

FMECA MODELLING AND ANALYSIS IN BLOOD TRANSFUSION CHAIN

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ABSTRACT

This paper describes the modelling and analysis of the processes and activities used in the Blood Transfusion Centre of Hospital Brotzu (Cagliari – Italy), via FMECA (Failure Modes Effects and Criticalities Analysis) method, in order to enhance patient safety and improve clinical risk management. The first part of the study consists on an analysis of the present blood transfusion chain processes (AS-IS), obtained by reverse engineering. Then a concise description of the FMECA methodology is presented. After the introduction of the reengineered process (TO-BE), developed via introduction of RFID technology, the results of simulation will be presented. For each activity of the two configurations studied (AS-IS and TO-BE) some performance indicators were evaluated, then a sensitivity analysis has been carried out to investigate the consistency of FMECA analysis. Finally follows the comparison of results between the simulation of actual process and the reengineered one.

Keywords: FMECA, Blood Transfusion Chain, Sensitivity Analysis, Risk Priority Index

1. INTRODUCTION

Clinical Risk reduction, safety and quality improving of Italian Healthcare System (SSN) services, is nowadays a National priority and Transfusion medicine is one of the most interesting intervention areas. Due to high complexity of transfusion process, characterized by various checks, analysis and handlings of blood assets, probability of human errors is the most dangerous. Infectious exposure and mismatch between patient and assigned blood component group are the most serious transfusion risks.

Recent international studies reveal that pre analytical and clinical errors, which include incorrect ABO bedside testing and mistaken or missing patient identity check, represents about 80% of total adverse events (Ahrens, Pruss, et al. 2005). Particularly, “Acute

Haemolytic Reaction” has deadly consequences in about 10% of cases (De Sanctis Lucentini, Marconi, et al. 2004). Statistical data of ABO-incompatible RBC transfusions incidence are relevant in different countries (rarely data are collected with standard procedures): Germany 1:36000; USA (New York) 1:38000; France 1:135207 (including autologous blood); Ireland 1:71428 (Ahrens, Pruss, et al. 2005).

Viral transmission has been reduced since the early '90, thanks to the introduction of compulsory tests based on serology and Nucleic Acid Amplification Technique (NAT). Estimates of the risk per unit of blood in the post-NAT era are approximately 1:1,900,000 for HIV and 1:1,600,000 for HCV (Goodnough 2003).

Error rate reduction is the key factor for service quality and safety enhancing. Aims of the study are to devise a method to enhance patient safety and improve blood inventory management processes through an RFID-based process reengineering and also to estimate the potential clinical risk reduction (Orrù, Borelli, et al. 2010; Borelli, Pilloni, et al. 2010).

A key aspect for the success of the work consists in adopting the appropriate operational methodology for the analysis of the current and revised processes. In this field, the FMECA (Failure Modes and Effects Analysis Criticalities) is a valuable and tested tool, not only for the analysis of processes transfusion (Trucco, Cavallin 2010; Gianino, Finiguerra, et al. 2008) but also for the study of clinical risk in sensitive hospital areas (Coles 2006) and for the administration of drugs (Saizy-Callaert, Causse, et al. 2002).

The introduction of RFID technology in transfusion process, with the aim of improving the safety and quality of the processes involved, is nowadays under examination and it is the source of several application examples (Hohberger, Davis, et al. 2012; Sandler, Langberg, et al. 2006; Abarca, de la Fuente, et al. 2009; Van der Togt, Bakker, Jaspers 2011).

Although there are several problems associated with the use of this tracking technology in the hospital environment, such as privacy issues, the assessment of the effects of electromagnetic fields on biological materials (blood, platelets, plasma, etc.) (Otin 2011; Uysal, Hohberger, et al. 2012; Wang Q.L, Wang X.W, et al. 2013) and the economic feasibility of its use (Borelli, Orrù, Zedda 2012), the benefits achievable, especially in terms of patients safety, encourage the adoption of RFID in this field.

