured, including operational and personnel for general storage and transport activities, which should be competent, technically updated and trained for the position held [11].
- Staff should be aware of existing standards and working arrangements, continuous training in the quality system and sufficient time to do the work and for activities such as inspection and verification[11].
- It should be borne in mind that individual roles and responsibilities are clearly defined, documented and disseminated in a way that avoids gaps and overlaps. The responsibilities assigned to each person will not be so numerous as to constitute a risk to the quality of the products [11].
- It is recommended to have written procedures on staff selection, training and training processes [11].

4 Conclusions

The results of the prioritization made it clear that the critical risks of the process are aimed at the teams and people involved throughout the chain. It is important for the country and public health to invest in blood banks by the state using prioritization techniques such as the one developed in this work to channel and target the best investment opportunities.

Table 3. Results of prioritization.

N°	Type of Risk	Description of the Risk	IPRF
		Very high risk	**552,0**
6	Risks of the equipment	Equipment without sufficient technology for temperature control (Devices with built in temperature control failures and maintenance threshold overruns alarms).	486,4
2	Risks of the equipment	Equipment used in unstandardized transport and storage.	470,3
N°	**Type of Risk**	**Description of the Risk**	**IPRF**
10	Risks of the Personnel	Absence/Error in the labelling of transport units.	442,0
7	Risks of the equipment	Equipment's inability to maintain a stable temperature under extreme ambient temperature and humidity conditions (from +2 °C to +6 °C, the operating temperature of the equipment being +4 °C).	439,4
		Risk High	**431,1**
8	Risks of the Personnel	Lack of or inadequate advice from the operator or transporter to the sender on the technical specifications for the transport of the total blood, hemocomponents and samples.	427,7
1	Risks of the equipment	Equipment's that make up the cold chain without meeting minimum specifications and international standards (WHO).	419,0
3	Risks of the equipment	Lack of availability of technical support, spare parts and maintenance services for cold chain equipment.	396,2
9	Risks of the Personnel	Lack of professionals specialized in Transfusion Medicine.	370,4

Energy options for the cold chain as solar powered refrigerators would set a long term precedent for handling the hostile climates of the Colombian geography, as these places are the most affected by the states of the equipment and energy problems.

The most important limitation is related to the questionnaire. It is sent to many experts, but it is not easy for them to respond.

For future work, continuing research on risk management around the blood supply chain, the issue of risk quantification could be addressed by considering also the impact of the social component of blood supply. Future work could consider the economic elements related to these risks.

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