This study describes the experiences developed at Blood Transfusion Centre (BTC) of Brotzu Hospital (AOB) in Cagliari (Sardinia Island, Italy), where a new Blood Lab has been recently realized. Brotzu Hospital Blood Transfusion Centre operates in all standard transfusion processes: blood and platelet letting, therapeutic apheresis, blood-components separation, typing, analysis and assignment. About 50,000 blood units are treated every year, 60% of which are imported from other Italy regions in order to cover high Sardinian demand.

2. REVERSE ENGINEERING

In the first part of the study, a reverse engineering of present processes was performed, in order to map processes, to define information and material flows and to analyse infrastructure and technology status. Visits in Unit wards and in the Labs during working hours were scheduled and involved operators were interviewed. This study step involved BTC, the “Thalassemia adult patients day hospital ward of Thalassemia Hospital in Cagliari (MCT), and the “Cooley” BTC sub-department.

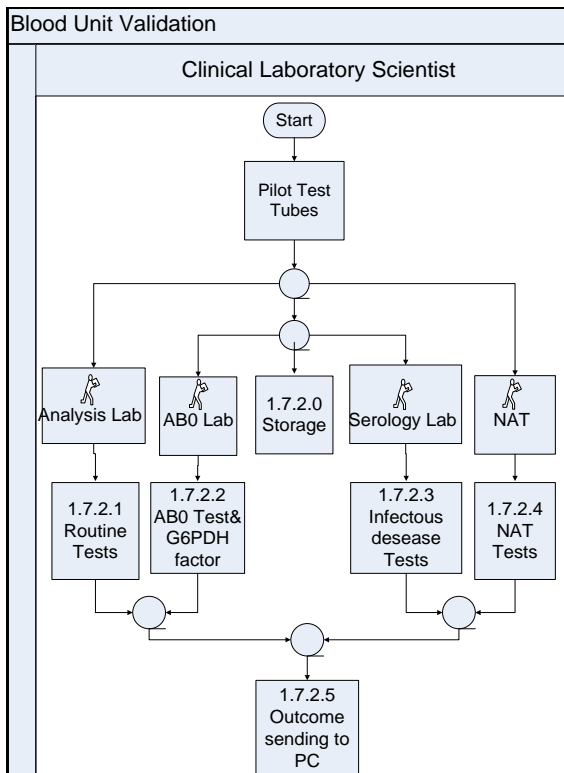


Figure 1: Flow-Chart example: Blood Unit Validation

Two main analysis tools were used: Flow Charts (figure 1) and Activity Forms. Flow chart is an algorithm graphical language. It allows to describe all process operations as a scheme. More than 20 Flow charts were designed, including both deep analysis charts and overall macro-process analysis charts. A specific form, which contains important data, was filled for each activity.

The whole Blood Chain has been conceptually split into two sub-systems in order to simplify and improve the analysis. The first one, called “Transfusion Loop”, includes three macro-processes related to patient admission and blood component transfusion (Cooley; MCT Request; MCT Transfusion); the second one includes two process related to donation, blood components separation, validation and storage (Blood Donation; BTC). Analysis and synthesis study steps were independently performed for each sub-system; nevertheless they are mutually complementary (Orrù, Borelli, et al. 2010; Borelli, Pilloni, et al. 2010).

3. FMECA

Criticalities and process error sources were highlighted through a process FMECA, the improved evolution of FMEA (Failure Modes Effects Analysis), in order to suggest actions for process refinement. Since 2001 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires the incorporation of prospective process analysis methods as FMEA into organizational patient safety plans. FMEA approach is "bottom up": potential error modes were considered for each activity, causes were searched and potential consequences related to efficiency and effectiveness (patient safety) were evaluated.

While this step (FMEA) provided only a qualitative failure modes analysis (risk estimation), FMECA provided a criticality evaluation of each failure mode (risk evaluation): it was possible to pass from a qualitative to a quantitative analysis through the assignment of three numerical parameters (table 1), with values variable from 1 to 10, related to Detection Possibility (D), Severity (S) and error Frequency (F) and consequently by defining a Risk Priority Index (RPI):

$$RPI=D \cdot S \cdot F \quad (1)$$

Table 1: RPI's Factors and Their Values

INDEX	DETECTION POSSIBILITY
1	Always
2	Very High
3-4	High
5-6	Average
7-8	Low
9	Very Low
10	Impossible

INDEX	FREQUENCY
1	Impossible
2	Very Low (once a year)
3-4	Low (once a month)
5-6	Seldom (once a week)
7-8	Usually (more times a week)
9	Frequent (once a day)
10	Always (more times a day)
INDEX	SEVERITY
1	No harm for patient or cycle
2	Some consequences for the cycle
3-4	Some harm for the patient without further treatment
5-6	Moderate Haemolytic Reaction
7-8	Delaying of patient hospitalization
9	Acute Haemolytic Reaction
10	Possible deadly consequences

The FMECA analysis described was performed on the present blood transfusion chain (AS-IS) and on the reengineered process (TO-BE), the latter developed via introduction of RFID technology. The second sub-system of Blood Chain has not been the subject of process reengineering. Based on the FMECA analysis, for each activity of the two configuration, the following Key Performance Indicators (KPI) have been evaluated: average value of the RPI; RPI's peak; activity amount. After, we calculated the Normal Probability Density Function (2) (NPDF curves), parameterized in terms of mean value and standard deviation.

$$f(x, \mu, \sigma) = \frac{1}{\sigma\sqrt{2\pi}} e^{-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2} \quad (2)$$

The analysis of the Normal Probability Density Function curves is very important because it allows to visually establish the risk status of each activity examined. Less risky activities have curves with the peak of maximum moved towards the left part of the chart, corresponding to low values of RPI, and a contained tail, the right part of the curve. In contrast, riskier tasks will be characterized by the positioning of the maximum peak towards high values of RPI, and a very noticeable tail.

Aiming to investigate the degree of consistency of FMECA analysis method and the reliability of the results obtained, a sensitivity analysis has been carried out. Each and every factor (severity, detectability, frequency) that makes up the RPI was modified considering the variation of ± 1 unit, outlining thus which are the factors that most influence the final result. In order to avoid the overstepping of the parameters outside their range (see table 1), the code has been programmed to saturate all the indexes to their boundary values (1-10). Finally, we compared the results of AS-IS and TO-BE, highlighting the

differences for all individual activities and for the overall transfusion process.

All the analysis hitherto presented were carried out using a code, written with MATLAB, in which was implemented a numerical model of the FMECA.

4. RESULTS

4.1. AS-IS

The results reported in table 2 and figure 2 clearly show that blood transfusion (MCT Transfusion), although having the lowest activity amount (15), is the most "risky" of all the activities. This can be seen by analysing the values of the "Average RPI", 114 vs. an average of 30-45, which cause a shift of the NPDF (Normal probability Density Function) curve to the right side of the graph, corresponding to higher indices risk.

Table 2: KPI Results, AS-IS Process

ACTIVITY	Average RPI	Peak RPI	Activity Amount
Donation	33.9	80	16
BTC	31.2	108	17
Cooley	39.7	144	45
MCT Request	45.2	144	22
MCT Transfusion	114.0	162	15
Blood Chain	56.31	162	115

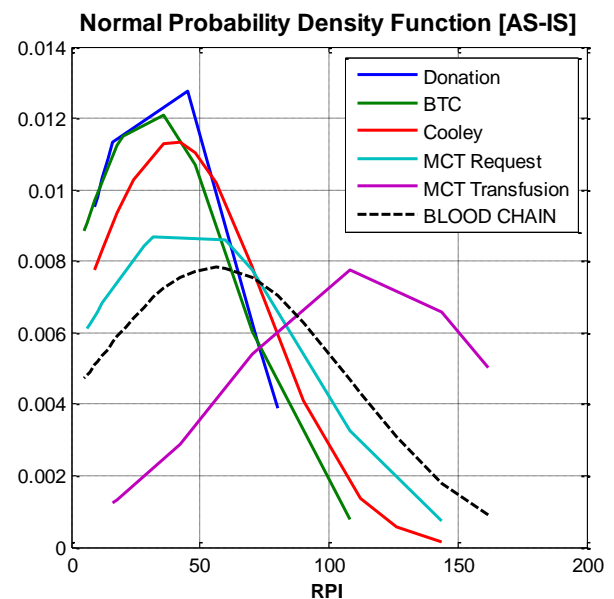


Figure 2: NPD Function associated with the activities of AS-IS configuration

Therefore all the efforts, through the reengineering procedure, must be focus on reducing the RPI of this particular process. Nevertheless, data suggest that even the other individual activities (especially those of the first level, such as Cooley, MCT Request, MCT Transfusion) are characterized by high values of KPIs that need to be controlled.

FMECA analysis highlights that the most critical activities are related to logistical assets recognition and manual operations, such as: patient identification; pilot test tubes and blood bags labelling; copying donation data from hand written papers to database management software; etc.

The results of AS-IS sensitivity analysis (table 3 and figures 3-4) show that the variation of the “frequency” factor entails greater changes in the KPI and NPDI curves, about 50%, while for the other two factors these changes are much smaller, about 10-20%.

During the collection of experimental data, via implementation of a pilot RFID system, will be therefore very important to quantify, with a low margin of error, the frequency of failure modes.

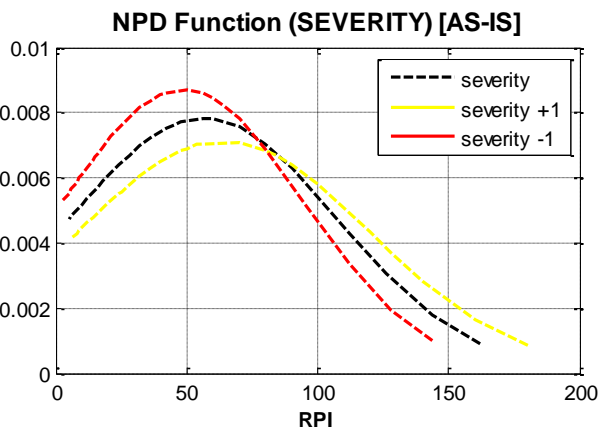


Figure 4: Sensitivity analysis of Severity [AS-IS]

Table 3: AS-IS Sensitivity Analysis

Index Variation	DETECTION	
	Average RPI	Peak RPI
± 0	56.31	162
+ 1	68.56 (+21.8%)	180 (+11.1%)
- 1	45.74 (-18.8%)	144 (-11.1%)
Index Variation	FREQUENCY	
	Average RPI	Peak RPI
± 0	56.31	162
+ 1	86.77 (+54.1%)	243 (+50.0%)
- 1	31.92 (-43.3%)	81 (-50.0%)
Index Variation	SEVERITY	
	Average RPI	Peak RPI
± 0	56.31	162
+ 1	64.09 (+13.8%)	180 (+11.1%)
- 1	48.64 (-13.6%)	144 (-11.1%)

4.2. TO-BE

The TO-BE configuration was analysed using the same methodology described for the AS-IS, both as regards the KPIs, both for sensitivity analysis.

Concerning KPI indices (table 4), the RFID technology implementation on processes of patient and logistic assets recognition, allowed us to obtain a significant reduction of the "Average RPI" and "Peak RPI" values of the following processes: MCT Request, MCT Transfusion.

Table 4: KPI Results, TO-BE Process

ACTIVITY	Average RPI	Peak RPI	Activity Amount
Donation	33.9	80	16
BTC	31.2	108	17
Cooley	24.8	70	48
MCT Request	16.9	36	23
MCT Transfusion	17.6	20	16
Blood Chain	23.92	108	120

Regarding the sensitivity analysis, it is possible to notice (Table 5, Figure 5) that results are quite similar to those of AS-IS configuration, with the frequency parameter able to lead to major deviations, about 30-60%, in case of overestimation or underestimation. The only exception to the AS IS model is represented by the factor "detection", whose changing involves a variation of 25-50% of the values of KPIs analysed.

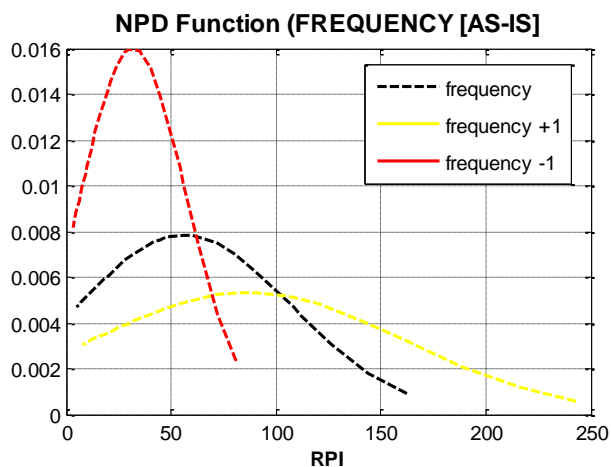


Figure 3: Sensitivity analysis of Frequency [AS-IS]

Table 5: TO-BE Sensitivity Analysis

Index Variation	DETECTION	
	Average RPI	Peak RPI
± 0	23.92	108
+ 1	35.51 (+48.5%)	135 (+25.0%)
- 1	17.80 (-25.6%)	81 (-25.0%)

Index Variation	FREQUENCY	
	Average RPI	Peak RPI
± 0	23.92	108
+ 1	38.72 (+61.9%)	144 (+33.3%)
- 1	16.19 (-32.3%)	72 (-33.3%)
Index Variation	SEVERITY	
	Average RPI	Peak RPI
± 0	23.92	108
+ 1	27.83 (+16.3%)	120 (+11.1%)
- 1	20.15 (-15.8%)	96 (-11.1%)

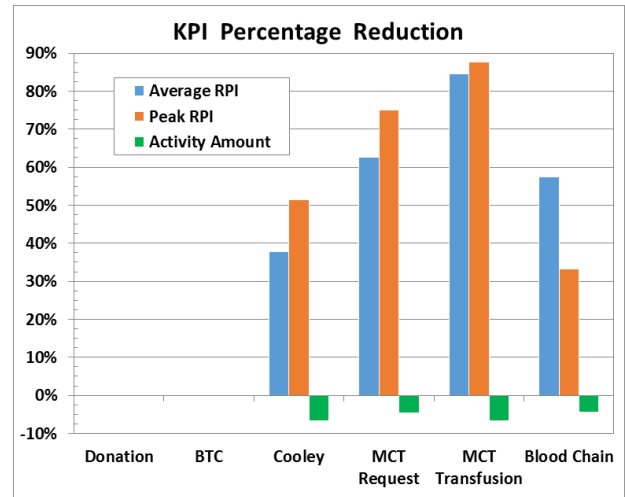


Figure 6: KPI Comparison, AS-IS vs. TO-BE

The difference between the current process and the reengineered one is clearly visible in figure 7. The graph shows both the improvement achieved in terms of reducing overall risk, shifting the mean value of the curve towards lower values of RPI, both the decrease of the peak values, the end of the curve at highest RPI. In the TO-BE process is also possible to appreciate the sharp decrease of the deviation of the values round the average, consequence of a widespread improvement on a large number of processes and activities.

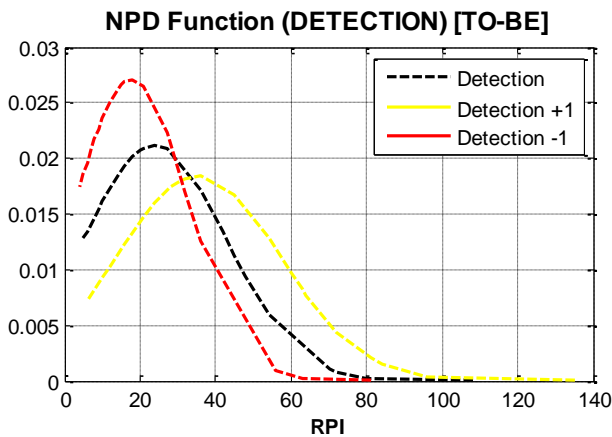


Figure 5: Sensitivity analysis of Detection [TO-BE]

4.3. Comparison AS-IS vs. TO-BE

The KPIs comparison of the two configurations analysed (table 6 and figure 6) shows that the average RPI of the TO-BE process (RPI = 23.9) is lower by about 57.5 % compared to the AS- IS (RPI = 56.3). This result was achieved mainly due to the significant reduction of clinical risk during the "MCT Transfusion" (-84.6 %) activity, obtained by the introduction of RFID technology in the processes of identification of patients and logistical assets (test tubes, blood bags, etc.). The introduction of the new technology, however, will result in a slight increase in the number of activities (+4.4 %) of the entire transfusion process.

Table 6: KPI Comparison, AS-IS vs. TO-BE Processes

ACTIVITY	Average RPI	Peak RPI	Activity Amount
Donation	0.0%	0.0%	0.0%
BTC	0.0%	0.0%	0.0%
Cooley	-37.7%	-51.4%	+6.7%
MCT Request	-62.6%	-75.0%	+4.6%
MCT Transfusion	-84.6%	-87.7%	+6.7%
Blood Chain	-57.5%	-33.3%	+4.4%

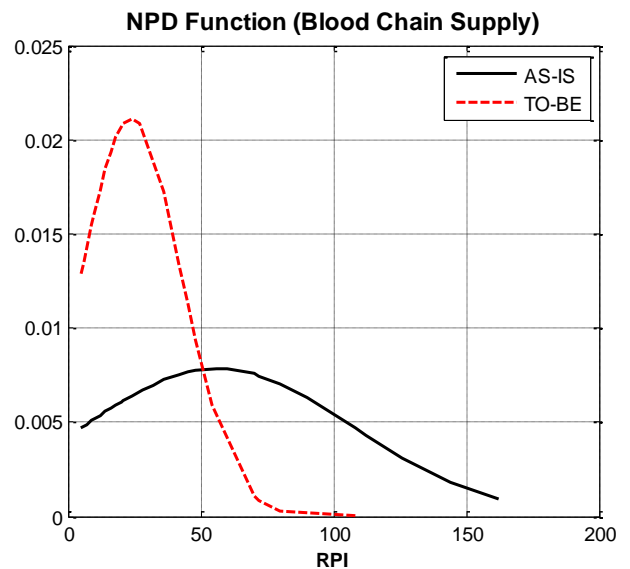


Figure 7: NPD Function comparison between AS-IS and TO-BE configuration

Despite the good results achieved, in terms of reducing the overall risk indicators (KPIs), it is possible to see in the TO-BE curve (figure 7) a queue corresponding to high RPI values and low NPD Function values. This is due to the lacking reengineering implementation of the second level of the Blood Chain, that is processes related to blood donation and the processing and storage of blood bags, both

performed in the Blood Transfusion Centre (BTC). Any future interventions on these two activities will improve the overall result, allowing a further reduction of the clinical risk. This result could be graphically evaluated through the shift of the peak of the curve to the left side of the graph, i.e. towards lower risk indices, and a consequent raising of the values of NPD function, which indicate an overall decrease of the probability of risk related to the fulfillment of the most adverse situations of an accident during the blood transfusion procedure.

5. CONCLUSIONS

A process reverse engineering was performed in order to identify and map the whole Blood Chain used in the BTC of AOB and in the “Thalassemia adult” ward of MCT, both located in Cagliari (Italy). Two configurations of the process were analysed: the first involving the actual blood chain (AS-IS), the other concerning the reengineered process (TO-BE), developed by introduction of RFID technology.

Using FMECA method, potentially error affected activities were founded and failure modes were classified by a risk priority index (RPI) which included detection possibility, severity and frequency factors.

Blood transfusion was identified as the process with foremost risk and FMECA analysis clearly pointed out that the most critical activities are related to logistical assets recognition and manual operations.

Results of the reengineered process have showed the improvement achieved in terms of reducing risk, not only of a large number of processes and activities, but of the overall Blood Transfusion Chain by about 57.5 %. This result was achieved mainly by the introduction of RFID technology in the processes of identification of patients and logistical assets (test tubes, blood bags, etc.).

Regarding the sensitivity analysis, results showed us that the variation of the “frequency” factor leads to greater changes in the KPI and NPDP curves, implying therefore the need of a very thorough quantification of this parameter to avoid errors about the clinical risk assessment.

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